The Diabetes Excess Weight Loss (DEWL) Trial:
High Protein vs Low Fat Diets

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Abstract

**Background:** Many studies have compared the effects of high protein diets (protein providing 25% or more of total energy) with relatively high carbohydrate diets (carbohydrate providing greater than 50% of total energy) on weight loss and blood lipids. Only five of those studies however, have been undertaken in individuals with type 2 diabetes and three of these studies were of short duration. Longer term studies are of particular interest in people with diabetes since substantial increases in protein intake may accelerate progression of renal disease especially in those who already have early nephropathy.

**Aim:** The Diabetes Excess Weight Loss (DEWL) Trial was a 2 year randomised controlled trial of 419 subjects to assess whether a high-protein:moderate-carbohydrate diet was more effective than a low-fat:high-carbohydrate diet in reducing weight and optimising glycaemic control, lipid profile and blood pressure in adults with type 2 diabetes. The impact of a high protein diet on renal function was also assessed.

**Methods:** Participants were recruited from the community by mail-outs, flyers and posters in Auckland, Wellington and Christchurch. The prescribed high-protein:moderate-carbohydrate diet consisted of 40% carbohydrate, 30% protein and 30% fat whereas the prescribed low-fat:high-carbohydrate diet consisted of 55% carbohydrate, 15% protein and 30% fat. Both diets aimed for no more than 10% of fat to be saturated. Both diets were energy reduced by 500kcal but participants could choose to follow either a portion system using 15g portions for protein and carbohydrate, or a prescribed 7-day sample meal plan. Recipes were provided that were specific to each diet. Participants were free living and provided all their own food. Participants were supported by group sessions with a dietitian, fortnightly for the first 6 months, then monthly for the second 6 months, with no intervention in the second year. Measurements (height, weight, waist circumference, blood pressure and body composition (% body fat and lean body mass)) and blood samples (HbA1c, fasting glucose, lipid profile) were obtained at baseline, 6, 12
and 24 months. A 24 hour urine collection was sampled for albumin:creatinine ratio and nitrogen, and an estimated 3-day diet record completed.

**Results:** Participants were 59% female, 74% NZ European and the average age was 57.9 years. Retention over two years was 70% with 294 participants completing the study. Overall participants maintained a 3kg weight loss in the intention to treat analysis. However, no differences were demonstrated between the diets for any variable. Protein intake in the high protein group was significantly higher than in the high carbohydrate group but did not reach the goal of 30% of total energy. An exploratory analysis of high protein intakes in pooled data using both categorical and continuous variables demonstrated that a higher protein intake was linked to lower triglycerides (multivariate estimate = -0.37 (95%CI -0.67, -0.06) p = 0.02) and better preservation of lean body mass (0.17kg per 1% increase in total energy from protein (0.04, 0.30) p = 0.01) at two years. However, systolic blood pressure at six months was higher in the higher protein categories (6.41 (0.75, 12.07) p = 0.03).

No adverse effects were observed on renal function. Seven individuals triggered the renal surveillance protocol on the study but were evenly distributed across the two diets. No differences between groups were observed for either serum creatinine or urinary albumin:creatinine ratio. In the exploratory analysis higher protein intakes were associated with a lower serum creatinine at two years (-7.97(-13.64, -2.30) p <0.01 and -8.89 (-16.03, -1.75) p = 0.02).

Analysis of qualitative information indicated that the influence of family and friends, eating out and lack of self-control were the major barriers participants faced in following their prescribed diet. Common themes from exit interviews included dissatisfaction with the allocated diet (22% of respondents) and lack of personal accountability (17% of respondents).

**Conclusion:** This study demonstrated that a high protein or high carbohydrate diet is equally effective for weight loss. Dietary compliance however was poor and drop out
rates were relatively high. In pooled analysis, a high protein diet is potentially beneficial in lowering triglycerides and serum creatinine while retaining lean body mass over time, but the effect on blood pressure requires further investigation. Achieving dietary change is difficult, thus in future targeting barriers identified by participants and using more focussed behaviour change approaches to food choices may improve dietary adherence.
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List of Abbreviations

ACR  Albumin:creatinine ratio
ADA  American Diabetes Association
AHS  Auckland Heart Study
BMC  Bone mineral content
BMI  Body mass index (kg/m^2)
BP   Blood pressure
CI   Confidence interval
CCK  Cholecystokinin
CRF  Chronic renal failure
CSIRO Commonwealth Scientific and Industrial Research Organisation
DEWL Diabetes Excess Weight Loss trial
DEXA Dual-energy x-ray absorptiometry
DIT  Diet induced thermogenesis
EASD European Association for the Study of Diabetes
EPIC European Prospective Investigation into Cancer
FM   Fat mass
FFM  Fat free mass
GFR  Glomerular filtration rate
GLP-1 Glucagon-like peptide-1
HbA1c Glycated haemoglobin
HDL  High density lipoprotein
HC   High carbohydrate
HP   High protein
IGF-1 Insulin-like growth factor-1
LDL  Low density lipoprotein
LFT  Liver function test
NZ   New Zealand
REE  Resting energy expenditure
sCr  Serum creatinine
SD   Standard deviation
S_I Insulin Sensitivity
T2DM Type 2 diabetes mellitus
TAG  Triglycerides
TE   Total energy
TEE  Total energy expenditure
TEF  Thermic effect of feeding
TGHb Total glycosylated haemoglobin
TTM  Transtheoretical model of behaviour change
ULN  Upper limit of normal
VAS  Visual analogue scale
WCRF Word Cancer Research Fund
WHO World Health Organisation
1. Introduction

With the social and financial burden of both type 2 diabetes mellitus and obesity increasing, weight loss remains the primary treatment in type 2 diabetes. The Look Ahead trial demonstrated that intensive lifestyle intervention and weight loss improved glycaemic control, blood pressure, blood lipids and kidney function in participants with diabetes over four years [1, 2]. The Diabetes Prevention Program demonstrated that as little as seven percent weight loss reduced progression to diabetes more effectively than treatment with metformin in patients with impaired glucose tolerance [3]. The “how’ of weight loss however, remains much more elusive than the “why”. Various diets become popular with little evidence to support their use, and with potential adverse effects not investigated. High protein diets have been investigated in the general population with some encouraging results, but there is as yet little evidence as to their efficacy and safety in people with type 2 diabetes. Particular concern exists as to the effect of protein on renal function in type 2 diabetes, making studies in this area a pressing need.

