Assessing Gastrointestinal Tolerance and Palatability of Fibre-Enriched Bread: a Randomised Control Trial.

Fiona Maria van Loon

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Abstract

Objective: The aim was to produce a fibre-enriched bread that contained 10g of fibre per serve (two slices), an amount approximately equivalent to the deficit in fibre intake between the average intake of adult New Zealanders and the nutrient reference value. This was incorporated in a convenient and widely consumed food vehicle (bread) and tested for palatability and gastrointestinal tolerance.

Design: Randomised double-blind crossover control trial.

Methods: A total of 79 healthy University of Otago students enrolled in the undergraduate Human Nutrition course participated in the study. They were randomised to either a Fruit fibre enriched bread (and control) or a FibreMax™ enriched bread (and control). Participants consumed approximately ten grams of the test fibre in two slices of bread. The palatability rating of the bread was assessed using a questionnaire composed of six visual analogue scales; visual appeal, smell, taste, texture, aftertaste and overall pleasantness. Gastrointestinal symptoms experienced including bloating, abdominal rumbling, flatulence, abdominal pain, nausea and vomiting were then rated using gastrointestinal questionnaires at baseline and one, two, three, eight and 24 hours post bread consumption.

Results: Both the FibreMax™ and Fruit fibre-enriched breads were well tolerated. More people reported feeling nauseous after eating the Fruit fibre bread compared with its control (p=0.02). There were no other differences between the Fruit fibre bread and its control, or between the FibreMax™ bread and its control.

The FibreMax™ bread was visually less appealing than its control (P=0.0039), although the overall palatability scores were not statistically different between the bread types (P=0.87). The Fruit fibre bread was less acceptable and had a lower median score for taste (P=0.0005),
smell (P=0.0003), rating of aftertaste (P=0.0000) and overall palatability rating (P=0.0003) compared with it’s control.

**Conclusion:** Both fibre-enriched breads were digestively tolerated in a single serve. Apart from the Fruit fibre having a poor taste and aftertaste that will require reformulation, the two fibre products created moist and palatable bread. There is place in the market and considerable potential for affordable and palatable bread with 10g fibre in a single serve (two slices), which does not induce gastrointestinal discomfort, such as those used in this study. If developed commercially it has the potential to reduce the gap between a low-fibre consumer’s actual and recommended fibre intake.
Preface

Fiona van Loon (candidate), Kate Harington, Jannie Yuan, and Rebecca Smeele conducted this study under the supervision of Dr. Bernard Venn. Dr. Bernard Venn was responsible for conceiving the research topic, the funding application, the process of ethics approval and communication with and buying of fibres. Hayley Dodd was responsible for the randomization of participants and taking anthropometric measurements. Carrington College catering staff were responsible for the production of the bread.

The candidate was responsible for the following:

• Being a team member making a full contribution to the running of the study including pretesting fibre products and fibre enriched food products, sampling and testing blood glucose, food purchase and preparation, liaising with Carrington College catering staff, bread weighing and packaging, designing and printing laboratory booklets and follow-up questionnaire and setting up and coordinating the experimental laboratories.
• Input into the study design including background research into an amount of fibre that could be added to the bread without resulting in unacceptable gastrointestinal symptoms.
• Modification of the gastrointestinal questionnaire.
• Modification of the palatability questionnaire.
• Continuing participant liaison to enhance compliance to the 8-hour and 24-hour gastrointestinal questionnaires.
• Collection and entry of the data.
• Development of an appropriate interpretive method for the data analysis.
• Statistical analysis of the data with guidance from the Department’s biostatistician, Jill Haszard.
• Writing and compiling this thesis.
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<th>Description</th>
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<td>AI</td>
<td>Adequate Intake</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<td>cm</td>
<td>Centimeters</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
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<td>CHD</td>
<td>Coronary heart disease</td>
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<td>CHO</td>
<td>Carbohydrates</td>
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<tr>
<td>EAR</td>
<td>Estimated Average Requirement</td>
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<td>g</td>
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<td>Millimetre</td>
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<td>n</td>
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<td>N.A.</td>
<td>Not assessed/ not applicable</td>
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<td>NNS</td>
<td>National Nutrition Survey</td>
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<td>SD</td>
<td>Standard deviation</td>
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<td>VAS</td>
<td>Visual analogue scales</td>
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1 Introduction

The rates of obesity, the metabolic syndrome and diabetes are of high concern in New Zealand (1, 2). In 2011/2012, 64% of New Zealand adults were either obese or overweight, with rates having increased markedly over the past fifteen years (1). Means of combatting these health problems are highly topical (1). Diets high in dietary fibre are of interest, due to evidence displaying the benefits of fibre consumption in the prevention of chronic diseases (3). It has been found that dietary fibre may exert a suppressive effect on appetite (4), but a lack of consistency is present as others have been unable to detect a significant fibre dampening effect on appetite (5-7). These differing results are likely to be due to inconsistent research methods, fibre amount and type (8, 9). Therefore, further research is required to substantiate this effect.

Fibre is available in a wide range of foods including fruit and vegetables, wholegrains, bran, beans, peas, nuts and seeds (10). Despite the availability of fibre containing foods in New Zealand, the population’s estimated intake of 17g/day and 22g/day is lower than the recommended adequate intake (AI) of 25g/day and 30g/day for females and males, respectively (11, 12). Barriers to achieving the recommended fibre intake may comprise individual taste preference, inconvenience, time constraint, family acceptance, peer pressure, and constant and widespread exposure to highly-processed low-fibre food (13, 14). Therefore, an alternative may be to recommend fibre as a supplement or to increase the amount of fibre available in food (15). This has resulted in interest in the supplemental form of fibre.

However, high or increased fibre intake can exert unwanted effects such as intestinal discomfort due to the osmotic power of fibre increasing water uptake, and fermentation by the gut’s microbiota resulting in gas production of methane, carbon dioxide and hydrogen (16-19). This manifests as symptoms such as bloating, flatulence, and abdominal rumbling (19). Although these effects are not necessarily harmful they are uncomfortable for the consumer.
and result in decreased compliance with fibre consumption (20, 21). Hence, prior to
determining the functionality of the fibre it is essential to establish a dose that is digestively
tolerable (22, 23). These factors are subjective and hard to evaluate at a group level,
especially as there are inter-individual differences as to what is perceived as an acceptable or
unacceptable gastrointestinal symptom (16, 18).

It is often believed that taste needs to be compromised when consuming a healthy diet (24).
With any food that exerts beneficial effects in the body the key to success is (25). However,
many people are not willing to sacrifice taste for foods with functional components (24, 26).
Foods that are high in fibre can have a low palatability (25). Some fibre may exert a slimy
mouth feel, affect texture and flavour and cause poor palatability (27). Consequently, it is
essential to evaluate the palatability of a high fibre product to establish whether the consumer
will be accepting of it.

Bread is the main contributor to energy (11%), protein (11%) and fibre (17%) intake in the
New Zealand population’s diet (11). Therefore, as a highly consumed product it has the
potential to be a vehicle for the addition of fibre. Fibre-enriched breads are only consumed by
4.6% of the New Zealand population (11). There are white, wholegrain and wholemeal breads
such as Tip Top ‘The One’, and Nature’s Fresh ‘Simply Fibre’ that are supplemented with
fibre. These products contain around 5g of fibre per serve (two slices), an amount that may
not be enough to raise low fibre consumers above the AI (28, 29). The prices of these fibre-
enriched breads are higher than or equivalent to regular bread products of the same brand and
higher than unbranded (budget) products (30). Thus, cost may be a limiting factor to their
consumption (13, 14). There is place in the market for palatable and affordable bread with a
higher amount of fibre that does not induce gastrointestinal discomfort. The addition of 10g
has the potential to close the consumers gap between the recommended fibre intake and the
actual fibre intake (11, 12).
2 Literature Review

2.1 Methodology of this literature review

The two main sections focused on are the gastrointestinal tolerance and palatability of fibre.

The following literature review aims to:

1. Provide a brief overview of fibre;
2. Investigate the physiological effects of fibre in the gastrointestinal tract;
3. Discuss amount of fibre and digestive tolerance;
4. Discuss the effect of fibre on the palatability of food;

Relevant literature published in English and using human participants was collected via the databases: Medline via Ovid, PubMed and Scopus. Keywords used included ‘Dietary fibre (dietary fiber)’, ‘tolerance’, ‘digestive tolerance’, ‘gastrointestinal symptoms’, ‘sensory characteristics’ and ‘palatability’. Additional literature was also collected using the reference lists of published articles. The inclusion criteria for research articles focused on healthy adults and randomised control trials.

2.2 Fibre

The term ‘Dietary fibre’ was first used by Hipsley in 1953, to explain the dietary constituent made up of plant cell walls (12). As early as the 1960’s Dr. Denis Parsons Burkitt’s observations led to the first hypothesis suggesting low fibre intake and its contribution to western diseases (31, 32).

Defining fibre is complex, with no singular globally agreed definition (12, 32, 33). In the US, dietary fibre is defined as the naturally intact components of plants that are consumed; functional fibre describes fibre that has been supplemented into food due to its physiological
benefits (34, 35) and total dietary fibre is the addition of the two (35). For regulatory purposes, Food Standards Australia New Zealand (12, 36) has defined dietary fibre as the ‘fraction of the edible parts of plants or their extracts, or rather than synthetic analogues, that are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine. Dietary fibre includes polysaccharides, oligosaccharides (degree of polymerization >2) and lignins, and promotes one or more of the following beneficial physiological effects: (i) laxation; (ii) reduction in blood cholesterol; (iii) modulation of blood glucose’ (h). There are a number of fibre types, each exerting different physiological effects in the body (34).

The structural, chemical and physical properties of fibre play an important role in its physiological effect within the body, altering its digestion, absorption, fermentation and excretion, which in turn contribute to its metabolic effect and benefits (3, 21, 33, 37-40). To determine nutritional benefit, the main distinctions can include solubility, viscosity and fermentation (8). The repercussions of fibre within the gastrointestinal passage and body vary intensely contingent on these categories (8). However, these distinctions are not always clear, as many fibre products have both soluble and insoluble components and viscosity is measured on a continuous scale (32, 41). Furthermore grinding, drying, heating and bleaching can modify the physical properties of the fibre particle and matrix (38, 42). This variability makes it difficult to group studies such that gastrointestinal tolerance is often assessed for individual fibre types as opposed to dietary fibre as a whole.

*Fibre and chronic disease:*

There is little doubt that dietary fibre contributes to health and wellbeing (18). Observational research has mainly been conducted on intrinsic plant fibres rather than synthetic analogues that are added to food products. Observations of diets high in fibre, particularly cereal fibre,
suggest a positive association with a reduction in the risk of developing type 2 diabetes (43-45). Furthermore, it was concluded from a meta-analysis including randomised control trials and observational studies that high fibre intake could contribute to an improvement in blood glucose response in diabetic patients (46), including a reduction in post-prandial serum glucose response. Viscous soluble fibres such as psyllium and guar gum may contribute to this effect by altering the viscosity of the intestinal contents resulting in the delay in glucose absorption through the interluminal barrier and postponing its presentation in the serum (35, 47, 48).

Dietary fibre intake has also been associated with a reduction in the risk of coronary heart disease (CHD). Ten prospective cohort studies from the US and Europe examining the association between dietary fibre and CHD incidence were pooled. It was concluded after a six to ten year follow-up that for every 10g/day increase of fibre intake from fruits and cereals, there was a 14% reduction in the risk of coronary events and a 27% reduction in the risk of coronary death (49). Multiple factors and mechanisms influence the association between dietary fibre intake and CHD, including the observed positive association between fibre intake and reduced stroke (50) and hypertension risk (51, 52). Fibre can also contribute to an improvement in serum cholesterol profile (46, 53), and lower blood pressure (51, 52, 54).

Weight gain may be a risk factor for both type 2 diabetes and CHD (1). An inverse relationship was observed between total and insoluble dietary fibre intake and body mass index (BMI) and waist-to-hip ratio (52). An increase of 5g was associated with a 10.6% decrease in the risk of being overweight (52). It has been suggested that fibre helps to suppress appetite, which may be associated with the effect fibre has on weight; however further research is required (4, 6, 7, 34). The suppression of appetite may be associated with prolonged stomach distension and delayed gastric emptying (55).
Additionally, dietary fibre may also contribute to bowel health. Fermentation of fibre in the large intestine may encourage the growth of beneficial bacteria and prevent the growth of harmful bacteria through altering the pH (3, 37, 40, 56, 57). Products of fermentation are energy sources for colonic anaerobic bacteria in the large intestine (23, 57, 58). Insoluble fibres such as bran have been shown to increase stool weight, which contributes to bowel regularity through increased water absorption and fermentation (17, 59, 60). There is a dose-dependent relationship between the benefits of fibre and the amount of fibre consumed, with increased quantities of fibre in the diet having a greater beneficial effect. Therefore, the quantity of fibre consumed is important.

In the 19th century and first half of 20th century patterns of food consumption changed with economic growth (61, 62). Until the industrial revolution ‘starchy staples’ formed a high proportion of caloric consumption, but consumption decreased with increased wages and there was a rise in the consumption of animal products, refined carbohydrates and sugar (61). By the 1960’s income became less of an influence on food choice, although there was an increase in restaurant food and ready to cook food consumption (62). Since then there has been little change, however the influence of health concern has increased (62, 63). By early 1990’s ‘starchy staples’ accounted for less than a quarter of calorie intake in developed areas such as Australasia, Western Europe and North America (64).

2.2.1 **Recommendations and New Zealand population’s fibre intake**

Fibre is not absorbed hence there is no biochemical assay that can be used to measure its status, although alkylresorcinols have been proposed as a biomarker for wholegrain wheat and rye intake (12, 35, 65). Recommendations for fibre intake were set using observations of adequate gastrointestinal function and laxation as opposed to reduction in chronic disease. These measures are difficult to assess, therefore, no Estimated Average Requirement (EAR)
could be calculated; instead a recommended AI was established (12). The New Zealand recommended AI for fibre is 30g/day and 25g/day for adult males and females, respectively (12). The New Zealand Adult Nutrition Survey (NZ ANS), 2008/09, revealed that males and females are currently consuming on average 22.1g and 17.5g of fibre per day, respectively (11). Since 1997 this consumption has remained relatively unchanged (11). Breads and cereals and vegetables and fruit are the highest contributors to fibre intake in New Zealand (11, 12). While fibre intake in New Zealand adults is considerably higher than those in the United States, who have an average consumption 17.7g/day in males and 14.2g/day in females, it still does not meet the recommended AI (12, 66).

2.3 Gastrointestinal symptoms

2.3.1 Physiological effects of fibre in the gastrointestinal system

The repercussions of fibre within the gastrointestinal passage and body vary contingent on solubility, viscosity and fermentability (8).

2.3.1.1 Fibre solubility

For analytical purposes fibre is often classified as either soluble or insoluble in water, although different products can have both insoluble and soluble components (3). The solubility of fibre is determined by the stability of the ordered and disordered chains in the structure (38). Crystalline or ordered structures are more stable in the solid state and are insoluble, whilst irregular or disordered structures are less stable and become soluble in fluid (38). Temperature may affect the order of the structure, and some fibre types that are insoluble in cold temperatures may be soluble in high temperatures (38).

Soluble fibre readily has the ability to absorb water and form a matrix (3), which captures nutrients, predominantly water-soluble nutrients (8). This facilitates the delay of transition
through the upper gastrointestinal passage (48) and delays gastric emptying (34, 37),
extending stomach distention (67). It is the water holding capacity of the hydrophilic nature
that affects stool bulking and transit. The ability of soluble fibre to absorb water contributes to
a shift in osmotic pressure in the gut, which may result in intestinal discomfort, bloating and
flatulence (22, 23, 68). The capability of fibre to hold water in the structure is affected by the
particle size, porosity and chemical structure along with the balance of hydrophilic to
hydrophobic chains (39).

Insoluble fibre on the other hand can increase or have no effect on small intestine transit (8,
37). Insoluble fibre is described as tough and fibrous (33). It often cannot be fermented by the
microbiota of the colon, resulting primarily in its excretion and contribution to faecal bulk (3,
33, 58). It has some capability to hold water within the pores of its network, contributing to its
effect of softening stools (33, 39). A larger number of pores and particle size increases its
ability to hold water like a ‘sponge’ (39). These aspects support its function in colon health
and regular bowel function (3, 69). It is likely that the gut may adapt to the effects of
insoluble fibre with increased exposure (8).

Insoluble fibres are often contained in wheat and rye products, while soluble fibres are
available in pulses, legumes, vegetables and grains including oats and barley (33). Soluble
fibre contributes to a shift in osmotic pressure, which may result in intestinal discomfort,
whilst insoluble fibres contribute to faecal bulk, softens stools and may result in watery stools
with excess intake (23, 33, 39).

