Glycaemic response to varying the proportions of starchy foods and non-starchy vegetables within a meal: A randomised controlled trial

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Abstract

Background: Glycaemic response is an important contributor to glycaemic control and is positively associated with the risk of developing diabetic complications. As it is largely determined by the type and amount of carbohydrate consumed, manipulating carbohydrate intake may have the potential to modify glycaemic response. Current guidelines recommend that one quarter of your plate contains starchy carbohydrate foods, one quarter protein based foods and the remaining half non-starchy vegetables. It is unsure to what extent altering the proportions of starchy foods and non-starchy vegetables within a meal will affect glycaemic response.

Objective: To examine the effect on glycaemic response in non-diabetic people of varying the proportions of a starchy carbohydrate food and non-starchy vegetables within a meal.

Design: Randomised controlled crossover trial

Methods: Over three separate testing days 74 healthy young adults consumed three test meals with varying proportions of starchy carbohydrate foods (30g, 45g, 60g available carbohydrate from either pasta or rice) and non-starchy vegetables. A gram for gram substitution of pasta or rice for non-starchy vegetables was used so as the total weight of each meal remained the same. Participants were randomised to receive either three pasta-based meals or three rice-based meals. Postprandial glycaemic response was measured by finger prick blood samples over a 90-minute period following the consumption of each test meal.

Results: Glycaemic response, measured by incremental area under the curve (iAUC) glucose, and 90-minute blood glucose concentration increased as the proportion of pasta or rice within the meal increased and the proportion of non-starchy vegetables decreased (p<0.001 and p<0.01, respectively). Mean iAUC for the pasta-based meals with the small (30g available carbohydrate) and medium (45g available carbohydrate) amount of carbohydrate was 92.9
(43.3) mmol*min/L and 117.6 (SD: 43.3) mmol*min/L, respectively and there was a
difference between them (p=0.002). iAUC for the pasta-based meal with the large amount of
carbohydrate (60g available carbohydrate) was 122.2 (55.1) mmol*min/L however there was
no difference between the medium and large meals (p=0.573). For the rice-based meals mean
iAUC was 128.6 (78.1) mmol*min/L, 140.1 (77.6) mmol*min/L and 196.9 (82.4)
mmol*min/L for the small, medium and large meals, respectively. There was no difference in
iAUC between the medium and small meals (p=0.314) however there was a difference
between the medium and large meals (p<0.001). Rice-based meals induced 16-46% larger
glycaemic responses than the pasta-based meals with there being a difference for the small
and large meals (p=0.048 and p<0.001, respectively) yet no difference for the medium meals
(p=0.243).

**Conclusion:** It is recommended that people follow the current plate model guidelines as the
meal with the smallest proportion of pasta or rice (30g or quarter of a plate) and the largest
proportion of non-starchy vegetables (half a plate) induced the greatest attenuation in
glycaemic response.

**Key words:** Type 2 diabetes, postprandial glycaemia, glycaemic response, vegetables, rice, pasta
Preface

This research project was conceived by Dr Bernard Venn and Ms Zhoushi Zhang in response to Ms Zhang’s work as a diabetes dietitian at the Waitemata District Health Board. The candidate (Kate Martin), fellow Master of Dietetics (MDiet) candidates (Eilis Woodward and Anna Worsfold) and Dr Bernard Venn (supervisor) jointly developed the research protocols. Dr Bernard Venn was responsible for gaining ethical approval and research funding.

The effect on glycaemic response of varying the proportions of starchy foods and non-starchy vegetables within a meal is reported in this thesis. Within this study, Eilis Woodward, Anna Worsfold and PhD candidate, Zhoushi Zhang collected data on speed of eating, energy intake and satiety, respectively. Their results will be presented separately and are not included in this thesis.

The candidate was responsible for the following under supervision:

- Development, product procurement and preparation of the test meals, presentation to potential participants, development of questionnaires and recording forms for data collection, participant attendance and organisation of the testing sessions (in partnership with fellow MDiet candidates).
- Taking a lead role in data collection, including: instructing and advising other members of the data collection team, collecting participants finger prick blood samples and timing participants meal duration
- Data collation and entry
- Consultation and input into the statistical analysis conducted by a biostatistician
- Development of included figures and tables
- Interpretation of results
- The writing of this thesis
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Firstly I would like to thank my supervisor Dr. Bernard Venn, your continued support and guidance has been extremely valuable throughout this research experience. The time and commitment you have given to myself and this project has been very much appreciated.

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### Abbreviations

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<tbody>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>AMDR</td>
<td>Acceptable Macronutrient Distribution Range</td>
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<tr>
<td>AvailCHO</td>
<td>Available Carbohydrate</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<td>CDA</td>
<td>Canadian Diabetes Association</td>
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<tr>
<td>CGMS</td>
<td>Continual Glucose Monitoring Systems</td>
</tr>
<tr>
<td>CHO</td>
<td>Carbohydrate</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular Disease</td>
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<tr>
<td>GI</td>
<td>Glycaemic Index</td>
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<tr>
<td>GL</td>
<td>Glycaemic Load</td>
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<tr>
<td>HbA$_{1c}$</td>
<td>Glycosylated Haemoglobin A$_{1c}$</td>
</tr>
<tr>
<td>iAUC</td>
<td>Incremental Area Under the Curve</td>
</tr>
<tr>
<td>IBS</td>
<td>Irritable Bowel Syndrome</td>
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<tr>
<td>MDiet</td>
<td>Master of Dietetics</td>
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<tr>
<td>OGTT</td>
<td>Oral Glucose Tolerance Test</td>
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<tr>
<td>TE</td>
<td>Total Energy</td>
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<tr>
<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
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<td>USA</td>
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1 Introduction

Diabetes prevalence is rapidly increasing worldwide (1). In 2015 estimated diagnosed cases of diabetes in New Zealand was 260,458 people, equating to over 5.8% of the population (2). The majority of these cases are type 2 diabetes mellitus (T2DM), a disease with modifiable lifestyle risk factors (1). The prevention and management of diabetes has therefore been identified as a priority health goal (1, 3, 4).

Controlling glycaemic response is an essential aspect of managing T2DM (5). This is due to postprandial hyperglycaemia being a significant risk factor for both macro- and microvascular complications (6-13) and diabetes related mortality (7, 8, 14, 15). As both the type and amount of carbohydrate are positively related to postprandial glycaemic response (16), there is the potential to influence glycaemic response by manipulating carbohydrate intake.

Main meals generally consist of three main components, starchy carbohydrate foods, non-starchy vegetables and protein-based foods. The starchy carbohydrate component of the meal largely determines glycaemic response as starchy foods generally contain more available carbohydrate (17) and have a higher glycaemic index (GI) (18, 19) than non-starchy vegetables. Whilst all health organisations recommend people with and without diabetes consume starchy foods, the amounts and proportions they advise vary. The New Zealand Ministry of Health advises having more non-starchy vegetables than starchy vegetables on a plate (20) and Diabetes New Zealand recommend one quarter of the plate be starchy carbohydrate foods, one quarter protein based foods and one half non-starchy vegetables (21). The United Kingdom (UK) suggests that meals should be based around starchy foods (22). Diabetes associations also recognise that carbohydrate requirements for people with diabetes need to be individualised based on body weight, physical activity levels and blood glucose control (23-25).
It is unclear to what extent altering the proportions of starchy foods and non-starchy vegetables within a meal will affect glycaemic response. A decrease in the amount of starchy foods tends towards a reduction in glycaemic response, however, some vegetables contain starch and sugars (17), therefore a compensatory increase in the amount of vegetables within a meal will likely influence glycaemic response. Currently no studies have measured the glycaemic effect of substituting starchy foods for non-starchy vegetables within a meal in people with or without T2DM. As it has been found that the relative glycaemic response is similar between individuals with differing glucose tolerance (26-28), it is likely that results obtained from people with normal glucose tolerance will also be applicable to people with impaired glucose tolerance and T2DM.

Therefore, the aim of this study was to examine the effect on glycaemic response in non-diabetic people of varying the proportions of a starchy carbohydrate food and non-starchy vegetables within a meal. These results could then be used to provide further evidence-based recommendations for the proportions of starchy and non-starchy foods that people should include within their meal.
2 Literature Review

2.1 Introduction

The purpose of this literature review was to examine the evidence for influencing glycaemic response through dietary manipulation.

Specifically this review focuses on:

- Providing an overview of glycaemic response and how this is influenced by glycaemic index (GI) and glycaemic load (GL).
- Discussing whether or not glycaemic response is clinically relevant for people with normal glucose tolerance, impaired glucose tolerance and type 2 diabetes mellitus (T2DM).
- Identifying strategies using meal components that may reduce glycaemic response and improve glycaemic control.
- Reviewing the current dietary guidelines and recommendations for carbohydrate and vegetable intake as well as the proportions of foods you should include on your plate.
- Recognising the gaps in the current literature around meal composition and glycaemic response to develop a rationale for this study.

Literature was sourced from the following online databases, Medline via Ovid, Pubmed and Scopus. Search key words included, ‘postprandial glycaemia’, ‘type 2 diabetes mellitus’, ‘glycemic index’, ‘glycemic load’, ‘carbohydrate’ and ‘vegetables’. Additional literature was identified from the reference lists of relevant articles that were collected. Studies conducted in human participants and written in English were considered appropriate to be included in this review.
2.2 Glycaemic response

Glycaemic response or postprandial glycaemia is the term used to describe the normal physiological response of plasma glucose concentrations after eating a meal (29). Typically plasma glucose concentrations begin to rise about ten minutes after starting a meal due to the absorption of dietary carbohydrate (29). The quantity, composition and timing of the meal are all key contributors to the postprandial glycaemic response (29). For healthy individuals glycaemic response generally does not exceed 7.8 mmol/L (140 mg/dl), and preprandial levels are restored within 2-3 hours (5) due to the insulin-stimulated uptake of glucose by the liver and peripheral tissues (29). However, for people with T2DM, decreased insulin sensitivity and secretion (30, 31) results in frequently occurring postprandial hyperglycaemia (32). This is defined as a plasma glucose level >7.8 mmol/l (140 mg/dl) 1-2 hours after the ingestion of food (International Diabetes Federation 2011).

Glycaemic response can be measured by collecting a series of fingertip capillary samples, typically in 15 to 30 minute time intervals following meal consumption (33). Alternatively, continual glucose monitoring systems (CGMS) provide another measure of glycaemic response by displaying blood glucose concentrations every few minutes (34). Post-challenge glycaemia describes the glycaemic response following an oral glucose tolerance test (OGTT) (5) and is often used in the research setting or to confirm a diabetes diagnosis. It is measured by collecting a single capillary blood sample two hours after the consumption of a standard glucose load (35).

It has been recognised that not all carbohydrates induce an identical postprandial response and instead both the type and quantity of carbohydrate consumed significantly impacts glycaemic response (36). To account for these differences, the glycaemic index (GI) concept was developed to rank foods based on the glycaemic response following consumption of a fixed amount of available carbohydrate (usually 50g) (37, 38). GI is calculated by expressing the
measured glycaemic response to a test food as a percentage of the measured glycaemic response to a reference food (38), therefore GI is a relative measure of glycaemic response (39). However, individuals do not always consume foods in portions containing 50g of available carbohydrate, therefore the glycaemic load (GL) concept has been developed (40, 41). GL is a product of a food’s GI and the total amount of carbohydrate consumed (GL = GI x available carbohydrate (g)). Thus, GL has been used as a practical predictor of the postprandial glycaemic response (40, 42).