The Diabetes Excess Weight Loss (DEWL) trial was designed to answer the questions concerning efficacy and safety of high protein diets in people with type 2 diabetes. A free-living, community based setting with no food or supplements provided, was chosen as the closest simulation to what would be possible to deliver in primary care. The level of intervention was therefore required to be cost effective, and able to be repeated in general practice. The trial was the largest high protein intervention in type 2 diabetes to date in the world, involving eight investigators, five research nurses, five dietitians, three administration staff, 419 participants and three centres.

The candidate was involved in the development of the DEWL trial from the outset as a named investigator contributing to both the funding and ethics applications. Once funding was confirmed, the candidate developed, pretested and finalised the concept and materials for the dietary intervention, including portion lists, sample menu plans, handouts, recording book and sourced recipes. The Dietary Intervention Manual was written by the candidate, detailing the process of calculating energy requirements, initiating the diet and running the group sessions. The candidate contracted, trained
and managed the nutrition staff, and supervised a dietetic student research project within the trial. In Wellington, the candidate delivered half of the group sessions, and all the motivational messages were sourced or written and sent by the candidate. All participant randomization was directed by the candidate according to generated lists from the statistician. The candidate contributed the exit interview and pedometer instruction and recording sheets to the main investigators brochure.

As diet records were returned, the satiety scores were coded by the candidate, the diet records were then entered by data entry staff and checked by the candidate. The diet materials questionnaire was written, collated and analysed by the candidate. The candidate assisted with the data entry of questionnaires and clinical data and data cleaning, and completed all statistical analyses for this thesis under guidance, except those from the quality of life questionnaire. Finally, the candidate contributed to the financial management of the study, undertaking most of the purchasing and monitoring the budget.
2. Literature Review

2.1 Obesity and Type 2 Diabetes Mellitus

Obesity (body mass index (BMI) > 30) is a well established burden on both the primary and secondary health systems in New Zealand and internationally. The rate of obesity in New Zealand is currently 1 in 4 adults (26.5%) [4]. Dyslipidaemia, hypertension and abnormal glucose tolerance occur more frequently in overweight and obese adults, indicating an increased risk of type 2 diabetes (T2DM) and cardiovascular disease [3].

The prevalence of diagnosed diabetes in New Zealand is currently 4.3% among Europeans, with the figures rising to 5.8% for Maori, 6.5% for Asian and 10% for Pacific Island peoples [4]. Type 2 diabetes accounts for approximately 90% of this and the number of people with undiagnosed T2DM is unknown but expected to be substantial [5].

Diabetes places a heavy burden on the individual, the economy and the health system. The death rate in New Zealand attributable to diabetes in 1996 was 5%, with predictions of a small rise by 2011 [5]. Further modelling of the disproportional impact of diabetes on ethnic groups demonstrated that diabetes contributes to the gap in life expectancy between Maori and Europeans by 22-33% and between Pacific Islanders and Europeans by 26-42% [6]. Diabetes causes significant morbidity, leading to retinopathy, nephropathy, neuropathy, cardiovascular, microvascular and cerebrovascular disease [7]. Swinburn et al estimated the cost to the New Zealand health system from diabetes related incidents at 62 million dollars for the year 1991 [8]. This included inpatient admissions, outpatient and GP appointments, laboratory tests and subsidised medications. The same monetary cost today would be approximately 92 million dollars taking into account the rate of inflation, although the true cost today would be higher due to an increased prevalence of diabetes [9].
2.1.1 Diabetes and Weight Loss
Once T2DM has been diagnosed and if overweight or obesity is co-existent, weight loss becomes an integral part of treatment. Increased adiposity, particularly central abdominal adiposity, contributes substantially to insulin resistance [10]. Weight loss in T2DM achieves improved glycaemic control by increasing insulin sensitivity and possibly insulin secretion [11]. The improvements begin with caloric restriction, even before weight loss has occurred [11]. The beneficial effects are experienced regardless of age, with some suggestion that results may be more pronounced in the elderly [12]. Weight loss also results in lowered blood lipids, thereby reducing cardiovascular risk [13].

2.1.2 Historic Recommendations for Diet and Diabetes
The earliest treatment for T2DM was to restrict carbohydrate in the hope of reducing the insulin requirement. Truswell et al reported from a survey of clinics in the United Kingdom that in 1975, 92% of overweight people with T2DM were put on a low carbohydrate diet [14]. Around this time research groups were starting to experiment with high carbohydrate diets that were lower in total fat, higher in polyunsaturated fats and included large quantities of fibre (up to 105g per day) [15-17]. This type of diet, later known as the “high carbohydrate-low fat” diet, was shown to be as good as or better than a low carbohydrate diet for blood glucose control and had the added benefit of reducing total cholesterol with the fat manipulation. By the 1980s, a high carbohydrate high fibre diet had become the standard recommendation for T2DM [18]. The western population however continued to gain weight and the incidence of T2DM continued to rise, hence it was assumed that either this approach did not work, or patients could not comply. Attention was turned to other dietary approaches that might be more favourable to patients. Studies then aimed to manipulate dietary fat intake [19, 20] or carbohydrate intake [21, 22] with varying degrees of success regarding both compliance and maintenance of weight loss.

The very low-carbohydrate, high-fat diet achieved popularity with the resurgence of the Atkins Diet [23]. The aim of this approach is to reduce initial carbohydrate content to 20g per day and thus induce ketosis. The theory follows that this allows an individual to use fat stores for energy instead of glucose. A recent meta-analysis of five trials, totalling 447 individuals concluded that individuals following a low-
carbohydrate diet lost more weight at six months than those following a low-fat diet, but there was no difference for weight loss at one year [24]. The low-carbohydrate diet resulted in favourable changes to triglycerides and high-density lipoprotein levels, but the low-fat diet resulted in favourable changes in total cholesterol and low-density lipoproteins. There were no differences in blood pressure.

Recently attention has turned to protein, which may offer a less extreme dietary manipulation to aid weight loss, while maintaining glycaemic control and optimal cholesterol profiles, and appealing to patients for better compliance. A high protein (HP) diet is hypothesised to be beneficial in weight loss due to increased satiety [25-31] and thermogenesis [32-35]. There is also a proposed benefit on glucose metabolism, as unlike carbohydrate, protein does not result in a post-prandial glucose excursion [36, 37].

2.1.3 Current Recommendations for Diet and Diabetes

The two main diabetes organisations worldwide that produce nutrition guidelines for the treatment of T2DM are the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) [38, 39]. These guidelines are not always in agreement, and reflect the different dietary practises of the continents from which they draw. Dietary guidelines have become more flexible and less prescribed, with broad guidelines instead of fixed recommendations. This gives much more freedom of choice for the individual with diabetes, in conjunction with health professionals, to make decisions on which dietary pattern is best for them to follow.