2.3.1.2 Fibre viscosity

Fibre viscosity may alter the transit speed of the upper gastrointestinal tract contributing to
prolonged stomach distension and bloating. Viscosity is a measure of the resistance to flow of
a fluid and can be explained by the relationship of shear force and shear stress using the equation; Viscosity = Shear stress/ shear force (38).

In relation to dietary fibre, viscosity refers to the thickening or gel formation of a liquid (3). Thickening is caused by physical interactions and entanglement of particles in the solution; further molecules interlock to develop a matrix formation (38). The concentration of the fibre and temperature affects its ability to form a viscous solution (38). At a low concentration of fibre, molecules can move around freely, with a higher concentration there is an increased chance of interaction (38). Some viscous fibre types result in the formation of a gel (3, 38).

Viscous fibre incorporates water-soluble nutrients in a gel matrix, increases the viscosity of the intestinal environment and delays gastric emptying (8, 37, 48, 58). With the delayed gastric emptying the exposure of nutrients to the intestinal receptors is slowed resulting in a slowing down of the appearance of the nutrients in the plasma (8, 33). It is important to recognize that although the transition and absorption of nutrients is delayed, the total amount absorbed remains relatively unchanged (18, 34, 37). The delayed effect may result in bloating due to prolonged stomach distension.

2.3.1.3 Fibre fermentation

Fibre is not digested or absorbed in the small intestine, but continues through to the large intestine where it is partially or completely fermented by colonic bacteria producing short chain fatty acids; principally propionic, acetic acid, and butyrate (3, 18, 33, 37-40, 58, 68, 70). Byproduct gases are produced and expelled; including carbon dioxide, hydrogen and methane, which may contribute to gastrointestinal discomfort such as flatulence (3, 18, 33, 37, 38, 58, 68).
Host and fibre factors affect the rate, site and degree of fermentation (3, 38, 39, 71). The availability of other fermentable products in the colon and the composition of microflora influence the rate and extent of fermentation (38, 39). The structure of fibre determines where in the body and how rapidly it is metabolized and in turn the degree of fermentation and thus, the contribution to faecal bulk and weight (23, 72). Soluble fibres are generally fermented earlier than insoluble fibre (38, 39) of which many are resistant to fermentation (33, 73). Particle size affects fermentation through amount of surface area available to the colonic bacteria (38, 71). The intensity of these gastrointestinal symptoms may be altered by the speed of fermentation of the fibre, with a rapid fermentation expected to produce a large amount of gas and water uptake in a short period of time (15).

2.3.2 Amount of fibre and digestive tolerance

Given that the New Zealand population is not meeting the recommended fibre intake there is potential to enrich food with fibre to increase intake (11, 12). As fibre may stimulate undesirable gastrointestinal symptoms it is necessary to establish guidelines for an acceptable amount of fibre that might be added to a product. The gastrointestinal effects of fibre that have been evaluated includes; flatulence, bloating/gas, belching, nausea, vomiting, stomach pain, stomach cramps, stomach noises, borborygmus, stool frequency and stool consistency (constipiation and diarrhea) (6, 22, 74). Gastrointestinal symptoms experienced are not necessarily harmful to an individual, however they can affect perception of wellbeing and may reduce consumer acceptance (18, 20, 21).
Figure 2-1 Total amount of tolerated fibre separated by number of doses given in a day

*If a range in number of doses was given then the middle dose was selected.
*Studies were not included if a tolerated dose was not found.
*Some studies did not assess quantities higher than those shown in the figure. For example, 2.5g of fibre was tolerated split in two doses, it is possible that a higher amount would have been tolerated but this was not assessed.
Evidence for fibre and digestive tolerance is provided in Table 2.1. Inulin and fructo-oligosaccharides are fermented by colonic bacteria and recognized for their prebiotic properties (6, 23). Participants tolerated 5g of fibre split in two doses, but not 7.8g of fibre split in two doses from inulin rich chicory root (75). In another study 8.8g of chicory inulin fibre was well tolerated in a single dose (15). In general findings showed that 10g/day of both inulin and fructo-oligosaccharide was well tolerated in 1-2 doses/day (7, 15, 68, 76, 77). Overall 2.5 to 45g/day of additional fibre was well tolerated in 1-4 doses as shown in Figure 2.1. In a single serve tolerance ranged from 7-29g of fibre per day (25, 77). The limiting or most common symptom was flatulence followed by abdominal rumbling and bloating (7, 15, 16, 22, 56, 76-78). Nausea and vomiting were rarely reported especially in doses as low as 10-20g (22, 56, 74, 76). Fibre intake and digestive tolerance have a dose-dependent relationship (7, 77). Many factors affect the frequency and intensity of gastrointestinal symptoms experienced (23). These can be attributed to the condition of consumption and the nature of the fibre; comprising of but not limited to chemical structure, individual physiology, usual intake and the food the fibre is incorporated in (6, 21, 23).

2.3.2.1 Type of food and number of doses

The condition in which fibre is taken has an effect on its digestive tolerance. An important factor is the number of doses of fibre per day. Split doses increase the amount of fibre that can be tolerated in a day (77). Promitor™ glucofibre, was tolerated as ~28g fibre in one dose or ~45g fibre when consumed in three doses (77). Another important factor is whether the fibre is incorporated in a liquid or solid food (18, 21, 23). There is evidence to suggest that the combination of fibre with solid foods is better tolerated than liquid foods, which moves swiftly through the gastrointestinal passage and is rapidly digested and absorbed resulting in faster fermentation (15, 23). Some foods and medications also have a natural laxative effect
and may contribute to a synergetic effect or alter gastrointestinal effect when consumed with fibre; however, this may vary amongst individuals (23).

2.3.2.2 Individual physiology

A consumer’s physiology plays a role in the experienced gastrointestinal effects of fibre (21, 23). There is an inter-individual variation in the intensity and frequency of gastrointestinal symptoms experienced (68). Factors may include aspects such as age, gender, genes, health condition, personality, weight, physical activity and usual fibre intake (21, 23). These factors may influence the bacterial composition of the gut, transition speed, perception of acceptance and efficiency and effectiveness of digestion and absorption (23). Personality affects tolerance to pain, and perception of what symptoms are acceptable (18). Various health conditions disturb gastrointestinal function, which may alter the digestion and absorption of fibre or contribute to gastrointestinal symptoms such as bloating, cramps, diarrhea and constipation (23). Adaptation may occur with increased fibre intake and tolerance may increase over time, therefore, a high usual fibre intake may result in a higher digestive tolerance (23).

2.3.2.3 Adaptation to fibre intake

The mass and species distribution of the gut microflora may change with exposure to fibre resulting in increased tolerance (23). Some studies included in Table 2.1 have been conducted to determine whether fibre tolerance can be increased through conditioning over time. Of the studies included in Table 2.1 there was little evidence to show that tolerance increased in the first 2-3 weeks. There was no change in the symptoms observed with ActistarRM resistant starch intake from day 14 to 21, showing no adaptation (79). Slight improvements in symptoms were noted in week two for an inulin type fructan, however these were not significant (16). Adaptation may have been seen if these studies had continued for a longer period of time (16, 79). Adaptation was seen with the intake of Nutriose FB and the
significant gastrointestinal symptoms seen at day 21 were no longer significant by day 35. Therefore, suggesting that adaptation to increased fibre intake requires up to four to five weeks (17). However, we cannot rule out an influence of adaptation in the first 2-3 of days of increased intake. This may vary from person to person and with different types of fibre.

In conclusion, 10-20g and even up to 29g in a single dose appears to be well tolerated. Generally multiple doses in a day and the inclusion in food resulted in a higher total amount of fibre tolerated per day (77). Adaptation appears to occur over a 4-5 week period. There was variability in tolerance seen in studies with different fibre types. In a clinical setting individual variability should be considered (18, 23, 76).

2.3.3 Measurement of gastrointestinal symptoms:

There are a wide variety of study designs and procedures when determining an acceptable amount of fibre. As these measures are often subjective it was hard to determine an acceptable amount of fibre that was tolerated, especially with symptoms such as flatulence that regularly occur without the consumption of fibre (18, 68). This made comparing studies difficult as each study was designed independently and differed in terms of measurement and acceptance of gastrointestinal symptoms. The majority of the studies included in Table 2.1 were primarily focused on determining the gastrointestinal effects of the added fibre. Various studies controlled the diet or limited the subject’s intake of high fibre or other gastrointestinal inducing products such as beans, onion, cabbage, raisins, and plums (7, 17, 22, 25, 59, 68, 75-79). Study periods varied from one day to as long as 4-5 weeks (7, 15, 17). Studies also varied in the subjects recruited including one or both sexes and ranged in age groups, however all were adult studies and included healthy participants (some participants were overweight) (6, 22). There was also a large variation in the measurement tool used to quantify the symptoms experienced.
2.3.3.1 Measurement tool

The gastrointestinal effects of fibre can be measured both objectively and subjectively. Objective measures include stool frequency and consistency, flatulence (rarely measured) and abdominal distension. The collection of faeces allows researchers to determine the consistency and frequency, looking particularly at bulk, water and nutrient content (23). However, this process has a high respondent and investigator burden and in the majority of studies faeces were not collected (23). Hydrogen breath analysis has been used to measure carbohydrate malabsorption, gastrointestinal effects and colonic fermentation. These values should be interpreted with caution as many factors can affect the validity, for example excreted fibre needs to be considered. In totality there is inconsistent evidence to show whether a correlation between gastrointestinal symptoms and breath hydrogen levels exists (23).

Subjective measurements using questionnaires, diaries or a combination of the two have been used in the majority literature to assess gastrointestinal symptoms experienced after fibre consumption (6, 7, 15-17, 23, 25, 56, 59, 75-79). Questionnaires outline symptoms of interest and incorporate a scale for severity and/or frequency. However, an accepted and validated questionnaire has not been developed. There is inconsistency in the approaches used to rate symptoms, some of which were contrasted to usual symptoms, whilst others asked subjects to rate their symptoms experienced (23). Individual diaries have also been used to give subjects the opportunity to report symptoms free of investigator direction (74, 80).

In some cases the frequency or severity of gastrointestinal symptoms were measured on a 4-10 point scale (6, 15, 25, 56, 59, 76-78), others used visual analogue scales (VAS) with a scale such as 0= none/ no symptom/ minimal through to 100= very intense/ unbearable symptom/ excessive (7, 16, 17, 22, 25, 74, 75). However, other studies have used a hedonic
scale 0= normal function and 3= considerably more symptoms than usual or 0= usual and 10= more than usual, to make a comparison between the gastrointestinal symptoms experienced and usual gastrointestinal function (25, 79). There is also literature exploring gastrointestinal symptoms not specific to fibre intake. Bovenschen et al, developed and validated a questionnaire to measure the presence and severity of gastrointestinal symptoms in people with dyspepsia (81). The symptoms were rated on a Likert scale from 0-6, where 0 = “none” and 6 = “unbearable”. The questionnaire was validated in terms of clarity and reproducibility. Six symptoms were chosen and validated, results showed that the questionnaire was understandable and had good reproducibility (81).

