“Comparing the effectiveness of dietitian delivered nutrition education either as a single intensive session or five short sessions for people with prediabetes”

A thesis presented in partial fulfilment for the degree of

Master of Science

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Abstract

Prediabetes is a worldwide growing epidemic and a key risk factor for progression onto type 2 diabetes. Interventions targeting prediabetes are required to delay or prevent the onset of diabetes.

A pilot study was undertaken involving 11 participants with prediabetes. The participants were randomly assigned to either a single session or multi session (five sessions) dietary education intervention conducted by a single dietitian with an overall contact time of 60 minutes. Outcome measurements were collected in the form of HbA1c, weight, blood lipids and nutrition knowledge score.

No significant differences were found between the intervention groups in either metabolic outcomes or nutrition knowledge. The analysis of the small sample size should be interpreted with caution and is for interest purposes only.

The small sample size may have contributed to the lack of statistically significant results and a larger sample size would be recommended. Few studies have compared similar methodology of consistent contact time over single or multiple sessions. Further programmes could incorporate a longer contact time which could be used to integrate more behaviour change techniques and individual goal setting which may result in greater improvement in measurements.
Preface

The research study undertaken in this thesis was conceived in discussion with supervisor Dr Bernard Venn, the candidate and with input and support from Pauline Giles (Nurse Practitioner, MidCentral DHB).

Central Primary Health Organisation supported this research through enabling the use of clinical time for undertaking the intervention and funding the research.

Feilding Health Care were the major General Practice Facility which enabled recruitment of patients and consultation space available to undertake the research. Feilding Health Care conducted the searches through their patient management system for eligible candidates. Their support is acknowledged.

Dietitian students assisted with recruitment of participants through making telephone contact and arranging consultation times.

Statistical analysis including the randomisation of the participants was undertaken by Dr Jill Haszard, Biostatistician, Department of Human Nutrition/Department of Women's and Children's Health, University of Otago.

The candidate was responsible for:

- Completing ethics application and area approval including local Maori consultation
- Designing and marketing the recruitment drive including posters
- Study design and protocol
- Developing lesson plan inclusive of resources
- Managing participant recruitment
- Undertaking the intervention sessions
- Collecting and entering all data
• Taking and entering all anthropometric measurements for participants
• Follow up processes including data collection for participants
• Writing the thesis
Acknowledgements

I would like to acknowledge the support of Central Primary Health Organisation as my employer enabling the research to be undertaken as part of my employment as a Clinical Dietitian.

I would like to acknowledge the support of Feilding Health Care as the primary general practice team whom assisted with recruitment of participants and also enabled access to facilities to undertake the intervention.

Thank you to the University of Otago for allowing this research study.

I also acknowledge the resource and continued support from supervisor Dr Bernard Venn whom has encouraged me along the way.
Table of Contents

Abstract ........................................................................................................................................... ii
Preface ................................................................................................................................................ iii
Acknowledgements ........................................................................................................................ v
Table of Contents .......................................................................................................................... vi
List of Tables ..................................................................................................................................... ix
Abbreviations ............................................................................................................................... x

1 Introduction ..................................................................................................................................... 12
  1.1 Diabetes Statistics .................................................................................................................. 12
  1.2 The Prevalence of Prediabetes in New Zealand .................................................................. 14
  1.3 Who is at Risk? ...................................................................................................................... 14
  1.4 The Cost of Diabetes ............................................................................................................ 15
  1.5 Current Research .................................................................................................................. 16
  1.6 Explanatory Note ................................................................................................................... 17

2 Literature Review ....................................................................................................................... 18
  2.1 Introduction .......................................................................................................................... 18
  2.2 Parameters of the Literature Review .................................................................................. 18
  2.3 Successful lifestyle interventions targeting high risk participants for delaying and or preventing the onset of Type 2 Diabetes ............................................................................... 19
    2.3.1 The Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) ......................... 20
    2.3.2 The Da Qing Impaired Glucose Tolerance (IGT) and Diabetes Study (Pan et al., 1997) ......................................................................................................................... 22
    2.3.3 The Diabetes Prevention Program (DPP) (Diabetes Prevention Program Research Group, 2002) ........................................................................................................ 23
2.3.4 Implementation of a lifestyle intervention programme for New Zealand Māori (McAuley et al, 2003) ................................................................. 26

2.3.5 Piloting of community health worker-based intervention among New Zealand Māori in Te Wai o Rona (Simmons D, Rush E & Crook N, 2008) .......... 27

2.4 Interventions/programmes that utilised Dietitians as the key nutrition educators ................................................................................................. 28

2.5 Interventions that used similar methodology around comparison of different modes of delivery ................................................................. 32

2.5.1 Multisite Randomized Trial of a Single-Session Versus Multisession Literacy-Sensitive Self-Care Intervention for Patients with Heart Failure DeWalt et al, 2012) ........................................................................................................ 33

2.5.2 Comparative Effectiveness of a Practice-Based Comprehensive Lifestyle Intervention vs. Single Session Counselling in Hypertensive Blacks (Schoenthaler et al, 2016) ........................................................................................................ 35

2.5.3 Balance – a pragmatic randomized controlled trial of an online intensive self-help alcohol intervention (Brendryen et al, 2014) ......................... 36

2.5.4 Telephone Counselling for Smoking Cessation: Effects of Single-Session and Multiple-Session Interventions (Zhu et al, 1996) ...................................... 37

2.5.5 Minimal Interventions for Weight Control: A Cost-Effective Alternative (Black et al, 1984) .......................................................... 39

3 Methods ........................................................................................................ 40

3.1 Ethics ........................................................................................................ 40

3.2 Study Design ............................................................................................. 40

3.3 Study Objectives ....................................................................................... 40

3.4 Recruitment Process ................................................................................ 41

3.5 Study Participants .................................................................................... 41
3.6 Health Questionnaire .................................................................................................................. 42
3.7 Education Intervention .................................................................................................................. 43
3.8 Study Protocol .............................................................................................................................. 43
3.9 Data Collection ............................................................................................................................ 44
3.10 Data Analysis .............................................................................................................................. 44

4 Results .......................................................................................................................................... 46
4.1 Participant Characteristics ........................................................................................................... 46
4.2 Health Questionnaire .................................................................................................................. 49
  4.2.1 Question 7: Plate model awareness and illustration. ......................................................... 51
  4.2.2 Question 8: Exercise ............................................................................................................. 51
  4.2.3 Question 9: Confidence and importance scale ................................................................. 52

5 Discussion ..................................................................................................................................... 53
5.1 Health Questionnaire Findings .................................................................................................. 59
5.2 Cost Effectiveness ........................................................................................................................ 60
5.3 Future Research .......................................................................................................................... 62

6 Conclusions and Recommendations ............................................................................................. 65
6.1 Recommendations ...................................................................................................................... 66

7 References ..................................................................................................................................... 68

8 Appendices ..................................................................................................................................... 74
List of Tables

Table 1. Identified groups at high risk of Type 2 Diabetes ........................................15
Table 2. Studies using Dietitians as Key Nutrition Experts .........................................30
Table 3. Baseline Characteristics of the Study Participants ...........................................47
Table 4. Mean change in individual outcome measurement for each group and
between groups comparing pre and post intervention (with SD and p-value) ..........48
Table 5. Health Questionnaire Results (Questions 1-6) .............................................50
Table 6. Mean difference in change of score between groups (95% CI) .......................52
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
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<tr>
<td>ANCOVA</td>
<td>Analysis of covariance</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>BP</td>
<td>Blood pressure</td>
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<tr>
<td>CHO</td>
<td>Carbohydrate</td>
</tr>
<tr>
<td>DHB</td>
<td>District health board</td>
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<td>DM</td>
<td>Diabetes mellitus</td>
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<td>DPP</td>
<td>Diabetes prevention programme</td>
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<tr>
<td>GPT</td>
<td>General Practice team</td>
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<td>HbA1c</td>
<td>Glycated haemoglobin</td>
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<td>HDL</td>
<td>High density lipoprotein cholesterol</td>
</tr>
<tr>
<td>IFG</td>
<td>Impaired fasting glucose</td>
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<tr>
<td>IGT</td>
<td>Impaired glucose tolerance</td>
</tr>
<tr>
<td>LDL</td>
<td>Low density lipoprotein cholesterol</td>
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<tr>
<td>MNT</td>
<td>Medical nutrition therapy</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of health</td>
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<tr>
<td>NCD</td>
<td>Noncommunicable disease</td>
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<td>NZSSD</td>
<td>New Zealand society for the study of diabetes</td>
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<tr>
<td>PCOS</td>
<td>Polycystic ovarian syndrome</td>
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<tr>
<td>PHO</td>
<td>Primary health organisation</td>
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<tr>
<td>PMS</td>
<td>Patient management system</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>TAG</td>
<td>Triglyceride</td>
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<tr>
<td>T2DM</td>
<td>Type two diabetes mellitus</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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<tr>
<td>Wt</td>
<td>Weight</td>
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1 Introduction

It is estimated that nearly one in five New Zealander’s over the age of 15 years have a blood glucose level that puts them at risk of developing type 2 diabetes (Coppell et al, 2013).

Prediabetes, impaired fasting glucose (IFG), intermediate hyperglycaemia, impaired glucose tolerance (IGT) and borderline diabetes are all names for a condition that is fast growing within our population.

Prediabetes (as referred to hereafter) is a condition defined as a person having blood glucose concentrations above the normal range, but not yet within the criteria for diagnosis of diabetes (New Zealand Society for the Study of Diabetes [NZSSD], 2011). Screening is undertaken by measuring glycated haemoglobin (HbA1c) with prediabetes diagnosed when HbA1c is in the range of 41-49mmol/mol. A normal value for HbA1c (normoglycaemia) is 40mmol/mol and a diagnosis of diabetes is made with a value of 50mmol/mol (in conjunction with NZSSD guidelines) (NZSSD, 2011).

This diagnosis of prediabetes elevates a person’s risk of later developing type 2 diabetes and cardiovascular disease compared to those within the normoglycaemic range (Tabak et al, 2012).

It is estimated that each year, around 3-10% of people with prediabetes will further go on to develop diabetes and long term, approximately 70% will ultimately develop type 2 diabetes (Tabak et al, 2012).

1.1 Diabetes Statistics

The current research will only refer to type 2 diabetes (the most common form of diabetes), however it is recognised that there are a number of different diabetic states. Type 2 diabetes is a chronic condition which is categorised by higher than
normal blood glucose levels and by which either “the body doesn’t produce enough insulin, or the cells in the body don’t recognise the insulin that is present”. (Diabetes New Zealand, 2016).

In the Global Report on Diabetes released by the World Health Organisation in 2016, diabetes was identified as one of the four priority noncommunicable diseases (NCD) that are being targeted for action by world leaders (World Health Organisation [WHO], 2016).

The report outlines some staggering statistics around diabetes. It is reported that diabetes prevalence has almost doubled since 1980 – rising from 4.7% to an estimated 8.5% of the adult population. In 2014, an estimated 422 million people globally were thought to have been living with diabetes (this includes other types of diabetes). The report further goes on to state that diabetes (type 1 and 2) has caused approximately 1.5 million deaths in 2012 and a further 2.2 million deaths through the increased risk of cardiovascular disease and other diseases by higher than optimal blood glucose control (WHO, 2016).

The list of diabetes related complications includes cardiovascular disease, diabetic nephropathy, neuropathy, retinopathy, lower limb ulcers, amputations and early mortality. They are all recognised as being related to poorly controlled diabetes management (Diabetes UK, 2011).

Type 2 diabetes is largely preventable. Although some risk factors such as genetics, ethnicity and age are not modifiable, other factors such as obesity, unhealthy diet, physical inactivity and smoking are all modifiable.

Early detection of people with prediabetes will enable treatment and interventions to be targeted and implemented to help reduce the burden of disease not only to the health system but also to the individual, their family and the wider community as a whole.
1.2 The Prevalence of Prediabetes in New Zealand

The 2008/2009 New Zealand Adult Nutrition Survey is a nationally representative survey that used American Diabetes Association (ADA) diagnostic criteria to determine the prevalence of prediabetes within the New Zealand Adult population (Coppell et al, 2013) (as a New Zealand criteria had not been agreed on at the time). Using HbA1c as the standard, the ADA cut-off for prediabetic diagnosis is 39-46mmol/mol. This is slightly different from the revised New Zealand cut-offs of 41-49mmol/mol, (NZSSD, 2011) nevertheless the survey produced some sobering results around the future health of our nation.

In the survey, the overall prevalence of prediabetes was found to be 25.5%. The highest prevalence was found amongst our Māori and Pacific population with 30.4% and 29.8%, respectively, meeting the criteria for prediabetes. Of those that were classified as obese, 32.2% also met the criteria for prediabetes. The authors also predicted that 41.3% of those with prediabetes would go on to develop diabetes within the next 7.5 years (Coppell et al, 2013). The implications around these numbers are wide spread and costly for our health system, our workforce, and for our community.

Prediabetes is a worldwide issue, with the United States of America rolling out a nationwide awareness campaign earlier this year to target and educate the one in three adult Americans estimated to have prediabetes (Consumer Healthday, 2016).

1.3 Who is at Risk?

The NZSSD guidelines recommends the screening of high risk individuals to be undertaken as part of a cardiovascular risk assessment (in accordance with national guidelines) and also opportunistic screening as able in clinical settings. The following groups have been identified as being at high risk of type 2 diabetes:
Table 1. Identified groups at high risk of Type 2 Diabetes

<table>
<thead>
<tr>
<th>Case</th>
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<tbody>
<tr>
<td>Those with known ischaemic heart, cerebrovascular or peripheral vascular disease</td>
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<tr>
<td>Those on long-term steroid or anti-psychotic treatment</td>
</tr>
<tr>
<td>Obese individuals (BMI ≥ 30 kg/m(^2) or ≥27 kg/m(^2) for Indo-Asian people)</td>
</tr>
<tr>
<td>People with a family history of early age onset of Type 2 diabetes in more than one first degree relative</td>
</tr>
<tr>
<td>Women with a past personal history of gestational diabetes mellitus</td>
</tr>
<tr>
<td>In addition, obese children and young adults (BMI ≥ 30 kg/m(^2) or ≥27 kg/m(^2) for Indo-Asian people) should be screened if there is a family history of early onset Type 2 diabetes, or if they are of Māori, Pacific or Indo-Asian ethnicity.</td>
</tr>
<tr>
<td>Women with Polycystic Ovarian Syndrome (PCOS)</td>
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1.4 The Cost of Diabetes.

Much is known about the consequences of developing diabetes for a person’s health status, but there is also a financial burden to the healthcare system.

In a paper released by the Ministry of Health in October 2015, it was estimated that the total direct health care costs for a person with diabetes is approximately three times that of people without diabetes (Ministry of Health [MOH], 2015). Major costs are incurred through service provision including general practice and nurse consultations, medications, other health professional visits, and secondary / tertiary health services. As well as direct health costs, there are other costs to be considered that increase the overall financial burden of the diabetes epidemic. These include the indirect costs such as lost productivity through illness and also the intangible cost such

1 Sourced from NZSSD
as changes in quality of life and the emotional aspects of the disease (Ministry of Health [MOH], 2009).

These costs not only affect the individual at the centre of the disease but the wider family, whanau, and community as people become more unwell and unable to fully participate in society.