The ADA’s latest position statement on medical nutrition therapy was published in 2008 [38]. The ADA in their latest statement has moved away from recommended macronutrient ranges, instead suggesting minimal limits. The EASD produced nutrition guidelines, written by the Diabetes and Nutrition Study Group, in 2004 [39]. These guidelines are still more traditional in setting out specific macronutrient ranges, and were used to inform the high-carbohydrate dietary intervention for the DEWL study. The relevant dietary advice on macronutrients from both organisations is summarised in Table 2.1.
<table>
<thead>
<tr>
<th>Macronutrient</th>
<th>ADA</th>
<th>EASD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrate</td>
<td>Include carbohydrate from fruit, vegetables, wholegrains, legumes and low fat milk. Monitoring carbohydrate intake is recommended. Use of the glycaemic index “may provide a modest additional benefit”. Sucrose containing foods may be exchanged for other sources of carbohydrate or compensated for by medication. Fibre intake is encouraged as per the general population.</td>
<td>Recommended intake between 45-60% TE. Eat a variety of fruits, vegetables, legumes and whole grain cereals. Where carbohydrate intake is at the upper end of the range, encourage foods high in fibre and low in glycaemic index. Low carbohydrate diets are not recommended. Quantity and type of carbohydrate should match medication.</td>
</tr>
<tr>
<td>Fat</td>
<td>Limit saturated fat to seven percent of total energy (TE). Minimise intake of trans fats. Limit dietary cholesterol to &lt;200mg per day. Recommended to consume two or more servings of fish a week.</td>
<td>Limit saturated and trans-fatty acids to &lt;10% TE. Monounsaturated fatty acids should provide 10-20% TE. Polyunsaturated fatty acids should provide &lt;10% TE. Total fat intake should be limited to 35% TE but in the overweight limiting this to 30% may aid weight loss. Two to three servings a week of fish is encouraged. Cholesterol intake should be limited to 300mg per day, less if low density lipoprotein (LDL) cholesterol is increased.</td>
</tr>
<tr>
<td>Protein</td>
<td>Suggests 15-20% of TE from protein, with a statement that diets</td>
<td>Protein is recommended to be between 10-20% of TE.</td>
</tr>
</tbody>
</table>
higher than 20% from protein have not been proven safe

| Weight loss | Either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short term (up to 1 year) |

### 2.1.4 Diabetes Group Education

The present study used group education as the platform to deliver the intervention.

Group education is a more effective use of resources compared with individual counselling [40] and allows for the sharing of common concerns and ideas [41]. Studies have tried to determine whether group based education interventions are more effective than one-to-one sessions in diabetes care [42-44] but the nature of the differences between these two styles of education make it difficult to determine if this one variable is the reason for differing outcomes.

Of particular note is a 5 year randomised controlled trial which looked at changes in knowledge, problem solving ability and quality of life in participants with T2DM who attended group education sessions versus those who received individual counselling (control) [44]. Knowledge of diabetes and problem solving abilities increased from year one of the intervention in the group participants while this worsened in the control group. A key aspect of the group intervention was that patients were encouraged to share personal experiences and to discuss real life situations in order to create positive group dynamics. This discussion exposed individuals in the group to life situations and problem solving experiences which the control group did not have access to. After two years quality of life improved for those in the intervention but
worsened in the control group. It was surmised that group dynamics and peer identification may improve self-perception and self-esteem while reducing disease-related anxiety. Knowledge in the group seemed to increase, rapidly over the first two years, while knowledge in the one-to-one group gradually declined. Like knowledge, HbA1c levels progressively worsened in the control group but not in the group care participants. Other health outcomes including HDL cholesterol and BMI improved in the individuals attending the group sessions and this may be the result of improved knowledge and self-esteem obtained by the group dynamic.

Group-based education can provide beneficial effects which individual sessions cannot, including interaction with and support from peers, opportunities to learn and gain motivation from each other through sharing experiences, beliefs and goals, reducing feelings of fear and isolation [42]. Groups provide an environment to help people accept their disease and facilitate behaviour change.

2.2 High Protein Diets

There is some debate as to the definition of a high protein diet, but an early review of the subject proposed that \( \geq 25\% \) of total energy (TE) intake as protein should be considered high, and \( \geq 35\% \) TE considered extremely high [45]. These categories are useful as protein \( \geq 35\% \) TE would result in an absolute amount of protein of 185g and higher for someone consuming 9000kJ per day. This is nearly twice the amount reported as routine consumption in people with T2DM in Britain [46]. As this amount could be too difficult to reach by free-living individuals, this review will adopt these categories and consider studies targeting 25 to 35% TE from protein.

2.2.1 High Protein Diets and Weight Loss

There have been a number of studies trialling a HP diet (25-34% TE) for weight loss in healthy obese subjects. Of the twenty studies listed in Table 2.2, nine demonstrated
a statistically significant greater weight or fat loss in those using a high protein diet [47-55]. Unfortunately there is no consistent factor that contributed to the success of these trials, but important predictors appear to be a high retention rate, a high level of compliance to the high protein diet and a high level of support to achieve this.

Claessons et al induced weight loss on a very low calorie diet for five weeks, then moved the participants to an ad libitum diet of either high carbohydrate (HC) with maltodextrin supplements, or HP with either whey or casein supplements [49]. Subjects on the HP diet had better weight maintenance than those on the HC diet and lost a significant amount more body fat despite being in the weight maintenance phase. The protein intake from 3-day diet records and confirmed by 24hr urinary nitrogen was approximately 10% (of TE) higher in the HP group than the HC group, plus the protein supplements added another 10% (of TE) again, resulting in a final difference in protein intake of 20% (of TE). However, as the participants were supplemented in both groups it makes this less applicable to a community setting.

Due et al followed 50 participants for two years with measurements taken at six, 12 and 24 months [50]. Energy intake was ad libitum and food was provided free for the first six months from a research based shop where food taken was monitored. An intense dietary counselling period then ran for the second six months. After 12 months 18% had dropped out and by 24 months 66% had been lost to follow up, greatly reducing the power of the study. Protein intake was significantly increased in the high protein group after the first six months, from 16% TE to 24% TE. After six months of the food being provided, the HP group lost significantly more weight (9.4 vs 5.9 kg) and body fat (7.6 vs 4.3 kg) than the HC group [50]. However the difference was not maintained to 12 or 24 months, despite the intensive dietary counselling between six and 12 months. The HP group gained 3.2kg and the HC group gained 1.6kg, which raises questions as to the sustainability of the diet in a free living community, if food is not being provided. However, it also illustrates that in an ad libitum trial, the high protein diet resulted in a lower energy intake.