Stool consistency has been rated using a 3-10 point scale (6, 78), the Bristol Stool Scale (77, 82, 83) or using VAS (7). The Bristol’s Stool Scale is a visual scale that describes the consistency of stools. It ranges from one through to seven where 1-nuts-like; 2-lumpy sausage; 3-sausage with cracks; 4-smooth snake; 5-soft blobs; 6-fluffy pieces and 7-watery (82-84). The validity of this scale has been measured in many studies and it has been found to be a tool that is useful in both clinical and research application to determine intestinal function through determining stool consistency (83).
<table>
<thead>
<tr>
<th>Author</th>
<th>Study Design</th>
<th>Subjects</th>
<th>Total Fibre</th>
<th>Fibre type</th>
<th>Food</th>
<th>Test period</th>
<th>Time + method of symptoms assessment</th>
<th>Symptoms assessed</th>
<th>Findings</th>
<th>Accepted total amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ripoll et al, 2010 (75) Study 1</td>
<td>Double blinded randomised crossover control trial.</td>
<td>18 healthy males + females (18-67yrs).</td>
<td>5g (Split 2x2.5g), 7.8g (Split 2x3.9g)</td>
<td>Inulin rich chicory extract vs. control (saccharose).</td>
<td>Instant coffee.</td>
<td>6-day test period.</td>
<td>Day 6 every 15mins for 1hr, then every 30min for 2hrs, then hourly for 6hrs. VAS: 0cm-none to 10cm-very great discomfort.</td>
<td>Overall intestinal discomfort.</td>
<td>Significant increase in overall gastrointestinal score (p=0.05) with intake of 7.8g test inulin fibre compared to control.</td>
<td>5g</td>
</tr>
<tr>
<td>Study 2</td>
<td>Double blinded randomised parallel control trial.</td>
<td>18 healthy males + females (18-67yrs).</td>
<td>2.5g (Split 2x1.25g)</td>
<td>Inulin rich chicory extract vs. control (sucrose).</td>
<td>Instant coffee.</td>
<td>4-week test (28 days) period.</td>
<td>Daily, Questionnaire: 0-none, 1-weak, 2-moderate, 3-high, 4-very high.</td>
<td>Flatulence, nausea, bloating + stool.</td>
<td>No significant results were seen in the test compared to the control, and there was no change from the first half to the second half of the test period.</td>
<td>2.5g</td>
</tr>
<tr>
<td>Williams et al, 2004 (25)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>48 healthy males + females (19-75yrs).</td>
<td>~5.5g + 1.6g</td>
<td>Guar gum + sodium alginate vs. control (Corn flour).</td>
<td>2x Crispy bars.</td>
<td>1-day test + 7-day washout periods.</td>
<td>24-hrs after consumption. Questionnaire 1-10 on 10cm line (VAS).</td>
<td>Flatulence, nausea, abdominal pain + distension.</td>
<td>Overall ratings were low, no difference was seen between the control and treatment group.</td>
<td>~7.1g</td>
</tr>
<tr>
<td>Bonnema et al, 2010 (15)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>26 healthy males + females (19-60yrs).</td>
<td>5, 10g</td>
<td>Inulin (88% fibre) or short-chain oligofructose vs. control (maltodextrin).</td>
<td>Orange juice with bagel.</td>
<td>1-day test periods.</td>
<td>A baseline, 2, 4, 24 and 48hrs. 4-point scale questionnaires 0-none, 1-mild, 2-moderate, 3-severe</td>
<td>Flatulence, abdominal pain, stool, nausea, bloating + abdominal rumbling</td>
<td>Overall symptom score tended to an increase. Only significant score was for 10g oligofructose. Most symptoms were mild and all doses were generally tolerated. Symptoms tended to appear at 4hr and persist to 24hr.</td>
<td>8.8g/d inulin fibre, ≤10g/d oligofructose</td>
</tr>
<tr>
<td>Tuohy et al, 2001 (80)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>31 healthy males + females (18-50yrs)</td>
<td>6.6g + 3.4g (Split 3x~3.3g)</td>
<td>Fructo-oligosaccharide + partially hydrolyzed guar gum vs. control.</td>
<td>3x biscuits.</td>
<td>21-day test + 2-day washout periods.</td>
<td>Daily. Stool diaries + questionnaire-none, mild, moderate, severe.</td>
<td>Flatulence, abdominal pain, stool + bloating</td>
<td>No change in stool frequency, increase soft stools in first few days, trend of flatulence, abdominal pain and bloating towards moderate in test fibre compared to mild in control.</td>
<td>&lt;10g mix</td>
</tr>
<tr>
<td>Author</td>
<td>Study Design</td>
<td>Subjects</td>
<td>Total Fibre</td>
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<td>Bouhnik et al, 1999 (76)</td>
<td>Randomised parallel control trial.</td>
<td>8 healthy males + females (18-47yrs).</td>
<td>2.5, 5, 10, or 20g (Split 2x1.25g, 2.5, 5 or 10g)</td>
<td>Short chain fructo-oligosaccharide vs. control (sucrose).</td>
<td>Powder mix at end of main meal.</td>
<td>7-day test period.</td>
<td>Daily. Graded 0-none to 3-severe.</td>
<td>Flatulence, abdominal pain, stool bloating + abdominal rumbling.</td>
<td>Excess flatulence in 20g dose/day significantly more frequent in test compared to control, no nausea or diarrhea seen.</td>
<td>10g/d</td>
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<tr>
<td>Carabin et al, 2009 (74)</td>
<td>Double blinded randomised parallel control trial.</td>
<td>27 healthy males + females (18-55yrs).</td>
<td>10g (Split 2x5g)</td>
<td>Polyglycoplex (sodium alginate + xanthan gum) vs. control (skim milk).</td>
<td>Breakfast cereal, yoghurt.</td>
<td>21-day test period.</td>
<td>Daily. Diaries + VAS during visit 2 (wk1) and 3 (wk2).</td>
<td>Flatulence, abdominal pain, stool, nausea, bloating, abdominal rumbling, + vomiting.</td>
<td>No significant symptoms were found, except increased intensity of average abdominal pain per day at week 3. Nausea was higher in control at this point.</td>
<td>10g</td>
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<tr>
<td>Stewart et al, 2010 (6)</td>
<td>Single blinded randomised crossover control trial.</td>
<td>20 healthy males + females.</td>
<td>12g (Split 2x6g)</td>
<td>Pullulan, Resistant starch, soluble fibre dextrin or Soluble corn fibre vs. control (maltodextrin).</td>
<td>177ml lite applesauce.</td>
<td>14-day test + 21-day washout periods.</td>
<td>Day 3 + 14. 10-point scale: 1-minimal to 10-excessive.</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>Symptoms did not differ from day 3 to 14 and were pooled. A moderate but significant increase in each and combined symptoms were seen. Overall symptoms were low. Mean symptom scores ranged from 1.8-5.1 and seen as acceptable.</td>
<td>12g</td>
</tr>
<tr>
<td>Hess et al, 2011 (7)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>20 healthy males + females (18-64yrs).</td>
<td>10, 16g (Split 3x 3.3, 5.3g)</td>
<td>Short chain fructo-oligosaccharide vs. control.</td>
<td>Hot chocolate, 3x chocolate candies.</td>
<td>1-day test + 1-week washout periods.</td>
<td>Over the course of 24-hrs. 0-100mm VAS used 0 minimal to 100 excessive.</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>All doses were well tolerated; a dose-dependent relationship was seen with increased symptoms seen with an increased dose. Symptom score was higher in 16g test than control p&lt;0.046, all symptoms were minor and acceptable.</td>
<td>16g</td>
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<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Interventions</td>
<td>Methods</td>
<td>Outcomes</td>
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<td>Housez et al, 2012 (77) (Pilot study)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>18 healthy males + females (18-70yrs).</td>
<td>9g, 18g Inulin vs. control (maltodextrin).</td>
<td>Diluted orange juice.</td>
<td>1-day test periods.</td>
<td>At 24-hrs. Questionnaire 1-10: extremely weak to 10-extremely severe. Sum of four scores (0-50). Stool assessed using BSS. Flatulence, abdominal pain, stool, bloating + abdominal rumbling. No significant results were seen at 9g dose compared to control, but 18g resulted in an increase in gastrointestinal symptoms of 7.9 points (P &lt;0.0001) higher than the control. ≤18g</td>
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<td>Bruhwylar et al, 2009 (16)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>28 healthy males + females (18-45yrs).</td>
<td>5, 10g Inulin type fructan (Fibruline instant, fibrulose97 + Fibruline XL) vs. control (saccharose).</td>
<td>5g sachets in drink.</td>
<td>2-week (14 days) run-in + 2-week test (14 days) periods.</td>
<td>Daily. Diary card using VAS 0-100mm-unbearable symptom. Flatulence, abdominal pain, stool, nausea, bloating + abdominal rumbling. Only significant increase in symptoms was for 20g fibruline instant vs. control (p=0.001). Significant difference in symptoms between fibruline instant and fibrulose 97 (p=0.011). Dose effect was seen between 5g and 20g of fibruline instant (p=0.042). All symptoms acceptable. 20g</td>
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<td>Boler et al, 2011 (56)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>21 healthy males (20-40yrs).</td>
<td>21g Polydextrose, soluble maize fibre vs. control (no fibre).</td>
<td>Snack bars.</td>
<td>3-week test periods.</td>
<td>Daily. Symptoms rated on a 4-point scale; 1-none, 2-mild, 3-moderate, 4-severe. Flatulence, abdominal pain, stool, nausea, bloating, vomiting. Bloating was significantly increased with the intake of the polydextrose compared to the control. Flatulence was significantly higher with the intake of polydextrose and soluble maize fibre than the control. All scores were low and seen as only mild to moderate. ~21g</td>
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<td>Van den Heuval et al, 2004 (22)</td>
<td>Double blinded randomised crossover + parallel control trial.</td>
<td>10 healthy males (20-45yrs).</td>
<td>~5 then 16 then 32g Dextrin (NutrioseFB) vs. control (maltodextrin).</td>
<td>Caramel colour, aspartame sweetened powder.</td>
<td>1-week run-in, 3-week test, 1-week washout period.</td>
<td>Weekly about the last 6 days and 24 hours (end of dose period). VAS questionnaire of past six days or past 24 hours. Flatulence, abdominal pain, stool, nausea, bloating + abdominal rumbling. Day 1-6 flatulence increased for ~16, and ~32g this remained in the last 24hrs for the ~32g dose compared to control p&lt;0.05. Flatulence intensity increased for ~32g p&lt;0.05 compared to control in day 1-6. ~23g</td>
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<td>Author</td>
<td>Study Design</td>
<td>Subjects</td>
<td>Total Fibre</td>
<td>Fibre type</td>
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<td>Findings</td>
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<tr>
<td>Pasman et al, 2006 (17)</td>
<td>Double blinded randomised parallel control trial.</td>
<td>14 +16 healthy males (20-45yrs).</td>
<td>~16g, ~23g</td>
<td>Dextrin (NutrioseFB) vs. control (maltodextrin).</td>
<td>Yoghurt, hot or cold drinks with meals.</td>
<td>1-week run-in, 1-week 1/2 dose, 4-week test period.</td>
<td>Baseline and weekly about the last 6 days and 24 hours. 100mm VAS questionnaire.</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling</td>
<td>Both doses were well tolerated, the only significant result was increased stomach rumbling with dose ~23g from baseline to day 21 p=0.016 but this decreased by day 35.</td>
<td>~23g</td>
</tr>
<tr>
<td>Vuksan et al, 2008 (59)</td>
<td>Randomised crossover control trial.</td>
<td>23 healthy males + females (19-59yrs).</td>
<td>~ 25.0- 28.7</td>
<td>All bran, bran buds with corn, bran buds with psyllium or bran buds with corn with viscous fibre blend vs. control (low fibre cereal).</td>
<td>Cereals.</td>
<td>3-week (21 days) test + 1-week (7 days) washout periods.</td>
<td>Daily Symptom diary on a 5-point scale 0-none to 5-extreme.</td>
<td>Flatulence, abdominal pain, stool + bloating.</td>
<td>No significant gastrointestinal symptoms except increased bloating in the bran buds with corn and viscous fibre blend compared to the control P&lt;0.05. This was at the lower end of the scale and seen as an indicative of comfort.</td>
<td>~25.0-28.7</td>
</tr>
<tr>
<td>Cherbut et al, 2003 (78)</td>
<td>Double blinded randomised crossover + parallel control trial.</td>
<td>10 healthy males + females (22-38yrs).</td>
<td>10-70g 10-70g (incremental rise) (Split 2-6 doses).</td>
<td>Acacia gum, short-chain fructo-oligosaccharide vs. control (sucrose).</td>
<td>Orange juice.</td>
<td>18-day test + 14-day washout periods.</td>
<td>Daily. Diary card rated 0-absent, 1-mild, 2-moderate or 3-severe.</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>At doses greater than 30g/day all symptoms were more severe for both test fibres compared to the control p&lt;0.05. Bloating, abdominal rumbling and flatulence were more severe in the fructo-oligosaccharide than the gum (p&lt;0.05). No scores exceeded mild.</td>
<td>30g</td>
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<tr>
<td>Study</td>
<td>Design</td>
<td>Participants</td>
<td>Fiber</td>
<td>Doses</td>
<td>Intake Form</td>
<td>Consumption Period</td>
<td>Measurement</td>
<td>Symptoms</td>
<td>Results</td>
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<tr>
<td>Housez et al, 2012 (77) Part 2</td>
<td>Double blinded randomised crossover control trial.</td>
<td>20 healthy males + females (18-70yrs).</td>
<td>~21, 28, 35g</td>
<td>Soluble glucofibre vs. control (maltodextrin or glucose + fructose syrup).</td>
<td>Cereal bars, beverages, powdered sachets with breakfast</td>
<td>1-day test periods.</td>
<td>24hrs post consumption. Sum of four scores (0-50). Questionnaire 1 extremely weak to 10 extremely severe. Stool using BSS</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>Significant dose effect was seen (p&lt;0.0001). Higher combined symptoms were seen at all three doses (p&lt;0.05). These were only seen as clinically relevant at dose ~35g based on results seen with 18g intake of inulin in pilot study.</td>
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<td>~28g</td>
<td>Soluble glucofibre vs. control (maltodextrin or glucose + fructose syrup).</td>
<td>Cereal bars, beverages</td>
<td>1-day test periods.</td>
<td>24hrs and 48hrs post consumption. Sum of four scores (0-50). Questionnaire 1 extremely weak to 10 extremely severe. Stool using BSS</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>A significant difference was seen between ~49g test fibre versus the control (p&lt;0.01). The symptoms at this dose were seen as mild.</td>
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<td>~39g (spread out)</td>
<td>Soluble glucofibre vs. control (maltodextrin or glucose + fructose syrup).</td>
<td>Cereal bars, beverages</td>
<td>1-day test periods.</td>
<td>24hrs and 48hrs post consumption. Sum of four scores (0-50). Questionnaire 1 extremely weak to 10 extremely severe. Stool using BSS</td>
<td>Flatulence, abdominal pain, stool, bloating + abdominal rumbling.</td>
<td>A significant difference was seen between ~45g test fibre versus the control (p&lt;0.001). The symptoms at this dose were seen as mild and not seen as clinically relevant based on results seen with 18g intake of inulin in pilot study.</td>
<td></td>
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<tr>
<td>Storey et al, 2007 (79) Study 1</td>
<td>Double blinded randomised crossover control trial.</td>
<td>41 healthy males + females (18-24yrs).</td>
<td>0, 10, 20, 30, 40, 50, 60g + 10g (split up to 9 doses)</td>
<td>ActistarRM III resistant starch vs. control (digestible starch)</td>
<td>Cereals, vegetable soup, hot chocolate, cereal bars</td>
<td>1-day + 1-week washout periods</td>
<td>Hedonic scale 0 normal function to 3 considerably more symptom than usual</td>
<td>Flatulence, nausea, stool, bloating + abdominal rumbling.</td>
<td>No difference in frequency or intensity was found by dose. 73% of participants could tolerate a dose of 60g without significant effects on gastrointestinal symptoms.</td>
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<tr>
<td>Study 2</td>
<td>Longitudinal</td>
<td>39 healthy males + females (18-24yrs).</td>
<td>0g to 50, 60 or 70g (incremental increase)</td>
<td>ActistarRM III resistant starch (% fibre unknown)</td>
<td>Cereals, vegetable soup, hot chocolate, cereal bars</td>
<td>6 weeks</td>
<td>Hedonic scale 0 normal function to 3 considerably more symptom than usual</td>
<td>Flatulence, nausea, stool, bloating + abdominal rumbling.</td>
<td>Prolonged consumption resulted significant increase in bowel movement (p=0.023), and frequency of watery feces (p=0.0157) an flatulence</td>
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</tbody>
</table>
2.4 Palatability of fibre

The addition of functional products such as dietary fibre has the potential to affect the palatability of food, which may reduce consumer acceptability (85). Good sensory properties are a priority to consumers who may be unwilling to consume foods with functional components if they have to compromise taste (24, 26). Thus, manufacturers face the challenge of producing a food with functional components that does not compromise on taste or other characteristics (24). A food high in fibre is only beneficial if the subject consumes it (25). Consequently it is essential to evaluate the palatability of a high fibre product. The sensory evaluation of food to determine the palatability of fibre may include texture, taste, aftertaste and overall palatability (86).

Some types of fibre can exert a slimy mouth feel, affect texture and flavour and cause poor palatability (27). Dietary fibre can also increase the mastication requirement of food (3). Bakery products such as muffins, breakfast cereals and bread have been proposed as a good vehicle for fibre supplementation as they have a low moisture content (85, 87). Dietary fibre can modify the moisture content of these products by increasing water retention, this may create a moist and fresh product, but may also contribute to a reduction of loaf volume and an increase in crumb firmness (87, 88).

Studies assessing the palatability and sensory characteristics of fibre in a range of foods are shown in Table 2.2. A mango pulp and peel flour, high in fibre, was added to sponge cake in proportions of 0-30%. Although a different texture was detected using instrumentation, this difference was accepted by panelists, who did not adversely rate the texture or overall palatability (86). Three different fibres including chicory fibre enriched in white bread were rated as acceptable. The tests breads contained approximately 5g of fibre (87). Similarly, inulin fibre enriched white, brown and wholewheat bread were rated as acceptable by
untrained panelists (89). The sensory characteristics of breakfast cereals enriched with fibre were not rated significantly different from or were rated as more pleasant than low fibre cereals (8, 90).

Variability in the rating of sensory characteristics for different types of fibre may occur. Four fibre-enriched muffins were compared to a control. The muffin enriched with resistant starch had the lowest palatability, whilst the muffin enriched with polydextrose had the highest palatability, and was rated significantly higher than the corn bran and resistant starch enriched muffins (9). There may also be inter-individual variation in acceptability of these products including an age effect whereby children tend to have a preference for soft white bread, whilst many adults prefer wholegrain bread (91), or weight, where lean participants may have an acquired taste for fibre breads (92).

Milk puddings were perceived as a commonly consumed food (85). The addition of fibre in milk pudding was not acceptable in doses as low as 2-4%. Trained panelists rated all sensory characteristics significantly lower and untrained consumers detected a floury taste and reduction in sweetness, rating the overall palatability significantly lower than the control (85). Flaxseed fibre was tested in a drink and compared to a control drink. The sensory characteristics of the fibre-enriched drink were rated significantly lower than the control (93). Conversely, fibre in hot chocolate was not rated significantly different from the control (7).

The techniques of measurement of the sensory characteristics of food products can vary as shown in Table 2.2. Some studies have used trained panelists (25, 85, 86), although the majority used participants from the general population (7-9, 87-90, 92-94), whilst others used a combination of both (85) to determine the acceptability. Often VAS were used (7, 9, 93) to determine a participants rating of a sensory characteristic, however other measurements such as 7-10 point hedonic scales (86, 88, 89, 94) and 9-point box scales (85) were also utilized.
Overall, there are varying results in the palatability of fibre. Consumers often rated liquid products as having poor palatability, whilst solid foods such as bread, cereals and sponge were rated as being more palatable (8, 85, 86, 90, 92, 93). This may be attributed to the fact that these products already have a grainy and/or dry texture. The addition of fibre to these products creates a moist firm product that has an acceptable texture (85, 87).
### Table 2-2 summary of literature on palatability