Previous research by Diabetes New Zealand and PricewaterhouseCooper in 2001, 2007 and 2008 (as cited in Ministry of Health, 2009,) show a steady increase in the estimated direct costs (of publicly provided health services) from $247 million to $540 million and then $600 million respectively.

Global projections, from systematic reviews, calculate that diabetes has a direct health care cost in excess of US $827 billion a year (WHO, 2016).

1.5 Current Research

Prevention of diabetes is a key strategy in many countries, aimed at stemming the tide of this disease. There is a large body of research and interventions targeting those people that are at risk of diabetes. The aim of the current study was to use a Clinical Dietitian to undertake an intervention with individuals identified with prediabetes and provide dietary education for making healthy lifestyle choices to aid in the prevention or delay of the onset of type 2 diabetes.

In this intervention study, two arms of delivery mode were established to determine whether one was more effective than the other. The two arms included:

- A single, one-on-one consultation (single session, total time of 60 minutes).
- Five short one-on-one consultations spread over five weeks (multi session, total time of 60 minutes).
Both intervention arms would receive the same dietary education, and outcome measurements would consist of HbA1c, lipids, weight and nutrition knowledge score - measured pre and post intervention.

It was hypothesised that the multiple session intervention would result in a greater improvement in health which would be seen in a reduction of HbA1c, decrease in weight, and improvement in nutrition knowledge score than the single session group.

1.6 Explanatory Note

The initial intention of this research was to recruit and to conduct the intervention with a large sample size of approximately 70 participants. We ran into difficulty with the recruitment drive mid-way through the recruitment period. This was due to competing priorities with regards to other prediabetes management programmes. At the time of recruitment for the current study, other organisations and programmes were also being undertaken which meant less than anticipated numbers of participants were available for recruitment. We did not forestall such significant difficulty with recruitment and the decision was made to reduce the intervention to a pilot study in order to ensure that it could be completed within the allocated timeframe of an MSc. Therefore the statistics and analysis that were conducted for this pilot programme should be interpreted with caution and are presented for interest only.
2 Literature Review

2.1 Introduction

There is a significant amount of research undertaken in the field of diabetes, using many different facets or elements of methodology to compare and contrast. An increasing number of studies are being conducted in the field of diabetes prevention and, in particular, ‘at risk’ populations, with an aim of stemming the predicted pandemic of diabetes (Parker et al. 2014; McLellan et al. 2014; Norris et al. 2009; Greaves et al. 2011; Satterfield et al. 2003).

The intention of this literature review is to put the current research into context and provide some background on successful research and interventions undertaken in the area of diabetes prevention. In addition, this review serves to find research using similar methodology as was conducted for this study.

In order to focus the literature review three clear themes were recognised:

- Successful lifestyle interventions targeting high risk participants for delaying and or preventing the onset of diabetes
- Interventions or programmes that utilised dietitians as the key nutrition educators
- Interventions that used similar methodology around comparison of different modes of delivery (single versus multiple).

2.2 Parameters of the Literature Review

The current literature review searched the following online databases: CINAHL, Medline, Google Scholar, Scopus and PubMed. Terminology utilised included (in varying sequences):
Inclusion criteria included studies in English, adult populations, and type 2 diabetes. Research was excluded if they were not published studies, or older than 1980. This was to ensure up to date relevancy with the current study as science and research has changed over the last 40 years.

2.3 Successful lifestyle interventions targeting high risk participants for delaying and or preventing the onset of Type 2 Diabetes

The first aspect of this review looks at the current range of literature focused on the prevention of diabetes. Participants with prediabetes or impaired glucose tolerance were the starting point to interventions that look for an outcome (using biochemical markers) of a reduction or a delay in the onset of type 2 diabetes.

There is an abundance of literature available in this field with interventions covering an array of components such as diet, exercise, medications, psychological input or a variation of all of these. The resulting wealth of research in the area has generated large scale reviews and meta-analyses being created to amalgamate the results and determine the most effective interventions in terms of both outcomes and research components.

In a meta-analysis by Hopper et al (2011), interventions using either pharmacological or non-pharmacological approaches were reviewed. The conclusion from the ten randomised controlled trials (RCT) included was that an intervention helped to prevent/delay diabetes when compared to a control group, and that non-drug
approaches were superior in diabetes prevention than drug based approaches. To narrow down the field of research in this area, interventions that were followed up for more than three years were included and those that had a large number of participants (over 500) were examined. This was primarily to ensure that evidence around the delay or prevention of diabetes could be established after a significant amount of time lapse from intervention. Within many of the large scale reviews and meta-analyses, three large scale interventions were commonly reported on. These three studies have been cited numerous times as being some of the largest (by participant number) and longest running predominately lifestyle interventions of their kind. Therefore they have been reviewed in more detail. In order to show relevance to our unique New Zealand population profile, an additional search was undertaken to find similar lifestyle interventions studies in New Zealand. This resulted in very few papers being identified although two studies relevant to our indigenous population have been included.

2.3.1 The Finnish Diabetes Prevention Study (Tuomilehto et al., 2001)

This study was conducted to look at the effects and the feasibility of a program encouraging lifestyle changes to prevent or delay diabetes. The participants were all at risk of diabetes due to their diagnosis of impaired glucose tolerance (IGT), and were all recorded as being overweight (BMI of 25kg/m² or more). The participants (522) were randomly assigned to either an intervention group or to a control group. The intervention group were given individualised detailed information on diet and exercise and were followed up at least seven times within the first year by a nutritionist. The control group were given general oral and written information about diet and exercise but no specific individualised programme. Both groups were followed up for approximately three years.
As well as biochemical markers, the Finnish study looked at changes in the participants’ lifestyle using markers such as dietary intake, goal setting and change in exercise.

Results were collected from the participants at the end of year one and subsequently at the end of year two. They showed that body weight decreased significantly more in the intervention group during the first year. The intervention group also obtained changes in other biochemical indices including plasma glucose, waist circumference and serum lipids that were significantly better than those found in the control group (at the conclusion of year one). Similarly, the results indicate that some of these measurements were still significantly different at the conclusion of year two in favour of those participants in the intervention group.

The outcome of diabetes incidence was calculated in both groups and showed that the cumulative incidence of diabetes was significantly lower in the intervention group after two years (6% intervention group, 14% control group).

Using Cox regression analysis of all person-years accumulated, it was found that the intervention group had a 58% lower cumulative incident rate of diabetes compared with the control group. They also compared participants that set and achieved health goals and found there was an inverse relationship between those that achieved more goals and the incidence of diabetes, thus suggesting that goal setting helps with behavioural components of lifestyle change.

In 2006, a follow up report to the Finnish study found that the relative risk of diabetes progression was found to be sustained (a reduction risk of 43%) even after the intervention period had been completed (Lindström et al, 2006).
Another study to look at the benefits of interventions for people at high risk of diabetes is the Da Qing IGT and Diabetes Study (Pan et al., 1997). In this study, 577 participants with classified IGT were randomised into one of three treatment groups plus a control group. Similar to the Finnish study, the researchers were looking at interventions using lifestyle changes as a measure for diabetes prevention. Unlike the Finnish study which did not discriminate between lifestyle components (diet and exercise), this particular study did differentiate between: diet only intervention, exercise only intervention and diet and exercise intervention to determine which helped to reduce the incidence of diabetes more. A control was used as a comparison. The diet only and exercise only intervention groups were given prescriptive information, set goals individually and met regularly within a group setting. The combined diet and exercise group were given the same in-depth information as the other two groups. The control group received general information about diabetes and impaired glucose tolerance with no individualised or group information. The delivery of the intervention was at health care clinics and the interventions delivered were determined by which health care setting an individual attended. Each setting provided one of the intervention protocols. The follow up for this study was longer than the Finnish at approximately six years.

A total of 530 of the participants completed the study and were evaluated every two years and at the six year completion mark. The results from this trial for six year diabetes incidence (according to treatment group), showed a significant difference between those in any treatment group than those in the control group (overall between 25%-50% lower). They found no difference between the treatment groups in...
diabetes incidence suggesting that any intervention (treatment) is better than none (control).

One limitation that was noted by the authors included the allocation to a clinic rather than an intervention for an individual. This was due to the fact that each differing clinic was to provide one of the interventions. The authors did analyse the effect of this had on the results but concluded that the incidence of diabetes was not influenced by this.

The Chinese population are exploding with their rates of diabetes and like other ethnicities may require an intervention specifically developed and implemented that caters for their unique needs and ethnic makeup. Therefore this study may have limitations in its ability to be extrapolated to other ethnicities however it does suggest that any intervention (rather than no intervention) conducted on ‘at risk’ persons can result in a delay in the onset of diabetes which is our primary concern and question in the current study.

2.3.3 The Diabetes Prevention Program (DPP) (Diabetes Prevention Program Research Group, 2002)

The DPP was a large 27 centre clinical trial focusing on participants at risk of diabetes. People with a BMI of 24kg/m\(^2\) or greater and those with ‘prediabetes’ were recruited. For their criteria of ‘prediabetes’ they used the American Diabetes Association 1997 criteria which gives a slightly greater threshold then our current Ministry of Health guidelines (MOH, 2012). This makes comparison with other studies difficult when different criteria are used to establish a prediabetic population. In this randomised controlled trial of 3234 participants in the USA, the participants were assigned to one of three interventions:
1) standard lifestyle recommendations (an annual 30-40 minutes consultation for dietary education with written resources) plus metformin,
2) standard lifestyle recommendations plus placebo, or
3) intensive lifestyle modification (16 lesson curriculum, one-on-one, and monthly group and/or individual follow up)

The primary outcome was the incidence of diabetes after an average follow up period of 2.8 years. Adherence to the interventions was measured with a mixture of self-reported levels of activity, pill counts, and structured interviews.

The incidence of diabetes found in the DPP was lower in the metformin and intensive lifestyle group than in the placebo group. They also found that the incidence was even lower (39%) in the intensive lifestyle group then the metformin group.

This study reaffirms that type 2 diabetes may be prevented or delayed in those at high risk. It shows the benefit of providing the public with lifestyle modification education with a focus on dietary intake, physical exercise and weight loss. The difference in the DPP was the inclusion of medication as an aid to treat those most at risk of type 2 diabetes. Whilst they found it benefited participants by rate of diabetes incidence, intensive lifestyle intervention proved to be of more benefit. More research in the area of combining these medications with lifestyle interventions may assist in determining which population responds better to this inclusion of mediation.

In 2009, a follow up report was released from the DPP. The follow up study titled ‘10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study’ (Knowler, et al. 2009), collated the results of the original study (2.8 years follow up) with an additional follow up of 7.2 years. The authors wanted to establish whether the delay in the rate of diabetes development (found in
the original study) could be sustained. Of the original participants of the DPP, 88% continued with the follow up study.

All participants were offered the same version of the original lifestyle programme (16 sessions of group based lifestyle curriculum). The original lifestyle participants were offered more group sessions to cement their learnings whilst those on metformin continued as same if it was tolerated. Similar assessment was undertaken as the original study.

At the conclusion of the 10 year study and follow up, the rate of diabetes was reduced by 34% in the lifestyle group and by 18% in the metformin group when compared with the placebo group. Therefore the development of diabetes was delayed by four years in the lifestyle group and by two years in the metformin group.

Overall this 10 year study helps to cement the benefit of interventions targeting persons at risk of diabetes predominately through effective lifestyle programmes.

All of these large scale studies have shown a benefit of lifestyle interventions targeting those at risk of diabetes (prediabetes/IGT) in other population groups. In order to show applicability to the New Zealand environment and cultural needs, a search was undertaken to find similar interventions working within the NZ population. Although reports have shown that those more at risk of diabetes are our vulnerable populations (Coppell et al. 2013) including Māori and Pacific people; little research has targeted these groups. A literature search specifically targeting these populations yielded a small number of studies, with two intervention programmes targeting New Zealand Māori.
2.3.4 Implementation of a lifestyle intervention programme for New Zealand Māori (McAuley et al, 2003).

McAuley et al (2003) conducted a lifestyle intervention programme for the indigenous people of New Zealand. Māori are at a higher risk of developing type 2 diabetes compared with people of European descent and therefore the focus of this study. The original intention of the study was to randomise participants into modest or intensive lifestyle programmes or a control group. However this was not practicable in this setting due to the nature of the participants in sharing information between groups. The researchers also decided not to have a control group as it did not fit with the recommendations of the participants. Participants were eligible if they were of Māori ethnicity and they did not have to have a diagnosis of prediabetes as the focus of the study was on reducing risk of type 2 diabetes (and cardiovascular disease). Most of the participants had at least one family member with a diagnosis of type 2 diabetes.

The programme lasted for four months and included individual diet plans and exercise programmes for each participant, the details of which were reported in another paper (McAuley et al, 2002). Some of the food was provided for the participants.

The primary outcome measure was insulin sensitivity although other biochemical and anthropometric measurements were taken including weight, blood pressure and lipid profiles.

A total of 36 participants were recruited and 31 completed the programme. Of those initial 36, none were known to have diabetes, however five were found to have met the criteria for diabetes and four met the criteria for prediabetes after a result of impaired fasting glucose.

The results showed the participants that completed the programme had significantly improved insulin sensitivity as well as a reduction in weight, waist circumference, BMI,
systolic BP, fasting glucose and insulin. However no significant change in aerobic fitness was found even with an individualised exercise programme. This suggested that the programme may be effective at reducing the risk of type 2 diabetes for the Māori participants through improvements in biochemical and anthropometric measurements.

In the absence of a control group it is not possible to determine the independent effects of the dietary and exercise interventions. Nevertheless, a comparison was made by the authors with a parallel trial using predominantly European participants that included a control group and it was suggested that there would have been little change without the intervention. How the parameters of interest are affected by ethnicity is unknown, but this is an area that may need further research especially targeting different cultures known to be more at risk.

The level of support for the four month programme was reportedly high, which may not be a feasible approach to population health with limited budgets and resources and no long term data about the sustainability of these reductions in markers has been carried out. And owing again to the provision of some food items given to the participants, this also may reduce the feasibility as a general health prevention strategy. Further research could be undertaken to determine the longitudinal impact that any maintenance programme would have on these participants for the prevention or delay of onset of type 2 diabetes.

2.3.5 Piloting of community health worker-based intervention among New Zealand Māori in Te Wai o Rona (Simmons D, Rush E & Crook N, 2008)

As part of a wider Te Wai O Rona Diabetes Prevention Strategy, a pilot study (Vanguard study) was undertaken using a Māori health care work (personal trainer). This study is the largest intervention among Māori so far reported. As part of the intervention, a Māori personal trainer was upskilled to deliver a ‘message’ style
approach to participants which included strategies around creating successes and promoting goal setting and the use of community settings to establish a community approach to lifestyle change. It was a family orientated intervention with mixed nutritional messages being delivered, many of which were not extensively evaluated.

In this pilot study, the researchers hypothesised that by incorporating a family and community approach in which everyone was delivered lifestyle changes approaches, the degree in which those at ‘high risk’ of type 2 diabetes would need ongoing intensive lifestyle change (through the use of the Māori healthcare worker) would be reduced. Social mobilisation was a key component in the intensive programme to maximise the support for lifestyle change.