The trial by Evangelista et al was described as a feasibility study (small sample size n=14) and included participants with both T2DM and heart failure [51]. This study consisted of three treatment arms with a HP, a HC and a conventional diet. The key
difference between the HC and conventional diet was that the HC diet was energy restricted, whereas the conventional diet was ad libitum, although both were based on the American Heart Association recommendations for healthy adults. Dietary counselling was provided fortnightly for those on the HC and HP diets. The only difference observed for body weight was for the HP group when compared to the conventional diet, which is to be expected as the HP group was energy restricted. The HP group however did lose significantly more body fat than the HC group. Critically no macronutrient data or energy intakes were reported, so it is difficult to assess the level of adherence. Despite the inadequate sample size, the results of this study were encouraging, with the HP group losing on average 9.9kg in 12 weeks compared with 2.5kg in the HC group, in a free living community and with guided food choice.

McAuley et al studied the effects of HC (55% carbohydrate, 15% protein), HP (40% carbohydrate, 30% protein) and high fat diets in 96 insulin resistant women [48]. Participants were given no formal energy restriction, but the first eight weeks were intended to be a weight loss phase with weekly dietary counselling sessions, followed by a further eight weeks of weight maintenance with similar counselling, and a final eight weeks with no contact. Participants were then invited back for a twelve month follow up. Total energy intakes were not significantly different between the diet groups at any time point, but were reduced from baseline. Neither diet group met macronutrient targets but the HP group consumed 20g more protein than the HC group. The HP group lost significantly more weight than the HC group at six months (8 vs 5.9 kg) [48], but the difference was not significant at 12 months [56], and there were no significant differences in body fat. The strength of this study was that individuals were free living and no food was provided, therefore participants had to make food choices for themselves making the findings more directly translatable to a real world setting.

The study by Meckling et al used a slightly different approach, comparing a 3:1 ratio of carbohydrate to protein with a 1:1 ratio, and the same diets with added exercise over twelve weeks [53]. In the diet only groups, fifteen participants were randomised to the HC group with only eight completing the study, and fifteen randomised to the HP group with only ten completing the study. As data from drop-outs were not included, this was not an intention-to-treat analysis. The authors considered that with
drop-outs the study was still powered to detect a 1.7kg difference in weight. Energy intake was reduced by 500kcal relative to their habitual intake determined by diet record at baseline, with all groups meeting this goal. The HP group consumed significantly more protein (84 vs 56g) and less carbohydrate (127 vs 171g) than the HC group. The HP group lost significantly more weight than the HC group and both exercise groups lost more weight than their corresponding diet only groups. The HP group with exercise lost the most weight (-7kg compared with -4kg for the HC group with exercise) and this was also statistically significant.

Two recent studies demonstrated significantly greater weight and fat loss on a HP diet when compared to a HC diet [47, 55]. In the first study, 83 women were energy-restricted for eight weeks [55]. The HC diet was deliberately also high in fibre (>35g) to ensure that the source of carbohydrate was the most appropriate. The HC group was provided with six servings per day of high fibre carbohydrate foods, and the HP group was given supermarket vouchers and instructed to purchase lean meat, fish and chicken. This high provision of food ensured good compliance, reaching 28% of total energy from protein in the HP group and a 1.3kg greater weight loss. In the second study, another 89 women were randomised to either a HP high fibre diet or a control diet for ten weeks [47]. Energy intakes were ad libitum in the first four weeks, then energy restriction was encouraged for the remaining six weeks. The control group received generic dietary advice based on the New Zealand Food and Nutrition Guidelines. The HP group were instructed to increase both protein and fibre intakes, and were provided with a main meal each day, some grocery items and a protein supplement. Both protein and fibre intakes were significantly higher on the HP diet. The changes in weight were already being seen at four weeks, before participants were encouraged to begin energy restriction. This study achieved 25% of total energy from protein, not as high as the previous study, even with significant food provision.

Some studies report greater weight loss in one diet but no differences in energy intakes. The diet record, however, which was used by eleven of the studies [47, 49-51, 53-58] to record food intake, is not sensitive enough to detect small differences in energy intakes, which over time could result in differences in weight loss [59]. Seven of these studies used 3-day records [47, 49, 51, 52, 55-57], one used a 5-day record [58] and three used a 7-day record [50, 53, 54]. Five studies reported weighed records
and the other six studies did not report whether they were weighed or measured. One study provided all meals pre-prepared and did not use any other measure of dietary intake [60]. Two studies used electronic records of departmental food shopping along with the diet records [50, 54]. A further two studies used three phone 24hr diet recalls [61, 62]. Finally four studies used weighed daily checklists [63-66].

While these nine studies showed significantly more weight and/or fat loss on a high protein diet, a further eleven studies [57, 58, 60-68] failed to show any difference in weight or fat loss (Table 2.2). Several suggestions could explain these differences including compliance measures, retention rate, whether food was provided, ad libitum versus fixed energy intakes or differences in dietary counselling. These nine studies are a mix of all of the above, with five providing food, and four not. Four were ad libitum and five were energy restricted. All had some degree of dietary counselling although the details were not always reported. However potential predictors of a successful outcome appear to be: a high level of support and counselling, some food provided by the study and shorter duration (less than six months) therefore a higher retention rate. Whilst level of counselling can be translated to “real world” situations, long-term provision of food clearly cannot which makes such studies rather artificial.

The magnitude of difference in weight loss in these studies, between the HP and HC groups, ranged from 0.9kg to 3.7kg, with an average of 1.9kg. While this difference may seem small, any weight loss is beneficial in diabetes, with as little as a 7% weight loss contributing as much benefit to insulin sensitivity as treatment with metformin as demonstrated in the Diabetes Prevention Programme [3].

The trials that failed to demonstrate a difference in weight loss between the diets however, were by no means lesser quality. Several also demonstrated high retention rates with high levels of compliance and good overall control. Others however did experience high drop out rates and hence corresponding reductions in the power of the study. Some studies quantified caloric expenditure whereas others did not, which may explain some of the differences in weight loss between groups.
Brinkworth et al published two high protein studies in the same year, one in individuals with hyperinsulinemia and one in people with T2DM [65, 66]. Neither study demonstrated any difference in weight or fat loss between the HP and HC groups. Both studies began with a period of energy restriction followed by energy balance. In both studies the HP group maintained better weight loss at the final time point but neither was statistically significant, probably due to the high drop out rates (34% and 58%) which reduced the power of the study.