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Design</th>
<th>Amount of fibre</th>
<th>Type of fibre</th>
<th>Subjects</th>
<th>Method</th>
<th>Sensory characteristics</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ares et al, 2009 (85)</td>
<td>Single blinded randomised control trial.</td>
<td>1-4%</td>
<td>High amylose maize starch vs. control (0 and 5%) in 30 grams of milk pudding.</td>
<td>7</td>
<td>Created individual descriptors using the 5% vs. 0%. Then used a 10cm scale nil through to high for each of these descriptors with the 0% and 5% as a reference for low and high (repeated twice)</td>
<td>Created individual descriptors using the 5% vs. 0%. Then used a 10cm scale nil through to high for each of these descriptors with the 0% and 5% as a reference for low and high (repeated twice)</td>
<td>Significant effect on all the sensory descriptors p&lt;0.001 was seen even at concentrations as low as 1%. The fibre had a negative effect on manual and oral thickness, roughness melting, creaminess, rough after feel, floury taste and sweetness.</td>
</tr>
<tr>
<td>Hess et al, 2011 (7)</td>
<td>Double blinded randomised crossover control trial.</td>
<td>10, 16g (Split 2x5, 8g)</td>
<td>Short chain fructooligosaccharide vs. control in hot chocolate (+ candies)</td>
<td>50 male and females (18-63yrs).</td>
<td>Untrained consumers. 9-box scale 1-dislike very much to 9-like very much. Also asked yes/no to would you buy this product</td>
<td>Texture, taste + overall acceptability.</td>
<td>No difference was found in the test beverages compared to the control although the texture was not examined.</td>
</tr>
<tr>
<td>Williams et al, 2004 (25)</td>
<td>Single blinded crossover randomised control trial.</td>
<td>~5.5g + 1.6g</td>
<td>Guar gum + sodium alginate vs. control (Corn flour) in 2x crispy bars</td>
<td>Trained panel.</td>
<td>Details not given.</td>
<td>Compared for 10 flavour attributes</td>
<td>Texture and appearance and were judged to be very similar- good palatability.</td>
</tr>
<tr>
<td>Ibrugger et al, 2012 (93)</td>
<td>Single blinded crossover randomised control trial.</td>
<td>2.5g</td>
<td>300ml flaxseed fibre drink vs. control drink.</td>
<td>25 males and females.</td>
<td>VAS 100mm.</td>
<td>Taste, visual appeal, smell + off-taste.</td>
<td>The control drink was rated preferred over the flaxseed drink for all of the parameters p&lt;0.05. Not well tolerated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5g</td>
<td>Flaxseed fibre tablet with drink vs. 300ml flaxseed fibre drink.</td>
<td>50 males and females.</td>
<td>Untrained consumers. VAS 100mm.</td>
<td>Taste, visual appeal, smell + off-taste.</td>
<td>The flaxseed tablets were preferred for taste over the flaxseed drink p&lt;0.05, but not for off-taste p&lt;0.01, overall there was no significant difference.</td>
</tr>
<tr>
<td>Author</td>
<td>Study Design</td>
<td>Amount of fibre</td>
<td>Type of fibre</td>
<td>Subjects</td>
<td>Method</td>
<td>Sensory characteristics</td>
<td>Findings</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-----------------------------------</td>
<td>-----------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
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<td>-------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Porikos et al, 1986 (92)</td>
<td>Single blinded randomised parallel control trial.</td>
<td>3.3g vs. 0.2g (per slice)</td>
<td>High fibre bread vs. low fibre bread.</td>
<td>25 males, some were overweight/obese.</td>
<td>Questionnaire rating how well the subjects liked the bread and sandwiches they made up.</td>
<td>Obese subjects liked the low fibre bread significantly more than the high fibre bread. There was no significant difference in liking of the breads in lean subjects.</td>
<td></td>
</tr>
<tr>
<td>Aziah et al, 2011 (86)</td>
<td>Single blinded randomised crossover control trial.</td>
<td>10, 20, 30% Mango peel flour and mango pulp flour vs. control (wheat four) in sponge cake.</td>
<td>30 males and females.</td>
<td>Trained panel.</td>
<td>Hedonic sensory evaluation 1-dislike very much through to 7-like very much was used.</td>
<td>Texture, taste, visual appeal, smell, aftertaste + overall palatability.</td>
<td>There was no significant difference in the overall acceptability of any of the sponges. However, the 20% mango peel flour was rated lowest for aroma and overall acceptability.</td>
</tr>
<tr>
<td>Willis et al, 2009 (9)</td>
<td>Randomised crossover control trial.</td>
<td>8.0-9.6g Corn bran, barley beta glucan + oat fibre, resistant starch or polydextrose, vs. low fibre (1.6g) tested in muffins.</td>
<td>20 males and females (18-65yrs).</td>
<td>Untrained consumers</td>
<td>5 VAS to assess the muffin palatability at 15 minutes post consumption 0mm-good through to 100mm-bad, aftertaste 0mm-much through to 100mm-none.</td>
<td>Taste, visual appeal, smell, aftertaste + overall palatability.</td>
<td>The overall pleasantness of the polydextrose muffin was higher than corn bran and resistant starch muffin p&lt;0.05. The barley beta glucan + oat fibre was rated lower for overall pleasantness than the control muffin p=0.03. Resistant starch had the lowest palatability.</td>
</tr>
<tr>
<td>Hamedani et al, 2009 (90)</td>
<td>Randomised crossover control trial.</td>
<td>26g Corn + wheat bran blend vs. control (cornflakes 1.5g) in the form of breakfast cereal.</td>
<td>32 males and females (20-65yrs).</td>
<td>Untrained consumers</td>
<td>VAS of the palatability of the cereal.</td>
<td></td>
<td>High fibre cereal was rated as more tasty than the low fibre cereal p=0.046. The low fibre cereal was crushed so this may affect the sensory characteristics of it.</td>
</tr>
<tr>
<td>Delargy et al, 1997 (8)</td>
<td>Randomised control trial.</td>
<td>3g, 22g Psyllium gum, wheat bran in breakfast cereal as high soluble, high insoluble or low fibre vs. control (light)</td>
<td>15 males (17-29yrs).</td>
<td>Untrained consumers</td>
<td>Design was not explained.</td>
<td></td>
<td>There was no difference in the tastiness or pleasantness noted between any of the cereals.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Fibre Type</td>
<td>Participants</td>
<td>Results</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Wang et al, 2002 (87)</td>
<td>Crossover control trial</td>
<td>Carob fibre, chicory inulin, pea fibre vs. control (wheat flour ~2.96g fibre) in bread</td>
<td>Untrained consumers</td>
<td>Rated 1-lowest through to 10-highest, considered acceptable if the overall mean was higher then 5. Texture, taste, smell + overall palatability. Grain, crumb smoothness, aroma, flavour and overall acceptability were all rated above 5 and were not different from the control. It was well tolerated.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iserliyska et al, 2011 (89)</td>
<td>Single blinded trial</td>
<td>Inulin vs. mineral enriched white, brown wholewheat and wholewheat breads.</td>
<td>Untrained consumers</td>
<td>9 point hedonic scale 1-dislike extremely to 9-like extremely. Texture, taste, visual appeal, smell, aftertaste + overall palatability. All overall ratings were above 6 and thus all were accepted. Appearance of the white flour was significantly higher than the wholewheat bread. Participants preferred the samples in bread rather than rolls.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdul-Hamid et al, 2000 (88)</td>
<td>Double blinded crossover control trial</td>
<td>Defatted rice bran, fibrex™ (sugar beet fibre) vs. control (no fibre) in bread.</td>
<td>Untrained consumers</td>
<td>9-point hedonic scale 9-likely extremely, 1-dislike extremely. Visual, taste, smell, texture + overall acceptability. All sensory characteristics were rated lower for fibre breads than the control except 5% bread for chewiness and 5% Bran fibre for softness. The lowest rating was the 10% fibrex™ bread. But all were acceptable.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Garcia et al, 2002 (94)</td>
<td>Single blinded randomised crossover control trial</td>
<td>Several dietary fibres (wheat, oat, apple, peach + orange) in low fat dry fermented sausages vs. control (low fat and normal).</td>
<td>Untrained consumers</td>
<td>Non-structured 10cm hedonic scales 0-very unpleasant to 10 very pleasant. Odour, texture, visual, taste + overall acceptability. 3% were rated significantly lower than the rest in overall acceptability p&lt;0.05. Texture had a high influence on this in many of the fibres. 1.5% cereals and fruit fibre were accepted.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.5 Summary, conclusion and clinical implications

Gastrointestinal symptoms and palatability are crucial determinants in the consumption of fibre and to an individual’s perception of wellbeing (23). In many studies an accepted dose that resulted in no or minimal gastrointestinal side effects was determined, however, there was a large variability among individuals. From a clinical perspective, dietitians need to discuss the potential gastrointestinal side effects along with the benefits of fibre. Clients need to be aware that a sudden increase in intake may result in unwanted side effects and need to understand that this is normal and not harmful (21). It may be important to determine an amount and type of fibre that best suits an individual as acceptability can vary and adaptation can occur.

The evidence is suggestive that the intake of fibre in combination with food and in split doses, may reduce unwanted effects (18, 23, 76). In general the addition of 10-20g of fibre in a single dose appears to be well tolerated for most types of fibre. Generally bakery products such as muffins, breakfast cereal and bread were the most accepted vehicle for fibre supplementation. However, as variation in the acceptance of fibre can be seen new fibre products added into the market need to be assessed for palatability and gastrointestinal tolerance.
3 Objective Statement

A large number of the New Zealand population are not meeting the recommended AI (11, 12). Barriers to achieving this recommendation may include personal taste preference, inconvenience, time constraints, family acceptance, peer pressure, constant and widespread exposure to unhealthy food, and real or perceived gastrointestinal effects (13, 14). From previous research, it is clear that the acceptability of fibre varies with differing quantities and types of fibre (7). Palatability and digestive tolerance may both influence the acceptance of additional fibre. Acceptability is essential in terms of compliance of consumption and determining whether it is clinically feasible to recommend the addition of 10g of fibre into a food product (20, 21).

The objective was to develop and test a fibre-enriched bread that contained sufficient fibre (10g) in a single serve to potentially bring the average intake of consumers above the recommended AI (12, 66). The fibre would be added to a convenient and widely consumed vehicle (bread) with the aim of achieving palatability and avoiding gastrointestinal discomfort. This research would occur in two stages:

Step 1: Development of bread with approximately 10g fibre in one serving (two slices).

Step 2: Testing the palatability and gastrointestinal discomfort post bread consumption.
Figure 4-1 Study Design
4 Methods

4.1 Ethical Approval

The University of Otago ethics committee approved the protocol of this study (Appendix A). Relevant participant information outlining the study requirements, including the information sheet, consent form, and medical history questionnaire were encompassed in the ethics submission (Appendix B, C, D, E). Prior to the study, participants were given an information sheet outlining the study protocol in an electronic portable document format (pdf) (Appendix C). Participants gave written consent at the beginning of the study (Appendix D).

4.2 Design

Figure 4.1 illustrates the outline of the study design. The study was a randomised, double blinded, crossover control trial. Two fibres, an experimental Fruit fibre and FibreMax™ a commercial product, were incorporated in bread and assessed for palatability and gastrointestinal tolerance. Participants attended two test days and were randomised to assess either the Fruit fibre product (and control), or the FibreMax™ product (and control). Participants were allocated to either a morning or afternoon laboratory. There was a one-week washout period between the two test days. Questionnaires were used to assess palatability and gastrointestinal symptoms over a 24-hour period. Within this study other MDiet (Masters of Dietetics) students assessed the effect of these fibres on glycaemic response, and satiety, these results do not form part of this thesis.

4.3 Subjects

Participants were recruited through the University of Otago. Students enrolled in an undergraduate course in Human Nutrition were invited to participate as part of a class exercise. It was optional for students to participate in the study and no pressure was placed on them to do so. Those who chose not to participate had the opportunity to observe the
experiment and were not disadvantaged in any way. Screening in the form of a medical history questionnaire occurred at the first laboratory that participants attended (Appendix E). Questions covered medication administration, supplement intake, disease states including gastrointestinal disorders, diabetes and coeliac disease, along with general demographic information. Participants’ heights and weights were measured by Hayley Dodd, using calibrated Seca alpha scales (model 770) and a Holtain Limited Stadiometer. Another medical questionnaire was filled on the second test day to determine whether participants had made any changes to their eating patterns or medications since the first test day and to determine alcohol consumption around the test days (Appendix F). The number of participants selected was based the upper number of participants used in other studies looking at fibre and gastrointestinal symptoms, whilst taking into account the requirements for the other components of the study.

4.3.1 Inclusion and exclusion criteria

All students enrolled in the undergraduate Human Nutrition course were initially included. Participants were then excluded if they were pregnant; were taking antibiotics or laxatives; had a relevant self-reported medical condition including gastrointestinal sensitivity/disorder, coeliac disease or diabetes; or did not give consent.

4.3.2 Randomization

Using the ‘random function’ in Microsoft® Office Excel 2011, all students were randomised to a fibre type (Fruit fibre or FibreMax™), an order of fibre consumption (fibre then control or control then fibre) and a session time (am/pm). During randomization any timetable clashes were taken into account. Hayley Dodd completed the randomization process with the advice of Prof Sheila Williams, Preventative and Social Medicine of Otago.
Table 4-1 Bristol Stool score for stool frequency and consistency (77, 82)

<table>
<thead>
<tr>
<th>Stool frequency and consistency</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than three stools of type BSS &lt; 6</td>
<td>0</td>
</tr>
<tr>
<td>Three stools of type BSS &lt; 6</td>
<td>2</td>
</tr>
<tr>
<td>Four stools of type BSS &lt; 6</td>
<td>4</td>
</tr>
<tr>
<td>Five stools of type BSS &lt; 6 or one stool of type BSS 6 or 7</td>
<td>6</td>
</tr>
<tr>
<td>Two stools of type BSS 6 or 7 or more than five stools (including two stools of type BSS 6 or 7)</td>
<td>8</td>
</tr>
<tr>
<td>More than two stools of type BSS 6 or 7 (as more than two stools of type 6 or 7 per day is considered as diarrhea)</td>
<td>10</td>
</tr>
</tbody>
</table>
4.4 Questionnaires

Two questionnaires were developed and used:

4.4.1 Gastrointestinal symptoms questionnaire

Gastrointestinal symptoms were assessed using a modified version of Bovenschen et al.’s questionnaire, designed as a validated assessment tool for patients with dyspepsia (Appendix G) (81). This questionnaire was modified to make it specific to symptoms that may be experienced with high intakes of fibre. The original questionnaire had 17 symptom questions and of those seven were used. The following symptoms were assessed: flatulence, abdominal rumbling, bloating, abdominal pain, nausea, vomiting, stool frequency and stool consistency. These symptoms were selected based on those assessed in van den Heuval et al, Bruhwyl et al, and Carabin et al, all of whom were evaluating the effects of fibre on gastrointestinal tolerance (16, 22, 74). The descriptors used to assess the intensity and frequency of these symptoms were comprised of none, mild, moderate, quite a lot, severe, very severe and unbearable. These were used to help determine whether participants perceived their symptoms as acceptable. The questionnaires that were used can be seen in Appendix H.

An investigator was present in the room if participants had any questions regarding the questionnaires. The questionnaire was filled out at baseline and at one, two, three, eight and 24-hours post meal consumption. Stool frequency and consistency were reported at baseline and 24-hours post meal consumption. The question regarding stool consistency was adapted from the Bristol Stool Scale, a well-established tool for assessing stool consistency (82). Stool frequency and consistency ratings were then used to calculate a Bristol Stool Score as reported in Housez et al using Table 4.1 (77). The calculated score was then used for statistical analysis.
4.4.2 Palatability questionnaire

The Palatability questionnaire was designed using a modified version of Flint et al’s questionnaire shown in Appendix I. Flint et al’s questionnaire included VAS designed to measure the visual appeal, smell, taste, aftertaste, and overall palatability of a food product (95). The questionnaire was enhanced to include the parameter ‘texture’ which is considered appropriate when assessing fibre-enriched bread. An option was also incorporated in which participants could indicate whether they found the aftertaste ‘pleasant’ or ‘unpleasant’. For each question the statements ‘Bad’ and ‘Good’ were replaced with ‘Dislike very much’ and ‘Like very much’ as the latter were considered to be more descriptive of the sensation. The palatability questionnaire that was used can be seen in Appendix J.

4.5 Study materials

4.5.1 Fruit fibre

The fruit fibre was produced specifically for this project by a New Zealand company. The product was reported to comprise of dried and powdered fruit skins. The Company requested not to be named and withheld the specifics of production as commercially sensitive information.

4.5.2 FibreMax™

FibreMax™ is a commercially available natural fibre powder that contains a combination of soluble and insoluble fibre. It was manufactured for and distributed by New Image International, 19 Mahunga Drive, Mangere Bridge, Auckland 2022, New Zealand. It forms part of the Ultra Diet 2 weight management program and is advertised to support healthy blood glucose, gut health and digestive comfort, bowel health and regularity and to naturally support normal appetite management.
Table 4-2 Nutritional Composition of FibreMax™

<table>
<thead>
<tr>
<th>Nutritional Information per serve (15g)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy content</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calories</td>
<td>18.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kilojoules</td>
<td>78.7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibre</td>
<td>13.5g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polysaccharides</td>
<td>1.0g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>0.1g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fat</td>
<td>0.05g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4-3 the ingredients added to each of the four bread types

<table>
<thead>
<tr>
<th></th>
<th>Control Breads</th>
<th>FibreMax™ Bread</th>
<th>Fruit Fibre Bread</th>
</tr>
</thead>
<tbody>
<tr>
<td># of loaves</td>
<td>1</td>
<td>10¹</td>
<td>1</td>
</tr>
<tr>
<td>Flour</td>
<td>820g</td>
<td>8.2kg</td>
<td>604g</td>
</tr>
<tr>
<td>Salt</td>
<td>15g</td>
<td>150g</td>
<td>15g</td>
</tr>
<tr>
<td>Fibre</td>
<td></td>
<td></td>
<td>216g</td>
</tr>
<tr>
<td>Oil</td>
<td>60ml</td>
<td>600ml</td>
<td>60ml</td>
</tr>
<tr>
<td>Sugar</td>
<td>60g</td>
<td>600g</td>
<td>60g</td>
</tr>
<tr>
<td>Yeast</td>
<td>14g</td>
<td>140g</td>
<td>14g</td>
</tr>
<tr>
<td>Water</td>
<td>400ml</td>
<td>4L</td>
<td>700ml</td>
</tr>
</tbody>
</table>

¹The two control breads were mixed in a single batch then separated and brown food colouring was then added to the control for the Fruit fibre bread.
According to the package label it is composed of 47% (44.6g soluble fibre) chicory root extract, 23.5% (20.5g soluble fibre) psyllium, 23.5% (1.3g soluble fibre) soy fibre, 5.0% (0.4g soluble fibre) oat bran, and 1.0% (0.9g soluble fibre) pectin. The nutritional composition of the FibreMax™ product according to the nutritional panel is shown in Table 4.2. FibreMax™ is available in a 420g tin with a recommended dosage of 12.5g of fibre (15g product) 1-2 times per day.