As a result of this pilot study, participants with ‘high risk’ (as determined by impaired glucose tolerance/ impaired fasting glucose) were found to have a significant reduction in weight which alluded to the successful nature of a community based intervention targeting not only those at ‘high risk’ in this population, but also their wider family and community. This suggests that for the Māori population, interventions incorporating a community and family support network would be beneficial to reduction of risk of type 2 diabetes.

2.4 Interventions/programmes that utilised Dietitians as the key nutrition educators

The second key element for the literature review was looking at interventions that used registered Dietitians to deliver nutrition education. Dietitians are the leaders in the field of nutrition and have a valuable role to play in educating and supporting people with chronic conditions through lifestyle and behavioural changes. The current research was undertaken using a registered Dietitian as the main provider of nutrition information and looking for evidence to support this unique element of an intervention was the goal for this focus of the literature review.
The search for literature in this field focused predominantly on looking for studies that used Dietitian as the main components or key word in the literature.

The following table summarises some of the literature found in this regard which supports the use of registered Dietitians in the field of nutrition education and support for lifestyle change within the inclusion as mentioned previously.
Table 2. Studies using Dietitians as Key Nutrition Experts

<table>
<thead>
<tr>
<th>Author &amp; Study</th>
<th>Study Parameters</th>
<th>Intervention</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Nisak et al. 2012.  
*Medical Nutrition Therapy administered by a Dietitian Yields Favourable Diabetes Outcomes in Individual with Type 2 Diabetes Mellitus.* | *prospective single group, pre/post design trial  
*12 week intervention  
*104 Malaysian participants  
*T2DM – poorly controlled* | All participants given one-on-one individualised dietary counselling at baseline, week four and week 12.  
Nutrition knowledge assessment pre and post intervention  
Measurements: weight, height, BP, HbA1c and lipid profiles | Increasing knowledge scores from baseline (p <0.001)  
Reduction in HbA1c – change of 0.4%  
Those with higher pre HbA1c produced a larger reduction at post intervention (statistically significantly) compared to those with an optimal HbA1c at start. | Showed positive nature of individualised MNT intervention when administered by a dietitian – supporting other evidence  
No control group  
Age and ethnicity were influencing factors on adherence to diet  
High retention rate – which could have been due to the individualised nature of the intervention and the frequency of visits. |
| Huang et al. 2009.  
*Prospective Randomised Controlled Trial to Evaluate Effectiveness of Registered Dietitian-Led Diabetes Management on Glycemic and Diet Control in a* | *randomised controlled trial (RCT) of intervention versus control  
*12 month trial  
*154 Taiwanese participants  
*T2DM –on diet/and or medication  
*Primary health setting* | Control: routine care - basic dietary principles delivered by a nurse  
Intervention: routine care, plus ongoing individualised, exercise and nutrition dietary plans every 3 months (30— | No significant changes in HbA1c by either group.  
Those with poorly controlled diabetes in the intervention group did achieve a greater improvement then those in the control group. | The dietitian led intervention programme did assist in the treatment and glycaemic control of those participants with poorly controlled diabetes. |
<table>
<thead>
<tr>
<th>Author &amp; Study</th>
<th>Study Parameters</th>
<th>Intervention</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Care Setting in Taiwan</td>
<td>Outcome measurement: HbA1c, fructosamine, anthropometry measurements, BP, lipid profile, insulin levels, dietary intake, knowledge on nutrition.</td>
<td>60min consultation) plus information for self-monitoring of blood glucose levels delivered by a Registered Dietitian.</td>
<td></td>
<td>Whilst not significant, this is in support of other research.</td>
</tr>
<tr>
<td>Franz et al. 1995</td>
<td>* prospective, RCT, comparing basic nutrition care with practice guidelines of nutrition care, inclusive of a comparison group (non randomised) *179 participants in USA *T2DM *six month trial</td>
<td>Intervention: Basic: (BC)one 60 minutes consultation with a dietitian Practice Guidelines(PGC) 3 sessions (total minutes 120-150) delivered by a dietitian Comparison group – routine care from general practice team – no dietetic intervention. Primary variable was the intensity of the intervention between the two intervention groups. Participants were evaluated at baseline and at three and six months</td>
<td>At 6 months: BC – significantly lower HbA1c and weight loss from baseline, no significant difference in total cholesterol. PGC – significantly lower HbA1c, total cholesterol and weight loss from baseline Comparison group – no improvement of glycaemic control or HbA1c – other measurements were not investigated. No significant differences on outcomes were found between the groups, however they found those that had diabetes for 6 months or longer did better with the more intensive intervention than the shorter intervention.</td>
<td>Largest improvement was found in the early stages (0-6 weeks) and was maintained to 3 months, however it was noted that values tended to deteriorate at this point which may suggest another intervention by a dietitian to maintain and continue to improve clinical outcomes for these patients. Demonstrates the effectiveness of having dietitians on the multidisciplinary team to provide medical nutrition therapy The use of a behavioural approach, using goal setting and problem solving was found to be an effective component.</td>
</tr>
</tbody>
</table>
As illustrated in Table 2, the use of a registered Dietitian to provide nutrition therapy for those with type 2 Diabetes has shown positive outcomes in the form of glucose control, weight management and dietary intake. A registered Dietitian plays a key role in the nutritional assessment, intervention and evaluation of participants with this disease. The provision of adequate, evidenced based dietary education is pivotal in the management of type 2 diabetes and as demonstrated in these three studies, is also cornerstone to improving health and therefore health outcomes in the future.

2.5 Interventions that used similar methodology around comparison of different modes of delivery.

The third key feature for the literature review was to look for research that studied interventions comparing different modes of delivery. The current study consisted of the same nutrition education and duration of intervention (overall contact time). It was hypothesised that if the education was given in a number of short sessions spread over a longer period of time, then the resulting outcomes (both biochemical and health information retention) would be greater than if the education was given in a single session (single vs multi).

A study by Roher and Pashler (2014), looking at the mechanisms of learning, illustrated that there is a relationship between the duration of a study session, with the spacing of study sessions across multiple sessions and therefore outcomes achieved (or knowledge retained/learned). They also show a relationship between the above conditions with the interval between study session and test. In our study, we used a fixture of weekly study sessions (education consultations) with a 12 week period before testing (follow up).

However, this was a difficult area to review as there are limitations in the body of literature. Looking at the provision of dietary education comparing single versus multiple sessions (but using the same overall time) yielded very little in the literature
search. The search was then expanded to include areas other than dietary education (smoking cessation, nurse led teaching and the education sector) to try and establish whether the comparison of differing modes of delivery had been previously researched. Whilst single versus multi – session style mode of delivery has been compared, it was difficult to gather accurate comparisons using a single vs multi-session approach whilst maintaining identical contact time with the professional.

Of those studies that were found, there are stark differences in some of the methodology used which may go some way to explaining the outcomes found. The unique aspect of the current study (single versus multiple session comparison) was not used as a format in any of the reviewed literature.

2.5.1 Multisite Randomized Trial of a Single-Session Versus Multisession Literacy-Sensitive Self-Care Intervention for Patients with Heart Failure (DeWalt et al, 2012)

The purpose of this study was to investigate differences in outcome between intensive multisession intervention compared with a single training session, assessed using the incidence of hospitalization or death. Patients were interviewed at six and 12 months to ascertain whether any hospitalization had occurred in the preceding months. The hypothesis being that more intensive education would lead to an increase in self-management and therefore a decrease in hospitalisations. This outcome takes the presumption that those the self-care education given lends itself to more patient activation on own health, therefore decreasing illness and poor management through less hospitalization trips.

The methodology used in the DeWalt study meant that all participants received the same initial information for a period of 40 minutes. The multisession group were then followed up via phone contact for an average of 14.2 phone calls at an average of 12
minutes with additional, new information that was not given to the single session participants.

The DeWalt study and the current study are both looking at outcome measurements that have a positive effect on the wider health system (hospitalizations in DeWalt versus reduction of HbA1c and progression to diabetes in current study) using the delivery of health information to the patient.

The results from the 12 month study showed that there were no statistically significant differences in the main outcome of hospitalisation or death between the two groups. The conclusions reached by DeWalt and colleagues were that multi session teaching (of additional information) did not appear to offer any additional benefits overall when compared with the single education session. This may be a result of the additional information being of no additional benefit and therefore the initial information was sufficient for most patients to make changes and to self-manage their own health. The study also looked at participant literacy level and researchers suggested those with higher literacy levels would benefit more from an intensive (multi session) intervention. They did find that those with higher literacy level in the multisession group appeared to have a higher hospitalisation rate than those with a lower literacy level in the multi-session group. This suggested that an effect modification owing to literacy levels may mean that subsets within the group may benefit from different intensities of education.

Within the subsets of the two groups, one parameter that was found to be different was quality of life score. This was improved to a greater extent in the multi-session group compared with the single session. Those with higher literacy tended to maintain the differential over time whereas the difference between single and multi-session retention in people with lower literacy waned over time. This suggests that determining the literacy level of patients may be important when designing education strategies.
2.5.2 Comparative Effectiveness of a Practice-Based Comprehensive Lifestyle Intervention vs. Single Session Counselling in Hypertensive Blacks (Schoenthaler et al, 2016)

In this study undertaken in the United States, researchers looked specifically at black participants whom had a diagnosis of hypertension. The two arm comparative RCT compared 10 weekly group sessions plus three individual telephone consults with a single individual 30 minute consultation. Both groups were given the same written resources as the intention of the researchers was that the content of the education for the groups remained the same. This parallels with the current research as both groups were given the same information both orally and written to determine whether the delivery of the material (dose/intensity/duration) played a role in outcomes. The study was for a period of 6 months and participants were not excluded if they were on medication for their hypertension.

The results of the study found that participants in both groups had a reduction in blood pressure over the course of the study and the researchers found no significant differences between the groups in this reduction. This result suggested that both of the interventions were beneficial to the same degree. One of the reasons for this was suggested by the authors that the single session group still obtained all the relevant information and education that was given to the multi session group – there was no advantage in respect to knowledge or information. This may highlight a more feasibly approach to interventions that can be extrapolated into more health care settings with a viable approach when resources are scarce. They also found that only one third of participants completed all the recommended multi group sessions, whilst 90% of those in the single session group attended the session. This may have also influenced the results and suggests potentially reducing the number of sessions to ensure a comparative nature of the two arms.
One of the limitations reported on in this study showed an imbalance between the
groups with respect to diabetes status and medication adherence. The intensive
intervention group appeared to have a higher proportion of diabetics and higher rate
of non-adherence to medications. This shows a slight discrepancy in the allocation of
participants to either group. However the researchers found that after analysis, these
differences did not appear to change the overall result. They also found that attrition
rate was higher for the intensive intervention group which may have been a
correlation between the makeup of this group with these known factors compared to
the single session group. There was no comparative ‘usual care’ arm to the trial. This
meant no control group to analyse the effect that being on an intervention can have,
though the authors noted that this was an ethical discussion as they stated that it was
unethical not to provide any information to these at risk participants. They could have
used those participants that declined the intervention as a measure of a control group.

As noted by the authors, the extrapolation of these results may need to be further
investigated as the setting of the research (hospital-based primary care practice) may
have prejudiced the outcomes and the intervention may not be relevant to other
settings. The research concludes that a single session education session complete
with all relevant information (both oral and written) is a beneficial way of targeting
participants with hypertension whilst maintaining an economical approach to health
care requirements.

2.5.3 **Balance – a pragmatic randomized controlled trial of an online intensive
self-help alcohol intervention (Brendryen et al, 2014)**

Another paper researching brief versus intensive education session was conducted in
Norway using an intervention for alcohol consumption. The study was designed using
an online forum as the intervention component. In the trial, participants who self-
classified themselves as an ‘at risk drinker’, were recruited through the internet. They
were then randomised into either the ‘brief’ or ‘intensive’ intervention groups. Both
groups received the same online single session that provided personalized normative feedback to the participant. From there, the ‘brief’ intervention participants’ received a booklet (online) that contained information about alcohol and the risks and harms of drinking. The ‘intensive’ group were given 62 online sessions that were released in a sequence over a period of six months. They were also contacted through email and text messages. Follow up was undertaken at two and six months.

The outcome measure for the online intervention was self-reported alcohol intake. At the two month mark, there were inconclusive results, indicating no significant difference between the two groups. At the six month mark, both groups reported a reduction in intake and the researchers found that those in the intensive intervention group had significantly lowered their alcohol intake than the brief intervention group. There are more limitations found in this study due to the nature of the intervention. The participants were recruited through their own self selection of being an ‘at risk’ drinker according the health guidelines in Norway. Attrition rate was relatively high and this may have been due to a number of issues such as the intensity of the intervention, and the constant influx of reminder emails/texts which may have put some participants off completing the course.

The study does go some way to provide another avenue for health intervention by using the online forum and providing some results to support education to promote self-management for health conditions.

2.5.4 Telephone Counselling for Smoking Cessation: Effects of Single-Session and Multiple-Session Interventions (Zhu et al, 1996)

In a study conducted in the USA: Zhu et al (1996) randomised 3030 smokers into 1 of 3 interventions: (1) self-help quit kit, (2) quit kit plus one telephone counselling session, or (3) quit kit plus up to six telephone counselling sessions to compare the effects of two different intensities of counselling with that of a self-help approach. They
hypothesised that the counselling interventions (either) would produce higher abstinence rate than the self-help group, and of the two different counselling interventions, the multi sessions would again produce a higher abstinence rate than the single session. The study ran for approximately 13 months and was evaluated at different stages along the timeframe. The results were calculated by varying degrees including overall abstinence rate by intention to treat. They found that for every length of time considered (abstinent time); the counselling groups had a higher abstinence rate than the self-help group. They also found that multiple counselling achieved greater abstinence rates than single although at six month the rate was not significant. The quit attempts calculation found that those in either counselling group had significantly higher quit rates than the self-help group. They also calculated time to relapse and found that the multiple counselling group took six times longer to relapse than the single counselling. The researchers did conclude that counselling was an effective aid for smoking cessation in terms of incidence and duration of quit attempts. They also found a dose-response relationship between the number of sessions and the duration of the quit attempts – suggesting that in this circumstance, more sessions is likely to result in better outcomes.

The above four studies give mixed results around the benefits of single versus multiple sessions of an intervention. It is difficult to compare the studies with each other as they have variable components such as delivery (face to face/online), and outcomes (smoking, blood pressure, heart health, alcohol intake). They do all appear to agree that any intervention produces better results than a control group whilst one intervention did not have a control to compare with.
2.5.5 Minimal Interventions for Weight Control: A Cost-Effective Alternative (Black et al, 1984)

Although this is not a comparison of multi-versus single-session, the purpose of the intervention aligns with the same goals: to explore the effectiveness of different intervention approaches to health outcomes. In this paper, the effective and efficient use of resources in the treatment of weight loss were tested. The authors hypothesised that a short, simpler intervention would be as beneficial and more cost effective to implement that a longer intense intervention. Indeed, after seven months, equivalent weight loss was achieved independent of the intervention. A point of interest was a financial incentive in which people that paid a deposit and were then refunded for attendance achieved more weight loss than those who did not have this incentive. This study utilised the approach of efficiency and practicality especially when looking at population based health promotion or treatment programmes.