Gardner et al compared four popular dietary approaches to weight loss – the Atkins, Zone, LEARN and Ornish diets over one year [61]. The Atkins and Ornish diets were ad libitum, whereas the Zone and LEARN diets advocated energy restriction. The commercially published diet books for each diet were used as the basis for eight sessions of dietary counselling with a dietitian. The Zone diet (HP) had the smallest weight loss of the four diets, despite no appreciable difference in energy intake between the diets. The Zone group achieved 23.7% TE from protein at month 2, compared with 27.7% TE in the Atkins group. It may have been that the Zone group did not achieve a high enough protein intake, considering the aim was 30%, although it was significantly higher than the LEARN and Ornish diets at 20.1 and 16.9% respectively. The Zone material may also have been too difficult to follow for participants as it was published, as the requirement to balance the carbohydrate, protein and fat blocks at each meal is complicated. Drop out numbers were similar across groups at 12-22%.

A small (20 participants), short (six weeks) but well-controlled study by Johnston et al produced all meals in a metabolic kitchen for consumption by participants [67]. The drop out rate was 20%, and compliance was reportedly good in remaining participants. However this study relied on participants to eat the food prepared for them and to reliably report uneaten portions. There were no differences in any measurements between diets for any time point.

Two studies by Luscombe et al also considered metabolic factors of energy expenditure in their analysis [57, 63]. Compliance was good, aided by the provision of key foods and dietary counselling. Drop out rates were 0 [57] and 16% [63] respectively. They were able to demonstrate that there was no difference in weight
loss between the groups, and that differences in resting energy expenditure (REE) and total energy expenditure (TEE) were explained by calorie restriction. Both studies also considered the thermic effect of feeding (TEF), both finding the effect greater following the HP meal at baseline, but no effect of diet by the end of the study. One of the studies however did demonstrate a time-by-diet-by-gender effect for women on the HP diet, experiencing a very small increase in TEF, compared to women on the LP diet experiencing a decrease in TEF [63].

While studies did not universally demonstrate a greater weight or fat loss with a high protein diet, not a single study demonstrated the opposite – that a high carbohydrate diet produced better results for weight or fat loss that were statistically significant.

2.2.2 High Protein Diets and Blood Lipids

Of the sixteen studies reporting blood lipids, seven reported statistically significant results (Table 2.3). No study showed an overall detrimental effect of a high protein diet on lipids. These results, however, do not all favour the HP diet, unlike the previous section on weight loss. One study demonstrated a positive result for total cholesterol for those on the HP diet [69]. Two studies favoured the HP diet for better HDL results, dependant on the type of protein and fat encouraged by the study. There was a differential benefit for plant derived protein and fats over animal sources [51, 52]. Two studies recorded a greater decrease in LDL on the HP diet [51, 69], but in contrast Layman et al demonstrated a six-fold greater decrease in LDL for the HC diet [52]. This corresponded to a dramatic decrease in saturated fatty acid intake seen in the HC diet but not the HP diet. The most consistent results for the HP diet appear to be in the effect on triglycerides, where six studies demonstrated a significantly greater decrease on the HP diet compared to the HC diet [51, 52, 56, 64, 68, 70]. High carbohydrate diets have been shown to increase plasma triglycerides however, so this effect is due to the reciprocal reduction in carbohydrate, rather than the increase in protein [71, 72]. As with any outcome variable these changes rely on compliance to the specified diet.
2.2.3 High Protein Diets and Glycaemic Control in Type 2 Diabetes Mellitus

While weight loss per se is important in the treatment of diabetes, the macronutrient composition of the diet may also have independent effects on glycaemic control. It is difficult to isolate the effects of one macronutrient in dietary intervention studies. To maintain an isoenergetic diet, changes in the proportion of one macronutrient must be balanced by reciprocal changes in the others. If the content of one macronutrient is altered in isolation then the necessary change in total energy intake will also have confounding effects. To date five studies have considered the effect of a HP diet and glycaemic control in subjects with T2DM (Table 2.4). A study of subjects with hyperinsulinemia, but without diabetes, suggested that protein may blunt the post-prandial glucose rise which in a person with diabetes may improve glucose handling and glycaemic control [64]. In a group with diabetes Evangelista et al measured HbA1c and reported no difference between the diets or control group, despite greater weight loss in the HP group [51]. This agreed with the findings of the most recent study (Larsen et al) where no difference was observed for HbA1c between diets at either three or twelve months [58].

Against this hypothesis, Gannon et al compared a 15% protein diet with a 30% protein diet in a crossover study of 12 subjects with untreated T2DM [70]. Subjects completed both diets for five weeks with a minimum of a two week washout period. All food was provided for both diets which ensured good compliance. Body weight was not reported but stated as unchanged throughout the diets. No significant difference was noted between diets for fasting glucose or insulin, but there was a significantly greater decrease in HbA1c on the high protein diet [70]. As fasting glucose was not affected, this suggests a decrease in post-prandial glucose excursions related to the high protein diet. Despite the small sample size and short duration this study was able to demonstrate an effect on HbA1c independent of weight loss. As food was provided this would have resulted in much higher compliance than that observed in a community setting.

Gannon et al used the same cross over design in a separate study to experiment with varying levels of total energy from fat and carbohydrate with protein constant at 30%. In the first study, the diet entitled Low Biologically Available Glucose, was tested on eight men in the five week crossover design [73]. This test diet was 30% protein, 20%
carbohydrate and 50% fat. After five weeks on the HP diet, fasting glucose and total glycosylated haemoglobin (TGHb) were significantly lower than after the HC diet.

The second study of eight men used a variation of the first diet, with 30% protein, 30 carbohydrate and 40% fat. Total glycosylated haemoglobin (TGHb) was significantly lower after the HP diet [74]. Only six of the eight subjects completed the cross over design, the remaining two completed only the study diet. The design of this study was also different in that subjects receiving hypoglycaemic agents prior to the study were taken off them, and then commenced on the diets after six weeks of stable blood glucose levels. This may have adversely affected measures of glycated haemoglobin as glycaemic control may have deteriorated without medication and would not be at a steady state after just six weeks. These studies are substantially higher in fat, and some of the effects may be due to the fat content rather than the protein level, or to the reduction in carbohydrate. The high fat levels may also be difficult to sustain in a free living population.

Sargrad et al randomised 12 subjects with diabetes to a self-selected, energy restricted HP or HC diet for eight weeks [62]. Patients were reviewed weekly by the dietitian and study team. No differences occurred in weight or fasting serum insulin in either group. Significant changes in HbA1c and fasting glucose concentrations occurred in the HC group only. The differences cannot be explained by dietary variables, as energy intakes were not different, and those on the HC diet actually consumed less fibre than those on the HP diet (p = 0.02). Insulin sensitivity was also improved in the HC group (SI by Euglycaemic Clamp method) with a 25% improvement in glucose disposal. [62]. Although patients were instructed to keep exercise levels the same, no data were presented to show that this was the case so it is difficult to know whether an increase in exercise contributed to the improvement in SI.