4.5.3 Bread

Carrington College Catering baked the bread under the supervision of Ms. Susan Stockwell. The fibre was provided to the college along with a basic recipe, which was adapted to larger quantities and is shown in Table 4.3. In the fibre-enriched bread the quantity of flour used was reduced by a quantity equal to the amount of fibre added. The fibre bread also required more water than the control bread to make a workable dough. Brown food colouring was added to the control for the Fruit fibre bread to match the colour. All other ingredients were kept uniform between the control and fibre-enriched breads.

Each bread type was designated one of four colours: green, yellow, blue and pink, which were used as a coding system to blind the researchers and participants. The colour code was only disclosed after the completion of the data analysis. After the bread was cooled it was removed from the tin and passed through a commercial slicer with the spacing set at 10mm. The bread was then placed as loaves into a sealed plastic bag with the correct colour code. The bread was frozen and stored at -18 degrees Celsius.

Approximately 16 hours prior to consumption the bread was removed from the freezer and defrosted at room temperature. A serving of bread (two slices) was spread with a total of 10g of Craig’s margarine, and then placed into a resealable airtight bag with a sticker corresponding to the colour code of the bread. The weight of each serve was recorded and
differed slightly due to the shape of the loaf. Each bag was then stored in the refrigerator at four degrees Celsius. The bread was removed from the refrigerator and left at room temperature 45 minutes prior to consumption.

Gribbles Labnet Dunedin analyzed the nutritional composition of each bread type for the following components: protein (method 981.10); moisture (method 950.46); ash (method 950.46); total fibre content (method 985.29); insoluble fibre (method 991.42), soluble fibre (method 993.19) and energy using AOAC methods (96), carbohydrate by difference and total fat (97).

4.6 Procedure

Participants were given a brief explanation of the study but were not given details regarding the specifics of study design. They were told that they would be given bread on two occasions with various amounts and types of fibre. After the study completion they were told that they participated in a cross over control trial and were given details on the types of bread they had consumed. Not giving full detail of the study allowed for better blinding of the test and control breads. The intention was to reduce the influence of prior nutritional knowledge and opinions regarding fibre.

Participants were asked to abstain from consuming alcohol or conducting vigorous exercise prior to and during the test day. They were required to fast (refrain from consuming any food or liquid other than water) overnight from 10pm if they were assigned to a morning laboratory, or to fast from 8am after consuming their usual breakfast if they had been assigned to the afternoon laboratory. An email reminder was sent out the day prior to ensure participants understood these requirements and to increase compliance (Appendix K).

At the beginning of the laboratory participants were given seats and asked not to discuss any aspects of the experiment to minimize participants influencing each other. After filling out a
baseline gastrointestinal symptoms questionnaires participants were asked to consume the bread they had been assigned at their leisure but within a 15-minute period along with 250ml of water. Participants were then asked to rate the palatability of the bread using the palatability questionnaire (Appendix J). Symptoms were then rated on the gastrointestinal symptom questionnaires (Appendix H). Once each questionnaire was filled out it was taken off the participants to decrease the likelihood of them copying previous ratings. Participants were also given other tasks throughout the laboratory related to other sections of this study that are not reported in this thesis. This included finger pricks and additional questionnaires. A full copy of the laboratory booklet can be seen in Appendix L. Participants were provided with a meal three hours post bread consumption. This consisted of pasta and a plain tomato based pasta sauce. After consumption of this meal they were allowed to leave the laboratory setting.

Participants were asked to complete a gastrointestinal symptoms questionnaire eight hours and 12 hours post meal consumption. A text reminder was sent out at these times to increase compliance. The questionnaires were handed in the following week in an assignment box at the University of Otago.

4.7 Statistics

All data were analyzed using Stata Statistical Analysis Software (version 10.1, Stata Corporation 2008) under the supervision of Jill Haszard, a statistician at the University of Otago. A p-value of <0.05 was perceived as statistically significant.

Palatability

The palatability variables were measured on a VAS from 0mm to 100mm and entered to the closest 1mm. The variable were analysed for mean, standard deviation, median, interquartile range and range. Some of the sensory characteristics had a normal distribution whilst others
were not normally distributed, for analytical consistency all were treated in the same way. A Wilcoxon two-sided sign test was used to determine whether the pairs were equally distributed about the median.

**Gastrointestinal symptoms**

The aim was to determine whether the gastrointestinal symptoms experienced by the participants were acceptable or unacceptable when consuming the test fibre-enriched bread. There is no single method of assessing gastrointestinal symptom data. It has been done on scores taken at each timepoint (79), totaling of all symptom scores (77), averaging scores over time (75), or area under the curve (7). Each method has limitations. For example, analyzing data at each timepoint raises the numbers of comparisons and the probability of statistical error. On the other hand, averaging over time may result in a low average score (indicative of tolerance) when symptoms may have been fine most of the time but unbearable at one of the time points. Consequently, a score was developed with the aim of enhancing the strengths of the different analytical approaches. A symptom score of ‘none’ or ‘mild’ at all time points was coded as 0, whereas a response of ‘moderate’, ‘quite a lot’, ‘severe’, ‘very severe’ and ‘unbearable’ at any time point after consumption was coded as 1. A code of 0 for a symptom was considered ‘acceptable’ and code of 1 for a symptom was considered ‘unacceptable’. This dichotamization of symptom scores reduced the number of tests whilst positively identifying gastrointestinal discomfort. Pearson’s chi-square test and fisher’s exact test were then completed to determine whether an association existed between the bread and the ratio of ‘unacceptable’ symptoms.

A logistic regression analysis was undertaken to determine the odds ratio of having gastrointestinal symptoms with fibre bread compared to control. This was adjusted for order and time of consumption (am/pm).
Undergraduate Human Nutrition students randomisation, n= 91

Fruit fibre and control, n=46
Excluded:
Did not agree to participate, n= 3
Initial screening:
Medical and general well being questionnaire, n= 43
Excluded:
Coeliac disease n=1
Prescribed gluten free diet n=1
Prescribed antibiotics n=1
Eligible participants, n=40
Completed both labs n=39

Fibre Max and control, n=45
Excluded:
Did not agree to participate, n= 0
Initial screening:
Medical and general well being questionnaire, n= 45
Excluded:
Sensitive bowel n=1
Coeliac disease n=1
Diabetes n=1
Prescribed antibiotics n=2
Eligible participants, n= 40
Completed both labs n= 40

Figure 5-1 Process of screening and randomizing participants
5 Results

5.1 Baseline characteristics of participants

There were 91 students who were randomised to either the Fruit fibre group or FibreMax™ group. Of those 79 participated in the study. The randomization and exclusion of participants can be seen in Figure 5.1.

5.1.1 Fruit fibre group

Of the 91 students randomised 46 students were allocated to the Fruit fibre group and its respective control. Of those students, three chose not to take part. A further three participants were excluded as they did not meet the inclusion criteria, one of whom had coeliac disease, one was prescribed antibiotics and the third was on a prescribed gluten free diet. Another participant who was allocated to the Fruit fibre bread in week one withdrew at the beginning of the first laboratory after finding the taste of the bread intolerable.

During their first test day two participants only consumed three quarters of their bread within the allocated 15-min period and the remaining bread was not consumed. One of these participants was consuming the Fruit fibre bread and the other its respective control bread. There were also two participants who withdrew after the first test day and did not complete the second test day. The reason for one person withdrawing was illness unrelated to the study and the other was for personal reasons. All data collected from these four participants were analyzed in the intention to treat analysis.
<table>
<thead>
<tr>
<th></th>
<th>Fruit fibre</th>
<th>FibreMax</th>
<th>131</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong> # (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>6 (15.4%)</td>
<td>6 (15.0%)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>33 (84.6%)</td>
<td>34 (85.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong> # (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>32 (82.1%)</td>
<td>30 (75.0%)</td>
<td></td>
</tr>
<tr>
<td>Chinese</td>
<td>5 (12.8%)</td>
<td>6 (15.0%)</td>
<td></td>
</tr>
<tr>
<td>Indian</td>
<td>1 (2.6%)</td>
<td>1 (2.5%)</td>
<td></td>
</tr>
<tr>
<td>Korean</td>
<td>1 (2.6%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Malaysian</td>
<td>0 (0%)</td>
<td>1 (2.5%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>2 (5.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Smoking status</strong> # (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoked</td>
<td>36 (92.3%)</td>
<td>37 (92.5%)</td>
<td></td>
</tr>
<tr>
<td>Past smoker</td>
<td>1 (2.6%)</td>
<td>2 (5%)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>2 (5.1%)</td>
<td>1 (2.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong> Mean (S.D)</td>
<td>22.42 (3.2)</td>
<td>21.35 (1.9)</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>22.07 (1.8)</td>
<td>23.92 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>22.49 (3.4)</td>
<td>20.89 (0.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Height</strong> Mean (S.D)</td>
<td>168.6 (8.4)</td>
<td>167.6 (7.6)</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>184.4 (4.7)</td>
<td>178.3 (4.1)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>165.7 (4.9)</td>
<td>165.7 (6.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Body Mass</strong> Mean (S.D)</td>
<td>65.1 (10.6)</td>
<td>62.52 (10.2)</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>82.2 (4.6)</td>
<td>75.83 (13.1)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>62.0 (8.1)</td>
<td>60.17 (7.7)</td>
<td></td>
</tr>
<tr>
<td><strong>BMI</strong> Mean (S.D)</td>
<td>22.8 (2.5)</td>
<td>22.2 (2.9)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>24.2 (1.1)</td>
<td>23.8 (4.0)</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>22.5 (2.6)</td>
<td>21.9 (2.7)</td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.1.2 FibreMax$^\text{TM}$ group

The remaining 45 students were allocated to the FibreMax$^\text{TM}$ group and its respective control, all of whom agreed to take part in the study. Five participants were excluded as they did not meet the inclusion criteria, one of whom had coeliac disease, another had a sensitive bowel condition, two were prescribed antibiotics and another was a diabetic. All participants completed both laboratories.

The demographics and characteristics of participants in the Fruit fibre and FibreMax$^\text{TM}$ group are presented in Table 5.1.

5.2 Fibre Intake

The range in weights of bread given to participants are shown in Table 5.2. The table shows that each participant received approximately 10g additional fibre when consuming the test fibre-enriched bread compared to the control bread.

<table>
<thead>
<tr>
<th></th>
<th>Fruit fibre bread</th>
<th>Fruit Fibre control bread</th>
<th>FibreMax$^\text{TM}$ bread</th>
<th>FibreMax$^\text{TM}$ control bread</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bread</td>
<td>129-137</td>
<td>99-108</td>
<td>118-128</td>
<td>86-94</td>
</tr>
<tr>
<td>Total fibre</td>
<td>13.4-14.3</td>
<td>3.3-3.6</td>
<td>12.9-14.0</td>
<td>3.3-3.7</td>
</tr>
<tr>
<td>Difference$^\dagger$</td>
<td>9.9-10.8</td>
<td>9.4-10.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soluble fibre</td>
<td>2.1-2.2</td>
<td>0.3-0.3</td>
<td>4.1-4.5</td>
<td>0.3-0.3</td>
</tr>
<tr>
<td>Insoluble fibre</td>
<td>11.4-12.1</td>
<td>3.0-3.2</td>
<td>8.73-9.47</td>
<td>3.0-3.4</td>
</tr>
</tbody>
</table>

$^\dagger$The amount of extra fibre participants received when consuming the fibre-enriched bread compared to the control. The difference was calculated for each individual participant and the range was then obtained.
The nutritional composition of the four bread types is shown in Table 5.3. Gribbles Labnet Dunedin analyzed the breads for nutritional composition on the 26/03/13.

Table 5-3 The composition of the four bread types per 100g and serve

<table>
<thead>
<tr>
<th>Nutritional components¹</th>
<th>Fruit fibre control</th>
<th>Fruit fibre TM control</th>
<th>FibreMaxTM control</th>
<th>FibreMaxTM control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>/100g /133g /105g</td>
<td>/100g /123g /100g /92g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Energy (kJ)</td>
<td>752 /1,000 /1,207</td>
<td>1,267 /1,088 /1,338</td>
<td>1,210 /1,113</td>
<td></td>
</tr>
<tr>
<td>Protein (g)</td>
<td>6.6 /8.8 /10.4</td>
<td>10.9 /7.6 /9.3</td>
<td>10.4 /9.6</td>
<td></td>
</tr>
<tr>
<td>Moisture (g)</td>
<td>55.3 /73.5 /34.0</td>
<td>35.7 /39.0 /48.0</td>
<td>33.1 /30.5</td>
<td></td>
</tr>
<tr>
<td>Total fat (g)</td>
<td>0.7 /0.9 /5.5</td>
<td>5.8 /4.1 /5.0</td>
<td>4.9 /4.5</td>
<td></td>
</tr>
<tr>
<td>Ash (g)</td>
<td>1.3 /1.7 /1.5</td>
<td>1.6 /1.8 /2.2</td>
<td>1.5 /1.4</td>
<td></td>
</tr>
<tr>
<td>Total CHO (g)</td>
<td>36.1 /48.0 /48.6</td>
<td>51.0 /47.5 /58.4</td>
<td>50.1 /46.1</td>
<td></td>
</tr>
<tr>
<td>Available CHO (g)²</td>
<td>25.7 /34.2 /45.3</td>
<td>47.6 /36.6 /45.0</td>
<td>46.3 /42.6</td>
<td></td>
</tr>
<tr>
<td>Total dietary fibre (g)</td>
<td>10.4 /13.8 /3.3</td>
<td>3.5 /10.9 /13.4</td>
<td>3.8 /3.5</td>
<td></td>
</tr>
<tr>
<td>Insoluble fibre (g)</td>
<td>8.8 /11.7 /3.0</td>
<td>3.2 /7.4 /9.1</td>
<td>3.5 /3.2</td>
<td></td>
</tr>
<tr>
<td>Soluble fibre (g)</td>
<td>1.6 /2.1 /0.3</td>
<td>0.3 /3.5 /4.3</td>
<td>0.3 /0.3</td>
<td></td>
</tr>
</tbody>
</table>

¹ Composition given in amount per 100g and amount per serving size.
² Available carbohydrates (CHO) calculated as the total carbohydrate minus dietary fibre.
Table 5-4 Number of participants who experienced acceptable or unacceptable gastrointestinal symptoms in Fruit fibre group compared with the control.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Fruit fibre</th>
<th>Control fibre</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>34/5</td>
<td>32/2</td>
<td>0.60</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>35/4</td>
<td>31/6</td>
<td>0.33</td>
</tr>
<tr>
<td>Flatulence</td>
<td>34/5</td>
<td>33/4</td>
<td>0.53</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>35/4</td>
<td>34/3</td>
<td>0.53</td>
</tr>
<tr>
<td>Nausea</td>
<td>33/6</td>
<td>33/0</td>
<td>0.02*</td>
</tr>
<tr>
<td>Vomiting</td>
<td>38/1</td>
<td>37/0</td>
<td>0.51</td>
</tr>
<tr>
<td>Bristol stool scale ³</td>
<td>35/1/0/1/0/1</td>
<td>35/0/0/0/1/1</td>
<td>0.75</td>
</tr>
</tbody>
</table>

¹ Values are presented as number of participants with ‘acceptable’/‘unacceptable’ (calculated as per methods section) gastrointestinal symptoms and p-values calculated using the Fisher’s exact test, unless otherwise indicated.

² Values are presented as numbers of participants who experienced ‘no/yes’ vomiting.

³ Values are presented as number of participants with a score of ‘0/2/4/6/8/10’ for the Bristol stool scale score.

⁴ Statistically significant
5.3 Gastrointestinal symptoms

On occasion participants did not indicate a score in the questionnaire, this was for only approximately one percent of the data. The baseline gastrointestinal symptom score experienced by participants consuming the test bread was compared to that of the participants consuming the control bread. There were no statistically significant differences detected in baseline gastrointestinal symptom scores within either the Fruit fibre group or the FibreMax™ group.