2.3 Clinical relevance of controlling glycaemic response

2.3.1 For healthy individuals with normal glucose tolerance

It is unclear to what extent people with normal glucose tolerance need to be concerned about glycaemic response. Blood glucose concentration is under tight homeostatic control and in response to a carbohydrate containing meal, the body releases insulin to lower blood glucose concentration to the basal value. While there is some evidence that a diet high in total carbohydrate or in rice may increase the risk of developing T2DM (43) data are inconsistent, as no relationship (44-46) and even a protective effect of high rice or total carbohydrate intakes have been reported (47, 48).

Furthermore, in these studies the associations explored were between food or nutrient intake and risk, rather than directly measuring glycaemic response and relating it to risk. Dietary GI and GL are the most widely used surrogate markers of glycaemic response, despite methodological shortcomings in the collection and estimation of these exposures (49). Relationships between dietary GI/GL and T2DM risk have been inconsistent. In several large prospective studies, positive associations between GI and/or GL and the incidence of T2DM have been found (40, 50-53), whereas no such associations have been found in other studies (44, 54, 55).
Short-term intervention trials examining the effect of low GI compared to high GI diets on intermediate risk factors for T2DM have also produced mixed results. While several studies found low GI diets to improve insulin sensitivity and secretion (56-58), others found no such effect (59, 60). Many studies were also unable to achieve differences in postprandial glucose profiles between treatment groups (61-64) and differing definitions of low GI and high GI diets introduced considerable heterogeneity between studies. Due to this inconsistency in results, the American Diabetes Association (ADA) have no recommendations for using GI to guide carbohydrate intake in order to prevent T2DM (35). It therefore still remains uncertain whether there is any clinical relevance in targeting a reduction in glycaemic response for healthy individuals. Further well-designed studies are required before evidence-based conclusions can be made.

2.3.2  For individuals with impaired glucose tolerance or T2DM

In contrast to the conflicting evidence regarding the relationship between glycaemic response and the risk of developing T2DM, there is ample evidence supporting the necessity to control glycaemic response in people with impaired glucose tolerance or diabetes mellitus (65, 66). Glycaemic response contributes to overall glycaemic control, represented by haemoglobin A1c (HbA1c)(67). HbA1c reflects the average glucose exposure over the preceding 2-3 month period. Healthcare providers regularly measure HbA1c to assess adequacy of patient’s therapy and adherence to treatment plans (29, 35). Postprandial glycaemic response was found to be as important if not more important than other glycaemic markers for the prediction of HbA1c, therefore targeting glycaemic response is an important strategy for HbA1c reduction (67-69).

A positive association has been identified between glycaemic response and the risk of cardiovascular disease (CVD) and diabetes related mortality (6-9). The DECODE study, including 22,514 participants from ten European prospective cohort studies found that the addition of post-challenge glycaemia data to fasting plasma glucose data significantly
improved the prediction of all cause mortality (p=<0.001) and cardiovascular mortality (p=<0.005) (14). A positive relationship has also been found between glycaemic response and the incidence and progression of diabetic retinopathy in long-term prospective cohort studies (11, 12).

While an association has been identified between glycaemic response and the risk of developing diabetic complications, the effectiveness of using treatment specifically targeting glycaemic response for improvements in clinical outcomes is unclear (5, 70). The HEART2D randomised controlled trial compared the effects of selectively reducing either fasting plasma glucose or glycaemic response, using different insulin regimens (71). Participants in the glycaemic response targeted group achieved lower daily mean postprandial glycaemic response than the basal group, indicating the effectiveness of the intervention (71). However, there was no difference in HbA1c and cardiovascular outcomes between the two groups (71). Another large and long-term randomised controlled trial in which an insulin release stimulant was used, failed to attenuate glycaemic response and therefore no significant benefit on cardiovascular outcomes was found (72).

Acarbose targets glycaemic response by slowing the rate of carbohydrate digestion (73). Large and long-term trials in which this has been used have found conflicting results. The UK Prospective Diabetes Study randomised 1946 people with T2DM to receive a maximum dose of 100mg of acarbose three times per day or a matching placebo for three years. Although treatment with acarbose improved HbA1c significantly more than treatment with a placebo, there was no difference in the relative risk of micro-vascular disease or any diabetes related end point between the two groups (74). In contrast, using the same dosing regimen in 1368 people with impaired glucose tolerance over a period of three years, the risks of T2DM, CVD and hypertension were reduced relative to a placebo control group (75, 76). Analysis of several more studies was undertaken in a meta-analysis from which it was concluded that
acarbose was more effective than a placebo at reducing the risk of myocardial infarction and other cardiovascular events (77). However, in a subsequent meta-analysis it was concluded that there was no significant difference in morbidity and mortality between treatment with acarbose or a placebo (78). This body of literature therefore suggests that acarbose will likely attenuate glycaemic response and despite the evidence being unclear, it may improve clinical outcomes.

The mechanism for the effect of acarbose can be argued as although acarbose is purported to work by slowing the rate of carbohydrate absorption, evidence from ileostomy patients indicates that it also prevents digestion of up to 44% of carbohydrate intake (79). It is therefore uncertain whether any clinical effect of acarbose observed in some of the above studies was as a result of a reduction in glycaemic response or a decreased energy utilisation leading to weight loss. A study indeed found a significant difference in weight loss favouring the acarbose group (77). However, regardless of the mechanism, a reduction in glycaemic response by treatment with acarbose may be beneficial for improving clinical outcomes.

In summary, while further research is needed to confirm whether or not glycaemic response should be treated preferentially, it is still an extremely important aspect of achieving optimal glycaemic control and therefore managing T2DM and preventing complications.

2.4 Potential dietary strategies to reduce glycaemic response and improve glycaemic control

Lifestyle interventions targeting diet and physical activity have been found to improve glycaemic markers and to delay the progression from impaired glucose tolerance to T2DM (80, 81). However, it is not possible to attribute these findings to a reduction in glycaemic response as body weight and physical activity levels improved in these interventions as well (80, 81). Examining the use of dietary strategies which more specifically target glycaemic
response provide greater evidence for ways in which glycaemic response can be manipulated to improve glycaemic control.

2.4.1 Decreasing carbohydrate consumption

There is a dose response relationship between the amount of carbohydrate consumed and glycaemic response (16, 82, 83). Therefore, reducing the amount of carbohydrate in an individual’s diet may have the potential to influence overall glycaemic control. However in the Canadian Trial of Carbohydrates in Diabetes, 150 people with T2DM were randomised to follow diets containing 39%, 47% or 52% carbohydrate for 12 months, and it was found that changes in HbA1c were independent of the dietary assignment (84). In another 12 month randomised trial, 115 participants with T2DM consumed either a very low carbohydrate diet (15% total energy (TE) from carbohydrate (CHO)) or an energy matched higher carbohydrate diet (50% TE from CHO) (85). No difference in HbA1c was found between groups, although participants on the low carbohydrate diet did have greater reductions in some measures of glycaemic variability (85). In a number of intervention studies designed to compare low fat, high carbohydrate diets (~50% TE from CHO) to low carbohydrate diets (30-40% TE from CHO), no significant difference in HbA1c was again found (86-88).

In several other intervention studies, low carbohydrate diets have been found to produce reductions in HbA1c. A 12 month randomised trial found that in the group of participants with T2DM (n=54), HbA1c decreased more in the group following a low carbohydrate diet (33% TE from CHO) than in the group following a conventional weight loss diet (50% TE from CHO) (89). Another long term study in which 133 participants chose to follow either a loosely restricted carbohydrate diet (45% TE from CHO) or a conventional diet (57% TE from CHO) for two years also found significantly greater reductions in HbA1c for participants following the lower carbohydrate diet (90). Shorter-term intervention studies where participants acted as their own control found that a lower carbohydrate diet (10% and 32% TE
from CHO) reduced HbA1c significantly more than a higher carbohydrate diet (~40% TE from CHO) (91, 92). A meta-analysis also concluded that lower carbohydrate diets reduced HbA1c significantly more than a variety of comparison diets (93).

Several of these studies did however have a number of limitations, including small participant numbers, short study durations and high dropout rates (90, 91). Furthermore, the effect of weight loss was often not considered, therefore it is uncertain whether the observed results are due to a diet lower in carbohydrate or that participants lost more weight (88, 90, 91). Considerable heterogeneity between studies included in the meta-analysis, particularly in the types of control diets that were used, limit the reliability of the conclusion (93).

While there is inconsistency in the data, some evidence suggests that following a lower carbohydrate diet may improve glycaemic control. Therefore, individuals with T2DM who consume large amounts of carbohydrate may benefit from reducing their consumption. This is supported by the ADA as they recognise that monitoring the amount of carbohydrate that people with T2DM consume is an important strategy for controlling glycaemic response and achieving optimal glycaemic control (24).

### 2.4.2 Increasing non-starchy vegetable consumption

Non-starchy vegetables have both a low GI (18, 19, 94) and contain very little carbohydrate (17) thus it is likely that they would induce a lower glycaemic response compared to other carbohydrate-containing foods. Significant inverse associations between HbA1c and total vegetable intake and between HbA1c and green leafy vegetable intake in people with T2DM have been found (95, 96). However, inverse relationships were also found between vegetable intake and body mass index (BMI) and vegetable intake and consumption of other food groups such as nuts, legumes and fish (95). It is therefore unsure how much of the association can be attributed to vegetables (95).
In an intervention study, 68 overweight people were randomised to follow a high fruit and vegetable diet or a healthy reference diet for four months (97). The intervention group consumed significantly more vegetables than the reference group however there was no difference in HbA1c between the two groups (97). Another study randomised 750 people to a low fat, high fibre, high fruit and vegetable diet or to no intervention diet. They found that despite the intervention group increasing their consumption of vegetables more than the control group, there was no significant difference in serum glucose samples between the two groups (98). However a favourable effect of increased vegetable consumption was found in another trial that randomised 101 people with T2DM to either consume their vegetables before starchy carbohydrate foods or to use food exchange lists that included the energy and nutrient content of foods to guide meal planning (99). The vegetables before carbohydrate group consumed significantly more green vegetables and less rice than the exchange based meal plan group and had a significantly greater reduction in HbA1c (99).

The effect on glycaemic control of following dietary patterns with high intakes of non-starchy vegetables has also been investigated. Long-term randomised controlled trials have provided evidence for a beneficial effect of a Mediterranean diet compared to a low fat, higher carbohydrate diet or an ADA recommended diet for improvements in glycaemic control (100-102). One study found that participants following a low fat vegan diet had significantly greater reductions in HbA1c compared to those following an ADA recommended diet (103). Another study found no significant difference in HbA1c between groups following a vegetarian diet or a diabetes recommended diet (104). It is therefore difficult to make any conclusions about the effectiveness of vegetarian or vegan diets for glycaemic control. Furthermore, any potential glycaemic benefit of these dietary patterns cannot be solely attributed to a higher intake of non-starchy vegetables. It is unsure whether other aspects of these dietary patterns that have proven health benefits, such as a decreased consumption of
saturated fat and an increased consumption of unsaturated fat, may in fact be responsible for influencing glycaemic control.

While there is not a large body of evidence regarding the effects of increasing non-starchy vegetable consumption, there is some evidence to suggest that it may improve glycaemic control.

2.4.3 Lowering glycaemic index and glycaemic load

The GI of a food is calculated from its relative postprandial glycaemic response and GL has been found to be positively related to glycaemic response (82, 83, 105). Therefore, in theory choosing lower GI and GL foods would cause acute reductions in glycaemic response, with these accumulating over a longer period of time to reduce HbA1c. However in practice this may be more difficult to achieve. In a six-month intervention study which randomised 210 people with T2DM to either a low GI (GI=70, GL=129) or a high cereal fibre diet (GI=84, GL=166) a significantly greater reduction in HbA1c was found in the low GI group (106). Another large three month randomised controlled trial comparing a low GI diet incorporating increased legume consumption (GI=66, GL=133) with a high wheat fibre diet (GI=82, GL=142) also found HbA1c reductions favoured the low GI group (107).