The weight loss achieved in both groups may explain the lack of differences between groups for SI. Overall there is not enough evidence currently to make any recommendations on the possible effects of a high protein diet on glycaemic control in people with T2DM beyond the very short-term.
2.2.4 High Protein Diets and Blood Pressure

Twelve of the described studies measured blood pressure (BP), with nine studies [49, 51, 53, 56, 58, 60, 61, 64, 65] reporting no effect of diet on blood pressure, and the remaining three studies reporting favourable effects for the high protein diet. Brinkworth et al found BP decreased equally in both diets over the active phase of the study, but the HC group experienced a greater increase in BP in the follow up period [66]. Te Morenga described a greater reduction of diastolic blood pressure (-3.7mmHg) in the high protein group [69]. Finally, a larger decrease was noted for the HP group by Sargrad et al, with systolic BP decreasing by 10.5 mmHg and diastolic by 18 mmHg [62]. This effect was independent of weight loss.

2.2.5 Protein and Satiety

One of the possible beneficial effects of a high protein diet is an increase in satiety, resulting in reduced caloric intake. As part of normal energy homeostasis, hunger increases as energy intake declines, to drive the individual back to equilibrium. This is a powerful and very fundamental biological system mediated by a number of hormones including leptin, ghrelin and GLP-1 among others. It is a system that involves the central nervous system, adrenal glands, gastrointestinal tract, pancreas and adipose tissue [75]. In obese people it is thought that this system is somehow faulty, with faltering mechanisms of satiety feedback, resulting in over-eating. The search continues for the explanations as to why obese people have reduced satiation and hence continue to over-eat. The drive to equilibrium contributes significantly to the difficulty for an individual to maintain weight lost. Therefore in obesity management the search for a macronutrient composition that will blunt the fall in satiety is important for long term adherence and sustained weight loss. Satiety can be measured in three ways, by visual analogue scale (VAS), by subsequent caloric intake after a preload or meal, and by hormonal response as measured by blood sample. Satiety is complex however, and is influenced not only by macronutrient composition but also by energy content, taste, meal weight and volume [76-78].

2.2.5.1 Studies using Visual Analogue Scales

Visual analogue scales (VAS) are subjective measures of hunger and satiety before and after eating. Visual analogue scales have been validated for appetite research in
both young and older participants. The scale is administered before and after a test meal with or without appetite suppressants, and the scores correlated with the amount of energy consumed. Studies have confirmed that the VAS assessment correctly relates to appetite [79, 80]. The visual analogue scale was used in the present trial to compare hunger and satiety between groups. Five studies in the non-diabetic population have used VAS to measure the perceived hunger and satiety of participants acutely consuming differing amounts of protein. All five studies demonstrated a positive relationship between protein intake and satiety [25, 26, 33, 81, 82]. A small study of university staff and students compared satiety of a high protein/high carbohydrate diet with a high fat diet [33]. The high protein/high carbohydrate diet resulted in significantly higher satiety scores than the high fat diet during meals and over the next 24 hour period. It is unknown however whether this was a result of the protein or carbohydrate content of the meal, or a combination of both. Vandewater and Vickers used high and low protein versions of yoghurt and pork sandwiches to demonstrate that the high protein versions resulted in less hunger and more stomach fullness than the lower protein versions [82]. However, while the yoghurts were identical in weight, the high protein sandwich was heavier than the low protein one (264g versus 181g). This is likely to have influenced the results as meal weight is known to affect satiety [78].

In the two studies considering longer term intakes however, results differed. Long et al reported a small increase in satiety following a HP meal for subjects who habitually consumed a low protein (LP) diet, once all meals were combined, but no significant differences for individual meals [83]. This small study divided the subjects in half according to habitual protein intake, so the lowest seven intakes formed the low protein group and the higher seven intakes the high protein group. The intakes of the high protein group were then increased to reach 2g/kg/day for two weeks, and the low protein group decreased to 0.65g/kg/day (usual recommendation 1.2g/kg/day). A high protein test meal was then given to both groups three times in one day and subjects scored ratings on a VAS before and after eating. In response to this test meal satiety was greatest in those on the LP diet. The lack of difference in satiety for the HP group in this study may be due to the habitual intakes of the subjects prior to the study having accustomed them to the effect.
Finally in a clinical trial of weight loss using a high protein/high fat diet, satiety was recorded using a cognitive eating restraint and hunger questionnaire over six weeks (The Eating Inventory) [84]. A significant decrease in hunger was noted from baseline to week six in the high protein/high fat group, but not in the high carbohydrate/low fat group. No differences were noted in eating restraint between diet groups.

2.2.5.2 Studies using Preloads or Meals

Nine studies have considered the effect of a high protein meal or preload on subsequent caloric intake in the non-diabetic population. Of these, seven studies found favourable effects of protein in reducing the subsequent caloric intake [26-31, 85]. Latner and Schwartz gave isocaloric liquid lunches consisting of predominantly either protein or carbohydrate or a mixture of the two and then measured caloric intake at dinner [27]. At the subsequent meal, caloric intake was 20% higher after the carbohydrate lunch than after the mixed lunch and 33% higher than after the protein lunch. Barkeling et al tested a high protein compared with a high carbohydrate lunch on ad libitum dinner intake [28]. Subjects ate 12% fewer calories at the dinner meal after the high protein lunch. This study however used a meat meal versus a vegetarian meal, which may have influenced taste and palatability. Poppit et al compared the effect of a carbohydrate, protein, fat or alcohol preload on the caloric intake of lunch 90 minutes later [29]. The protein preload resulted in the lowest energy intake at lunch. Porrini et al compared high protein and high fat foods as a preload (first course of a meal) or as a snack two hours before a meal [30]. The protein preload resulted in a lower energy intake than the fat preload being consumed at the meal. There was no difference in energy intakes following either snack however.

For the two studies that found no reduction in subsequent energy intake after a protein preload, both looked further than one subsequent meal to total energy intake over the day. De Graaf et al compared the effect of high carbohydrate, fat or protein liquid breakfasts of three different energy contents on energy intake for the rest of the day, and one control meal (8kcal) in a total of ten different tests [76]. No differences were noted in energy intake over the day for any test meal. Stubbs et al gave high protein, carbohydrate or fat breakfasts and an equal mix of the three macronutrients [86]. Subjects ate more at the subsequent meal after the high fat breakfast than the other three but this corrected itself by dinner and total daily energy intake was then similar
across all groups. Taken together, the evidence suggests that while protein may contribute to an immediate reduction in caloric intake, this may not persevere past the subsequent meal. None of these studies has specifically addressed the effect of repeated high protein meals on ad libitum energy intake over 24 hours in a controlled environment.