5.3.1 Fruit fibre

Analysis revealed a statistically significant difference between the numbers of ‘acceptable’ to ‘unacceptable’ nausea symptoms experienced between participants who consumed the Fruit fibre bread and the control bread. Consumption of the Fruit fibre bread resulted in an increased number of participants experiencing ‘unacceptable’ nausea symptoms. All other gastrointestinal symptoms experienced were not statistically significant different between the test and control bread. One incident of vomiting was recorded but was attributed to alcohol consumption prior to the study. Most other gastrointestinal symptoms were mild and not recorded frequently. The frequency of ‘acceptable’ and ‘unacceptable’ symptoms experienced are given in Table 5.4.

The results of the logistic regression indicated that neither time nor order of consumption had a statistically significant effect on the association of gastrointestinal symptoms experienced by participants in the Fruit fibre and control group.
Table 5-5 Number of participants who experienced acceptable or unacceptable gastrointestinal symptoms in FibreMax\textsuperscript{TM} group compared with the control.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>FibreMax\textsuperscript{TM}</th>
<th>Control fibre</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n= 40</td>
<td>n= 40</td>
<td></td>
</tr>
<tr>
<td>Bloating</td>
<td>36/4</td>
<td>35/5</td>
<td>0.50</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>34/6</td>
<td>31/9</td>
<td>0.28</td>
</tr>
<tr>
<td>Flatulence</td>
<td>31/9</td>
<td>36/4</td>
<td>0.11</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>39/1</td>
<td>37/3</td>
<td>0.31</td>
</tr>
<tr>
<td>Nausea</td>
<td>40/0</td>
<td>38/2</td>
<td>0.25</td>
</tr>
<tr>
<td>Vomiting\textsuperscript{2}</td>
<td>40/0</td>
<td>40/0</td>
<td>NA\textsuperscript{4}</td>
</tr>
<tr>
<td>Bristol stool scale\textsuperscript{3}</td>
<td>36/2/1/1/0/0</td>
<td>39/2/0/0/0/0</td>
<td>0.29</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Values are presented as number of participants with ‘acceptable/unacceptable’ (calculated as per methods section) gastrointestinal symptoms and p-values calculated using the Fisher’s exact test, unless otherwise indicated.

\textsuperscript{2} Values are presented as numbers of participants who experienced ‘no/yes’ vomiting.

\textsuperscript{3} Values are presented as number of participants with a score of ‘0/2/4/6/8/10’ for the Bristol stool scale.

\textsuperscript{4} No incidents of unacceptable vomiting symptoms were experienced in either the test or control bread groups so the Fisher’s exact analysis was not possible.
5.3.2 FibreMax™

There were no statistically significant differences between the FibreMax™ and the control group for any of the gastrointestinal symptoms experienced. The majority of the gastrointestinal symptoms experienced by participants were mild and did not frequently occur. The frequency of ‘acceptable’ and ‘unacceptable’ symptoms experienced are given in Table 5.5.

The results of the logistic regression indicated that neither time nor order affected any of the variables except abdominal rumbling. Abdominal rumbling was significantly affected by the time of day (am vs. pm) and was 1.7 times more likely to be experienced in the morning than in the afternoon, \( P=0.021 \). However, this difference did not alter the non-association between the test bread and the control bread. This significant effect was only seen in the FibreMax™ and control group, not in the Fruit fibre and control group.
Figure 5-2 Box plot figures for the six sensory characteristics comparing the median, range and interquartile range scores of Fruit fibre to its control.
5.4 Palatability

The palatability questionnaire was well answered with approximately 98% completion. The small proportion of missing data was generally around aftertaste.

5.4.1 Fruit fibre

The median ratings for the Fruit fibre-enriched bread were statistically lower for smell, taste, pleasance of aftertaste and overall palatability parameters than its respective control bread. The aftertaste of the Fruit fibre-enriched bread was also regarded as unpleasant by 90% of the participants. Figure 5.2 shows the median, interquartile range and range of each of the six sensory characteristics. Table 5.6 shows the median and interquartile range.

**Table 5-6: Median and interquartile range of each palatability marker of Fruit fibre and respective control.**

<table>
<thead>
<tr>
<th></th>
<th>Fruit fibre bread</th>
<th>Control bread</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (interquartile range)</td>
<td>Median (interquartile range)</td>
<td></td>
</tr>
<tr>
<td>Visual:</td>
<td>25.0 (19.5-47.5)</td>
<td>30.0 (20.0-50.0)</td>
<td>0.080</td>
</tr>
<tr>
<td>Smell:</td>
<td>20.0 (11.5-35.0)</td>
<td>40.0 (27.0-50.0)</td>
<td>0.00034</td>
</tr>
<tr>
<td>Taste:</td>
<td>20.0 (26.0-60.0)</td>
<td>49.0 (26.0-60.0)</td>
<td>0.00054</td>
</tr>
<tr>
<td>Texture:</td>
<td>20.0 (9.5-39.5)</td>
<td>30.0 (17.0-53.0)</td>
<td>0.74</td>
</tr>
<tr>
<td>Aftertaste:</td>
<td>53.0 (27.5-75.5)</td>
<td>30.0 (11.0-50.0)</td>
<td>0.12</td>
</tr>
<tr>
<td>Rating of aftertaste:</td>
<td>53.0 (27.5-75.5)</td>
<td>30.0 (11.0-50.0)</td>
<td>0.12</td>
</tr>
<tr>
<td>Overall palatability:</td>
<td>20.0 (7.5-27.5)</td>
<td>45.0 (30.0-60.0)</td>
<td>0.00034</td>
</tr>
</tbody>
</table>

1 The p-value was calculated using a Wilcoxon two-sided sign test of the medians of the scores rated from 0 (dislike very much)-100mm (like very much) for all parameters unless otherwise indicated.
2 Aftertaste was rated on a scale 0 (none)- 100mm (much)
3 Rating of aftertaste was measured as 0=pleasant, 1=unpleasant, the p-value was calculated using a Wilcoxon two-sided sign test of the means.
4 Statistically significant.
Figure 5-3 Box plot figures for each of the six sensory characteristics comparing the median, range and interquartile range scores of FibreMax\textsuperscript{TM} to its control.
5.4.2 FibreMax™

The visual appeal median rating for the FibreMax™-enriched bread was significantly lower than the control. The median scores of all other palatability parameters were not statistically different between the two breads. Figure 5.3 shows the median, interquartile range and range of each of the six sensory characteristics. Table 5.7 shows the median and interquartile range.

Table 5.7: Median and interquartile range of each palatability marker of FibreMax™ and respective control.

<table>
<thead>
<tr>
<th></th>
<th>FibreMax™ bread Median (interquartile range)</th>
<th>Control bread Median (interquartile range)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual:</td>
<td>30.0 (20.0-42.0)</td>
<td>47.5 (27.5-60.0)</td>
<td>0.0039⁴</td>
</tr>
<tr>
<td>Smell:</td>
<td>50.0 (40.0-60.0)</td>
<td>53.0 (40.0-71.3)</td>
<td>0.38</td>
</tr>
<tr>
<td>Taste:</td>
<td>50.0 (37.5-70.0)</td>
<td>60.0 (34.0-70.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Texture:</td>
<td>37.5 (20.0-61.3)</td>
<td>39.5 (20.0-70.0)</td>
<td>0.39</td>
</tr>
<tr>
<td>Aftertaste:</td>
<td>50.0 (20.0-70.0)</td>
<td>45.0 (20.0-60.0)</td>
<td>0.38</td>
</tr>
<tr>
<td>Ratings of aftertaste:</td>
<td>50.0 (30.0-60.8)</td>
<td>60.0 (37.5-70.0)</td>
<td>0.73</td>
</tr>
<tr>
<td>Overall palatability:</td>
<td>50.0 (30.0-60.8)</td>
<td>60.0 (37.5-70.0)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

¹The p-value was calculated using a Wilcoxon two-sided sign test of the medians of the scores rated from 0 (dislike very much)-100mm (like very much) for all parameters unless otherwise indicated.
²Aftertaste was rated on a scale 0 (none)- 100mm(much)
³Ratings of aftertaste were measured as 0=pleasant, 1=unpleasant, the p-value was calculated using a Wilcoxon two-sided sign test of the means
⁴Statistically significant.

Figure 5.2 and Figure 5.3 highlight that there is a difference in ratings between the visual appeal of the FibreMax™ and control but not between the Fruit fibre and control. It also highlights that there is a difference in ratings between the smell, taste, and overall palatability of the Fruit fibre and control but not between the FibreMax™ and control. It shows that for all
sensory characteristics there is a large range in scores, some ranging all the way from 0mm to 100mm. The interquartile range for amount of aftertaste appeared large for all of the bread types, whilst the interquartile range for smell and visual appeal appeared smaller. This showed that there might have been a greater variability in the judgment of the amount of aftertaste.
6 Discussion

The digestive tolerance and sensory characteristics of two fibre-enriched bread products were assessed. Both products were well tolerated. The severity and frequency of adverse gastrointestinal symptoms experienced overall was low. The palatability of the FibreMax™ enriched bread was acceptable, while the palatability of the Fruit fibre enriched bread was not satisfactory.

The average New Zealand population intake of fibre is approximately 10g below the recommended AI (11, 12). Approximately 10g of either FibreMax™ or Fruit fibre were added to a serve (two slices) of bread. The test bread contained approximately two times more fibre per serve than fibre-enriched bread products such as Tip Top ‘The One’, and Nature’s Fresh ‘Simply Fibre’ (28, 29). At the beginning of this study the Natures Fresh ‘Simply Fibre’ was not yet available. A consumer’s willingness to consume a food with functional properties can be inversely associated with the number doses that need to be consumed (24). So there may still be room in the market for bread with an even higher level of fibre than the fibre-enriched breads currently on the market. Bread is a good vehicle for fibre supplementation as it is a commonly consumed food in the New Zealand diet (11).

Evidence supports a role for dietary fibre in disease prevention and management (18). Positive associations have been found between fibre intake and disease prevention, particularly in diabetes, cardiovascular disease (CVD) and obesity (12, 43-46, 49, 52). High consumption of energy dense food is associated with an increased risk of weight gain and obesity (98). The increase in moisture content seen in the Fruit fibre enriched bread was associated with the decrease in energy density (99). This resulted in the energy content of the Kiwifibre enriched bread product being 455KJ/100g lower than the control (99). Thus, Fruit fibre had an energy displacement role when added to the bread.
Palatability:

Often the addition of functional products to food alters their perceived sensory characteristics, which may result in reduced acceptability (85). The palatability of the two fibre-enriched breads differed. The FibreMax™ was well accepted whereas the palatability of the Fruit fibre bread was rated as low. The sensory characteristics of the FibreMax™ bread were not rated differently to the control. The only significant difference was a lower visual appeal score for the fibre-enriched bread. This may be explained by a higher moisture content in the FibreMax™ bread, so it did not rise as high as expected and resulted in a denser appearance. It has been noted in previous research that a reduction in loaf volume and increase in water absorption may occur with the fibre-enrichment of bread (87). There was also a grey shade to the FibreMax™ bread. It is unlikely that this difference in rating would affect compliance to consumption, especially as the overall palatability of the bread was not affected. This shows that it is possible to add 10g of fibre to bread (two slices ~123g) without adversely affecting palatability. It is suggested in previous work that breads and cereals can be a common and acceptable vehicle for the addition of fibre (9, 25, 86, 87, 89, 90), especially compared to milk pudding products and drinks, which tended to be disliked by participants (85, 93).

FibreMax™-enriched bread may particularly appeal to families with children or those who refuse to eat wholegrain or wholemeal bread. Often children prefer softer mild white breads rather than bread with hard particles in it (i.e. wholegrain) (91). If children don’t like the texture or flavour of wholegrain or wholemeal bread then this could be a way to include additional fibre without significantly altering the texture or taste. This bread has the added benefit of fibre but appears similar in appearance to white bread, so the children may not notice the difference. Further product development may be required to produce bread that would rise better in terms of developing a commercial bread product.
The palatability of Fruit fibre enriched bread was low. Taste, smell and overall palatability were all rated significantly lower for the Fruit fibre-enriched bread than for the control. The majority of participants also regarded the aftertaste as unpleasant. Additional fibre added into the diet has been shown to affect the sensory characteristics of the final product (38, 85, 93). For example subjects preferred the smell, taste and overall palatability of a control drink compared to a flaxseed containing drink (93). Up until recently, for the most part small amounts of fibre have been added to food due to their undesirable effect on palatability (38).

In our study the texture and visual appeal of the Fruit fibre bread was not rated significantly different from the control bread. It supports the idea that bread products may have the ability to mask the texture-altering effect of the fibre. It has been suggested that it is unlikely that consumers will accept foods with functional components that have a lower taste rating than conventional foods (24, 26). Thus, the primary issue with the Fruit fibre was the taste and aftertaste.

One explanation may be an unwanted fermenting fruity taste and aftertaste that was detected in the Fruit fibre, which participants did not enjoy. Verbal feedback from participants included terms such as “weird”, “unusual” and “disgusting”. This fruity fermenting factor may have also affected the smell of the product. It is possible that the product would have been rated more acceptable if a fruit jam were added to cover this unwanted flavour, however further research would be required. Also it may not be practical to require the incorporation of jam to make the fibre tolerable, as not everyone enjoys jam and it has a high calorie density and high sugar content (100).

The bread selected may not have been the ideal bread type to act as a vehicle for the Fruit fibre. Wholegrain and wholemeal bread products have a more depth in taste and a higher nutrient density than white (refined) bread (100, 101). It may be possible that a wholegrain or wholemeal bread would have made the taste of the fibre more tolerable. The fibre may also
have been served in too high of a dose. The fruity taste may have been tolerated if a smaller amount of fibre was added. However, reducing the amount of fibre would not be ideal, as people would need to consume more bread to consume the target amount set by this study of 10g (11, 12). It has been shown in previous work that willingness to consume a food with functional components is inversely associated with the number of doses required (24). Thus, people may be less willing to consume fibre enriched bread if they are required to consume more than one serve. Further research would be required to assess these theories and test the dose effect of the fibre.

The majority of the participants were female. It has been suggested in previous research that females are more concerned for health than males and that an increased concern for health is associated with an increased willingness to compromise the taste of a product for health (26). Therefore, this disparity in sexes may be a limitation. However, because we blinded the participants they did not know which bread contained the fibre product, meaning they did not know which was the healthier bread reducing the likelihood of this effect.

The FibreMax™ bread was well accepted. It would benefit from further development to remove the grey shade that was noted. The fibre or food manufacturers may have techniques or processing procedures to assist, whether through whitening or through its inclusion in a wholemeal or wholegrain bread. The visual appeal and texture of the Fruit fibre bread were accepted and it has the potential to be well tolerated. However, in it’s current state the taste and aftertaste are an issue. Further development would be required to produce a product free of the fruit flavour, or with a more accepted flavour.

_Gastrointestinal symptoms:_

The perception of gastrointestinal symptoms and digestive tolerance may be affected by inter- and intra-personal variation. The sensitivity to digestive tolerance may differ from person to
person and what is an acceptable symptom to one person may be unacceptable to another. Gastrointestinal symptoms are a subjective measure of tolerance and the interpretation of the gastrointestinal parameters may vary amongst the participants (68, 69). These are all limitations in the assessment of the digestive tolerance of fibre. Adapting a validated questionnaire regarding fibre intake and gastrointestinal symptoms, using a large participant size (39/40 participants) and making use of a cross-over design are strengths of this study and helped to mitigate the effects of these issues (102). Previous studies ranged from 8-48 participants with most averaging around 20 in number (25, 76). In the present study, intra-personal variation was controlled for through asking participants to eat similar meals and to keep exercise consistent prior to each test day, as well as to abstain from excessive exercise prior to test day and to fast overnight/during morning. Some of these protocols were also required of participants in previous research (7, 15, 25, 56). However, not all participants complied with these requirements but randomization would have helped to mitigate the influence of this. Baseline gastrointestinal symptom values were also analysed to ensure there was no difference in baseline values detected between the test and control breads.

This research was conducted over a 24 hour time period with a one-week washout period, this is very similar to the design of Hess et al and others whom administered fibre and measured gastrointestinal symptoms over a 24-hour period (7, 77). The participants spent the first three hours in a controlled laboratory setting; the setting for the remainder of the assessment period was not controlled. During this time no restrictions on food consumption were set. In some other studies restrictions on the consumption of high fibre foods, or gastrointestinal symptoms inducing foods were made (7, 17, 22, 75-78). This is a limitation of this study as other confounding factors may have influenced the results. However, by not restricting these foods or controlling the setting the results may be more applicable to what would be expected in every day life.
The gastrointestinal symptoms experienced were assessed using a questionnaire comprising of a scale of 0 (no symptoms) through to 6 (unbearable). For analysis, the data were dichotomized into a combined score indicative of acceptable (coded 0) or unacceptable (coded 1). This method avoided some of the limitations as described in the Methods section. Strengths of the method are less statistical comparisons and recognition that a rating above ‘mild’ is unacceptable at any timepoint. A drawback is that it may reduce the ability to compare the results of this study with other studies although the more common methods of analysis can be undertaken if necessary for future publication.