In a longer term intervention study no difference in HbA1c was found between people following a low GI (GI=55, GL=133), high GI (GI=63, GL=135) or low carbohydrate diet (GI=59, GL=110) despite the low GI group having significantly lower 2hr-post OGTT blood glucose concentrations than the other two groups (84). A randomised crossover study of 20 people with T2DM used CGMS to measure the glycaemic impact of a low GI (GI=48, GL=109) and high GI diet (GI=61, GL=142) (108). No difference in glycaemic response or any other measures of glycaemia between the two diets were found over four consecutive 24-hour periods (108).
It therefore remains unclear whether lowering the GI or GL of a diet will reduce glycaemic response and improve glycaemic control in people with T2DM. However as a number of studies suggest positive results it is a strategy that may be useful for some individuals.

2.5 Current dietary guidelines and recommendations

2.5.1 New Zealand

Guidelines for carbohydrate intake in New Zealand are based on the Acceptable Macronutrient Distribution Range (AMDR) of 45-65% total energy from carbohydrate per day (109-111). Practically, both the Ministry of Health guidelines for New Zealand adults and the Diabetes New Zealand guidelines recommend at least six servings per day of carbohydrate based foods and at least three servings per day of vegetables (20, 21). The diabetes guidelines include starchy vegetables in the carbohydrate category whereas the Ministry of Health guidelines consider these as vegetables (20, 21). This discrepancy is likely due to starchy vegetables containing more carbohydrate than non-starchy vegetables (112). Therefore, if consumed in large quantities they have a greater tendency to raise blood glucose concentration, which is particularly important for people with diabetes to avoid (112).

Guidelines for the proportions of foods that a meal should contain include the Ministry of Health’s recommendation to have more non-starchy than starchy vegetables on a plate (20). Diabetes New Zealand and Vegetables.co.nz advise that meals follow the ‘Healthy Plate Model’, where one quarter of the plate are starchy carbohydrate foods, one quarter protein foods and the remaining half non-starchy vegetables (21, 113). It therefore appears as though there is a consensus in New Zealand that non-starchy vegetables should be the largest component of a meal.

For the quantity of foods to include within a meal, Diabetes New Zealand mentions that approximately 3-4 serves of carbohydrate at each main meal is the quantity that most people
with diabetes require. As one serve equates to 15g of carbohydrate, this is roughly 45g of carbohydrate per main meal (23). However, carbohydrate requirements are individual depending on body weight, activity levels and glycaemic control, therefore this amount of carbohydrate will not suit everyone (23).

The focus of both the Ministry of Health and Diabetes New Zealand guidelines is on a healthy and well balanced diet (20, 21). Despite recognising that a low carbohydrate diet may work for some people if it is carefully managed, Diabetes New Zealand does not promote its use (114).

2.5.2 Worldwide

Recommendations for carbohydrate intake in Australia, USA and Canada are the same as New Zealand, 45-65% total energy from carbohydrate per day (110, 115, 116). The UK recommends a population average of around 50% of total energy from carbohydrate per day (117). However, based on systematic review evidence, both the ADA and Diabetes UK have taken the position that there is no optimal percentage of carbohydrate in the diet that is widely applicable to the diabetic population (24, 118, 119). Instead they advise a much more individualised approach, based on metabolic status, weight management and glycaemic control goals, similar to Diabetes New Zealand (23, 24, 119).

Practically, Canadian guidelines recommend 7-10 servings of fruit and vegetables and 6-8 servings of grain products per day (120). Rather than recommending a number of servings, the American dietary guidelines advise 2-3 cups of vegetables and 6-8 ounces (170-230g) of grains per day (115, 121). The UK Eatwell Guide recommends that both fruit and vegetables and starchy foods should each make up just over one third of your diet and similarly to New Zealand, you should consume at least 5 portions of fruit and vegetables per day (20, 22).
The Canadian Diabetes Association (CDA), ADA and Singaporean Health Promotion Board promote a plate model with the same proportions of carbohydrate, protein and non-starchy vegetables as the Diabetes New Zealand and vegetables.co.nz plate model (21, 113, 122-124). However, the UK Eatwell Guide advises that meals should be based around starchy foods (22), indicating that a worldwide consensus on meal proportions has not been formed.

Diabetes UK, the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes and the CDA recommend low GI and GL diets. They also suggest that carbohydrate intakes at the lower end of the recommended range may be an option for some people (25, 119, 125). However, they do not support very low carbohydrate diets in order to prevent high fat intakes (25, 125). The ADA is of the opinion that there is insufficient evidence to recommend following a low GI, GL or carbohydrate diet (24). All of these organisations are in agreement that is important for people with T2DM to incorporate vegetables into their diet (24, 25, 119, 125).

2.6 Conclusion and rationale for research

The prevalence of diabetes, particularly T2DM, is rising both in New Zealand (2) and around the world (1). This is largely due to an increase in risk factors, most importantly physical inactivity and obesity (1). The World Health Organization has therefore identified diabetes as one of the four priority non-communicable diseases and has committed to reducing its burden (1, 3, 4). As there is inconsistency in the literature, the relationship between glycaemic response and the risk of developing T2DM remains unclear (40, 44, 50-55). However, glycaemic response has consistently been recognised as an important contributor to T2DM management as it is positively associated with HbA1c (67-69) and diabetes related complications (6-9, 11, 12, 14, 88).

As non-starchy vegetables have a lower GI and contain less available carbohydrate than starchy carbohydrate foods (17-19, 94, 126) they have the potential to induce a lower
glycaemic response. Despite inconsistency in the data, some evidence does suggest that lowering the carbohydrate content of the diet (89-92), increasing vegetable consumption (99) and reducing dietary GI and GL (106, 107) may improve glycaemic control in people with T2DM. However, no studies have investigated the glycaemic effect of directly substituting starchy carbohydrate foods for non-starchy vegetables. Altering the proportion rather than the types of foods within a meal may be a strategy that is easier for people with T2DM to implement. Therefore, given the current gap in the literature, this study was conducted to assess the effectiveness of substituting non-starchy vegetables for starchy carbohydrate foods, to reduce glycaemic response and improve glycaemic control.
3 Objective Statement

The aim of this study was to examine the effect on glycaemic response of varying the proportions of a starchy carbohydrate food and non-starchy vegetables within a meal. Results could then be used to form evidence-based recommendations for the proportions of foods to include within a meal for the attenuation of glycaemic response.

Objective one: To determine whether altering the proportions of a carbohydrate-based food and non-starchy vegetables has a significant effect on glycaemic response, as measured by incremental area under the blood glucose curve (iAUC).

Objective two: To compare the effects on glycaemic response of consuming two different types of carbohydrate-based foods (pasta or rice) within a meal.

Objective three: To determine whether altering the proportions of a carbohydrate-based food and non-starchy vegetables within a meal will affect blood glucose return to baseline represented by the blood glucose concentration 90 minutes following meal consumption.
4 Methods

This study was a randomised controlled trial conducted at the Department of Human Nutrition, University of Otago, Dunedin, New Zealand, during March and April, 2016.

4.1 Ethics

The University of Otago Human Ethics Committee granted ethical approval for this study (Appendix A, B). Māori consultation from the Ngāi Tahu Research Consultation Committee was sought and approved (Appendix C). Prior to recruitment potential participants were given a brief presentation outlining the study rationale and participant requirements. A participant information sheet was also provided, which reiterated these requirements and listed contact details where any concerns or queries could be directed (Appendix D). Written consent forms were obtained from all participants before testing commenced (Appendix E). This trial was registered with the Australian New Zealand Clinical Trials Registry (trial ID:ACTRN12616000716460) (Appendix F).

4.2 Participants

4.2.1 Sample size calculation

It was estimated from previous work (127), that a sample size of 34 participants in both the pasta and rice arms of the study would have 90% power to detect a 30% difference in iAUC at the alpha 0.05 level. To allow for a 10% dropout we aimed to recruit 38 participants per group. A 30% difference was chosen to be clinically relevant as this corresponds to the difference in iAUC between a low and high GI food.
4.2.2 Recruitment

Participants were recruited from a convenience sample of University of Otago undergraduate human nutrition students in March 2016. They were invited to participate by both email and an in class presentation.

4.2.3 Eligibility criteria

Participants were required to be between 18 and 60 years of age and without any special dietary requirements that were unable to be catered for within the confines of this study. Prior to study commencement an email was sent to all participants requesting information on any special dietary needs.

4.3 Study design

This study was a randomised controlled crossover trial in which participant’s consumed three test meals with varying proportions of a starchy food (pasta or rice) and non-starchy vegetables. Half of the participants were allocated to receive three pasta-based meals and the other half to receive three rice-based meals. Meals were comprised of 30g, 45g and 60g of available carbohydrate from either pasta or rice. Within each intervention group participants consumed all three meals at separate testing sessions. The meal containing 45g available carbohydrate was set as the reference, with 30g and 60g available carbohydrate representing a one serve (15g of carbohydrate) (23) difference from this meal. Non-starchy vegetables were used as a direct substitution for pasta or rice, therefore the total weight of each meal remained the same. A constant portion of mince was also included in the meal. Blood glucose concentration was measured for 90 minutes following the consumption of each meal to determine glycaemic response. The three different meal proportions (30g, 45g and 60g available carbohydrate from pasta or rice) are shown in Figure 4.1.
Included in this study, fellow Master of Dietetics candidates and a PhD candidate also collected data on speed of eating, energy intake and satiety. Their results will be presented separately and are not reported in this thesis.

Figure 4.1 Small (30g available carbohydrate), medium (45g available carbohydrate) and large (60g available carbohydrate) pasta and rice-based meals

4.4 Randomisation

Eighty participants were invited to take part in the study and randomised to receive either pasta (n=40) or rice (n=40) based meals. Males were block randomised to ensure equal sex distribution between the two groups, controlling for any potential sex variability in glycaemic response. Participants were also randomised to the order in which they were to receive the three test meals; to three out of the five available testing sessions; and to a start time (11:50 or 13:00). Figure 4.2 illustrates the different orders of intervention that participants were randomised to. There were some changes to these allocations following randomisation as it was necessary that gluten free and vegan participants received rice-based meals and a number of participants were unavailable on certain test days or at their designated times.
Dr Jill Haszard, a biostatistician in the University of Otago, Department of Human Nutrition used Stata Statistical Analysis Software (version 13.1, Stata Corporation, Texas) to carry out the randomisation after consultation with the research team.
Figure 4.2 Representation of study design and the different orders of intervention that participants were randomised to
4.5 Development of the test meals

4.5.1 Identifying ingredients

The ingredients were selected with the consideration of developing a meal that was palatable, visually appealing, affordable and representative of a meal that the general population would regularly consume. Pasta and rice were chosen as the starchy foods due to their similar carbohydrate content. This allowed the required amount of available carbohydrate to be obtained in equal cooked weights of each food. The type of pasta selected was penne because it complemented other meal components well and was easy to consume. Jasmine rice was chosen due to its high GI value, therefore providing the largest contrast in GI between the rice and pasta (18, 19, 126). Frozen stir-fry vegetables were selected as they included the greatest variety of non-starchy vegetables, were of high quality and were easy to prepare. To complete the meal it was decided to include a protein portion. Beef mince flavoured with a store bought pasta sauce was chosen as it mixed easily with the carbohydrate components and is generally well accepted by the participant’s age group.