In summary, the literature review revealed a number of interventions that show some promise in regards to helping delay or prevent the onset of type 2 diabetes. These interventions have utilised both dietary and lifestyle education components and have been successful when delivered by a registered Dietitian (Nisak et al. 2012; Huang et al. 2009; Franz et al. 1995). However, there is little in the literature describing single versus multi-session education interventions, none of which has compared equal intervention time, an important factor given limited dietetic resources. There is clearly a need for this type of intervention study using dietitian delivered nutrition education.
3 Methods

3.1 Ethics

This study was approved by the University of Otago Human Ethics Committee (Appendix 1). Additionally, as an employee of Central Primary Health Organisation (PHO), the candidate obtained consent to undertake this study from the Chief Executive Office of Central PHO. This involved the candidate completing an application form for locality approval from the MidCentral District Health Board (DHB) (Appendix 2). Access to General Practice teams and client medical records were obtained through this approval. Māori consultation was undertaken and approved by Ngāi Tahu Research Consultation Committee (Appendix 3). The local Māori Health Team within the PHO was also consulted to ensure all cultural requirements and considerations were met.

3.2 Study Design

This was a randomised parallel education intervention of participants with a diagnosis on their medical record of prediabetes (HbA1c 41-49mmol/mol). The participants were randomised to either a single session (hereafter referred to as Intervention A) or five short sessions (hereafter referred to Intervention B) for an education intervention.

3.3 Study Objectives

To access whether one intervention delivery method was more effective than the other based on resulting biochemical indices and pre and post health knowledge questionnaire results.

To compare glycated haemoglobin (HbA1c) pre and post nutrition education.

To compare blood lipid levels pre and post nutrition education.
To increase nutrition knowledge and health literacy through nutrition education with a registered Clinical Dietitian.

3.4 Recruitment Process

Participants were recruited from local Manawatu General Practice Teams (GPT’s). Several strategies were used simultaneously to recruit the required number of eligible participants:

- A query build (search tool) was created through a local general practice patient management system (PMS) to find patients that met the inclusion criteria,
- Recruitment posters were created (Appendix 4) and given out to local GP teams, put into the local GP mail out (for the MidCentral District) and handed out to other clinical staff at Central PHO.
- Eligible patients were screened through the current Central PHO Clinical Dietitian referral criteria (Appendix 5).

3.5 Study Participants

Sample size – This study was designed as a pilot programme to assess whether there were indications that a different mode of delivery would affect educational and metabolic outcomes (HbA1c and lipids).

Randomisation – in order to achieve a randomised population, the biostatistician stratified for sex using randomly allocated block sizes between two, four and six in length. The randomly ordered codes representing interventions A and B were placed in opaque envelopes for each sex offsite such that the candidate was unaware of patient allocation until the opening of the envelope. To assign to treatment, the candidate picked the next envelope corresponding to the sex of the participant.
Eligibility – participants were invited into the study if they met the following conditions: recent HbA1c of between 41-49mmol/mol within the last 6 weeks and had been coded/recorded (on their clinical records within the PMS system) as having ‘prediabetes’, aged between 18-80 years old, and enrolled within the Central PHO. Exclusion criteria included: participants on medications prescribed for prediabetes, and pregnancy. Patients must also not have had previous dietary education by a registered Dietitian.

Consent – potential participants were provided with an information sheet (Appendix 6), a consent form (Appendix 7) and a health questionnaire (Appendix 8). The candidate discussed the purpose of the study with potential participants and answered any questions. All agreed to proceed and signed the consent form.

Anthropometric measurements – height was measured with shoes to the nearest 0.1cm using a Seca stadiometer. Weight was taken without shoes to the nearest 0.1kg using Seca scales. Body mass index (BMI) was calculated from the height and weight data using the formula BMI = weight/height squared (kg/m2)

3.6 Health Questionnaire

A questionnaire was developed to assess participants’ pre and post nutrition knowledge and health literacy.

The ten item questionnaire (Appendix 8) was created from information that would be presented to the participant during the intervention study. It also involved an assessment of the participants’ confidence and motivation for behavioural change both pre and post intervention. For this purpose, questions that reflected these factors were presented in a scale format. The questionnaire was reviewed by health colleagues as well as consumer for language use, font, and general usability and the feedback was incorporated into the final copy.
3.7 Education Intervention

**Intervention A:** One consultation of approximately 60 minutes duration.

Education included: What is prediabetes (HbA1c chart, prediabetes resource given). Goal of intervention (to delay or prevent diabetes and gain nutrition knowledge). Carbohydrate foods (what are they, what foods are they found in, resource given). Food groups (the four food groups and minimum serves required, resource given). Plate model (to illustrate portions of protein, carbohydrate and vegetables, resource given). Label reading (using 10/10/5 guideline - find foods with <10 grams of fat per 100 gram, <10 grams of sugar per 100 gram and >5 grams of fibre per 100 g, resource given)

**Intervention B:** Five consults, initial consult of approximately 20 minutes, follow up sessions of 10 minutes.

*Session 1:* What is prediabetes (HbA1c chart, prediabetes resource given), goal of intervention (to delay or prevent diabetes and gain nutrition knowledge).

*Session 2:* Carbohydrate foods (what are they, what foods are they found in, resource given).

*Session 3:* Food groups (the four food groups and minimum serves required, resource given).

*Session 4:* Plate model (to illustrate portions of protein, carbohydrate and vegetables, resource given).

*Session 5:* Label reading (using 10/10/5 guideline, resource given)

3.8 Study Protocol

Once the participants were recruited and assigned to intervention A or B, they were booked into the appropriate consultations with the Clinical Dietitian (the candidate).
They were seen in the clinic rooms of the Central PHO at one of two locations; either Feilding or in Palmerston North City, Manawatu, New Zealand.

The consultations took place according to the particular intervention group of the participant. The intention was to space the multi session participants to attend a session once a week for five weeks. This occurred for four of the sessions, however in one instant the candidate withdrew from the study as was unable to attend any follows up due to new work commitments. In one instance, a candidate missed a consecutive session and wanted to hold two sessions in one week in order to fit around other commitments. Due to time constraints, one candidate was seen at intervals of two sessions a week on separate days for two weeks and the last session on the third week.

Participants were also followed up 12 weeks post intervention.

3.9 Data Collection

Blood tests (HbA1c and lipids) were collected post intervention through the Medlab facility as per Medlab protocol. The results were then sent to the participants’ General Practitioner as per their policy. The relevant records were then collected and entered onto a spreadsheet and compared with the pre intervention results.

All participants completed a post intervention health questionnaire and this was collected in paper copy. Participants’ weight was also recorded and documented at this time.

3.10 Data Analysis

All biochemical data including HbA1c, lipids and body weight were entered into Microsoft Excel.
For each intervention group, the data were analysed for mean change pre and post intervention in each outcome variable using ANCOVA. The mean change for each intervention group was recorded for pre and post intervention.

For analysis of the health questionnaire, questions one through six, all answers were given a value for number of correct answers. These were then calculated to determine overall total score. The total score for the multi-session group was compared and analysed using Stata 12 (StataCorp LP, College Station, Texas) with the total score for the single session group to determine any between group differences in score for pre verses post questionnaire results. The results for question seven were not statistically analysed due to the wide ranging variety of answers and the pictorials that were illustrated. Question eight, whilst not statistically analysed, was reported in text in the results.

The confidence intervals for question nine was analysed using Stata to determine any differences between the single and multi –session groups over the time period of the intervention.

The original intention for recruitment into the intervention was based on a power calculation to determine effect size. To estimate the required sample size needed, it was assumed that mean HbA1c at baseline will be approximately 45nmol/mol with a standard deviation of 3nmol/mol. A detectable difference of HbA1c of 2 nmol/mol between the groups was decided. The correlation coefficient between baseline and follow-up measures of HbA1c is approximately 0.75 (used unpublished local data). For 90% power at the 0.05, two-sided significance level the sample size would need to be 21 in each group (42 altogether). Allowing for some dropout it was recommended 26 in each group (52 altogether).
4 Results

4.1 Participant Characteristics

Participant characteristics and baseline data for each intervention group (single and multi-session) are shown in Table 3. The 11 participants who completed the intervention study ranged in ages from 32 – 74 years. The mean age was similar in both groups. Each intervention group had a single male participant. All participants had a baseline HbA1c of between 41 – 49 mmol/L and all identified themselves as of European ethnicity. No participant had been seen previously by a registered Dietitian. Baseline weight for all participants ranged from 49.6kg to 132.8kg (mean 94.0kg). One participant had a BMI of under 20 kg/m2 whilst the other ten had a BMI over 25 kg/m2, putting them in the overweight/obese category. Of the eleven participants, two did not have a baseline lipid profile on record. For the nine people with pre intervention cholesterol results, the range for total cholesterol was 4 – 7.2mmol/L (mean 5.44), LDL range was 1.8 – 5.0 mmol/L (mean 3.22), HDL range was 1.0 – 1.9 mmol/L (mean 1.39), triglyceride range was 1.2 – 2.9 mmol/L (mean 1.86).

At commencement of the intervention, all participants were located and registered with Central Primary Health Organisation and were enrolled with a local General Practice. One participant moved towns during the intervention and no follow up weight was recorded. Seven of the participants reported a family history of type two diabetes (sister, brother and / or parents), two reported no family history, whilst two did not want to divulge any family history information. Most of the participants were in some form of employment (63%), with seven of the participants working in either full or part-time employment, two were retired, and two were not in any form of paid employment.
Table 3. Baseline Characteristics of the Study Participants

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<th>Baseline</th>
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<tr>
<td></td>
<td>Single</td>
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<tr>
<td>n</td>
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<td>HbA1c (mmol/mol)</td>
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<td>Total (mmol/L)</td>
<td>n=5</td>
<td>n=4</td>
</tr>
<tr>
<td>Mean</td>
<td>5.66</td>
<td>5.18</td>
</tr>
<tr>
<td>Range</td>
<td>4-7.2</td>
<td>4-6.1</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>3.44</td>
<td>2.95</td>
</tr>
<tr>
<td>Range</td>
<td>1.8-5</td>
<td>2.2-3.7</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.36</td>
<td>1.43</td>
</tr>
<tr>
<td>Range</td>
<td>1-1.9</td>
<td>1-1.9</td>
</tr>
<tr>
<td>Triglyceride (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.92</td>
<td>1.78</td>
</tr>
<tr>
<td>Range</td>
<td>1.2-2.9</td>
<td>1.5-2.3</td>
</tr>
</tbody>
</table>
The main metabolic and weight outcomes for each intervention are shown in table 4 along with the mean differences between interventions. The method used to find mean difference estimate was ANCOVA with baseline value as a covariate. The single session group saw a mean decrease in HbA1c (-2.7 mmol/mol) whereas the multi session group saw little change (+0.8 mmol/mol). On average the single session group had a 3.3 mmol/mol greater decrease in HbA1c compared with the multi session, however this was not significant (p=0.112). For total cholesterol both the single and multi-session groups saw a mean decrease (-0.7 mmol/L and -0.5 mmol/L respectively), but no significant difference (p=0.977) between the groups.

Table 4. Mean change in individual outcome measurement for each group and between groups comparing pre and post intervention (with SD and p-value)

<table>
<thead>
<tr>
<th></th>
<th>Single session</th>
<th>Mean change single session (SD)</th>
<th>Multi session</th>
<th>Mean change multi session (SD)</th>
<th>Mean difference in change(^1) (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c(^2) (mmol/mol)</td>
<td>6</td>
<td>6 -2.7 (3.7)</td>
<td>5</td>
<td>0.8 (1.3)</td>
<td>3.3 (-1.0, 7.7)</td>
<td>0.112</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>5</td>
<td>-0.7 (1.2)</td>
<td>4</td>
<td>-0.5 (1.1)</td>
<td>0.0 (-1.7, 1.8)</td>
<td>0.977</td>
</tr>
<tr>
<td>LDL(^3) (mmol/L)</td>
<td>5</td>
<td>-0.6 (0.9)</td>
<td>4</td>
<td>-0.4 (1.0)</td>
<td>0.0 (-1.4, 1.4)</td>
<td>0.995</td>
</tr>
<tr>
<td>HDL(^4) (mmol/L)</td>
<td>5</td>
<td>0.0 (0.2)</td>
<td>4</td>
<td>0.0 (0.2)</td>
<td>0.0 (-0.2, 0.3)</td>
<td>0.759</td>
</tr>
<tr>
<td>TAGS(^5) (mmol/L)</td>
<td>5</td>
<td>-0.2 (1.0)</td>
<td>4</td>
<td>-0.2 (1.1)</td>
<td>-0.1 (-1.5, 1.3)</td>
<td>0.851</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>5</td>
<td>-3.6 (5.2)</td>
<td>4</td>
<td>-2.0 (2.7)</td>
<td>3.7 (-4.8, 12.1)</td>
<td>0.327</td>
</tr>
</tbody>
</table>

\(^1\) Group B compared to group A  \(^2\) Glycated haemoglobin (A1c)  \(^3\)low-density lipoprotein,\(^4\) high-density lipoprotein,\(^5\) triglyceride
A mean decrease was also found for both single and multi-session groups for LDL (-0.6mmol/L and -0.4mmol/L respectively) with no mean difference found between the groups (0.0). No mean change was found for HDL for either single or multi session groups. Both groups had a mean decrease for TAGS (-0.2 mmol/L for both groups), with no significant difference in the mean differences between the groups (p=0.851).

The single session group saw a mean decrease in weight of -3.6kg whilst the multi session group saw a mean decrease of -2.0kg. The mean change difference between the groups suggested a 3.7kg greater decrease for the single session group, however this was not significant (p = 0.327).

4.2 Health Questionnaire

All eleven participants were given the same nine question health questionnaire at pre and post intervention (Appendix 8). Of those eleven, eight participants completed this at both pre and post intervention. Three participants did not attend a face-to-face follow up consultation due to other issues (one had moved out of town, and time factor and convenience was reported for the other two) and therefore did not complete a post intervention questionnaire.
<table>
<thead>
<tr>
<th></th>
<th>Pre−intervention</th>
<th>Post - intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Single session</td>
<td>Multi-session</td>
</tr>
<tr>
<td></td>
<td>group (n=5)</td>
<td>group (n=3)</td>
</tr>
<tr>
<td>Prediabetes definition n (%)</td>
<td>3 (60%)</td>
<td>1 (34%)</td>
</tr>
<tr>
<td>Five commonly consumed CHO foods –</td>
<td>5 (1)</td>
<td>4 (2)</td>
</tr>
<tr>
<td>out of 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c definition n (%)</td>
<td>1 (20%)</td>
<td>0</td>
</tr>
<tr>
<td>Three foods containing saturated fats</td>
<td>3 (1)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>- out of 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two healthy facts on label</td>
<td>2 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>- out of 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two unhealthy facts on label</td>
<td>1 (0)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>- out of 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Four food groups - out of 4</td>
<td>1 (3)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serves of food groups - out of 4</td>
<td>0 (2)</td>
<td>0 (1)</td>
</tr>
<tr>
<td>Median (range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score - out of 22</td>
<td>12.4 (1.35)</td>
<td>11.7 (2.62)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The between-group difference (95% CI) in the change in total score pre- to post-intervention was 0.07 (-5.25, 5.39), p=0.975
Table 5 shows that the single session group showed a baseline mean (SD) total score (for questions 1-6) of 12.4 (1.35). At the completion of the intervention the mean total score for this group was 13.8 (2.62).