### 2.2.5.3 Studies using Measures of Hormonal Change

There are several hormones produced in response to food intake that are considered to be markers of satiety, including ghrelin, cholecystokinin (CCK), glucagon-like peptide-1 (GLP-1) and leptin. There is insufficient research currently on the differences between the general population and the T2DM population so this section focuses on what is known in the general population. There is likely to be some differences in those with long-standing T2DM as delayed gastric emptying is a possible long term adverse effect of T2DM. Ghrelin levels increase before meals to prompt hunger and food intake and decrease after eating [87]. Ghrelin decreased with weight loss in one study and there was no effect of diet or meal composition. This study used two test meals, one high protein, one high fat, before and after three months of weight loss and one month of weight maintenance with the same diets [88]. In two similar studies ghrelin increased after an oral glucose preload, then caloric intake at a subsequent buffet meal was 10% higher after the glucose preload [89, 90]. In the second study the ghrelin concentration fell to below baseline by 180 minutes after the protein preloads, indicating satiety, but remained elevated following the glucose preload [90]. Lejuene et al however found no difference in ghrelin concentrations between subjects fed either a HP or normal protein diet for 24 hrs in a respiration chamber [91].

Erdmann et al conducted two studies to elucidate the action and importance of ghrelin in satiety, neither of which demonstrated any relationship between ghrelin and satiety [92, 93]. The first study used test meals of high carbohydrate, protein or fat and also a vegetable and fruit test meal [92]. Subjects were then offered a meal four hours later. The highest intake of food at the subsequent meal occurred after the fruit and vegetable test meals and the lowest after the fat meal. Ghrelin was significantly decreased after the carbohydrate meal but increased after all other meals. No correlation occurred between ghrelin and satiety, but ghrelin predicted later hunger
and the amount eaten at the subsequent meal. Overall the literature around ghrelin and satiety per se remains confusing.

Cholecystokinin inhibits gastric emptying and reduces food intake [87]. Cholecystokinin in the first preload study was higher after the protein preloads which corresponded with satiety but did not translate to less energy intake [89]. In the second preload study GLP-1 and CCK remained high following the protein preloads for longer than after the glucose preload, suggesting greater satiety [90]. Blom et al however, tested a high protein and a high carbohydrate breakfast and observed no difference in VAS scores of satiety or subsequent energy intake, despite the HP meal increasing CCK and decreasing the gastric emptying rate [94].

Glucagon-like peptide-1 inhibits gastric emptying and energy intake [87]. Lejeune et al fed subjects either a HP or normal protein diet for 24 hrs in a respiration chamber [91]. Satiety measured by VAS was higher during the HP diet and GLP-1 concentrations were increased after dinner on the HP diet compared with the normal protein diet.

Leptin is secreted by adipose tissue and inhibits food intake [95]. Weigle et al used isocaloric high or normal protein diets for two weeks, followed by a period of ad libitum intake for 12 weeks in 19 subjects [96]. Carbohydrate intake remained constant on both diets. For subjects on the HP diet, satiety increased and hunger decreased as measured by VAS, and energy intake spontaneously decreased on the ad libitum diet. This study noted no difference in circulating leptin concentrations while on the HP diet, but on the ad libitum diet following, leptin concentrations decreased and ghrelin concentrations increased. This is counter-intuitive to the expected effect, but suggests that perhaps leptin and ghrelin are more responsive to weight loss and lowered caloric intake, and that the satiating effect of protein counteracted this.

In summary it appears that there may be some favourable effects of protein on satiety in the short term. Protein appears by these measures to be consistently more satiating than fat, but not always more satiating than carbohydrate. It also seems that while protein may induce changes in appetite hormones, notably CCK and GLP-1, this does not always lead to a reduction in energy intake. The relationship between background
hormonal milieu, level of body fatness and the acute changes in these hormones with energy intake, physical activity and other factor is extremely complex. Understanding of these hormonal changes in relation to diet composition and caloric intake is still very limited, and much research is yet needed before this is clarified. These studies were also highly variable as to the percentage of the test macronutrient in meals or preloads, use of normal or overweight subjects and whether the subjects were in energy balance making it difficult to compare studies. Often artificially constructed foods were used that are not representative of usual intake making it difficult to translate the research into a community setting.

2.2.6 Protein and Energy Expenditure
It has been suggested that an advantage of increased protein intake in promoting weight loss is that it may increase energy expenditure, namely through increased diet induced thermogenesis (DIT). Diet induced thermogenesis forms only a very small fraction (approx 10%) of an individuals’ total daily energy expenditure, although it is conceivable that meaningful increases to DIT could be significant.

Crovetti et al observed a DIT (measured by indirect calorimetry) of 261 ± 59 kJ for a HP meal, compared to 92 ± 67 kJ for a HC meal and 97 ± 71 kJ for a high fat meal where the energy content of the meal was the same [35]. The high protein meal was the most thermogenic (p < 0.001). Robinson et al reported a significantly higher DIT over the subsequent nine hours after a protein meal was 9.6 ± 0.6% of the total energy intake versus 5.7 ± 0.4% after a high carbohydrate meal (p<0.01) [34]. This study also used indirect calorimetry. Using an equation based on ATP requirements, the study estimated that 36% of the DIT for the carbohydrate meal and 68% for the protein meal would have been used for an increase in protein synthesis. Also using the ventilated hood, Raben et al found that while alcohol produced the largest increase in DIT, protein produced a response 17% higher than carbohydrate and fat [32]. In the previously described highly controlled study in a respiration chamber, Westerterp-Plantenga et al demonstrated that in lean women a high protein/high carbohydrate diet produced a greater DIT than a high fat diet [33]. Finally, Claessens et al observed a higher DIT for soy protein than for carbohydrate, but not for pea protein suggesting that protein source, and potentially the amino acid composition, may also be relevant [97].
Therefore the few studies reported seem to be in agreement that protein increases DIT more than carbohydrate and fat, but whether this makes a clinical difference in weight loss is unknown. The DIT observed by Crovetti et al of 261 kJ for the HP meal would constitute around 3% of a daily intake of 8000 kJ. This could potentially contribute to a small and gradual weight loss if sustained over time if all of the increase in DIT was available, which the study by Robinson et al suggests it may not be [34].