Using questionnaires, it was found that both the FibreMax™ and Fruit fibre bread were well tolerated. The Fruit fibre enriched bread resulted in a significantly higher number of ‘unacceptable’ nausea symptoms than the control. Nausea is defined as “feeling in the stomach that vomiting is about to take place” (page S9)(103). Previous work has stated that rapid fermentation can induce stomach aches or abdominal discomfort (33, 103). Generally, nausea has not been experienced with additional fibre intake at doses of approximately 10g (15, 22, 56, 74, 76). In other work the limiting factor or most commonly observed symptom resulting from the addition of fibre has been flatulence (7, 15, 16, 22, 56, 76-78), which was not a significant factor in this study. Thus, it appears unlikely that the nausea was caused by the digestion and fermentation of the Fruit fibre. Nausea may therefore be attributed to the palatability of the product. The lack of desired taste and smell may have contributed to the participants feeling unwell especially as they were required to fast beforehand.

Consistent with other literature looking at the digestive tolerance of fibre products primarily composed of chicory root, 10g of the FibreMax™ product did not induce intolerable or unacceptable gastrointestinal symptoms (15). In general 10g of any fibre in a single setting was denoted as digestively acceptable (6, 7, 15-17, 22, 56, 59, 76-78).
Some of the New Zealand population, particularly teenage males are higher consumers of bread (11); it is possible that consuming more than two slices of this bread would result in adverse gastrointestinal symptoms experienced. There was a time and resource restriction, so only one dose of the fibre-enriched bread was tested and this may be regarded as a limitation if generalizing to higher bread consumers. The population of participants targeted included healthy adults. As participants were undergraduate nutrition students they may have had a higher intake of fibre than the general population. This could be a limitation as their tolerance may be higher but could also mean that high intakes of total dietary fibre can be tolerated. Small children and the elderly may experience more gastrointestinal symptoms due to their size and smaller consumption of food (11, 35). Tolerance may also be limited or altered in people with gastrointestinal issues or diseases such as irritable bowel syndrome, coeliac or diverticulosis (104). Therefore, it is possible that these results are more relevant to the healthy adult population.

The gastrointestinal tolerance of both the FibreMax™ and Fruit fibre-enriched bread were high. This study adds to the literature and confirms that 10g of fibre was tolerated in one serving of bread over the short time period (24-hours). There is space for further research to determine the dose effect of the fibre-enriched bread, the inclusion wholegrain or wholewheat bread and the digestive tolerance in a wide range of population groups who may have an altered tolerance, for example children, the elderly and those with gastrointestinal disorders. There is also place to determine the long-term implications of the consumption of the bread used in this study.

Cost:

One of the suggested barriers to the consumption of healthy foods such as fruit and vegetable is cost (14). The FibreMax™ product is expensive to buy in its current form. Further research
may be beneficial to investigate the benefits and acceptability of the primary components of FibreMax™, such as chicory root, in their natural form as a cheaper alternative. Fibre enriched breads currently on the market such as Natures fresh ‘Simply Fibre’ and Tip Top ‘The One’ are available at prices more than or equivalent to other bread products of the same brand (premium prices) and are more expensive than unbranded (budget) products (30). Not only is there an issue around whether consumers are prepared to pay more for a nutritious product, but also whether certain sections of the population should have limited access to the positive nutrition due to price premiums (63). The price may be relevant to people on restricted budgets who may benefit from additional fibre given that obesity and type 2 diabetes are most prevalent in low socioeconomic status groups (99, 105). To ensure the broadest consumer base, and thus, potential maximum benefit possible the bread would need to be available on the market at the same price as regular bread, not as a premium priced product. For this to be feasible in a commercial product the fibre would need to have the same gram-to-gram cost as flour, so that the price of the ingredients would not differ between the regular and high fibre product. There would also need to be a large increase in demand for the product to increase number of loaves produced and therefore reduce the production cost per loaf.

If derived from waste products there is potential for the resource cost of fibre to be low. There is also an environmental argument for the use of natural fibres from food that would otherwise be a waste product making their way back into the local food supply, for example fruit skins. Increasing economic growth has resulted in an increase in consumption of foods that require more natural resources worldwide (106). There is increasing concern for the environment and the effect the use of natural resources is having (106). The aim is to move towards more sustainable food consumption through increased efficiency, prevention or substitution (106). The use of food waste products can be nutritionally valuable and has been
proposed as sustainable (107, 108). Fruit fibre is made from waste products thus, will likely be a sustainable, environmentally friendly and economically stable product.

6.1 Conclusion/Summary

The benefits of fibre consumption are numerous including the reduction in the risk of diabetes, obesity and CVD, with an improvement in blood lipid profile, post prandial glycaemic response, blood pressure, BMI and bowel health (3, 35, 37, 43-49, 51-54, 56). Development and consumption of high fibre products should be desirable for health and bowel regularity (87). The average population deficit of fibre intake is approximately 10g, the quantity of fibre that was available in one serve (2 slices) of the test bread assessed in this study (11, 12). Bread could be a highly suitable candidate as a food vehicle given that it is highly consumed by the New Zealand population; it is not introducing a new component into the diet, and is a main meal component that fills the consumer (11).

The supplementation of FibreMax™ has proven to be well tolerated and palatable and has shown that it is feasible to add 10g to a single serve of white bread. Although the Fruit fibre bread was not as palatable, with reformulation it has the potential to be a sustainable fibre supplement. It also has the added benefit of being an economical and environmentally friendly product. There is potential for further development and processing of the Fruit fibre to produce a better or neutral tasting product. Overall this study has presented a practical approach to incorporating sufficient fibre into the diet.
7 Application to clinical dietetics

A good daily intake of fibre is associated with general health and well-being, including the prevention of weight gain and the reduction in the risk of developing diabetes or CVD (43-54, 106). With ongoing concern for these disease states it is incumbent upon the dietetic profession to implement means to increase the dietary fibre intake of clients and indeed all of New Zealanders. The average population deficit of fibre intakes is approximately 10g (11, 12). In our work it was found that the addition of 10g of fibre to bread in a single setting did not induce gastrointestinal symptoms. Apart from the Fruit fibre having a poor taste and aftertaste that will require reformulation, the two fibre products created moist and palatable bread. Additionally it was found from the work of another MDiet candidate on this project that there were glycaemic advantages to both the fibre breads. The Fruit fibre also had an energy displacement effect. All of which are positive qualities.

A food first approach, believed to be the best way to ‘reduce the risk of chronic disease’ and ‘promote optimal health’, involves choosing from a large range of nutrient dense foods (109). With its presence in food products such as wholegrains, fruits and vegetables improving food choices and eating patterns leads to an increase in fibre consumption (10). However, there are many barriers to the consumption of these healthy foods (13, 14). This research has presented a practical and acceptable approach to increasing a consumers fibre intake, enabling them to reach the to the recommended AI threshold (12). As a highly consumed product by the New Zealand population bread has shown to be an excellent vehicle for the supplementation of fibre (11). There is future potential for public health campaigns in which affordable fibre-enriched breads products could be available on the market at usual bread cost.

Clinically there is also the potential for the recommendation of fibre supplementation when advising individuals seeking dietary advice. However, there is a large individual variation and
thus, each recommendation needs to be tailored to the client needs (18, 23, 76). It may be possible to recommend smaller doses to begin with for children, elderly and those with a sensitive bowel. It is also essential to monitor and evaluate the outcomes of the individual and adjust accordingly (110).

It is necessary for the dietetic profession to implement means to increase dietary fibre intake. Increasing nutrient density whilst decreasing energy density of food products is a realistic method to optimize health. This research has presented a practical and acceptable approach to increasing a consumers fibre intake. There is place in the market and considerable potential for affordable and palatable bread with a higher amount of fibre, which does not induce gastrointestinal discomfort, such as those used in this study. This would provide dietitians with a good option when advising clients regarding increasing fibre intake.
8 References


Appendices

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Appendix A
Dr B Venn  
Department of Human Nutrition  
Division of Sciences  

30 January 2013  

Dear Dr Venn,  

I am writing to let you know that, at its recent meeting, the Ethics Committee considered your proposal entitled “HUNT311 glycaemic and satiety laboratory: a repeated teaching activity”.  

As a result of that consideration, the current status of your proposal is:- Approved  

For your future reference, the Ethics Committee’s reference code for this project is:- 13/022.  

The comments and views expressed by the Ethics Committee concerning your proposal are as follows:-  

While approving the application, the Committee would be grateful if you would respond to the following:  

The Committee would be grateful for your comment and clarification regarding the teaching versus the research content of this study. Will any research outcomes be achieved? Please confirm that, for ACC purposes, this project is not considered to be a clinical trial.  

As this is a repeated teaching activity, approval is for up to three years from the date of this letter. If the repeated teaching activity will continue beyond three years from the date of this letter, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.  

Yours sincerely,  

[Signature]  

Mr Gary Witte  
Manager, Academic Committees  
Tel: 478 8256  
Email: gary.witte@otago.ac.nz  

[Signature]  

c.c. Emeritus Professor L J Holloway  
Head Department of Human Nutrition  

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Appendix B
HUMAN ETHICS APPLICATION: CATEGORY a

1. University of Otago staff member responsible for project:
   (surname) (first name) (title)
   Venn Bernard Dr

2. Department: Human Nutrition

3. Contact details of staff member responsible: Ph 4795068
   Email bernard.venn@otago.ac.nz

4. Title of project: HUNT311 glycaemic and satiety laboratory; a repeated teaching activity

5. Indicate type of project and names of other investigators and students:

   Staff Research  y  Names  Dr Bernard Venn

   Student Research  □  Names  MDiet, MSc, PGDipSc or PhD students may be involved year to year in this repeated teaching activity at the discretion of Dr Bernard Venn

   External Research/  □  Names  Foods may be provided year to year in which case the supplier would be given anonymous group mean data only
<table>
<thead>
<tr>
<th>Collaboration</th>
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<tbody>
<tr>
<td>Institute/Company</td>
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</table>
6. Is this a repeated class teaching activity?
   YES

7. Fast-Track procedure
   Do you request fast-track consideration?
   NO

8. When will recruitment and data collection commence?
   March 2013

   When will data collection be completed?
   May 2016 (repeated teaching activity)

9. Funding of project.
   Is the project to be funded by an external grant?
   No

10. Brief description in lay terms of the purpose of the project (approx. 75 words):
    The purpose of the glycaemic and satiety laboratories is for students to experience participation in a clinical nutritional trial. Measured outcomes will be changes in blood glucose and feelings of hunger in response to consuming various carbohydrate containing foods. The laboratory will be a source of individual and group data to be used in a class assignment with potential for publication using anonymous group data.

11. Aim of project, including the research questions the project is intended to answer:
    The aim of this laboratory is to test the glycaemic and satiating properties of carbohydrate containing foods. This information will be used by HUNT311 students as a learning exercise and in the writing of his or her assignment.
12. **Researcher or instructor experience and qualifications in this research area:**

Dr. Venn is experienced in conducting research trials involving human participants. Testing will be carried out according to our standard procedure in the Department of Human Nutrition Undergraduate Laboratories.

13. **Participants**

13(a) **Population from which participants are drawn:**

Human nutrition students

13(b) **Specify inclusion and exclusion criteria:**

Inclusion: men and women in the age range of 18 - 60 y inclusive.

Exclusions: People diagnosed with chronic disease including diabetes mellitus, cardiovascular disease, cancer, and diseases of the digestive system; that suffer from food allergies; and women who are pregnant.

13(c) **Estimated number of participants:**

All HUNT311 students (currently 100+)

13(d) **Age range of participants:**

18-60 y

13(e) **Method of recruitment:**

Recruitment will be by invitation to the students by email and in class at the University of Otago.

13(f) **Please specify any payment or reward to be offered:**

None

14. **Methods and Procedures:**

The purpose and scope of the laboratory will be discussed in class. An Information Sheet (attached) will be given to students and teaching and research staff will be available to answer questions regarding the study. If students are willing to continue, a
Application Form for ethical consideration of research and teaching proposals involving human participants

consent form (attached) will be given to them. Participants will have their height and weight measured in a screened-off area to ensure the participants privacy. A questionnaire will be administered to ensure that eligibility criteria are met.

Test foods will be provided to participants. In 2013, the foods will be two weighed slices of white bread and two slices of fibre-enriched bread. The bread will be baked at Carrington college. Each student will consume bread containing one of two natural fibres; either a commercially available product (FibreMax, New Image International, Auckland) or a kiwifruit extract fibre provided by Anagenix, Auckland. The recommended dose for the Fibre Max product is 15g (providing 12.5g fibre, 1g carbohydrate, 1g water and traces of fat and protein). This amount of fibre is unlikely to cause gastrointestinal discomfort. An equivalent amount of the kiwifruit extract will be weighed to yield 12.5g fibre.

For measuring blood glucose, capillary blood is collected by finger pricking using a sterilised disposable lancet. During each test, a series of eight blood samples are collected over a period of three hours following the consumption of the food. Each student will test two foods, each on a separate non-consecutive day. The Department of Human Nutrition will use trained personnel to do the finger pricking.

Students will attend the laboratory after an overnight fast of at least 10 hours. On the evenings preceding each of these test days, participants will be advised not to exercise and to ensure that their evening meal contains a carbohydrate-rich food. On each of the test days, two finger-prick blood samples will be taken five minutes apart as a baseline blood glucose concentration. This method of collecting blood for analysis causes minimal discomfort to the participant. Blood glucose concentrations will be determined from a drop of blood using a Hemocue Glucose 201 Analyzer. Following this, a test food will be consumed over a fifteen minute period and a series of six more finger-pricks will be undertaken at 15, 30, 45, 60, 90 and 120 min. In the event of an abnormal result, a repeat fingerprick may be required. Adhesive plasters will be provided to hold in place a cotton wool swab covering the small incision. The total volume of blood extracted from the finger-pricks will be less than one millilitre. There is no excess blood for disposal. During this laboratory, students will also be given a set of questions regarding how hungry they feel as a measure of satiety.
15. Compliance with The Privacy Act 1993 and the Health Information Privacy Code 1994 imposes strict requirements concerning the collection, use and disclosure of personal information. These questions allow the Committee to assess compliance.

15(a) Are you collecting and storing personal information directly from the individual concerned that could identify the individual?

YES

15(b) Are you collecting information about individuals from another source?

Please explain: No

15(c) Collecting Personal Information:

- Will you be collecting personal information?
  YES

- Will you be informing participants of the purpose for which you are collecting the information and the uses you propose to make of it?
  YES

- Will you be informing participants who will receive the information?
  YES

- Will you inform participants of the consequences, if any, of not supplying the information?
  YES

- Will you inform the participants of their rights of access to and correction of personal information?
  YES

Where the answer is YES, please make sure the information is available in the Information Sheet for Participants.

If you are NOT informing them of the points above, please explain why:

15(d) Please outline your data storage and security procedures.
The information will remain confidential to the study investigators. Paper copies will be kept in a lockable office and electronic data stored on departmental computers. The results of this study may be published but no individual’s identity will be revealed.

At the end of the project any personal information will be destroyed immediately except that, as required by the University's research policy, any raw data on which the results of the project depend will be retained in secure storage for five years, after which it will be destroyed.

15(e)  **Who will have access to personal information, under what conditions, and subject to what safeguards?**

Only Dr Bernard Venn will have permanent access to the personal information. Paper copies will be stored in Dr Venn’s University of Otago office and any information transferred into digital form will be stored on Dr Venn’s University computer.

If a nominated postgraduate student enters data, this will only be done on a desktop university password-protected computer. At the completion of data entry, the student will be asked to transfer the electronic file to Dr Bernard Venn and to delete the file from the student computer.

The statistician will be given anonymous data.

**Will participants have access to the information they have provided?**

Yes, they will have access only to his or her own information if they request to view it.

15(f)  **Do you intend to publish any personal information they have provided?**

NO

If YES, please specify in what form you intend to do this?

15(g)  **Do you propose to collect demographic information to describe your sample? For example: gender, age, ethnicity, education level, etc.**
Application Form for ethical consideration of research and teaching proposals involving human

Yes

15 (h) Have you, or do you propose to undertake Māori consultation? Please choose one of the options below, and delete the options that do not apply:

(Please see http://www.otago.ac.nz/research/maoriconsultation/index.html).