The multi session group had a baseline mean total score of 11.7 (2.62) and a mean of 13 (3.74) at the conclusion of the intervention.

When comparing the multi-session with the single session group, with a p value of 0.975, the total scores were not significantly different over the intervention period.

4.2.1 Question 7: Plate model awareness and illustration.

In the single session group, at pre intervention, four out of five participants were aware of the plate model and one could accurately draw it. By the end of the intervention, all five participants were aware of the plate model and four could accurately draw it.

In the multi session group, at pre intervention all three participants were aware of the plate model with one able to accurately draw it. By the end of the intervention, all three were aware of the model and two could accurately draw it. This showed a tendency for increase in awareness of the plate model for both intervention groups.

4.2.2 Question 8: Exercise

All participants were asked about their average daily time spent doing exercise over the preceding week. Due to the large variation of numerical and description responses to this question analysis could not be undertaken.

At pre intervention, the single session group reported their quantity of exercise ranged from 17 minutes to 68 minutes a day whilst the post intervention results ranged from 30 minutes to 90 minutes a day.
At pre intervention, the multi session group had variable results which ranged from none to walking most nights (no time given). At post intervention, the group ranged from a specified 15-20 minutes up to a descriptive active at work.

Both groups had a variety of activity that they classified as exercise which included walking, swimming, gardening, moving boxes, housework, shopping, bike-riding, climbing stairs and chopping wood.

### 4.2.3 Question 9: Confidence and importance scale

Question 9 contained three different questions asking the participants to rate their own confidence and the importance they place on a healthy diet on a scale of 0-10.

<table>
<thead>
<tr>
<th>Question</th>
<th>Key Words</th>
<th>Mean (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>9a</td>
<td>Importance of eating a healthy diet</td>
<td>-0.8 (-1.6, 0.03)</td>
<td>0.057</td>
</tr>
<tr>
<td>9b</td>
<td>Confidence on knowledge of healthy diet</td>
<td>0.6 (-4.3, 5.5)</td>
<td>0.765</td>
</tr>
<tr>
<td>9c</td>
<td>Confidence you are eating a healthy diet</td>
<td>-1.1 (-6.1, 3.9)</td>
<td>0.588</td>
</tr>
</tbody>
</table>

Table 6 shows the 95% confidence interval and the P value of the comparison between the multi session group with the single session group over the intervention period on this scales.

None of the three confidence/importance scale questions were found to be statistically significant when comparing between the two groups.
Discussion

Interventions targeting people with prediabetes are being investigated as a means of preventing progression to diabetes, with successful outcomes (Tuomilehto et al, 2001; Pan et al, 1997; Diabetes Prevention Program Research Group, 2002). Nutrition education has been recognised as a crucial element in the delivery of effective diabetes self-management (Bowen et al, 2016) and therefore can be considered as a crucial component in the interventions and programmes targeting those at risk of developing diabetes. Dietitians with their nutritional knowledge deliver key nutrition messages in relation to health and disease and therefore play a pivotal role in helping educate and support people in creating healthy lifestyles. Dietary education and other more rigid therapies such as medical nutrition therapy (MNT) are delivered to help a person increase their knowledge and skills which in turn should aid in behaviour change. In theory, any gains in dietary knowledge through these mechanisms should directly affect dietary change (Racine et al, 2011).

In this study, the effectiveness of dietitian education delivered was tested by comparing various metabolic and learning outcomes. We were looking at the different modes of delivery—a single session consultation compared with five multiple sessions spaced over five weeks, both with a total contact time of 60 minutes. Contact time has been recognised as a significant predictor of effects in intervention studies, particularly relating to diabetes self-management education (Bowen et al, 2016). However, there are no reports comparing efficacy of equal dietitian contact time on metabolic and knowledge outcomes using different modes of information delivery.

We hypothesised that the multi session intervention would show a bigger decrease in HbA1c and a larger increase in nutrition knowledge. In this instance, we were relying on the consistent and regular nature of the multi session intervention to impart higher nutrition knowledge resulting in more changes in behaviour which would manifest as a
decrease in HbA1c. This was a deliberate strategy as contact time with dietitians is extremely limited (Segal et al, 2013), and ways of optimising learning outcomes are necessary.

It has been difficult to identify published work in the nutrition field in which a single-session versus multi-session comparison has been used. To put our work into context has meant finding single versus multi-session approaches in other areas of health science in which the concept has been tested. For example, in a one year, randomized controlled trial, researchers delivered education to heart failure participants either as a single session or as multi sessions delivered via the telephone (DeWalt et al, 2012) The researchers found that overall no difference was found between single and multisession groups; however in the multisession group, a higher hospitalisation rate was recorded for those with higher literacy levels. They suggested that the multi-session interaction created a perceived increased awareness of symptoms which, ironically, may have led to a closer level of attention and therefore to a greater likelihood of seeking hospitalisation (a positive outcome in the context).

In other work, dose response relationships have been found between the number of contacts and improvements in measured outcomes. One of these studies was a smoking cessation trial which measured attempts to quit (as defined in the study) and quit rate in three different intervention comparisons (Zhu et al, 1996). The results showed a higher quit rate was associated with a higher level of contact. There are a number of key differences between this smoking cessation trial and our dietitian counselling study but it also illustrates support for the original hypothesis for better outcomes for multi-session interventions.

The delivery medium used in the smoking cessation trial differed from the current study which used face to face interaction. The use of telephone counselling would enable barriers such as transportation and scheduling conflicts to be reduced, particularly if the counselling sessions were arranged at the most convenient time for
the participant. The home setting in which this counselling took place, may also have allowed a greater adherence to the messages as it could provide the participants with a comfortable and safe environment in which to make the necessary changes.

Another difference of comparison between the smoking cessation trial and the current study is the complexity of information provided. In the smoking cessation trial, new information may not have been delivered to the participants during the repeated telephone sessions, but rather a reinforcement of the same message – to eliminate a single component (in this case, cigarettes). The degree of reinforcement and encouragement of this singular message may contribute to the adherence to follow through with the suggested behavioural change and therefore improve the measured outcomes. In the current study, participants were given a number of new dietary messages and these were not specifically reinforced or repeated during the trial which may have had a bearing on the outcomes.

Motivation of study participants is another element that should be considered when comparing trials of this nature. Whilst this was not specifically a component measured during the current study, on reflection it could have been a part of the planning and design of the study. Many people diagnosed with prediabetes are asymptomatic and therefore may not have any clear motivation to make the necessary changes needed to reduce the risk of progression to diabetes. Smokers on the other hand may have clearer motivators to quit such as financial benefits, improved health and family pressure. The use of tools such as motivational interviewing may help elicit positive behaviour change in individuals through its client centred approach and method of increasing a person’s own intrinsic motivation which aids in encouraging long term behavioural change (Rubak et al, 2005).

Another study that showed a relationship between the amount of contact time and outcome was an alcohol reduction trial (Brendryen et al, 2014). Brief versus intensive interventions were compared in a self-help online forum with outcome measured as
self-reported alcohol intake. As with the smoking cessation trial, the medium of
delivery used is different to the current study, which makes comparisons challenging
as this medium has both positives and negatives which may have influenced the
outcomes. Similarly, a dose response effect was also seen with the results indicating a
greater decrease in alcohol units (a positive effect) associated with a more intensive
intervention.

Thus, a multi-session intervention approach appears to be helpful when people are
trying to stop smoking or to reduce their alcohol intake.

In the smoking and alcohol interventions, the outcome measurement was relatively
straightforward; to reduce or eliminate a particular substance (cigarettes and alcohol)
and therefore relatively easy to measure. In the current dietary intervention outcome
measurements become more complex in nature as they are dealing with education,
information and instruction on dietary habits and choices. The process for making any
dietary changes requires significant processes including food literacy, food choices,
food availability and food security. The current study did not set any specific
measureable dietary goals but instead gave generalised education on dietary
requirements and portion control (with particular focus on prediabetes). Any
evaluation of a successful intervention can only be made through the health
questionnaire and the perceived improvement in knowledge which we anticipated
would translate into a behavioural change and therefore metabolic changes.

More support for our hypothesis has been found in a position statement by The
American Diabetes Association, in which they make reference to the frequency of
participant contact (to an intervention) and the positive effect on weight loss. Their
statement regarding weight loss supports more frequent contact with having a greater
outcome in producing longer term results (Franz, 2002).
Weight loss was not an objective of the study, however it became a positive consequence for some of the participants. The majority of the participants in the current study lost weight throughout the intervention (typically 0.5kg – 3kg). Of note, one participant in the single session group lost 12.6kg whilst one participant in the multi session group lost 6.1kg. Overall (combining both the single and multi-session groups), the loss was not significant (p=0.067) but the tendency was for weight loss in both groups. It is interesting to note that all but one participant, (who was already in normal BMI range) managed to lose some weight whilst engaged in the intervention. This shows a positive result of an intervention targeting dietary changes. We could speculate that the two participants who lost the most weight (12.6kg, 6.1kg) were highly motivated and that engaging in the study was the catalyst they needed to make healthy dietary changes. The duration of the intervention (12 weeks) appeared to be sufficient time to see these weight changes occur.

Whilst weight loss was not a key outcome measure in the study, it has been recognised that weight reduction (in those overweight/obese) can help reduce risk for type 2 diabetes. The American Diabetes Association promote weight loss of around 5-7% of starting weight as a measure of improving insulin resistance and measures of glycemia in order to aid the delay or prevention of type 2 diabetes (Franz et al, 2002). Similarly the Australian Diabetes Association are in agreement by also supporting weight loss (of around 5-7% starting body weight) as a beneficial prevention strategy (Twigg et al, 2007). A review of six studies by Edelstein et al found that when analysed together, BMI was found to be associated with incidence of type 2 diabetes (independent of glucose control) (Edelstein et al, 1997), therefore suggesting that reducing BMI could help reduce the incidence of type 2 diabetes. A review by Norris et al (2009) further consolidates the view that interventions using weight loss strategies and producing significant weight reduction show a decrease in the incidence of diabetes. Therefore, although we did not find significant results in our primary outcome measures, reducing a participant’s weight could help reduce their risk factor
and should be monitored frequently in combination with metabolic indices to
determine overall risk.

It should be highlighted that there is a difference between regular weight loss visits
(weigh-ins promote adherence) as in the Edelstein review and the current study which
involved spreading the education over a number of sessions and in which the
participants did not have an immediate goal to strive for (neither weight or HbA1c).
Although the weight loss resulting from the current study was not statistically
significant it does help cement the role of nutrition education in aiding or facilitating
weight loss and further benefits may result including reduction in metabolic indices
(HbA1c and lipids) over a longer period of time.

Total blood cholesterol concentrations were not found to be different between the
intervention groups (p-value 0.977) however both groups were found to have a mean
decrease in LDL and triglycerides over the intervention period. It was thought that if
dietary behaviour had changed through the mechanism of education then an
improvement may have been found with reduced cholesterol concentration.

In the current study, time was an important component in the study design. It was
hypothesised that sufficient education to elicit outcomes could be given in the
allocated contact time (60 minutes). As the results showed no difference between
interventions, this may indicate that the allocated time was insufficient to deliver the
complexity of the dietary messages. Whilst no participants reported feeling rushed
during the intervention, allowing more time may be beneficial to allow them to ask
questions, get reinforcement of the key points, or even air any concerns or conflicts
they may have. This may lead to a higher retention of the information provided, and
therefore result in more dietary behavioural change, which in turn will show up as
improved metabolic indices (and knowledge score). Resourcing and cost play a role
with time allocation also, particularly in the public health system, and therefore need
to be considered when developing interventions. The use of additional telephone
calls to participants to reinforce messages could be relatively cost effective process that aids in knowledge retention.

5.1 Health Questionnaire Findings

A secondary hypothesis examined in this study was that the multi session group would achieve a greater improvement in nutrition knowledge as calculated by the health questionnaire given at both pre and post intervention. After calculating the total score (questions 1-6) and comparing the change in total score between both intervention groups, no significant difference was found (p=0.975). Our hypothesis was therefore rejected as neither group showed a significant improvement in nutrition knowledge over the other. The small sample size may have contributed to this lack of significant finding. In developing the questionnaire, it was assumed that all participants had equal ability to understand, retain and then recall the nutrition information received. We know that this is not likely to be true; however this was beyond the scope of this research.

As well as a nutrition knowledge aspect, participants were also asked to use a confidence and importance scale to rank their own perceptions on three measures of healthy eating. The importance for themselves of eating a healthy diet (question 9a), their confidence around knowledge of a healthy diet (question 9b) and their confidence that they are currently eating a healthy diet (question 9c). These questions were included to establish whether their perception of their own abilities changed over the period of the intervention. The results for these scales indicated no difference between the intervention groups.

There were some interesting findings from these results on an individual basis. For the single session group, four out of five had an improvement in score for the importance of eating a healthy diet and confidence that they were eating a healthy diet. For the multi session group, two out of the three had improved confidence in
their knowledge of a healthy diet, whilst they all maintained the same scale for the
importance of a healthy diet. These improvements show that on an individual basis,
most participants gained knowledge or skills by taking part in the intervention study.

Although no difference was found between the groups for improvement in nutrition
knowledge, feedback from individual participants’ suggested that the mode of delivery
was subject to a person’s literacy levels and to their current stage of change. As this
was informal feedback these factors were not assessed in the present project,
although they should be controlled for in future work. Some participants enjoyed the
regular contact of the multi-session and felt that this enabled them to be more
accountable to the education provided from previous consultations. Two participants
on the single session intervention reported that they gathered sufficient information
in the intensive intervention and were happy with that mode of delivery. Participants
were unable to compare a preference owing to the fact that they would only
experience one intervention arm.

5.2 Cost Effectiveness

Any research that undertakes health promotion or prevention programmes should
also consider the cost effectiveness of such programmes. With a high demand for
health services and resources, it is imperative that any programme or strategy
considers the financial implications to ensure that the health dollar is spent wisely and
efficiently to get the best value for money. The New Zealand health system is
constantly required to provide more with less money and to make the dollar stretch in
all different directions. With our aging population, this will consequently mean
stretching the health dollar even further as we see more consumers utilising our
health care system. As with many health professionals, dietitians’ time is limited and
resource is scarce, so we need to ensure that the time provided into any prevention or
health promotion programme is efficient and effective in terms of time, resourcing
and to ensure best health outcomes.
A minimal intervention study on weight control was undertaken by Black et al. They undertook two differing studies to determine if using a minimal approach with respect to time and resources used would result in any difference in weight lost by the participants. They concluded that the amount of weight lost was similar in both minimal and shortened interventions which indicate that programmes can be effective in their achievement of outcomes via minimal interventions and resources (Black et al, 1984). This provides evidence in support of an approach to public health treatment that uses a cost-effective approach to cater to the high demand for treatment.

Providing cost-effective nutrition education to people diagnosed with prediabetes will be essential as the rate continues to rise in the population. In that context, the current study had some unique strengths. It was performed under controlled conditions including all documentation, nutrition education, and resources having been developed (or resourced) by the same dietitian. This dietitian also delivered all the dietary education to each participant. The use of a single educator enables the ability to eliminate other confounding factors (such as other educators/different delivery style) when analysing the data. A key feature of this study was that total contact time (with the dietitian) was the same for both intervention groups (60 minutes).