4.5.2 Determining the quantity of the meal components

The reference meal was set at 45g available carbohydrate from pasta or rice in response to both Diabetes New Zealand and diabetes dietitian, Zhoushi Zhang’s advice to patients with T2DM to follow the healthy plate model (21). This model indicates that one quarter of the plate should be starchy foods, which theoretically equates to 45g available carbohydrate in a starchy food (21, 23). The 30g, 45g and 60g available carbohydrate in the three meals corresponded to 100g, 150g and 200g of either cooked pasta or rice, as outlined in Appendix G. The quantity of non-starchy vegetables in the reference meal (45g available carbohydrate from a starchy food) was set at 200g as this best represented the healthy plate model’s half a plate (21). The amount of cooked mince was kept constant for all test meals at 200g. This
quantity was representative of one quarter of a plate, as recommended by the healthy plate model (21).

### 4.5.3 Special dietary requirements

Special meals were prepared for participants who were unable to consume the standard meal due to special dietary requirements. A mycoprotein based mince alternative was used in place of beef mince for participants who were vegetarian (n=6) or participants who required a meal that was Halal (n=2). By substituting the mince for chickpeas a meal was created for participants who were vegan (n=2). Participants with Irritable Bowel Syndrome (IBS) (n=2) received a meal with a pasta sauce and stir fry vegetables that contained no onions.

### 4.5.4 Composition of the test meals

The composition of each test meal is shown in Table 4.1. The standard, vegetarian and IBS meals all weighed 550g. The vegan meals had an extra 25g of pasta sauce, as this was required for palatability when mixed with the chickpeas, therefore, each of the vegan meals weighed 575g. The meals were described as small, medium and large, representing 30g, 45g and 60g of available carbohydrate from either pasta or rice respectively.

<table>
<thead>
<tr>
<th>Meal type</th>
<th>Starchy food</th>
<th>Non-starchy vegetables</th>
<th>Mince or mince alternative$^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>100g pasta</td>
<td>250g</td>
<td>200g</td>
</tr>
<tr>
<td>Medium</td>
<td>150g pasta</td>
<td>200g</td>
<td>200g</td>
</tr>
<tr>
<td>Large</td>
<td>200g pasta</td>
<td>150g</td>
<td>200g</td>
</tr>
<tr>
<td>Rice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>100g rice</td>
<td>250g</td>
<td>200g</td>
</tr>
<tr>
<td>Medium</td>
<td>150g rice</td>
<td>200g</td>
<td>200g</td>
</tr>
<tr>
<td>Large</td>
<td>200g rice</td>
<td>150g</td>
<td>200g</td>
</tr>
</tbody>
</table>

$^1$ All weights listed as cooked weights

$^2$ 200g mince was replaced with 100g chickpeas + 125g pasta sauce for the vegan meals
4.6 Study procedure

Testing took place over the lunchtime period at the University of Otago, Department of Human Nutrition Undergraduate Laboratory. Five weekly testing sessions were held across a seven-week period, allowing for a two-week break when participants were unavailable. Participants were required to attend three testing sessions and were allocated an arrival time of 11:50 or 13:00. There was a washout period of between one and five weeks depending on which sessions participants had been allocated to and not because a washout period of this length was necessary.

Participants were asked to arrive at the laboratory having had nothing to eat or drink (except for water) for the previous two and a half hours. This was to ensure their baseline blood glucose concentrations were similar across the testing sessions and they did not begin testing already in a postprandial state. Participants were also asked to not consume water 30 minutes before the session began as a large intake of water immediately prior to testing may have limited their ability to consume the entire meal. To reduce variability, participants were regularly reminded to keep their timing and type of food and drink consumption as well as exercise prior to the session consistent across their three testing days. If they were walking or cycling to the laboratory participants were asked to do so slowly, to prevent elevating their blood glucose levels.

A single finger-prick blood sample was taken from participants 5-15 minutes after their arrival, allowing time for blood glucose levels to stabilise. This result was used as their baseline blood glucose concentration and the time the sample was taken was recorded as time ‘zero’. Participant’s allocated test meal was then delivered to them and they were instructed to begin eating straight away. Blood glucose concentration was measured over the following 90-minute period with measurements being taken at 15, 30, 45, 60 and 90 minutes after time ‘zero’. If a participant’s baseline blood glucose concentration was above 6mmol/L they were
questioned as to whether they had consumed any food or drink within the required fasting period. If they admitted to not having fasted for this period of time they were asked to reschedule their testing session (n=1).

Participants were informed that they were required to consume the entire meal. There was no time frame within which they had to finish the meal as their speed of eating was also being measured. A single 250ml cup of water was provided for participants to drink during meal consumption, with additional water available on request after they had finished the meal. Participants were asked to remain seated for the duration of the testing session, with exceptions being toilet visits if required.

A number of measures were used to maintain consistency of procedures:

- All data were collected over a 7-week period
- Testing was undertaken on the same day of the week and at the same time for each participant
- The candidate and two members of the research team prepared all test meals
- Standardised preparation and cooking procedures were used
- All members of the data collection team were trained in the technique of taking finger prick blood samples by a registered nurse

4.6.1 Measuring blood glucose concentration

Before blood sample collection began, the participants chosen finger was sanitised using a 70% isopropyl alcohol swab (Webcol™ Alcohol Prep, Covidien™ Ltd.; United States of America). While allowing time for this to dry, the participant’s finger was gently massaged to increase blood flow. A 1.8mm disposable lancet (Unistik® 3 Normal, Owen Mumford Ltd; England) was then used to prick the finger by firmly pressing down off centre of the fingertip. The finger was again gently massaged to form a small drop of blood, with this first drop being
wiped off using a non-woven swab (Multisorb®, BSN medical Limited; United Kingdom). The finger was further massaged until a larger drop of blood was formed and drawn up by a microcuvette (HemoCue®; Sweden). The microcuvette was wiped on a non-woven swab (Multisorb®, BSN medical Limited; United Kingdom) to remove any excess blood and then immediately placed into the HemoCue® Glucose 201+ Analyser (Aktiebolaget Leo Diagnostics, Helsingborg; Sweden) to determine blood glucose concentration. Each morning before data collection began, the Hemocue was calibrated using a solid control provided by the manufacturer (Appendix H). The result of each blood glucose measurement was recorded by both the participant, on an individual recording sheet (Appendix I), and by the trained research assistant responsible for obtaining their blood samples (Appendix J).

4.6.2 Demographic questionnaire

All participants completed a single demographic questionnaire with information on gender, date of birth, ethnicity and smoking status (Appendix K). Questions on ethnicity and smoking status were taken from the New Zealand census (128).

4.6.3 Anthropometric measurements

Height and weight were recorded (Appendix K) using a single measurement following standardised procedures (129). To ensure consistency, one person was responsible for taking all participants’ measurements, using the same freestanding calibrated stadiometer (Holtain Limited, United Kingdom) and calibrated electronic scales (Seca Alpha, model 770, Germany) throughout. Participants were asked to remove their shoes and any excess clothing or heavy personal items in their pockets. These data were used to calculate BMI for each participant using the equation: weight in kilograms/ height in metres squared (kg/m²).

4.6.4 Preparation of the test meals

All meals were prepared in the University of Otago, Department of Human Nutrition, metabolic kitchen. Food safety principles were adhered to throughout the entire food
preparation process (130). Weights of all meal components were measured using electronic kitchen scales (Salter, model 3010, England) to within 3g of the nominated weight. Excluding the rice, all meal components were precooked, cooled and appropriately proportioned into round foil plates. Meals were then covered in tinfoil and placed in a freezer. Coloured stickers were used to label each meal according to the proportions and type of starchy food they contained. Special meals were identified by an additional written descriptor. The morning prior to each testing day, meals were removed from the freezer and placed into a fridge to thaw. On the day of testing a convection oven preheated to 180°C was used to reheat the meals for 1 hour and 45 minutes. Before consumption a sub sample of meals were temperature tested using a temperature probe to ensure they were above the required 60°C for food safety and palatability reasons (130). Fresh rice was cooked each testing day and portioned immediately prior to consumption. The methods used to prepare each component of the standard meal are further described on the following page. Appendix L outlines the methods used for the components of the special meals.
Rice:
A 1:2 ratio by weight of Jasmine rice (Pams®; New Zealand) to water was used. The rice was cooked in two rice cookers (Tefal Automatic Rice Cooker, model Serie R07, China) that automatically switched to a keep warm mode once the rice was cooked.

Pasta:
Dried penne pasta (San Remo, San Remo Macaroni Co Pty Ltd; Australia) was added to boiling water and cooked until the pasta was al dente. A ratio of 2.5kg dried pasta: 10L boiling water was used. Once cooked, the pasta was strained through a colander and cold water was run through it to stop the cooking process. Finally the pasta was tossed with canola oil (Sunfield Oils, Tasti Products Ltd, Auckland; New Zealand), 2 tablespoons oil for every 2.5kg dried pasta.

Vegetables:
A 750g portion of vegetables (Asian Stir Fry Vegetables, Watties®, Heinz Watties Ltd, New Zealand) was steamed with one-quarter of a cup of water in a microwave for 10 minutes.

Mince:
Raw premium beef mince (New World, Dunedin; New Zealand) was cooked in batches in a large saucepan with canola oil (Sunfield Oils, Tasti Products Ltd; New Zealand). Once the mince was browned a jar of pasta sauce (Extra Bolognaise Pasta Sauce, Dolmio®, Mars Food; Australia) was added. For every 1kg of raw mince, 1kg of pasta sauce and 2 teaspoons of oil were used.
4.6.5 Calculation of glycaemic index and glycaemic load

The GIs of meal ingredients were selected from published databases and studies (18, 94, 126). A GI of 43 was chosen for the penne pasta (18) and a GI of 115 for the jasmine rice (126). A number of the non-starchy vegetables included in the meal, such as cauliflower and broccoli, did not have published GI values. It was decided to assign an estimated GI of 31 to the non-starchy vegetables, as this was the measured GI of carrots in a similar study population (94) and it was understood that almost all non-starchy vegetables have a low GI (131). Calculation of GI and GL for each meal type and its components is presented in Appendix M. To account for the proportion of available carbohydrate (AvailCHO) within the meal that each component provided, the following equation was used to calculate meal GI (132):

\[
\text{Meal GI} = \frac{\{(\text{GI}_{\text{Food A}} \times \text{AvailCHO}_{\text{Food A}} (g)) + (\text{GI}_{\text{Food B}} \times \text{AvailCHO}_{\text{Food B}} (g)) + \ldots\}}{\text{AvailCHO}_{\text{Meal}} (g)}
\]

Meal GI was then used to calculate meal GL using the following equation (40):

\[
\text{Meal GL} = \frac{(\text{Meal GI} \times \text{AvailCHO}_{\text{Meal}} (g))}{100}
\]
4.7 Statistical analysis

Stata Statistical Analysis Software (version 13.1, Stata Corporation, Texas) was used for incremental area under the curve (iAUC) analysis. All other data handling and analysis was carried out with the statistical programme Microsoft Excel (Microsoft® Excel® for Mac 2011. Version 14.1.3. Microsoft Corporation 2011). A P-value of <0.05 was set as statistically significant. The nutritional composition of the test meals was calculated using the dietary assessment software Kai-culator (version 1.131, Department of Human Nutrition, University of Otago, New Zealand).

In accordance with Brouns et al. the trapezoidal rule was used to calculate incremental area under the curve (iAUC), with any area beneath the baseline concentration ignored (42). iAUC for each test meal and each participant was calculated individually then averaged according to meal type. A mixed effects regression analysis with participants as a random effect was used to determine the statistical difference in iAUC between the different meal proportions. To analyse the mean difference in iAUC between the pasta-based and rice-based meals a linear regression model was used for each meal size. Because the variance of iAUC increased with increasing means, data was log-transformed to stabilise the variance.