YES We have ALREADY undertaken consultation [please attach a copy of your completed Research Consultation with Māori Form]

16. Does the research or teaching project involve any form of deception?

NO

If yes, please explain all debriefing procedures:

17. Please disclose and discuss any potential problems: (For example: medical/legal problems, issues with disclosure, conflict of interest, etc)

As this is a repeated teaching activity, research students may be involved in data collection and analysis from year to year. The students will only work with data with the University of Otago student ID as an identifier, rather than student names.

From time to time, a food manufacturer may supply the food. When this occurs the manufacturer will be supplied with anonymous group mean data only.

The carbohydrate rich foods may contain added dietary fibre. For such foods, students will be asked to give feedback on any gastrointestinal discomfort.

There may be some discomfort from finger pricking
18. Applicant's Signature: .................................................................

[Principal Applicant: as specified in Question 1]

Date: ................................

19. Departmental approval: I have read this application and believe it to be scientifically and ethically sound. I approve the research design. The Research proposed in this application is compatible with the University of Otago policies and I give my consent for the application to be forwarded to the University of Otago Human Ethics Committee with my recommendation that it be approved.

Signature of *Head of Department: .................................................................

Name of Signatory (please print): Linda Holloway

Date: ................................

*(In cases where the Head of Department is also the principal researcher then an appropriate senior staff member in the department must sign)

Please attach copies of the Information Sheet, Consent Form, and Advertisement for Participants

[Please send the original and 16 copies of the application, double-sided and stapled, to Academic Committees, Room G23 or G24, Ground Floor, Clocktower Building, University of Otago]
Application Form for ethical consideration of research and teaching proposals involving human participants

Research consultation with Māori

HUNT311 glycaemic and satiety laboratory: a repeated teaching activity

Principal Investigator 1

Name: Dr Bernard Venn

Department: Department of Human Nutrition

Campus: DUNEDIN

Email: bernard.venn@otago.ac.nz  Telephone: Not Supplied

Is this Otago District Health Board research?

No

Does this research involve human participants?

Yes

Description in lay terms of the proposed research

The purpose of the glycaemic and satiety laboratories is for students to experience participation in a clinical nutritional trial. Measured outcomes will be changes in blood glucose and feelings of hunger in response to consuming various carbohydrate containing foods. The laboratory will be a source of individual and group data to be used in a class assignment with potential for publication using anonymous group data.

Description in lay terms of the potential outcomes of the area of research

The laboratory will give the students the experience of being involved in a clinical trial and data collection and analysis and write-up of the experiment. The aim is to give the students insight and awareness of issues in conducting experimental work. It will provide a better understanding of research for those graduating and a foundation for those students progressing to postgraduate research studies.
Potential areas that are of interest to or of concern for Māori

Maori students who in the future may be giving nutrition advice or teaching will benefit from the first hand experience of being involved in a clinical trial.

Collaborations in this area of research

Potential funding bodies

Departmental funds

Location

Undergraduate laboratories Dept Human Nutrition University of Otago

Other relevant information

Relevance Score

Reference

16354
Application Form for ethical consideration of research and teaching proposals involving human participants

[Reference Number as allocated upon approval by the Ethics Committee]

[Date]

UNIVERSITY
OF OTAGO
To ikei Wairongo Otogo
NEW ZEALAND

HUNT311 glycaemic and satiety laboratory; a repeated teaching activity

INFORMATION SHEET FOR PARTICIPANTS

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

What is the Aim of the Project?

The aim of this study is to test the glycaemic and satiating properties of carbohydrate containing foods. This requires attending the laboratory on two occasions. You and other HUNT311 students will use the information in the writing of a HUNT311 assignment. If you choose not to participate, you will still be required to attend the laboratory to observe and data will be provided to you; the assessment of your assignment will in no way be affected.

What Type of Participants are being sought?

HUNT311 students

What will Participants be Asked to Do?

You will be asked to attend the Department of Human Nutrition Undergraduate Laboratory on two occasions. Upon receipt of a consent form, we will collect some personal information from you comprising demographics, height and weight. Following this, the first test will be conducted. Testing is conducted in the morning with a start time of between 7 - 8 am. You will be required to fast, i.e.: to have no food or drinks except water after 10 pm on the night before the test. We would prefer that you did not walk to the University. If you do walk or
cycle we would like you to arrive 20 minutes early so that your heart rate and blood glucose have a chance to settle down before you start the test. On arrival and five minutes after, a finger-prick blood sample will be taken in the fasting state. You will then be given a test food to eat. After this, additional finger-prick blood samples will be taken at 15, 30, 45, 60, 90, and 120 min. The fingerpricks may cause some discomfort. In the event of an abnormal result, a repeat finger-prick may be required. The total volume of blood collected will amount to less than half a teaspoon. You will also be asked to answer questions on how hungry you feel. During this three hours we would like you to remain seated in the room with the exception of toilet visits if necessary. You are free to read or talk. At the end of three hours there will be some food for you to eat on the premises or to take away.

Consumption of the fibre-enriched bread may cause symptoms such as bloating or flatulence; however, as the dose is recommended by the manufacturer, any discomfort should be mild. Fingerpricking causes minimal discomfort.

**What Data or Information will be Collected and What Use will be Made of it?**

We will collect data on your age, ethnicity, smoking habits and gender and we will be measuring your height and weight. The purpose of collecting this information is to describe the overall characteristics of the study population. We will also ask you to fill in a medical questionnaire to ensure you meet the study eligibility criteria (no diagnosis of diabetes mellitus, cardiovascular disease, cancer, diseases of the digestive system, you are not pregnant, you do not suffer from food allergies or take medication that affects glucose absorption and metabolism). From your blood samples we will be testing glucose concentration. The information will remain confidential to the study investigators. Paper copies will be kept in a lockable office and electronic data stored on a departmental computer. The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity. The data collected will be securely stored in such a way that only those mentioned below will be able to gain access to it. Data obtained as a result of the research will be retained for at least 5 years in secure storage. Any personal information held on the participants such as contact details may be destroyed at the completion of the research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

If you choose not to supply information this may exclude you from taking part in the study. You have rights of access to the personal information that you have given to us and you may correct or change this information. You will be provided with the results of the study. Note that the breads are commercial brands. If the study results are published together with the manufacturer/brand details, then the GI of the bread may become publically available.

**Can Participants Change their Mind and Withdraw from the Project?**

You may withdraw from participation in the project at any time and without any disadvantage to yourself or to your HUNT311 assessment of any kind.

**What if Participants have any Questions?**

If you have any questions about our project, either now or in the future, please feel free to contact either:-

Dr Bernard Venn
Application Form for ethical consideration of research and teaching proposals involving human participants

Department of Human Nutrition

University Telephone Number: 03 479 5068
Email Address Bernard.venn@otago.ac.nz

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 03 479 8256). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Application Form for ethical consideration of research and teaching proposals involving human participants

[Reference Number as allocated upon approval by the Ethics Committee]
[Date]

HUNT311 glycaemic and satiety laboratory; a repeated teaching activity

CONSENT FORM FOR PARTICIPANTS

I have read the Information Sheet and understand the procedures. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:-

1. My participation in the project is entirely voluntary;
2. I am free to withdraw from the project at any time without any disadvantage to myself or to my HUNT311 assessment;
3. Personal identifying information will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for at least five years;
4. The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve my anonymity
5. Fingerprick blood sampling may cause some discomfort.
6. Consumption of the fibre-enriched bread may cause symptoms such as bloating or flatulence; as the dose is as recommended by the manufacturer any discomfort should be mild.
7. If food has been provided by an external supplier, anonymous group mean data may be sent to that supplier.

I consent to attending the laboratory on two days following an overnight fast, consuming the study food and providing eight blood samples obtained by finger pricking over three hours on each test day.
Application Form for ethical consideration of research and teaching proposals involving human participants

I agree to take part in this project. Date ..........................

Name ......................................... Signature ..........................

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph 03 479 8256). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Appendix E
HUNT311 glycaemic and satiety laboratory; a repeated teaching activity

PARTICIPANT QUESTIONNAIRE

Name:

Are you male or female?

Postal address:

Email address: (if applicable)

Telephone numbers: (Work/Home/Mobile)
Date of birth:

Are you a non-smoker, past smoker, current cigarette smoker, cigar smoker or pipe smoker?

Frequency of smoking (if applicable)

Have you been diagnosed with diabetes mellitus, heart disease, stroke, cardiovascular disease, cancer, diseases of the digestive system?

Please list current medicines, dose and frequency:

Please list current supplements, brand and frequency:
Application Form for ethical consideration of research and teaching proposals involving human participants

Are you pregnant?

Please list any food allergies:

Which ethnic group do you belong to? Please tick the box or boxes that apply to you.

☐ New Zealand European

☐ Māori

☐ Samoan

☐ Cook Island Maori

☐ Tongan

☐ Niuean

☐ Chinese

☐ Indian

☐ other such as Dutch, Japanese, Tokelauan. Please specify: ____________________________
Appendix F
1. In the last two weeks have you changed anything major in regards to your eating habits or eating patterns? (e.g. purposely increased/decreased portion sizes, eliminated or increased a food group)?

Yes / No

- If yes, please briefly explain:

2. On the day of your last lab, did you:

   a) Fast from 10pm or 8am depending on your lab time?  
      - If No, what time did you fast from: _____

   b) Refrain from drinking alcohol the previous night?  
      - If No, how many standards did you consume? _____

   c) Drink alcohol in the following 24 hours after completing the lab?  
      - If Yes, how many standards did you consume? _____

3. Today did you:

   a) Fast from 10pm or 8am depending on your lab time?  
      - If No, what time did you fast from: ______

   b) Refrain from drinking alcohol last night?  
      - If No, how many standards did you consume? ______

   c) Do you plan to drink 3+ standard alcohol drinks in the following 24 hours after completing the lab?  
      - Yes/ No

4. Are you currently taking any medication?

Yes/ No

- If yes, please name the medication and what it is for:
### Abdominal or Epigastric symptoms

**Did you experience during the last 4 weeks:**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>none</th>
<th>mild</th>
<th>moderate</th>
<th>quite a lot</th>
<th>severe</th>
<th>very severe</th>
<th>unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Abdominal pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- in common</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- postprandial</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- feeling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- doesn’t decline after defecation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>2. Epigastric pain</td>
<td></td>
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<tr>
<td>- in common</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- during daytime</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- at night/asleep</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Heartburn</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>4. Regurgitation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>5. Abdominal rumbling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>6. Bloating</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>7. Empty feeling</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>☐</td>
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<tr>
<td>8. Nausea</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>9. Vomiting</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>10. Loss of appetite</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>11. Postprandial fullness</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>12. Belching</td>
<td>☐</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>13. Flatulence</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>14. Haematemesis</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>15. Dysphagia</td>
<td></td>
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<tr>
<td>- liquid food</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<tr>
<td>- solid food</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>16. Stools</td>
<td></td>
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<tr>
<td>- melena</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>- bloody</td>
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<td>☐</td>
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<tr>
<td>- mucous</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- frequent hard</td>
<td>☐</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- diarrhoea</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- alternately solid or loose</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- constipation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- frequently with pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- urging stools</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>- incomplete</td>
<td>☐</td>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- steatorrhoea</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>

18. Describe your abdominal or epigastric pain during the last 4 weeks by marking the line below with a cross. No text.
**Questions on the participant’s gastrointestinal well-being:**

**Time:** 0 minutes (baseline)

This questionnaire is designed to assess any gastrointestinal symptoms pre-meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 24 hours</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Flatulence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Nausea</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Vomiting</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stool frequency</th>
<th>None</th>
<th>One</th>
<th>Two</th>
<th>Three</th>
<th>Four</th>
<th>Five</th>
<th>Six plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Separate hard lumps</td>
<td>○</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sausage shaped lumpy but sausage shaped lumpy</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Like sausage cracked</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Like sausage smooth/soft</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soft blobs</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mushy stool</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watery</td>
<td>○</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stool consistency</th>
<th>Separate hard lumps</th>
<th>Sausage shaped lumpy but sausage shaped lumpy</th>
<th>Like sausage cracked</th>
<th>Like sausage smooth/soft</th>
<th>Soft blobs</th>
<th>Mushy stool</th>
<th>Watery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Questions on the participant’s gastrointestinal well-being:

**Time:** 60 minutes

This questionnaire is designed to assess any gastrointestinal symptoms experienced post meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 1 hour</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Flatulence</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Nausea</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vomiting</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
</tbody>
</table>
Questions on the participant’s gastrointestinal well-being:

**Time:** 120 minutes

This questionnaire is designed to assess any gastrointestinal symptoms experienced post meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 2 hours</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Flatulence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Nausea</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Vomiting</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Questions on the participant’s gastrointestinal well-being:

**Time:** 180 minutes

This questionnaire is designed to assess any gastrointestinal symptoms experienced post meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 3 hours</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Flatulence</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Nausea</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vomiting</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Questions on the participant’s gastrointestinal well-being:

Time: 8 hours

This questionnaire is designed to assess any gastrointestinal symptoms experienced post meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 8 hours</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Flatulence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Nausea</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Vomiting</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Questions on the participant’s gastrointestinal well-being:

Time: 24 hours

This questionnaire is designed to assess any gastrointestinal symptoms experienced post meal. Please make a mark on the circle under each title according to the intensity or frequency of the gastrointestinal symptoms you have.

<table>
<thead>
<tr>
<th>Did you experience during the last 24 hours</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Quite a lot</th>
<th>Severe</th>
<th>Very Severe</th>
<th>Unbearable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloating</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal rumbling</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Flatulence</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Nausea</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Vomiting</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stool frequency</th>
<th>None</th>
<th>One</th>
<th>Two</th>
<th>Three</th>
<th>Four</th>
<th>Five</th>
<th>Six plus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stool consistency</th>
<th>Separate hard lumps</th>
<th>Sausage shaped but lumpy</th>
<th>Like a sausage with cracks</th>
<th>Like a sausage smooth/soft</th>
<th>Soft blobs</th>
<th>Mushy stool</th>
<th>Watery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Appendix I
Questions on palatability of test meals

This questionnaire is designed to assess how much you enjoyed the meal. Please make a mark on the lines under each title according to how you felt about each aspect of the meal.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual appeal</td>
<td>Bad to Good</td>
</tr>
<tr>
<td>Smell</td>
<td>Bad to Good</td>
</tr>
<tr>
<td>Taste</td>
<td>Bad to Good</td>
</tr>
<tr>
<td>Aftertaste</td>
<td>None to Much</td>
</tr>
<tr>
<td>Palatability</td>
<td>Bad to Good</td>
</tr>
</tbody>
</table>
Appendix J
Date:  
AM/PM (please circle):  
Number:

Questions on the palatability of the test meals - the bread

**Time:** 15 minutes

This questionnaire is designed to assess how much you enjoyed the meal. Please make a mark on the lines under each title according to how you felt about each aspect of the meal.

<table>
<thead>
<tr>
<th>Visual appeal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislike very much</td>
<td>Like very much</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislike very much</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Taste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislike very much</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Texture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislike very much</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aftertaste</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall pleasantness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dislike very much</td>
</tr>
</tbody>
</table>
Appendix K
Week one email reminder:

Hi all

Reminder to those of you streamed into a lab tomorrow:

For morning lab stream (starting 7:45-8am)

Tonight you need to:
- Record what you eat for dinner including quantity (so you can eat the same meal the night before your next lab)
- Fast from 10pm (only water is allowed)
- Do not drink alcohol

Tomorrow you need to:
- Avoid vigorous exercise
- Do not drink alcohol
- If walking or cycling to university allow 10min for blood glucose to settle down before the lab starts

For afternoon lab stream (starting 1pm)

Tonight you need to:
- Not drink alcohol

Tomorrow you need to:
- Have breakfast before 8am and record what you eat including quantity (so you can eat the same breakfast before your next lab)
- Avoid vigorous exercise before the lab
- Do not drink alcohol
Week two email reminder:

Hi all

Reminder to those of you streamed into a lab tomorrow:

**Make sure you come to the same lab stream!**
So if you went to the morning lab last time go to the morning lab tomorrow, if you went to the afternoon lab last time go to the afternoon lab tomorrow. Lab will be at the same place.

Also remember to do the following:

**Morning stream (starting 7:45-8am)**

Tonight you need to:
- Fast from 10pm (only water is allowed)
- Eat the same dinner
- Do not drink alcohol

Tomorrow you need to:
- Avoid vigorous exercise
- Do not drink alcohol
- If walking or cycling to university allow for 10min for blood glucose to settle

**Afternoon lab (1pm start)**

Tonight you need to:
- Not drink alcohol

Tomorrow you need to:
- Have breakfast before 8am (remember to eat the same breakfast)
- Fast from 8am (only water is allowed)
- Avoid vigorous exercise before the lab
- Do not drink alcohol