Whilst no significant difference between interventions was found, reported verbal feedback from participants suggested that both modes of delivery had merit and either intervention was preferable to having no provision of education. This may suggest that the outcome was independent of mode of delivery.

This study had limitations. Primarily, in any clinical trial, an adequate sample size is required in order to be able to generalise any results to the whole population studied, and also to detect any differences between interventions (Lachin, 1981). The current study had a small sample size which resulted in limited power in statistical analysis. The difficulty of recruitment arose from limited eligible participants available within the time constraints imposed by a Masters Research project. The slow rate of
recruitment and lack of eligibility was not anticipated and occurred partly as a result of another prediabetes initiative coinciding with the study being described here. This study is limited in the reach of high risk ethnicities as only those whom identified as European were recruited and completed the intervention.

5.3 Future Research

There is a clear gap in the research when looking at interventions that compare different modes of delivery (single session versus multiple sessions) in a dietary education setting. The unique aspect of the current study of maintaining identical contact time meant finding similar research difficult. Although our research did not show a preferential intervention group, there is future research that could be undertaken to add to the pool of current literature. It would be beneficial to conduct an intervention with adequate sample size, to fully understand if the hypothesis is supported. Embedding components such as individualised goal setting, cognitive-behaviour therapy and/or motivational interviewing would also be an important feature of further research as these are already well established and researched tools to aid in behaviour change (Britt, Hudson, Blampied, 2003). A measurement of health literacy and therefore ability to understand some dietary messages may be important information to gather in future interventions of this nature. This may help find a clear relationship between literacy levels and health outcomes and therefore design appropriate interventions. It would also be important to conduct and develop programmes that target ethnicities at higher risk of developing type 2 diabetes, including Māori and Pasifika) (Coppell et al, 2013) and ensuring culturally appropriate recruitment and intervention strategies around them. Another area to examine would be comparing the current methodology undertaken on individuals in group based settings. Group based interventions have been well established in the literature and are a cost effective approach especially when targeting the predicted levels of prediabetes in the community. The use of an online forum as an intervention tool would also be of interest as it is not currently well researched in the dietary field and
may give scope to greater coverage of dietary messages with minimal resourcing. This information could build on current research to establish effective, cost efficient, far reaching intervention programmes that target those most at risk of developing type 2 diabetes.

There are some practical issues that arise from both the intervention styles including multi session style being more time consuming in terms of administrative requirements for the facilitator (room bookings, consultation bookings) as well as for the participants (regular travel to the clinic) which could be seen as a deterrent to future participation (petrol costs, time away from work). For the single session participants, allowing one condensed education session could have caused an overload of information leading to reduced intake of the knowledge required to make dietary changes. No preference was reported by either group, and the facilitator was also impartial to a preference owing to the fact that in the single session, all information was delivered but ascertaining the level of understanding was not taken. The multi session intervention gave the facilitator a chance to interact more with the participants, gaining more trust and building a relationship that was felt to be of greater benefit to enabling behaviour change consequently altering dietary choices and therefore improving health outcomes. These general assumptions of no preference for either mode of intervention delivery and no clear difference found between the groups, allows for the conclusion that nutrition education should be delivered on that basis of cost, resource availability and uptake by participants. The outcome measurements in the current study were believed to be adequate enough to measure success but should also include elements of behaviour change measures and personalised goal setting to ensure that individuals are equipped enough to make the changes necessary to improve their own health outcomes.

With a 25.5% prevalence of prediabetes for adult New Zealanders, now is the time to ensure that any education programme utilises components such as literacy levels, motivation, appropriate platforms and methodology as well as effectiveness to target
the high risk individuals in order to ensure best possible health outcomes with the overall goal of disease prevention through informed, evidence based knowledge and support.
6 Conclusions and Recommendations

Up to 25% of the New Zealand adult population are estimated to have prediabetes (Coppell et al, 2013) and many of the risk factors are modifiable. Many interventions targeting diet and lifestyle issues have been successful in reducing and or delaying the progression to diabetes (Parker et al., 2014, Norris et al., 2009, Satterfield et al., 2013).

The current research used a nutrition education intervention on individuals with prediabetes and hypothesised that a multi session intervention would result in better outcomes than a single session. There were no differences found between the two intervention groups. One reason proposed for this was the small sample population used. There were unforeseen difficulties in the recruitment of eligible participants.

The literature in this area has shown mixed results when comparing single session versus multi-session interventions. It was found that in some studies, a single session intervention was of similar benefit than a multi-session intervention, and in fact was also more cost-effective (DeWalt et al, 2012, Black et al, 1984). There were variances in many of the studies with regards to education topic, duration of intervention, frequency of contact and method of delivery (face to face/online). It was identified in the literature search that there is a clear difference in interventions targeting diet and lifestyle factors (and the measured outcomes) and those that use a binary outcome measurement (e.g. smoking).

The current study adds to the literature by providing another avenue of methodology to explore. The unique nature of comparing mode of delivery – with consistent contact time – makes this study a new area that could potentially aid in establishing effective minimum components of a successful intervention.
6.1 Recommendations:

As more and more New Zealanders’ are developing type 2 diabetes and the health care system struggles to cope the continuing high demand, now is the time to embark on high quality, cost effective, evidenced based health promotion/prevention programmes to target high risk individuals and curb the tide of type 2 diabetes.

The 2016 report by the World Health Organisation (WHO, 2016), made some recommendations that can be utilised throughout the world as a starting point for reducing the burden of type 2 diabetes. These include:

- A whole of government approach – not only is it the health system, but also other governmental departments need to get on board – this includes education, social services, business, trade, agriculture and others. All of these departments have some impact of influence on the health of New Zealander’s from ensuring health is a part of the primary school curriculum through to ensuring the food industry improve the nutritional composition of our food.

- Creating policies that benefit the communities and support a healthy environment.

- Ensuring access to appropriate health needs and screen opportunities – and making this affordable and effective - both in outcomes and resources.

- Food security is important as having the knowledge and capability to change is good, but we also need to ensure people have the access to good quality food that is not only nutritious but also affordable to all.

- Creating, sustaining and maintaining supportive environments which are conducive to assisting physical exercise opportunities.

- Effective and sustainable, evidenced based interventions programmes that target, promote and support lifestyle change for improved health outcomes.
New Zealand needs to take note of these recommendations and ensure that they focus on the raising epidemic of type 2 diabetes through targeting those at high risk of developing it. Now is the time to invest in effective, evidence based, culturally appropriate interventions and ensure that New Zealanders are exposed to and educated about the risks and preventative measures that can be taken to delay the onset of type 2 diabetes.
7 References


Franz, M. J., Monk, A., Barry, B., McClain, K., Weaver, T., Cooper, N., & Mazze, R. S. (1995). Effectiveness of medical nutrition therapy provided by dietitians in the
management of non–insulin-dependent diabetes mellitus: a randomized, controlled clinical trial. Journal of the American Dietetic Association, 95(9), 1009-1017


8 Appendices

1. Ethics Application
2. Ethics Approval
3. MidCentral District Health Board Research Approval
4. Ngai Tahu Research Consultation Committee
5. Recruitment Poster
6. Central Primary Health Organisation Clinical Dietitian Referral Criteria
7. Participant Information Sheet
8. Consent Form
9. Health Questionnaire
Appendix 1

Ethics Application
Human Ethics Committee

Research Ethics (Health) Application Form

Health Research Approval Process

Researchers conducting health research must receive the approval of either:

The University of Otago Human Ethics Committee (Health) or Health and Disability Ethics Committee (HDEC)

Does your study require HDEC review? Please consult the University's research ethics web site or the HDEC web site

Please note if applying to the HDEC, it is a requirement of the Deputy Vice Chancellor (Research and Enterprise) that the approval letter from that ethics committee must be forwarded to the Academic Committees office.

9 Section 1 - Details of investigators, including student investigators and title of study

1.1 Principal Investigator (University of Otago staff member responsible for project)

Name: Bernard Venn  
Title: Dr

Department: Human Nutrition
Title of Study: Comparing the effectiveness of Dietitian delivered nutrition education either as a single intensive session or five short sessions for people with pre-diabetes.

1.2 Professional Advisor

Name: Pauline Giles
Department: Nurse Practitioner – Diabetes, HCD, MidCentral DHB
Email: Pauline.Giles@midcentraldhb.govt.nz

1.3 Student investigator

Name: Suzanne Aitken
Level of Study: Masters
Department: Email: suzanne.aitken@centralpho.org.nz

PART A

10 Section 2 – Protocol and summary

2.1 A protocol must be attached to this application before submission to the committee. If this protocol has a unique identifier, enter this below.

Protocol number (if applicable):

Briefly describe and justify the design of your study, including, if appropriate, the power calculation on which the number of participants is based. Provide power calculation if not explicitly stated in the protocol. [<200 words]

The design of the study will be an education intervention for which participants will be randomly assigned to one of
two groups. Both groups will be given the same Nutrition Education; however the groups will differ in the delivery of the Nutrition Education. One will be given the information in a one off consultation, whilst the other group will have the same information delivered in short sessions over five separate appointments.

2.1.1 Briefly and in plain English, what is the principal study question (hypothesis) that the study will test? You can refer to page numbers of your study’s protocol for further detail if you need to.[<100 words]

Our hypothesis is that nutrition education delivered as five short sessions by a registered Dietitian will result in metabolic improvements in people with pre-diabetes to a greater extent than the equivalent nutrition education given as a single session. The outcomes will be glycated haemoglobin (HbA1c) and blood lipid profiles (total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides).

A quantitative assessment of the two approaches on participant health literacy, understanding and information retention will be compared using a short knowledge style questionnaire.

2.1.2 Briefly describe the background for the study (including, where appropriate, brief discussion of previous research), the population from which the sample will be recruited, the inclusion and exclusion
criteria and the impact, if any, of the exclusions on the generalisability of results.

Pre-diabetes diagnoses are on the increase and the New Zealand Ministry of Health recently put out a paper on Pre-diabetes advice (August 2013). Evidence from randomized controlled trials (RCT) indicates that the risk of progression to diabetes can be reduced markedly through lifestyle modification*. This study aims to add to the current literature in support of risk reduction of diabetes diagnosis through the use of lifestyle modification.

The sample population will be recruited from those within the Central PHO Manawatu catchment area that have been diagnosed with pre-diabetes.

The inclusion criteria will be:

- Patients over the age of 18 years old
- Pre-diabetes diagnosis using HbA1c of 41-49mmol/mol
- Enrolled population of Central PHO

Exclusion criteria:

- previous nutrition education from a registered dietitian
- initiation of diabetic medication upon diagnosis
- under 18 years of age
- pregnancy

2.1.3 Briefly explain how the study will contribute to new knowledge or improve health outcomes.[<100 words]

Information and education delivered by a health...
professional can significantly contribute towards individual self-management by helping to initiate behavioral change. Whether dietary and metabolic improvements can be enhanced by an alternative delivery of nutrition education is the subject of this proposed research. The outcome of the research may be used to inform policy makers on the best way to deliver nutrition education.

2.1.4 Briefly summarise the Principal Investigator’s qualifications and experience relating to conducting studies of this nature. [<200 words]

Dr Bernard Venn has a PhD in human nutrition obtained from Otago University under the supervision of Prof Jim Mann. For the past five years Dr Venn has been teaching and conducting research into the most appropriate foods for people with and without type 2 diabetes. Dr Venn has supervised several MDiet and MSc projects within the theme of glycaemic and weight control and is currently supervising a PhD involving an activity intervention and dietary advice in people with type 2 diabetes.

2.2 Provide a brief summary of the main ethical issues that you believe your study may raise as well as detailing your approach or strategy for dealing with them. (This information would also normally be reflected in the participant information sheet under the heading ‘Is there any risk of discomfort or harm from participation’) [<200 words]

It is not envisaged that participants will be at risk of harm from an educational intervention conducted by a registered dietitian. Participants
will be consumers of health and disability support services but the intervention involves either standard advice delivered as a single educational session (the control group) or as five shorter sessions (the comparison group). A routine blood test will be undertaken at study entry followed by one more at six months post intervention.

A phlebotomist from a local commercial laboratory (MedLab) will take the blood samples. As is usual, sampling may give rise to some general discomfort around the needle site.

2.3 Provide the dates on which you plan to commence and conclude your study.

Planned commencement date: June 2014
Planned conclusion date: April 2015

11 Section 3 - Sponsors

3.1 The sponsor is the organisation with overall responsibility for the initiation, management, and financing arrangements of a study.

Which of the following best describe the sponsor(s) of your study?
☒ University of Otago
☐ another academic institution
☐ collaborative research group
☐ district health board (DHB)
☐ other government agency
☐ pharmaceutical company
☐ medical device company
☒ other (e.g. non-governmental organisation (NGO), or contract research organisation)

Please specify PHO
12 Section 4 - Localities and participants

Locality authorization is required from the establishment (hospital, health centre, surgery, etc.) from which the procedures outlined in the protocol are to be conducted. This authorisation confirms that the locality, if outside the University of Otago, has addressed research governance issues that may arise as a result of the study. Should this be the case, written confirmation from the locality is required. (see 4.1)

4.1 At which localities in New Zealand do you intend to conduct your study?

Written support is essential, whether your study is conducted in New Zealand or overseas and should be either attached to this application or forwarded to the Committee once ethical approval has been granted. The locality needs to be aware of the University’s protocol, governance and ethical issues.

☐ tertiary education institution
☐ district health board (DHB)
☒ primary health care organization
– verbal consent given, awaiting written authorization.
☐ private organisation
☐ other – please specify: __________ Please provide details: __________

4.2 Approximately how many participants do you intend to recruit:

In New Zealand?
1-50 ______ 51-100 ☒ 101-150 ______ 151-200 ______ Over 200 ______

Overseas?
1-50 ______ 51-100 ______ 101-150 ______ 151-200 ______ Over 200 ______

Grand total number of participants: __70____

13 Section 5 - Prior review

5.1 Is this application related to one or more previous applications to any ethics committee?
☐ yes  ☒ no
If yes, explain the relationship, giving the ethics reference number(s) of the previous application(s).

5.2 Has an application for this study (or a substantially similar study) previously been declined approval by any other ethics committee in New Zealand or overseas?
☐ yes  ☒ no  (go to section 6)

14 Section 6 – Study Design

6.1 Is your study:
☒ an intervention  study - Go to section 6.1.1
☐ an observational quantitative or laboratory study - Go to section 6.1.2
☐ a mixed methods study - Use appropriate sections of 6.1
☐ a qualitative study  - Go to section 6.1.3

6.1.1 Which of the following best describes your intervention study?

Blinding:
☒ open-label  ☐ single-blind  ☐ double-blind

Arms:
☒ two-arm  ☐ multi-arm

Design:
☒ parallel  ☐ crossover  ☐ dose-ranging  ☐ cluster  ☐ factorial

Control:
☐ placebo-controlled  ☒ active-controlled  ☐ uncontrolled

Randomisation:
☒ randomised  ☐ non-randomised
Aim:
☒ superiority ☐ equivalence ☐ non-inferiority
☐ none of the above – explain

6.2 Indicate whether peer review of the scientific and statistical quality of your study has been obtained from one or more of the following.
☐ the study’s funder
☐ the study’s sponsor
☒ senior colleague(s) in the field
☐ other - explain
If you have ticked any of the boxes above, briefly describe the peer review process that has been carried out for your study. Evidence of peer review must be attached to this application including responses to any recommended changes.