Both analyses were adjusted for the order in which participants were randomised to receive the intervention. As the distribution of participants who received a special meal was unequal between the pasta and rice-based intervention groups, a sensitivity analysis was run for the analyses that compared these meals. It was found that after adjustment for special meals this did not influence results. There were no values that were considered to be outliers.
Analysed (n=37)
Excluded from analysis (n=0)

Figure 5.1 CONSORT diagram: participant flow through the study
5 Results

Eighty participants were randomised to either the pasta or rice intervention groups and 74 participants chose to take part in this study. All data are included in this analysis. Figure 5.1 shows participant flow through the study.

5.1 Participant characteristics

Demographic characteristics of participants are presented in Table 5.1. Participants were between 19 and 36 years of age, with 93% under 24 years of age. The study population were predominantly female and of New Zealand European ethnicity. Most participants had a BMI within the healthy range (18.5 – 24.9kg/m$^2$), with only three participants categorised as obese (BMI $\geq$ 30kg/m$^2$). Just one participant in each intervention group reported that they were a current smoker.

Table 5.1 Demographic characteristics of study participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pasta (n=37)</th>
<th>Rice (n=37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender$^1$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (24%)</td>
<td>10 (27%)</td>
</tr>
<tr>
<td>Female</td>
<td>28 (76%)</td>
<td>27 (73%)</td>
</tr>
<tr>
<td>Age (years)$^2$</td>
<td>21.0 (2.4)</td>
<td>21.5 (2.0)</td>
</tr>
<tr>
<td>Ethnicity$^1$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>23 (62%)</td>
<td>29 (78%)</td>
</tr>
<tr>
<td>Maori</td>
<td>2 (5%)</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (32%)</td>
<td>6 (16%)</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)$^2$</td>
<td>23.4 (4.0)</td>
<td>23.6 (3.5)</td>
</tr>
</tbody>
</table>

$^1$ Results presented as n (%)

$^2$ Results presented as mean (SD)
5.2 Nutritional composition of the test meals

The nutritional compositions of the test meals are presented in Table 5.2. All standard meals were of equal weight (550g). As the amount of available carbohydrate within the meal increased so too did the energy content. There was an inverse relationship between the amount of available carbohydrate provided by the pasta or rice and the amount provided by the vegetables and pasta sauce. However, the overall available carbohydrate content of the meal increased as the proportion of pasta or rice increased. Dietary fibre content decreased as the amount of vegetables within the meal decreased, whereas protein and fat content remained similar between the meals.

A positive relationship was observed between an increased proportion of starchy foods and both meal GI and GL. There was a greater increase in meal GL than there was in meal GI and the estimated GIs and GLs of the rice-based meals were considerably higher than the pasta-based meals. The nutritional composition of the special meals is presented in Appendix N.

Table 5.2 Nutritional composition of the standard meals, per meal

<table>
<thead>
<tr>
<th>Meal type</th>
<th>Energy (kJ)</th>
<th>Avail CHO (g)</th>
<th>Dietary fibre (g)</th>
<th>Protein (g)</th>
<th>Fat (g)</th>
<th>Meal GI</th>
<th>Meal GL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Rice or pasta</td>
<td>Vegetables &amp; sauce</td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pasta</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>1832</td>
<td>30.0</td>
<td>11.3</td>
<td>41.3</td>
<td>10.5</td>
<td>38.0</td>
<td>10.5</td>
</tr>
<tr>
<td>Medium</td>
<td>2074</td>
<td>45.0</td>
<td>10.6</td>
<td>55.6</td>
<td>9.9</td>
<td>39.6</td>
<td>10.5</td>
</tr>
<tr>
<td>Large</td>
<td>2316</td>
<td>60.0</td>
<td>10.0</td>
<td>70.0</td>
<td>9.2</td>
<td>41.3</td>
<td>10.5</td>
</tr>
<tr>
<td>Rice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>1804</td>
<td>30.0</td>
<td>11.3</td>
<td>41.3</td>
<td>10.1</td>
<td>35.8</td>
<td>9.9</td>
</tr>
<tr>
<td>Medium</td>
<td>2030</td>
<td>45.0</td>
<td>10.6</td>
<td>55.6</td>
<td>9.3</td>
<td>36.3</td>
<td>9.9</td>
</tr>
<tr>
<td>Large</td>
<td>2255</td>
<td>60.0</td>
<td>10.0</td>
<td>70.0</td>
<td>8.5</td>
<td>37.4</td>
<td>9.9</td>
</tr>
</tbody>
</table>

1. Total cooked weight of all standard meals was 550g
2. AvailCHO = CHO content − dietary fibre
The macronutrient compositions of the standard test meals are presented in Table 5.3. As the proportion of pasta or rice within the meal increased, the percentage of total energy from carbohydrate increased and the percentage of total energy from protein and fat decreased.

Table 5.3 Macronutrient composition of the standard test meals (% of total energy)¹

<table>
<thead>
<tr>
<th></th>
<th>AvailCHO²</th>
<th>Protein</th>
<th>Fat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>43</td>
<td>35</td>
<td>21</td>
</tr>
<tr>
<td>Medium</td>
<td>48</td>
<td>32</td>
<td>19</td>
</tr>
<tr>
<td>Large</td>
<td>51</td>
<td>30</td>
<td>17</td>
</tr>
<tr>
<td>Rice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>44</td>
<td>34</td>
<td>20</td>
</tr>
<tr>
<td>Medium</td>
<td>49</td>
<td>30</td>
<td>18</td>
</tr>
<tr>
<td>Large</td>
<td>53</td>
<td>28</td>
<td>16</td>
</tr>
</tbody>
</table>

¹ Any small residual from available carbohydrate, protein and fat adding up to 100% is accounted for by the energy contribution from dietary fibre
² AvailCHO = CHO content – dietary fibre
5.3 Blood glucose concentration

The mean fasting blood glucose concentrations and mean 90-minute blood glucose concentrations are presented in Table 5.4. As the amount of pasta or rice within the meal increased, so too did the mean 90-minute blood glucose concentrations (p=0.009 and p<0.001 for trend respectively). The rice-based meals also produced higher 90-minute blood glucose concentrations than the pasta-based meals with this difference reaching significance for the small (p=0.028) and large (p=0.001) meals but not for the medium meals (p=0.068).

Table 5.4 Mean (SD) fasting and 90-minute blood glucose concentrations

<table>
<thead>
<tr>
<th></th>
<th>Fasting blood glucose concentration (mmol/L)</th>
<th>90-minute blood glucose concentration (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasta</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>4.5 (0.6)</td>
<td>5.0 (0.5)</td>
</tr>
<tr>
<td>Medium</td>
<td>4.4 (0.4)</td>
<td>5.2 (0.6)</td>
</tr>
<tr>
<td>Large</td>
<td>4.5 (0.6)</td>
<td>5.4 (0.7)</td>
</tr>
<tr>
<td>Rice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>4.7 (0.5)</td>
<td>5.4 (0.9)</td>
</tr>
<tr>
<td>Medium</td>
<td>4.7 (0.5)</td>
<td>5.6 (1.0)</td>
</tr>
<tr>
<td>Large</td>
<td>4.5 (0.5)</td>
<td>6.3 (1.2)</td>
</tr>
</tbody>
</table>

1 Baseline blood glucose concentration

5.4 Within group incremental area under the curve analysis

Mean adjusted iAUC following the consumption of the different test meals and the within group difference in iAUC between these meals is presented in Table 5.5. For both the pasta and rice-based meals there was an increase in mean iAUC as the proportion of a starchy food within the meal increased (p<0.001 for trend).

When comparing between the different meal proportions it was found that the glycaemic response to the small pasta meal was significantly less than the glycaemic response to the medium meal. There was however no significant difference between the medium and large pasta meals. The rice-based meals produced contrasting results, as there was no significant
difference between the glycaemic response to the medium and small meals whereas there was a significant difference between the medium and large meals.

When comparing between the large and small meals, significant differences were found for both the pasta and rice-based meals (p<0.001). There was a 29% (13.3, 45.3) reduction in glycaemic response from the large to small pasta-based meals and 68% (46.0, 90.5) reduction from the large to small rice-based meals.

Table 5.5 Mean iAUC and adjusted\(^1\) mean difference between the medium and small meal and the medium and large meal for both pasta and rice-based meals

<table>
<thead>
<tr>
<th></th>
<th>Mean (S.D) of iAUC (mmol*min/L)</th>
<th>Effect size (95% CI) (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>92.9 (43.3)</td>
<td>-24.7 (-40.7, -8.7)</td>
<td>0.002</td>
</tr>
<tr>
<td>Medium</td>
<td>117.6 (52.9)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>122.2 (55.1)</td>
<td>4.6 (-11.4, 20.6)</td>
<td>0.573</td>
</tr>
<tr>
<td>Rice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>128.6 (78.1)</td>
<td>-11.4 (-33.7, 10.8)</td>
<td>0.314</td>
</tr>
<tr>
<td>Medium</td>
<td>140.1 (77.6)</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Large</td>
<td>196.9 (82.4)</td>
<td>56.8 (34.5, 79.1)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

\(^1\) Adjusted for order of intervention

A comparison between the mean iAUCs of the different meal proportions is illustrated in Figures 5.2 and 5.3. No difference was observed between the pasta-based meals (Figure 5.2) during the first 30 minutes. However, there was some divergence between 30 and 45 minutes, with the small meal returning to baseline more quickly than the medium and large meals. The rice-based meals (Figure 5.3) showed greater variation. After the 15-minute time point the mean blood glucose concentrations diverged, with the large rice meal inducing a greater glycaemic response and returning to baseline less quickly than the medium and small meals.
Figure 5.2 Comparison of incremental area under the curve following the consumption of three pasta-based meals with different proportions of pasta and non-starchy vegetables.

Figure 5.3 Comparison of incremental area under the curve following the consumption of three rice-based meals with different proportions of rice and non-starchy vegetables.
5.5 Between group incremental area under the curve analysis

The adjusted mean difference in iAUC between the pasta and rice-based meals is presented in Table 5.6 and illustrated in Figure 5.4. While there was no significant difference in mean glycaemic response to the medium meals, both the small and large pasta-based meals induced a significantly lower glycaemic response compared to the rice-based meals. A sensitivity analysis was run that included whether the participant had a special meal (vegetarian, vegan or IBS) or not and this did not alter the results.

Table 5.6 Adjusted\(^1\) mean effect size difference between the pasta and rice-based meals

<table>
<thead>
<tr>
<th></th>
<th>Effect size (95% CI)(^2) (%)</th>
<th>(P)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>-27 (-46, -0.03)</td>
<td>0.048</td>
</tr>
<tr>
<td>Medium</td>
<td>-16 (-37, 13)</td>
<td>0.243</td>
</tr>
<tr>
<td>Large</td>
<td>-46 (-61, -25)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

\(^1\) Adjusted for order of intervention
\(^2\) Results are presented as pasta compared to rice

![Figure 5.4](image.png)

Figure 5.4 Comparison of incremental area under the curve between the pasta and rice-based meals for the different meal proportions

* Significant difference \((p<0.05)\) between the pasta and rice-based meals
6 Discussion

The aim of this study was to examine the glycaemic effect of varying the proportions of a starchy carbohydrate food (pasta or rice) and non-starchy vegetables within a meal. It was considered that as pasta and rice contain more available carbohydrate and have higher GIs than non-starchy vegetables, the substitution of a starchy food for non-starchy vegetables might attenuate glycaemic response. Results did indeed show a modest reduction in glycaemic response and 90-minute blood glucose concentration as more non-starchy and less starchy foods were included in the meal. For both the pasta and rice-based meals there was a significant difference in glycaemic response between the meals with the largest (60g available carbohydrate) and smallest (30g available carbohydrate) amount of starchy food. Using the medium meal (45g available carbohydrate from a starchy food) as a reference, there was no significant difference between the medium and large pasta-based meals, however there was a significant difference between the medium and small meals. For the rice-based meals there was a significant difference between the medium and large meals but no significant difference between the medium and small. A difference in iAUC of 57% was found between the medium and large rice-based meals with all other comparisons being comparatively smaller (<25%). Rice-based meals tended to induce a larger glycaemic response than pasta-based meals, although there was no significant difference in glycaemic response between the rice and pasta-based meals containing the medium amount of carbohydrate. Overall, there was a tendency for glycaemic response to increase with increasing amounts of pasta and rice.