[<200 words] A senior member of the Otago University Human Nutrition Department will look over and peer review our study.
☐ no review

6.3 How do you intend to report or disseminate the results of your study?
☒ article(s) in peer-reviewed scientific journals
☒ internal reports
☒ conference presentations
☐ publication on website
☐ other publications
☐ submission to regulatory authorities (e.g. Medsafe, TGA, FDA, EMA)
☐ other – explain

6.4 Will any restrictions be placed (for example, by your study’s sponsor or funder) on the publication of the results of your study?
☐ yes
☒ no

84
If yes, briefly describe these restrictions, and explain why they are in place.
[<200 words]

6.5 Might data generated in your study, but not reported, be made available for use in future research (e.g. for inclusion in an individual data meta-analysis)?
☒yes
☐no
If so, you should explain this clearly to potential participants.
Which of the following best describes the form in which data generated by your study will be published, stored, and, if consent for future use has been given, might be made available to other researchers?
☐identified
☐potentially identifiable
☐partially de-identified
☐de-identified
☒anonymous
☐other – describe: __________

15 Section 7 - Use of human tissue, including blood and other body fluids

7.1 The use of human tissue in New Zealand is regulated by the Human Tissue Act 2008 and the Code of Health and Disability Services Consumers’ Rights 1996.
Will human tissue be collected and/or used in your study?
☒yes
☐no If “no” go to Section 8

7.2 What types of human tissue will be collected and/or used in your study? [<100 words]
A laboratory blood test will be taken at 6 month post intervention. This will then be analysed by Medlab Central and disposed of through their usual channels. The results will be available on the MidCentral District Health Board Éclair system.
7.3 Will your study involve:
☒ human tissue collected from participants during this study? Go to 7.6
☐ existing stored human tissue samples?

7.6 Will any human tissue samples used in your study be imported from outside New Zealand?
☐ yes
☒ no

7.7 Briefly explain how human tissue samples will be stored during your study, and how the privacy of donors and participants will be protected. [<100 words]
After blood samples have been taken and processed by Medlab Central, they will be destroyed as due process according to the policies of Medlab Central.

7.8 Will human tissue collected in New Zealand be sent overseas as part of your study?
☐ yes
☒ no
If yes, you should explain this clearly to participants.

7.9 Will the use of all human tissue in your study be in accordance with the informed consent (including consent to future unspecified research) that has been or will be obtained from participants, donors of existing stored human tissue, or other persons entitled to give informed consent under the Human Tissue Act 2008?
☒ yes go to 7.10
☐ no

7.10 Is consent being sought for future unspecified use?
☐ yes – if so specify the general terms of the additional research

☒ no
7.11 What types of tests or analyses will be carried out on human tissue as part of your study?

[<100 words] We will have the human tissue (blood samples) analysed at the lab (Medlab) for HbA1c and lipid profile.

7.12 What will happen to human tissue at the end of your study, or if participants withdraw consent for its use in this study?

☒ disposal

☐ return to donor, whānau, or family member

☐ return to current holder of existing stored human tissue (e.g. a tissue bank)

☐ transfer to another tissue bank

☐ storage by the research team for use in another study

☐ storage by the research team as part of a new tissue bank

☐ other

7.13 Briefly explain your answer above.

[<100 words] Medlab dispose of all samples using standardised processes.

7.14 Will any human tissue collected or otherwise obtained from participants in this study but not used in the current study be stored and potentially used in unspecified future research? You should explain this clearly to potential participants.

☐ yes

☒ no

16 Section 8 - Risk of physical harm to participants

8.1 Briefly and in plain English, describe the risks inherent in the procedures to be undertaken by participants in your study and how these risks will be minimised. Including:

- risk minimisation by use of health questionnaires
- participant exclusion criteria
- monitoring during procedures
- training of research staff and availability of resuscitation equipment if appropriate
• use of EEG, ECG, MRI, TMS, FMRI, EMG, radiation, invasive or surface recordings. [<200 words]

After diagnosis of pre-diabetes through a laboratory blood test, the participants will be asked to complete a simple health questionnaire regarding their current nutrition knowledge and health literacy. The questionnaire will be kept to a selection of ten multi-choice questions and will be repeated at the conclusion of the intervention. There is no perceived risk to participants through this process.

The intervention itself will involve contact with a registered Clinical Dietitian and the participant will undergo a dietary assessment and education which are perceived to have no risk attached.

At the six month post-intervention mark, participants will also be asked to undergo another laboratory test at their earliest convenience from the local Medlab laboratory. This will involve an overnight fast and an experienced phlebotomist will draw blood as per standard operating procedure. The experienced phlebotomist will minimize any risk of harm or discomfort to the participant.

8.2 Will your study involve the administration of ionising radiation that is not needed for participants’ normal clinical management?

☐ yes
☒ no – go to 8.5

8.5 If this is an intervention study, briefly outline the criteria for its termination, including reference to your study’s protocol where appropriate. [<100 words]

Termination of the intervention study will conclude at the end of the study period – in which all participants have had a 6 month follow up blood taken and completion of the post-intervention health questionnaire.

17 Section 9 - Risks to participants other than physical risks of an intervention

9.1 Could participation in the study, or reporting of the findings, risk psychological harm to participants?

☐ yes
If yes, how this risk will be minimised and managed. [<100 words]

9.2 Could participation in the study, or reporting of the findings, risk stigmatising individuals or population groups, or punishment/harassment for participation?
☐ yes
☒ no
If yes, how this risk will be minimised and managed. [<100 words]

18 Section 10 - Risk of potential conflict of interest

10.1 Funding and remuneration
Briefly describe the main source(s) of funding for your study.[<100 words]

The recruiting and intervention sessions will be carried out as part of the routine duties of the Dietitian employed under Central PHO – as per contractual obligations. The funding for the extra laboratory testing will be obtained through Central PHO funds.

10.2 Does the Principal Investigator, any co-investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence his or her conduct in the study?
☐ yes
☒ no

10.3 Will the Principal Investigator or any co-investigator be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study (for instance, bonuses for favourable results or high recruitment rates)?
☐ yes
☒ no

10.4 Other potential conflicts of interest
Will any researchers in the study face other conflicts of interest (e.g. academic dependence, personal belief)?

☐ yes
☒ no

10.5 Briefly describe how the risks of any conflict of interest, described in sections 10.1 to 10.4 above, will be minimised and managed.[<100 words]

No conflicts were recognized.

19 Section 11 - Risk of breach of privacy and confidentiality

11.1 Before the study:
Will your study involve reviewing or screening health information, for example in order to identify potential participants?

The term “health information” is defined in the Health Information Privacy Code.

☒ yes
☐ no

In accordance with normal practice, only those health professionals involved in the study will have access to any relevant health information. This will be gathered through the participants health notes (at their GP office) or through the secure network of MidCentral District Health Board’s Éclair system. Normal operating procedures including password protection will be used throughout the collection and storage of participants data.

11.2 Will your study involve the use of surveys or questionnaires?

☒ yes
☐ no

20 Section 12 - Risks to researchers and third parties

12.1 Briefly indicate whether your study may pose any significant risks to researchers and/or third parties, and briefly explain how such risks will be minimised and managed. [<100 words]

No perceived risk has been recognized.
21 Section 13 - Informed Consent

13.1 Will all participants in your study be competent to, and asked to, provide their informed consent to participate?
☒ yes, all participants will be competent to, and asked to give informed consent - If yes go to 13.2
☐ no, one or more participants may not be competent to, or will not be asked to give informed consent

13.2 Does the research involve participants giving oral consent rather than written consent?
☐ yes
☒ no

13.3 Briefly explain the process by which potential participants in your study will be identified, approached, provided with an Information Sheet written in language appropriate to the intended participants, have the opportunity to ask questions, and be asked to give their informed consent free from undue influence. Identify the person or persons who will conduct the process.

Participants will be referred to Suzanne Aitken, registered Dietitian, for nutrition education through their local GP practices (general practitioner’s or practice nurses). Ms Aitken will contact the referred patient and explain that a dietary consultation has been requested by their general practice team and that it is recommended that an appointment be made. Setting of the appointment will be independent of whether they wish to take part in the study or not; i.e. they will receive the same counselling regardless of participation in the study. With an appointment agreed, the participant ill then be informed that a study is underway. The study will be explained to them and they will be asked if they would like to receive an information sheet. If they are agreeable, an information sheet will be sent to them. If they are not interested in taking part in the study then the dietetic consultation will stand without disadvantage to them.

13.4 Will consent be recorded by signature on an individual consent form?
13.5 Does the research involve deception, covert observations, or other ways in which information is deliberately withheld or concealed from participants?
☐ yes
☒ no

13.6 How will you ensure that participants receive information that becomes available during the study (for example, an unexpected incidence of adverse events in your study, or information from elsewhere) that may be relevant to their continued participation?
At the time of enrolment onto the study, participants’ will be asked for their preferred method of contact/communication – telephone, email, mail or face to face. Records will be updated to reflect this. This will then form the basis of any relevant information that needs to be communicated with the participants’ during the study period.

13.7 Will you inform participants of the results of your study?
☒ yes
☐ no
Either explain how you will inform participants or explain why you do not intend to do so.
A written copy of the results/brief write up will be made available to all participants.

13.8 Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?
☐ yes
☒ no

13.9 Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?
☒ yes
☐ no
22 Section 14 - Consultation with population groups

Population groups, particularly Māori, should be consulted in the design and conduct of research that is of relevance to them.

14.1 Describe whether and how your study may benefit Māori, and identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed.[<200 words]

The aim of this study is to benefit people who have been diagnosed with pre-diabetes. It is open to any person who meets the inclusion/exclusion criteria with no specific cultural groups being sought. It is not perceived that Māori participants will encounter any cultural issues whilst participating in this study. Māori advisors will be consulted should any unexpected issues arise during the course of the study.

14.2 According to the Health Research Council’s Guidelines for Researchers on Health Research Involving Māori, is formal consultation with Māori required for your study?

☒ yes
☐ no

14.3 The University of Otago has a Policy for Research Consultation with Māori. Have you already completed, or do you propose to undertake Māori consultation?

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

☒ yes, we have ALREADY undertaken consultation
☐ no - If no, provide a brief outline of reasons why not

PART B –

24 Section 15 - Compensation for injury to participants

15.1 Is the research considered a clinical trial?

☒ yes - if yes, go to Section15.2
☐ no - if no, go to Section 17
(The University of Otago Human Ethics Committee (Health) adopts the definition of clinical trial of the World Health Organization and the Ministry of Health, i.e., ‘a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes’.)

15.2 Will the proposed research be conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out?

☒ no - submit a Form A with your application. See template appended to this application
☐ yes - submit a Form B with your application. See template appended to this application

25 Section 16 - Risk of unexpected clinically significant findings

16.1 Might any aspect of your study produce findings that may be both unexpected and clinically significant for participants, donors of existing stored human tissue, or their families?

☒ yes
☐ no

If yes, what might these findings be, and how will participants, donors of existing stored human tissue, or their families be informed of them?[<100 words]

It is possible over the time course of the study that participant’s biochemical indices worsen, although this is considered unlikely given the relatively short timeframe (6 months) and the nature of the intervention (dietary advice aimed to improve metabolic risk factors). Further blood tests of HbA1c and lipids may reveal other potential diagnoses such as an increase – potentially diabetes or elevated (raised) cholesterol levels. If these findings were to eventuate, then the participant would be advised to contact his/her general practice team for consultation and guidance.

26 Section 17 – Privacy and confidentiality of health information

17.1 During the study
During your study, who will have access to health information used in your study?

The researcher (Suzanne Aitken), and the project supervisors (Dr Bernard Venn and Pauline Giles). The participants GP team would also have access to the biochemical data collected as part of this study.

17.2 Briefly explain how you will ensure the confidentiality of this health information during the study. [≤100 words]

As per processes within the organization (Central PHO), information will be stored using proper policies.

17.3 The Health (Retention of Health Information) Regulations 1996 require that some health information be retained for a period of ten years. For how long will health information generated in your study be stored? [≤100 words]

The information will be stored for a minimum of five years.

27 Section 18 - Health or disability support service providers

18.1 Will the Principal Investigator or any co-investigator also be the usual health or disability support service provider for one or more participants in your study?

☒ yes
☐ no

18.2 Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

☐ yes
☒ no

28 Section 19 - Impact on the provision of health and disability services

19.1 Might your study adversely impact on the provision of health and disability services?

☐ yes
☒ no
☐ not applicable
Appendix 2

Ethics Approval
Dear Dr Venn,

I am again writing to you concerning your proposal entitled “Comparing the effectiveness of dietician delivered nutrition education either as a single intensive session or five short sessions for people with pre-diabetes”, Ethics Committee reference number H14/077.

Thank you for your e-mail of 30th June 2014 addressing the issues raised by the Committee. The Committee appreciates the clarification given in respect of accessing participants medical records. It is understood that the dietitian is required to view the medical records as a matter of routine to check for co-morbidities and medications and as such you have amended the Consent Form to reflect this.

The Committee thanks you for the further comment in relation to the use of ‘Medical Nutrition Therapy’ (MNT) in the title. The Committee accepts that you have replaced this terminology with ‘nutrition education’.

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

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on
participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

gary.witte@otago.ac.nz jo.farrondediaz@otago.ac.nz

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of 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

c.c. Professor S Samman   Department of Human Nutrition
Appendix 3

MidCentral District Health Board Research Approval
Research Practice Title: Comparing the effectiveness of Dietitian delivered Medical Nutrition Therapy either as a single intensive session or five short sessions for people with pre-diabetes.

Principal Researcher: Suzanne Aitken

Designation: Clinical Dietitian
Service Area: Central PHO Manawatu

Research Practice Experience: PGDipDiet practicum

Other Researchers Involved: Dr Bernard Venn, Supervisor, Otago University, Pauline Giles (supervisor) Nurse Practitioner – Diabetes, HCD, Midcentral DHB

Brief Description of Research Practice Purpose and Methodology:

The design of the study will be an education intervention for which participants will be randomly assigned to one of two groups. Both groups will be given the same Medical Nutrition Therapy (MNT), however the groups will differ in the delivery of the MNT. One will be given the information in one of consultation, whilst the other group will have the information delivered in five separate occasions – short bursts of information.

Section A: Initial Registration and Approval of Research Practice

Documented evidence:

- Research purpose

- Consultation with all MCH involved parties

- Risk and indemnity cover
<table>
<thead>
<tr>
<th>□</th>
<th>Resources required <em>e.g. staff, equipment, other service involvement</em></th>
<th>□</th>
<th>Approved research budget</th>
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<tbody>
<tr>
<td>Operations Director signature to proceed :</td>
<td>Date:</td>
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<th>Professional approval gained, where applicable (<em>e.g. Professor of Nursing</em>)</th>
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<th>External approval gained, where applicable (<em>e.g. Central Regional Ethics Committee, Educational Institution</em>)</th>
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<tr>
<td><strong>State where from</strong>: Otago University Ethics Committee</td>
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Documented evidence (where applicable):

- □ National application form for ethical review of a research project (*NAF- 2005- v1*)
- □ 'Participants who are unable to give informed consent to participate' form (*NAF- Part 7*)
- □ Locality assessment form □ 'Use of human tissue' form (*NAF- Part 5*)
- □ 'Genetic research' form (*NAF- Part 6*)

**Section B : Final Operations Director Approval to Proceed**

- □ Final contractual agreement completed

Proposed start/end dates of research: _________________________________________________
Consultation with all involved parties:
Central PHO management
University of Otago Human Nutrition Department
Prof Jim Mann, DM PhD FRACP FFPHM, Otago University, Professor of Human Nutrition and Medicine.
Ngai Tahu Research Consultation Committee
Pauline Giles, Nurse Practitioner - Diabetes

Resources required:

Staffing: Project will be staffed by Suzanne Aitken in her current role as Clinical Dietitian working for Central PHO.

Equipment: Resources including hand-outs for clients, rooms for consultation, scales etc. will be sourced from already available sources within the Central PHO.

Other: Statistical analysis and additional academic requirements will be sourced from the University of Otago.

Laboratory testing: At six months post intervention, participants will be required to have a further blood test, this will be funded by Central PHO.
**Research purpose and parameters: (study protocol)**

**Comparing the effectiveness of Dietitian delivered Medical Nutrition Therapy either as a single intensive session or five short sessions for people with pre-diabetes**

Dr Bernard Venn, Ms Suzanne Aitken

**Aims:**

1. To reduce glycated haemoglobin (HbA1c) in people with pre-diabetes after effective Medical Nutrition Therapy.
2. To improve blood lipid levels by a reduction in cholesterol concentration.
3. To increase nutrition knowledge and health literacy through Medical Nutrition Therapy with a registered Clinical Dietitian.

**Methodology:**

**Trial design:** A randomised parallel education intervention on participants diagnosed with prediabetes (HbA1c 41-49mmol/mol) involving quantitative measures of biochemical indices (HbA1c, lipid profile) and a short health questionnaire.

**Participants:** A total of 70 adult participants, with a recent diagnosis of pre-diabetes (HbA1c 41-49mmol/mol), allowing 35 in each of the two intervention groups. Participants must not have had any dietary intervention or education from a registered Dietitian in the past.

**Intervention:** After participants have been randomised into one of the two intervention groups, they will attend either 1 or 5 Medical Nutrition Therapy sessions based around prediabetes nutrition education. The sessions will be focussed on:

- An basic understanding of pre-diabetes and HbA1c
- Carbohydrate foods,
- The four food groups,
- Portion sizes and the plate model
- Reading food labels

At pre and post intervention, participants will be asked to complete a short health questionnaire which will gather information on current nutrition knowledge and health literacy.
Outcomes: To achieve study aim 1 & 2, the participant will undergo a laboratory blood test at approximately 6 months post intervention. Glycated haemoglobin and lipid levels will be analysed in a commercial laboratory and reported through to the study researchers. This will be compared with the baseline diagnostic HbA1c and lipid levels to evaluate whether biochemical indices have improved.

For study aim 3, a short health questionnaire containing brief dietary questions will be performed by the participants at the beginning and at the end of the study. These results will be quantified and compared to determine whether improvements in nutrition knowledge have occurred both over time and between the different education interventions.

Sample size: A sample size of 70 participants has been chosen, giving 35 per group allocation.

Randomisation: The first 10 referred patients will be stratified by sex and assigned to either arm using a computerised random number generator. Subsequent referrals will be similarly grouped into blocks of 10 and randomly assigned. Randomisation will occur remotely at the University of Otago such that the dietitian will be unaware at the time of referral as to which intervention arm the participants will be allocated.

Statistical methods: ANCOVA will be used to estimate differences in HbA1c between groups at the end of the study. Secondary analyses on questionnaire data will include proportion tests and ANCOVA.
Appendix 4

Ngai Tahu Research Consultation Committee
Appendix 5

Recruitment Poster
Comparing the effectiveness of Dietitian delivered nutrition education either as a single intensive session or five short sessions for people with pre-diabetes

I am currently trying to recruit participants for my research project. I am investigating the effect of dietary education intervention on HbA1c levels of pre-diabetic clients. I am also looking at outcomes in terms of knowledge retention and health literacy.

I am looking for participants diagnosed with pre-diabetes having had a recent HbA1c of 41-49mmol/mol whom have not had any previous dietary education. They will either be placed in a single session education consultation or booked in for 5 short education sessions – gaining dietary and lifestyle education to promote behaviour change. They will then have a follow up HbA1c at 3 months post intervention.

I am hoping to have one day a week booked for these participants and if needed extra time when and where is appropriate.

If you are able to help with the recruitment of these participants – I would be most appreciative.

This study has been approved by the University of Otago Human Ethics Committee (Health)

Suzanne Aitken NZRD
Clinical Dietitian
Central PHO
Suzanne.aitken@centralpho.org.nz
0212740014,
063549107
Appendix 6

Central PHO Clinical Dietitian Referral Criteria
# Clinical Dietitian Service

## Summary of Service

The Nutrition and Dietetic Service for Central PHO focuses on clients with long term conditions within the Tararua, Horowhenua, Otaki and Manawatu community.

We provide a free service for individuals who fit our criteria as detailed below.

We can provide clinic 1:1 sessions (held either in our local health centres, GP surgeries or other community venues), home visit 1:1 sessions, specialised group sessions and Marae visits. We are also involved with health promotion events within the community.

## Criteria for Referral

Our referral criteria is based on long term conditions which include the following:

**Diabetes:**
- All T2DM with a HbA1c of >53mmol/l, including those established on insulin
- Pre-diabetes HbA1c 41-49mmol/l
- Post GDM weight management

**CVD:**
- CVD risk >20%
- Cholesterol >4mmol/l
- Blood pressure >130/80mm Hg

**Obesity: (adults)**
- Overweight BMI 25-29.9kg/m² with co-morbidities
- Obesity BMI >30kg/m² with or without co-morbidities

**Obesity: (child)**
- With no co-morbidities

**COPD:**
- Underweight BMI <18.5kg/m² with unintentional weight loss of 5% in 1 month
- Overweight BMI >25kg/m²

**Cancer:**
- Underweight BMI <18.5kg/m²
- Or significant weight loss of 5% in 1 month

**Renal Failure:**
- Stages 1-3 eGFR 30-60

**Mental Health:**
- Diagnosed with mild to moderate mental health condition and would benefit from dietetic input

Priorities will be given to the Māori and Pacific population with the above conditions and also those on a low income.
Appendix 7

Participant Information Sheet
Comparing the effectiveness of Dietitian delivered nutrition education either as a single intensive session or five short sessions for people with pre-diabetes.

**Principal investigator:** Dr Bernard Venn
Human Nutrition
Senior Lecturer
Contact phone number:
(03)4795068

**Introduction**

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, 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 this research project?**

Growing evidence is showing that lifestyle intervention and change can help reduce the progression of pre-diabetes to diabetes. The aim of this project is to compare the effectiveness of a once off intensive one-on-one nutrition education session by a Clinical Dietitian to that of five short nutrition education sessions for people diagnosed with pre-diabetes.

The aim is to see a decrease in clinical markers including HbA1c and lipid levels of those participants and to evaluate whether this decrease is greater when nutrition education is delivered as a single session or five short sessions.
Who is funding this project?
As part of the MidCentral DHB, Central PHO is contracted to provide Clinical Dietitian assessment and intervention to people with pre-diabetes. The funding for this project is sourced from already established contracts for these organisations.

Who are we seeking to participate in the project?
We are wanting participants that have recently been diagnosed with pre-diabetes (HbA1c between 41-49mmol/mol) and who have not yet made any lifestyle changes. Participants must be over the age of 18 years old and willing to attend up to five sessions (within a six month period), with a Clinical Dietitian either at their home, or at the Central PHO offices. Participants must also be willing to have an additional laboratory test which will be provided at no expense to themselves. Participants may decline to participate and will not be disadvantaged in anyway.

If you participate, what will you be asked to do?
Following on from a diagnosis of pre-diabetes, you will be randomly assigned to either a single nutrition education session with a Clinical Dietitian or to attend 5 short sessions with a Clinical Dietitian. The information provided in each will be the same for both groups.

A short health questionnaire will also be given out at the start of the study for you to complete, and will again be given at the completion of the study.

After a period of 3 months, you will be asked to undergo a blood test taken at a Medlab which will test your HbA1c and lipid levels.

Should you not want to participate in the project, you will not be disadvantaged and will be routinely asked whether you would like an appointment with a Clinical Dietitian as matter of process of diagnosis.

Participation within the study is entirely voluntary and your health care will not be disadvantaged should you decide not to participate. Participation also means that you consent to the investigator having access to your medical records to check for any co-morbidities or medications as part of a regular dietetic review and consultation.

No remuneration will be given for your participation.

Is there any risk of discomfort or harm from participation?
A laboratory blood test will be undertaken by an experienced phlebotomist, and there is perceived to be a slight, but minimal discomfort from this at the needle site.

What specimens, data or information will be collected, and how will they be used?
Data including: age, ethnicity, smoking status, relevant medical history, current medications and/or supplements taken will be collected. Height and weight will be measure and BMI will be calculated. Your current dietary practices, food intake and
food patterns will be assessed using a diet history questionnaire. The purpose of collecting this data is to describe the characteristics of the group. This information will be stored electronically on a secure network and all paper copies will be destroyed through secure processes. The electronic data will only be available to the study investigators and your healthcare team.

A blood test will be taken at Medlab and the specimen will be analysed for HbA1c and lipid levels. Any remaining sample will then be destroyed as per Medlab processes. The results will be made available to the study investigators and to your healthcare team.

The study results may be published but the research team will ensure that no participant will be identified. At the end of the study, any personal paper information will be destroyed through secure means. The biochemical results of testing will be made available to your health care team and will become a part of your permanent health record.

You have rights of access to any personal information given or collected from you to us and you may correct or change this information.

What about anonymity and confidentiality?

Your personal information will be kept confidential. All published results will ensure individual confidentiality and will not be traced back to you.

Only the research team and your health care team will have access to the information collected throughout the study.

We will strive to maintain and preserve confidentiality through non-identifying numbers, codes and using secure electronic data management.

If you agree to participate, can you withdraw later?

You may withdraw from participation in the project at any time and without any disadvantage to yourself.

Any questions?

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

<table>
<thead>
<tr>
<th>Dr Bernard Venn – Senior Lecturer</th>
<th>Contact phone number: 03 4795068</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Human Nutrition</td>
<td></td>
</tr>
<tr>
<td>Suzanne Aitken – Clinical Dietitian</td>
<td>Contact phone number: 06 3549107 / 0212740014</td>
</tr>
<tr>
<td>Central PHO</td>
<td></td>
</tr>
</tbody>
</table>
This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Appendix 8

Consent Form
Comparing the effectiveness of Dietitian delivered Medical Nutrition Therapy either as a single intensive session or five short sessions for people with pre-diabetes

Principal Investigator: Dr Bernard Venn Ph: (03)4795068 E: Bernard.venn@otago.ac.nz

CONSENT FORM FOR PARTICIPANTS

Following signature and return to the research team this form will be stored in a secure place for five years.

Name of participant: ..........................................................

1. I have read the Information Sheet concerning this study and understand the aims of this research project.

2. I have had sufficient time to talk with other people of my choice about participating in the study.

3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.

4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.

5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project at any time without disadvantage.

6. I know that as a participant I will be asked to complete a short health questionnaire pre and post study. Measurements including height and
weight will also be collected pre and post study. I will also undergo an additional laboratory test after the completion of the intervention to determine my HbA1c and lipid levels. This information will then be explained to me and kept on my permanent health record at my General Practice.

7. I know that the health questionnaire will explore my basic nutrition knowledge and that if the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and/or may withdraw from the project without disadvantage of any kind.

8. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.

9. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least five years.

10. I understand that the results of the project may be published and be available in the University of Otago Library, but that any personal identifying information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study.

11. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.

12. I understand that the blood samples will not be stored but be disposed of as per laboratory processes.

**Signature of participant:**

**Date:**

**Signature and name of witness:**

**Date:**
Appendix 9

Health Questionnaire
Comparing the effectiveness of Dietitian delivered nutrition education either as a single intensive session or five short sessions for people with pre-diabetes.

Health Questionnaire – Prediabetes

1. Pre-diabetes means:
   a) you have a higher risk of developing type 2 diabetes
   b) you have ‘mild’ type 2 diabetes
   c) you will get type 2 diabetes
   d) you will not get type 2 diabetes
   e) I don’t know/unsure

2. List below the five carbohydrate foods and drinks that you consume most often.

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

3. HbA1c (a lab test) measures your average blood glucose control over the past:
   a) Day
   b) Week
   c) 8-12 weeks
   d) 6 months
   e) I don’t know/unsure

4. Can you name three foods that contain saturated fat?

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
5. Looking at the following food label –

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<tbody>
<tr>
<td>Servings per package: 12.5</td>
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<tr>
<td>Serving Size: 20g (4 biscuits)</td>
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<table>
<thead>
<tr>
<th></th>
<th>Average Quantity Per Serving</th>
<th>Average Quantity Per 100g</th>
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<tbody>
<tr>
<td>ENERGY</td>
<td>350kJ</td>
<td>1750kJ</td>
</tr>
<tr>
<td>PROTEIN</td>
<td>2.2g</td>
<td>11.1g</td>
</tr>
<tr>
<td>FAT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- total</td>
<td>2.8g</td>
<td>14.1g</td>
</tr>
<tr>
<td>- saturated</td>
<td>1.5g</td>
<td>7.5g</td>
</tr>
<tr>
<td>CARBOHYDRATE</td>
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<td></td>
</tr>
<tr>
<td>- total</td>
<td>11.9g</td>
<td>59.7g</td>
</tr>
<tr>
<td>- sugars</td>
<td>1.0g</td>
<td>5.1g</td>
</tr>
<tr>
<td>DIETARY FIBRE</td>
<td></td>
<td></td>
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<tr>
<td>SODIUM</td>
<td>264mg</td>
<td>1320mg</td>
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</table>

List two factors that you think are healthy about the food:

List two factors that you think are unhealthy about the food:

6. Can you name the four food groups?

a. How many serves of each food group are we recommended to eat? (per day)
7. Are you aware of the ‘plate model’? Yes/No
   a. If yes, what is it?
   
   b. Feel free to use the space below to show/draw the plate model.

8. How much exercise is recommended to help with general health?
   
   a. Over the last week, how much exercise have you done each day? (in minutes/hours etc)
   
   b. What sort of activities has this included?
9. Please choose your current position on the following scales:

a. How important is it for you at the moment to be eating a healthy diet?

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<th>3</th>
<th>4</th>
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<th>6</th>
<th>7</th>
<th>8</th>
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<th>10</th>
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<td>Very important</td>
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b. How confident are you that you know what a healthy diet is?

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<th>7</th>
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<th>10</th>
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<tbody>
<tr>
<td>Not confident</td>
<td>Somewhat confident</td>
<td>Very confident</td>
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c. Thinking about the past month, how confident are you that you are currently eating a healthy diet?

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