The positive association between glycaemic response and the increasing proportion of starchy food can be attributed to meal GL. A product of GI and the amount of carbohydrate within a meal (40), GL has consistently been found to be a reliable predictor of glycaemic response (16, 82, 83, 105, 133, 134). As pasta and rice have a higher GI (GI=43 and GI=115 respectively) and carbohydrate content than non-starchy vegetables (GI=31) (17, 18, 94, 126),
replacing pasta and rice with non-starchy vegetables lessened meal GL (Table 5.2) and attenuated glycaemic response.

Another factor that may have influenced the differences in glycaemic response among meals was the change in percentage energy from macronutrients. As illustrated in Table 5.3, the percentage of meal energy from carbohydrate increased as the proportion of starchy food increased which consequently decreased the percentage from protein and fat. In some studies, protein and fat have been found to attenuate glycaemic response (135, 136). Likely mechanisms for this include the stimulation of insulin secretion by protein (135) and the delay of gastric emptying by fat (137). However despite these percentages changing, the amount of protein within the meal differed only slightly and the amount of fat remained the same (Table 5.2). It is therefore unclear whether changing the percentages rather than the amounts of protein or fat within the meal affected glycaemic response. It seems likely that the difference in glycaemic response between the meals is primarily due to the changes in available carbohydrate content.

The significant difference in glycaemic response found between the medium and small pasta-based meals and the non-significant difference between the medium and large, can likely be explained by the non-linear shape of the blood glucose concentration dose response curve. Several studies have shown that at lower intakes of carbohydrate the dose response in iAUC is approximately linear, while at higher intakes the rate of increase tends to decline and the curve flattens off (16, 82, 83, 105). Therefore, despite there being the same difference in available carbohydrate content between both the medium and small and medium and large meals, increasing the carbohydrate content of the meal at lower doses produced a greater difference in glycaemic response.

For the rice-based meals glycaemic response appeared to be exaggerated for the meal containing the largest proportion of rice whereas it seemed relatively insensitive between the
meals that contained smaller rice proportions. An 11% difference between the medium and small meals and a 57% difference between the medium and large shows that the medium meal was not centrally located between these two. It is unclear what caused the marked increase in glycaemic response between the medium and large meals and whether it is due to an exaggeration of glycaemic response to the large meal or suppression in response to the medium meal. It remains to be seen whether these results would again be observed if the study were to be repeated.

Although we did not measure the GI of the rice or pasta, or the GI of the meals, the larger glycaemic responses and 90-minute blood glucose concentrations from the rice-based meals compared to the pasta-based meals are likely due to the rice having a higher GI. However, the difference in glycaemic response to the pasta and rice-based meals was less exaggerated than the difference in estimated GI between these two foods (GI=43 and GI=115, respectively). There was also no significant difference in glycaemic response between the medium rice and pasta-based meals despite there being a considerable difference in the calculated GL of these meals. However, it is difficult to predict mixed meal GL (94) and this may account for these outcomes.

The interaction between calculated meal GI and the proportions of starchy foods and non-starchy vegetables is noteworthy. The GIs of the pasta-based meals were independent of the meal proportioning, attributed to the pasta and the non-starchy vegetables having similar GIs (GI=43 and GI=31, respectively). Whereas the rice had a much higher GI (GI=115) than the non-starchy vegetables, therefore, substituting non-starchy vegetables for rice increased meal GI (Table 5.2).

The increasing trend we observed in 90-minute blood glucose concentration, as more pasta or rice and less non-starchy vegetables were included in the meal makes physiological sense. The increase in available carbohydrate content of the meals increased glycaemic response
therefore it took longer for the body to clear this extra glucose from the blood stream and return the concentration to baseline. A number of other studies have also found a dose response relationship between the amount of carbohydrate and 90-minute blood glucose concentrations (16, 83, 133, 134). In participants with T2DM, increasing the amount of carbohydrate induced even larger differences in 90-minute blood glucose concentration and it took longer for blood glucose concentration to return to baseline than in people with normal glucose tolerance (83, 133, 134). This suggests that if people with T2DM consumed the meal with the smallest proportion of pasta or rice compared to the largest proportion this may result in considerably less time spent in the hyperglycaemic range.

6.1 Clinical implications

The findings from this study suggest that for glycaemic outcomes people with normal glucose tolerance may not have to be too concerned about getting the proportions of starchy to non-starchy foods within a meal exact. As despite significant differences being found, glycaemic response appears to be relatively insensitive between the different meal proportions. This is supported by literature finding no association between carbohydrate intake and the incidence of T2DM in a large European cohort (54). Although, data collected from this study by a fellow MDiet candidate found that the reduced energy density of the test meals lead to a decrease in total daily energy intake (138). Therefore, from an energy intake perspective, the general population should follow current advice to increase the proportion of non-starchy vegetables and decrease the proportion of starchy foods within their meal (20, 21). Non-starchy vegetables are less energy dense than starchy carbohydrate foods therefore substituting these foods reduces the energy density of a meal (139-142), which may support weight management (143).

For people with impaired glucose tolerance and T2DM the glycaemic findings may have more clinical relevance. In people with T2DM, the consumption of two meals of meat sauce
and white rice with similar amounts of carbohydrate (45.8g and 65.8g) to the medium and large meals in our study induced large differences in glycaemic response between the two meals (285 and 453mmol/L*min, respectively) (134). Additionally, the glycaemic response to mixed meals was significantly greater in people with T2DM compared to people with normal glucose tolerance (28). This suggests that for people with T2DM decreasing the amount of available carbohydrate in the meal by substituting starchy foods for non-starchy vegetables may produce greater reductions in glycaemic response. As glycaemic response contributes to HbA$_1c$ (67-69) and to the development of macro- and micro-vascular complications as well as diabetes related mortality (6-12, 14), any attenuation in glycaemic response could lead to improved glycaemic control and risk reduction. Furthermore, separate components of this study found that satiety and energy intake following meal consumption did not vary between the different meal proportions (138). Recommending that people substitute starchy foods for non-starchy vegetables will therefore not lead to them feeling more hungry or cause them to consume more food at subsequent meals. Potential reductions in energy intake will also be beneficial for people with impaired glucose tolerance and T2DM as weight loss has been found to improve glycaemic control and to reduce the risk of developing diabetes related complications (144, 145).

6.2 Strengths and limitations

A considerable strength of this study was that the meal was practical, affordable and used foods that are commonly consumed. Furthermore, it was developed with reference to New Zealand food guidelines (21, 23), strengthening the applicability and relevance of results to dietetic practice. The methodology required participants to keep their food consumption and exercise prior to each testing session consistent to minimise intra-individual variation. Participant diet records, completed for the purpose of another MDiet candidate’s thesis, indicated compliance to this dietary requirement as no significant difference in intake was
observed across the three testing sessions (138). Other methodological strengths included standardised meal preparation and blood collection procedures and the crossover design, controlling for inter-individual variation in glycaemic response as a source of confounding.

A limitation of this study was that participants with normal glucose tolerance were used rather than a study population of individuals with T2DM for whom clinical benefits may be more pronounced. However, it is likely that the glycaemic results have good generalisability to a diabetic population as studies have shown that relative glycaemic response (26-28) and the shape of the carbohydrate dose-response curve (16, 82, 83, 105, 133) are similar between individuals with and without T2DM. Often in glycaemic research, participants are instructed to finish a test food within a specified period of time; for example, GI methodology specifies 12-15 min (33). The participants in our study were not required to do this and instead asked to complete the meal at their own pace. This may limit comparability between our data and other literature, however this was done deliberately as it was more representative of people’s eating behaviours and another MDiet candidate was timing the meal duration. Lastly, inter-individual variation in glycaemic response may have influenced the reliability of comparisons between the pasta and rice-based meals, as the parallel aspect of this study design meant participants did not consume both of these starchy foods.

**6.3 Conclusion**

In a healthy young cohort of participants with normal glucose tolerance, glycaemic response was relatively insensitive to varying the proportions of starchy carbohydrate foods and non-starchy vegetables within a meal. However, for both the pasta and rice-based meals differences in glycaemic response were found between the meals with the smallest and largest amount of starchy foods. This suggests that consuming starchy foods and non-starchy vegetables in proportions of approximately one quarter starchy foods and one half non-starchy vegetables ensures a relatively low glycaemic response and is in accordance with current
guidelines (20, 21). Although there was a considerable difference in GI between pasta and rice, the difference in glycaemic response between the pasta and rice-based meals was less exaggerated. Choosing to include pasta instead of rice within a meal will reduce glycaemic response to some extent, as will changing the proportions of starchy foods to non-starchy vegetables.

Despite the argument that the relative glycaemic response should be comparable between people with and without T2DM, it is still recommended for future research that this study be conducted in a cohort of participants with T2DM. It would also be beneficial to undertake a long-term intervention study, as while some studies have asked people to increase their vegetable consumption (97, 98), none have asked people to directly substitute starchy foods for non-starchy vegetables within a meal. Assessing the practicality and acceptability of substituting these foods and measuring how HbA1c is affected would provide further information regarding the effectiveness of adopting this dietary strategy.
7 Application to dietetic practice

The prevalence of obesity and diabetes is rapidly rising both in New Zealand (2, 146) and around the world (1, 147). Therefore, supporting individuals to make dietary changes for both weight reduction and improvements in glycaemic control is an increasingly important aspect of dietetic practice.

In this study we found that the meal with the smallest proportion of pasta or rice and the largest proportion of non-starchy vegetables induced a reduction in glycaemic response compared to the meal containing the largest proportion of starchy food and the smallest proportion of non-starchy vegetables. Visually this preferred meal had one quarter of a plate starchy foods, one quarter protein and one half non-starchy vegetables, consistent with Diabetes New Zealand recommendations (21). Our data therefore provide evidence that strengthens the relevance and effectiveness of encouraging people to follow the healthy plate model (21). However, as results found glycaemic response to be relatively insensitive between the meals with the small and medium amount of starchy foods this indicates that it may not be critical for people to get the proportions of foods exact. Avoidance of the meal with the largest proportion of starchy food (half a plate) should still be recommended, however, some leniency with one quarter and one third of a plate may allow for personal preference.

As well as encouraging people to follow the plate model, it will be important for dietitians to discuss the selection of an appropriate plate size, as this directly relates to the amount of food a person will consume. Matching a person’s plate size and therefore meal size to their lifestyle and clinical goals will ensure that the plate model guidelines are applicable to the majority of the population.

Advising individuals to follow the plate model will likely be a simpler strategy to implement than adopting a vastly different diet, which may improve long-term compliance to dietary
changes. Furthermore, if people are consuming appropriate meal sizes another positive aspect of changing the proportions of meal components is that it will not alter the total quantity of the meal and therefore the meal will not appear smaller.

In our study the recommended one quarter of a plate of starchy foods equated to 30g available carbohydrate, however the total available carbohydrate content of the meal was much higher than this at around 50g, due to the additional carbohydrate provided by the vegetables and sauce. It is therefore necessary for dietitians to educate people with T2DM about the carbohydrate contribution from other aspects of a meal. Limiting the proportion of starchy foods to around one quarter of a plate will not be as effective at reducing glycaemic response if the remaining components of the meal include sauces and ingredients high in carbohydrate.

Advice to consume pasta instead of rice due to the lower glycaemic response that pasta induces should be given on an individual basis and not used as a blanket guideline. Cultural, ethnic and taste preferences as well as gluten allergies or intolerances may limit the practicality of this advice for some individuals.

The results from our study underline the usefulness of recommending a visual model for meal planning. Advice to follow the healthy plate model is a simple strategy for people to implement.
8 References


# Appendices

Appendix A: Ethics proposal

Appendix B: Ethical approval letter

Appendix C: Maori consultation approval letter

Appendix D: Participant information sheet

Appendix E: Participant consent form

Appendix F: Clinical trial registration

Appendix G: Calculation of the quantity of the starchy food in each test meal

Appendix H: Blood glucose meter calibration

Appendix I: Participant blood glucose recording sheet

Appendix J: Research assistant blood glucose recording sheet

Appendix K: Demographic questionnaire

Appendix L: Preparation methods for special meals

Appendix M: Glycaemic index and glycaemic load calculations

Appendix N: Nutritional composition of the special meals
Appendix A: Ethics proposal

UNIVERSITY OF OTAGO HUMAN ETHICS COMMITTEE
APPLICATION FORM: CATEGORY A

Form updated: Feb 2016

1. University of Otago staff member responsible for project:
   
   Surname       First Name       Title (Dr)
   Venn            Bernard

2. Department/School:
   Human Nutrition

3. Contact details of staff member responsible *(always include your email address)*:
   bernard.venn@otago.ac.nz
   Tel 03 479 5068

4. Title of project: HUNT311 clinical nutritional laboratory; a repeated teaching activity

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

<table>
<thead>
<tr>
<th>Staff Co-investigators</th>
<th>Names:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Liz Williams</td>
</tr>
<tr>
<td></td>
<td>Kate Martin</td>
</tr>
<tr>
<td></td>
<td>Eilis Woodward</td>
</tr>
<tr>
<td></td>
<td>Anna Worsfold</td>
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<table>
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<tbody>
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<td>MDiet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>External Researchers</th>
<th>Names:</th>
</tr>
</thead>
</table>
6. **Is this a repeated class teaching activity?** *(Delete answer that does not apply)*

YES

If YES and this application is to continue a previously approved repeated class teaching activity, provide Reference Number: 13/022

7. **Fast-Track procedure** *(Delete answer that does not apply)*

Do you request fast-track consideration? *(See 'Filling Out Your Human Ethics Application')*

NO

If YES, provide a robust justification on the need for urgency:

8. **When will recruitment and data collection commence?**

February 2016

**When will data collection be completed?**

April 2016

9. **Funding of project**

Is the project to be funded by an external grant?

NO

If YES, specify who is funding the project:

If commercial use will be made of the data, will potential participants be made aware of this before they agree to participate? If not, explain:

No commercial use
10. **Brief description in lay terms of the purpose of the project** (approx. 75 words):

The purpose of the HUNT311 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. Speed of eating will be timed. 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 and description of project**

The aim of this laboratory is to test glycaemic, satiating and speed of eating outcomes to cooked meals comprising meat, vegetables and carbohydrate in various proportions. This information will be used by HUNT311 students as a learning exercise and in the writing of his or her assignment.

12. **Researcher/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) **Inclusion and exclusion criteria:**

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

13(c) **Estimated number of participants:** All HUNT311 students

13(d) **Age range of participants:** 18-60y

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) **Specify and justify any payment or reward to be offered**

No payment or reward
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 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 and for collection of demographic data. Test foods will be provided to participants. In 2016, the foods will be meals prepared by the MDiet candidates.

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 three meals, 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 fasting for at least two and a half hours. On each of the test days, a finger-prick blood sample will be taken 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 meal will be consumed over a fifteen to twenty minute period and a series of five more finger-pricks will be undertaken at 15, 30, 45, 60 and 90 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 two millilitres. 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. The questions below allow the Committee to assess compliance.

15(a) Are you collecting and storing personal information (e.g.name, contact details, designation, position etc) directly from the individual concerned that could identify the individual? *(Delete the answer that does not apply.)*

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

NO

If YES, explain:

15(c) Collecting Personal Information (Delete the answer that does not apply):

- Will you be collecting personal information (e.g. name, contact details, position, company, anything that could identify the individual)?
  YES
- Will you inform participants of the purpose for which you are collecting the information and the uses you propose to make of it?
  YES
- Will you inform participants of who will receive the information?
  YES
- Will you inform participants of the consequences, if any, of not supplying the information?
  YES
- Will you inform participants of their rights of access to and correction of personal information?
  YES

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

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

15(d) Outline your data storage, security procedures and length of time data will be kept

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 in password protected files. 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? If you are obtaining information from another source, include details of how this will be accessed and include written permission if appropriate. Will participants have access to the information they have provided?

Only Dr Bemard 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 Bemard Venn and to delete the file from the student computer.

Statistical analysis will be done using anonymous data.

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

NO

If YES, 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.

Yes

15 (h) Have you, or will you, undertake Māori consultation? Choose one of the options below, and delete the option that does not apply:

(Refer to http://www.otago.ac.nz/research/maoriconsultation/index.html).

NO If not, provide a brief outline of your reasons (e.g. the research is being undertaken overseas):

YES We have completed the University of Otago online Māori consultation form attached (pages 14-15). It is scheduled for discussion at the Ngāi Tahu Research Consultation Committee meeting 18th Nov.

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

NO

If yes, explain all debriefing procedures:
17. **Disclose and discuss any potential problems or ethical considerations:** (For example: medical or legal problems, issues with disclosure, conflict of interest, safety of the researcher, etc. Note: if the student researcher will be travelling overseas to undertake the research, refer to item 12 of the *Filling Out Your Human Ethics Application* document. Please note that approval from the Human Ethics Committee does not override the University of Otago’s Field Policy and Travel Policy, which must be complied with.)

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

There may be some discomfort from finger pricking

18. **Applicant's Signature:** .................................................................

   *Name (please print):* .................................................................

   *Date:* .................................................................

   *The signatory should be the staff member detailed at Question 1.*

19. **Departmental approval:** I have read this application and believe it to be valid research 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 HOD (please print):* .................................................................

   *Date:* .................................................................

   **Where the Head of Department is also the Applicant, then an appropriate senior staff member must sign on behalf of the Department or School.**
Appendix B: Ethical approval letter

Note: This is a repeated teaching activity; therefore this ethical approval letter from November 2014 is still valid.

27 November 2014

Dr B Venn
Department of Human Nutrition
Division of Sciences

Dear Dr Venn,

I am again writing to you concerning your proposal entitled “HUNT311 clinical nutritional laboratory: a repeated teaching activity”, Ethics Committee reference number 14/204.

Thank you for your email responding to the Committee, for and providing the revised Information Sheet and Consent Form.

Thank you for clarifying the information for participants regarding the two aspects of the study, what they are being asked to consent to and what they will experience, and procedures in case of accidental findings. Thank you for providing three options on the Consent Form to allow participants to consent the main laboratory experiment, the saliva sample for genotyping, and the storage of the DNA for possible future testing.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

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,

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

cc. Professor S Semman Department of Human Nutrition
Appendix C: Māori consultation approval letter

Tuesday, 18 November 2014.

Dr Bernard Venn,
Department of Human Nutrition,
DUNEDIN.

Tēnā Koe Dr Bernard Venn,

**HUNT311 clinical nutritional laboratory; a repeated teaching activity**

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 18 November 2014 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (to that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

The Committee notes this is a class laboratory exercise but also notes it is dealing with some important aspects for Māori health. The Committee suggests that Māori health issues are outlined as part of this class to discuss important health disparities.

We wish you every success in your research and the committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 18 November 2014 to 18 May 2016.
Nāhaku noa, nā

Mark Brunton
Kaiwhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Otago
Ph: +64 3 479 8738
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz
Appendix D: Participant information sheet

HUNT311 clinical nutritional 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 three meals. This requires attending the laboratory on three 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 who are willing to participate. If you have special dietary needs please let us know. The meal will be gluten-free, dairy-free, and nut-free. A vegetarian option is available.

What will Participants be Asked to Do?

You will be asked to attend the Department of Human Nutrition Undergraduate Laboratory on three occasions, separated by one or two weeks apart. If eligibility criteria are met, you will be asked to read and sign 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 at lunchtime, you will be streamed to arrive at the laboratory either at 11:50am, or at 1:15pm. You will be asked not to eat or drink for two and a half hours before the start time (ie; for those people attending the 11:50 lab, please do not eat or drink after 9:15am: for those attending the 1:15pm lab, please do not eat or drink after 10:30 am). If you have eaten within this period of time you will be turned away and asked to reschedule your lab. Note: no sugar-sweetened chewing gum, you may drink water up until 30 min before the start time but please do not drink too much water as you are required to eat a full sized meal.

If you walk or cycle to the laboratory please do so slowly so as not to elevate your heart rate and blood glucose. On arrival a finger-prick blood sample will be taken in the fasting state using a single-use disposable lancet designed to minimize discomfort. You will then be given a meal. After this, additional finger-prick blood samples will be taken at 15, 30, 45, 60 and 90 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. During this time 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.
What Data or Information will be Collected and What Use will be Made of it?

For the main laboratory exercise 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. From your blood samples we will be testing glucose concentration. Personal 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 will be pooled and may be published and available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity. The data and samples collected will be securely stored in such a way that only those mentioned below will be able to gain access to it. Data and samples 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 and samples 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.

Testing blood glucose has the potential to reveal whether a person has diabetes or is at risk of pre-diabetes. If elevated blood glucose concentrations are found, you will be advised to make an appointment with student health or with your general practitioner.

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 contact -

Liz Williams; email e.williams@otago.ac.nz

Dr Bernard Venn; email bernard.venn@otago.ac.nz

Telephone: 03 479 5068

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: Participant consent form

HUNT311 clinical nutritional 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. Fingerprick blood sampling may cause some discomfort.
5. 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.

I consent to attending the laboratory on three days following a two and a half hour fast, having height and weight taken, consuming the meals and providing six blood samples obtained by finger pricking over two hours on each test day.

Yes ☐ / No ☐

Name ........................................... Signature................................................. . Date ............... .

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 F: Clinical trial registration

## Trial Review

### Trial registered on ANZCTR

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<tr>
<td>Date submitted</td>
<td>20/05/2016</td>
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<td>30/05/2016</td>
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### Titles & IDs

<table>
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<th>Public title</th>
<th>Glycaemic response to varying the proportions of carbohydrate and vegetables within a meal</th>
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<td>Scientific title</td>
<td>The effect of consuming meals with different proportions of carbohydrate and vegetables by healthy young adults on glycaemic response</td>
</tr>
<tr>
<td>Secondary ID [1]</td>
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</tr>
<tr>
<td>Universal Trial Number (UTN)</td>
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<td>Trial acronym</td>
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### Health condition

**Health condition(s) or problem(s) studied:**

- Postprandial glycaemia

### Condition category

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<tr>
<th>Diet and Nutrition</th>
<th>Normal metabolism and endocrine development and function</th>
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</thead>
<tbody>
<tr>
<td>Metabolic and Endocrine</td>
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### Intervention/exposure

**Study type**

Interventional

**Description of intervention(s) / exposure**

This is a dietary intervention study in which healthy young adults will consume test meals with differing proportions of carbohydrate (rice or pasta based meals) and non-starchy vegetables. Half of the participants will be randomised to receive pasta-based meals and the other half to receive rice-based meals. Within each intervention group participants will consume a meal with 30g and 60g of available carbohydrate at two separate testing sessions. The amount of rice and pasta corresponding to the 30 and 60g available carbohydrate will be 100 and 200g, respectively. The amount of non-starchy vegetables on the plate will be 250 and 150g, respectively (ie: a gram for gram replacement of rice or pasta with non-starchy vegetables). The amount of mince and sauce will be constant at 200g. The total weight of each meal will be 550g. Participant's blood glucose concentration will be measured prior to consuming the meal and then at 15, 30, 45, 60 and 90 minutes after this time point. The order of test meal consumption will be randomised. The meals will be served hot (>65 deg CI). Participants will consume the meals with instruction to finish all of the food on the plate in their own time while under supervision at the study site. The washout period between successive lunch meals will be one week.

**Intervention code [1]**

Lifestyle

**Intervention code [2]**

Treatment: Other

**Intervention code [3]**

Prevention

**Comparator / control treatment**

Participants will consume a third test meal with 45g of available carbohydrate at a separate testing session. This will act as the control as it is the amount of available carbohydrate that Diabetes New Zealand...
recommends individuals with type 2 diabetes mellitus to consume within a starchy food at a main meal. The meals with 30g and 60g of available carbohydrate represent a one serving (15g available carbohydrate) difference from this control meal.

Control group
Active

Outcomes

Primary outcome [1] Blood glucose concentration will be measured on fingerprick samples using a Hemocue glucose analyser at each timepoint. The blood glucose data will be plotted and incremental area-under-the-curve will be calculated using the trapezoidal rule.

Timepoint [1] Baseline and thereafter at 15, 30, 45, 60 and 90 min following consumption of test meal

Secondary outcome [1] Blood glucose concentration at 90 min

Timepoint [1] 90 min following consumption of the test meal

Eligibility

Key inclusion criteria Healthy university students
Minimum age 18 Years
Maximum age 60 Years
Gender Both males and females
Can healthy volunteers participate? Yes

Key exclusion criteria A dietary requirement that we cannot cater to. There will be no other exclusion criteria.

Study design

Purpose of the study Prevention
Allocation to intervention Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures) Participants will be randomly assigned to receive either rice or pasta-based meals and to the order they will receive the meals. The person who will determine if a subject is eligible for inclusion in the trial will be unaware, when this decision is made, to which group the subject will be allocated. Randomisation will be performed by the department statistician, the researchers will remain unaware of allocations until the laboratory phase.

Methods used to generate the sequence in which subjects will be randomised (sequence generation) Males will be block randomised to ensure equal sex distribution between the two groups, controlling for any potential sex variability in glycaemic response. Simple randomisation will be used for order treatment and all randomisation will be done using Stata statistical analysis software.

Masking / blinding Open (masking not used)

Intervention assignment Crossover

Other design features Crossover refers to the different proportions of starchy carbohydrate and vegetables on the plate, each person consumes three meals in randomised order containing 30, 45 and 60g starchy carbohydrate. There is also a parallel component to the study in which participants will be randomised to the starchy carbohydrate of either rice or pasta-based meals.

Phase Not Applicable

Type of endpoint(s) Efficacy

Recruitment

Anticipated date of first participant enrolment
Actual date of first participant enrolment 2/03/2016

Anticipated date last participant enrolled
Actual date last participant enrolled 9/03/2016

Anticipated date of last data collection
Actual date of last data collection

Target sample size 68
Actual sample size 74
**Recruitment status**  
Completed

**Recruitment outside Australia**

**Country [1]**
New Zealand

**State/province [1]**
Otago

**Funding & Sponsors**

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</table>
| Address [1]                 | Department of Human Nutrition  
PO Box 56  
Dunedin  
9054 |
| Country [1]                 | New Zealand |
| Primary sponsor type        | University |
| Name                        | University of Otago |
| Address [1]                 | Department of Human Nutrition  
PO Box 56  
Dunedin  
9054 |
| Country [1]                 | New Zealand |
| Secondary sponsor category [1] | None |
| Name [1]                    | University of Otago |
| Address [1]                 | Department of Human Nutrition  
PO Box 56  
Dunedin  
9054 |
| Country [1]                 | New Zealand |

**Ethics approval**

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| Ethics committee address [1] | PO Box 56  
Dunedin  
9054 |
| Ethics committee country [1] | New Zealand |
| Date submitted for ethics approval [1] | 02/02/2015 |
| Approval date [1] | 16/02/2015 |
| Ethics approval number [1] | 14/204 |

**Summary**

**Brief summary**  
A randomised controlled crossover trial in which participant’s blood glucose concentrations will be measured following the consumption of three test meals. Each meal will have different proportions of carbohydrate and non-starchy vegetables. The amount of starchy carbohydrate on the plate will be 30, 45 and 60g. The comparator will be the meal containing 45g starchy carbohydrate.

There will also be a parallel design in which the starchy carbohydrate will be rice or pasta. Participants will be randomised to either rice or pasta-based meals.

**Trial website**  

**Trial related presentations / publications**

**Public notes**

**Contacts**

**Principal investigator**

<table>
<thead>
<tr>
<th>Name</th>
<th>Dr Bernard Venn</th>
</tr>
</thead>
</table>
| Address | University of Otago  
Department of Human Nutrition  
PO box 56  
Dunedin  
9054 |
| Country | New Zealand |
Appendix G: Calculation of the quantity of the starchy food in each test meal

Pasta

- 73.8g CHO / 100g dried pasta (from product Nutrition Information Panel)
  = 0.738g CHO per 1g dried pasta
- 500g dried pasta → 1250g cooked pasta (from experimentation)
  1250g / 500g = 2.5g cooked pasta per 1g dried pasta
- 0.738g CHO / 2.5 = 0.2952g CHO per 1g cooked pasta
- 30g available CHO / 0.2952 = 102g pasta (practically rounded to 100g)
- 45g available CHO / 0.2952 = 152g pasta (practically rounded to 150g)
- 60g available CHO / 0.2952 = 203g pasta (practically rounded to 200g)

Rice

- 79g CHO / 100g raw rice (from product Nutrition Information Panel)
  = 0.79g CHO per 1g raw rice
- 500g raw rice → 1300g cooked rice (from experimentation)
  1300g / 500g = 2.6g cooked rice per 1g raw rice
- 0.79g CHO / 2.6 = 0.3039g CHO per 1g cooked rice
- 30g available CHO / 0.3039 = 99g rice (practically rounded to 100g)
- 45g available CHO / 0.3039 = 148g rice (practically rounded to 150g)
- 60g available CHO / 0.3039 = 197g rice (practically rounded to 200g)
Appendix H: Blood glucose meter calibration

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1. All values are in mmol/L.
Appendix I: Participant blood glucose recording sheet

Student ID: 
Date: 
Time: 11:50am or 1pm (please circle one)

HUNT311 Glycaemic labs – Data collection sheet

Time at baseline______________________________

Blood glucose measures:

Baseline_______________________________mmol/L
15-minutes_______________________________mmol/L
30-minutes_______________________________mmol/L
45-minutes_______________________________mmol/L
60-minutes_______________________________mmol/L
90-minutes_______________________________mmol/L

• Record your blood glucose reading at each time point
• Be aware of when your next blood glucose reading is due
• If you are due to be finger pricked and the ‘finger pricker’ has not done so yet, remind them to take your blood glucose reading.
Appendix J: Research assistant blood glucose recording sheet

Recorders name:  
Date/ lab number:  
Time: 11:50am or 1pm (circle one)

HUNT311 Glycaemic Labs – Data collection sheet

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</table>
Appendix K: Demographic questionnaire

Demographics Questionnaire:          Student ID#:______________

Please complete this questionnaire in full and as accurately as possible. Your answers will not only inform our research, but will also inform your assignment!

Which sex are you? (please circle)

Female                       Male

What is your date of birth? (DD/MM/YYYY)

___/___/______

Please read the next two questions carefully, and note the difference between nationality and ethnicity. Nationality is the country one is born or 'belongs to', and ethnicity refers to ancestral affiliations/bloodlines. e.g. Nationality: New Zealander, Ethnicity: Maori.

Which Nationality are you? (please circle)

New Zealander    Samoan
Tongan           Chinese
Indian           American
Other: __________________________________________________________

Which ethnic group do you affiliate with? (please circle)

New Zealand European   Maori
Samoan                 Cook Island Maori
Tongan                 Niuean
Chinese                Indian
Other: __________________________________________________________
Do you smoke regularly (that is, one or more a day)? (please circle)

Yes
No

Have you ever been a regular smoker of one or more cigarettes a day? (please circle)

Yes
No

How many times (not days) in an average week do you partake in moderate to intense exercise? (Please circle)

Not at all
1-2
3-4
5-6
7+

On average how long do you exercise for at a time? (Please circle)

I don’t
30mins
1hr
2hrs+

Your height and weight will be measured either before baseline, or after your 90-minute blood glucose reading. Please record these measures below.

Height: ___________cm

Weight: ___________kg

BMI: ___________kg/(m²)

Thank-you for completing this questionnaire!
Appendix L: Preparation methods for special meals

Vegetarian mince alternative:
The vegetarian mince alternative (Quorn™, Marlow Foods Ltd; Australia) was prepared using the same cooking method as the regular mince. For every 1kg of raw vegetarian mince alternative, 1kg of pasta sauce (Extra Bolognaise Pasta Sauce, Dolmio®, Mars Food; Australia) and 2 teaspoons of canola oil (Sunfield Oils, Tasti Products Ltd, Auckland; New Zealand) were used.

IBS meals:
Raw premium beef mince (New World, Dunedin; New Zealand) was prepared using the same cooking method as the regular mince. Instead of the regular pasta sauce a pasta sauce free of onions (Passata Cooking Sauce Italian Herbs and Spice, Leggo’s, Simplot Australia Pty Ltd; Australia) was used with a ratio of 700g raw mince: 700g pasta sauce: 1.5 teaspoons canola oil (Sunfield Oils, Tasti Products Ltd, Auckland; New Zealand). The vegetables (International Stir-fry Mix, Wattie’s®, Heinz Wattie’s Ltd, New Zealand) were prepared using the same cooking method as the standard vegetables.

Vegan protein alternative:
Strained canned chickpeas (Chickpeas in spring water, Wattie’s®, Heinz Wattie’s Ltd, New Zealand) were placed onto the plate and the pasta sauce (Extra Bolognaise Pasta Sauce, Dolmio®, Mars Food; Australia) was spread over them, with a ratio of 100g chickpeas: 125g pasta sauce.
## Appendix M: Glycaemic index and glycaemic load calculation

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<tr>
<th>Meal type</th>
<th>GI</th>
<th>AvailCHO (g)</th>
<th>GL&lt;sup&gt;2,3&lt;/sup&gt;</th>
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¹: \( \text{Meal GI} = \left(\frac{\text{GI}_A \times \text{AvailCHO}_A (g)}{\text{Food A}} + \left(\frac{\text{GI}_B \times \text{AvailCHO}_B (g)}{\text{Food B}}\right) + \ldots\right) / \text{AvailCHO}_\text{Meal} (g) \)

²: \( \text{GL} = \frac{\text{GI} \times \text{AvailCHO} (g)}{100} \)

³: \( \text{Meal GL} = \left(\frac{\text{Meal GI} \times \text{AvailCHO}_\text{Meal} (g)}{100}\right) \)
### Appendix N: Nutritional composition of the special meals

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<th>Avail CHO (g)3</th>
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<th>Protein (g)</th>
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1. All values are presented per meal
2. Total cooked weight was 550g for all vegetarian and IBS meals and 575g for all vegan meals
3. AvailCHO = CHO content – dietary fibre