2.2.7 Effect of Protein on Glycaemic Response
Postprandial insulin and glucose responses are related, in part, to the rate of gastric emptying, and hence the effect of protein on gastric emptying may predict its effect on glycaemia. The addition of protein to glucose during an oral glucose tolerance test increased the gastric half-emptying time from 45 minutes for glucose alone to 51 minutes with the addition of protein. The test meals were 300ml drinks containing either 50g glucose, 30g protein, or both combined. Blood glucose levels were lower at their peak with the addition of protein in healthy men (8.0 vs 9.4) [37]. An earlier study with the same approach showed the addition of protein to the glucose load increased insulin secretion approximately twofold compared with glucose alone [36]. A separate study by Claessens et al demonstrated that soy protein resulted in a glucagon response, but no glucose response, whereas carbohydrate induced the opposite effect [97]. This study also used drinks as the test meal in healthy male volunteers. This suggests that protein exerts a balanced increase in insulin and glucagon secretion.

2.3 Potential Risks of High Protein Diet

As HP diets have gained popularity there have been some concerns raised that there may be risks associated with increasing the protein content of the diet. This relates primarily to renal function, bone loss and cancer risk. Three observational studies have looked at the mortality risks of low carbohydrate and increased protein diets. Trichopoulou et al used data from the Greek sample of the European Prospective Investigation into Cancer and Nutrition (EPIC) study, comprising 22 944 men and women aged 20-86 [98]. The highest protein decile consumed was 20%TE. The
analysis demonstrated a reduction of total mortality for the highest intake of carbohydrates (mortality ratio 0.94, 95% CI 0.89-0.99) and reported a non-significant increase in total mortality for the highest intake of protein (1.02, 95% CI 0.98-1.07). While the increase in mortality was non-significant, it would have been interesting to see if this trend had continued with a higher protein intake. On the other hand however, it may suggest that intakes are not realistically sustained above 20%TE.

Adding together the high protein score with the low carbohydrate score produced a mortality ratio of 1.22 (95% CI 1.09 – 1.36). This indicates that the effect may be more influenced by reduced carbohydrate. There are also potential confounding issues with such an observational study that the habitual diet may be due to underlying disease rather than causally related to the disease.

The study by Lagiou et al used a cohort of 49, 261 Swedish women aged 30-49 from the Women’s Lifestyle and Health study [99]. These women had a slightly higher maximum protein intake at 23%TE. The risk of mortality for every decile less carbohydrate was 1.06 for all causes (1.00-1.12) while the risk was 1.10 for every decile higher protein (1.01-1.2) for cardiovascular mortality. While the study controlled for saturated fat intakes, the suggestion is that reduction of fruit, vegetables and fibre with a possible increase in meat consumption may explain these findings [99].

An analysis of mortality due to low-carbohydrate diets was undertaken using the Nurses Health Study and the Health Professionals Follow Up Study [100]. This study specifically looked at low-carbohydrate score, not protein. The results demonstrated a mortality score of 1.23 (95% CI 1.11 – 1.37) for low carbohydrate diets from animal sources but a mortality score of 0.80 (95% CI 0.75 – 0.85) for low carbohydrate diets from vegetable sources. This implies an effect of either the protein or fat contents of these diets, or both, but not necessarily the carbohydrate.

While epidemiological studies can only identify questions and examine associations, the risks illustrated by these three studies are concerning and should elicit caution until the effects of such diets are better understood.
2.3.1 Renal Function

A low-protein diet has been the standard recommendation for the treatment of moderate to severe microalbuminuria for some twenty years. A modest benefit of slowing disease progression has been demonstrated by reducing the urinary protein excretion [101]. The suggestion then follows that a high protein diet might accelerate renal disease in susceptible individuals, for example those with T2DM. Studies in T2DM however are limited. Pijls et al randomised 63 people with T2DM and microalbuminuria to protein restriction of 0.8 g/kg/day and 68 to a control group and followed them for 28 months [102]. No significant differences were found in glomerular filtration rate (GFR) or microalbuminuria but the difference in protein intake was not sustained past six months. Analyses were adjusted for age. This does not support the need for protein restriction.

Meloni et al have conducted two studies in subjects with either type 1 or type 2 diabetes, with results not separated for type [103, 104]. Both studies achieved good compliance with protein intake. The earlier study included 69 people with type 1 or 2 diabetes and diabetic nephropathy [103]. The participants were randomised to either a low protein diet (0.6g/kg/day) or an ad libitum diet. There was no significant difference between the two groups for GFR after twelve months. The latter study compared a group of 80 patients with diabetic nephropathy (type 1 and 2) with a group of 89 suffering from chronic renal failure (CRF) but no diabetes [104]. Half of each group were assigned to a protein restriction (0.8g/kg/day) and the other half to an ad libitum diet. There were no differences in measures of renal function in the group with diabetes, but in the CRF only group there was a significant reduction in the rate of decline of renal function in the protein restricted group, suggesting a low protein diet is appropriate for treatment of CRF of other causes.

Therefore the evidence available suggests that in type 2 diabetes protein restriction does not slow the progression of renal failure in patients with some renal impairment. Is there evidence that a high protein diet or an increase in protein intake accelerates renal impairment? Two of the previously discussed HP weight loss studies also monitored serum creatinine and reported no changes for either study group [62, 70].
A cross sectional study by Summerson et al recruited 283 patients with T2DM and tested for an association between proteinuria and dietary protein intake [105]. There was no statistically significant association of protein intake with microalbuminuria. A second cross sectional observational study however did find a significant association, with patients with microalbuminuria consuming more protein and more animal protein than patients with normal renal function [106]. Once again the cross sectional data is unable to establish causality, no conclusion can be drawn from this on whether increases in protein result in microalbuminuria.

2.3.2 Bone Loss
It has been suggested that protein from animal sources reduces bone mineral content, due to producing a net acid excreting state, which requires calcium from bone to buffer, thereby reducing calcium stores [107]. Since increasing total protein intake in non-vegetarians is likely to increase animal-protein intake, this is potentially a concern. The observational study often cited to support this hypothesis demonstrated that in older women, a high ratio of animal to vegetable protein resulted in a greater risk of hip fracture [107]. Older women who have diabetes may also be at higher risk of fractures due to diabetes complications such as neuropathy and retinopathy increasing the risk of falls [108]. High protein diets have been observed to increase calcium excretion, which is at least partly due to increased bone resorption [109].

Three of the weight loss studies described measured markers of bone turnover. Noakes et al described a cascade of changes related to weight loss, where bone resorption markers increased with weight loss but some increase in bone formation markers were also seen to compensate [68]. As there was no difference in bone markers between the two diets, it seems that weight loss may be more important than diet. Farnsworth et al also observed no diet effect on bone turnover or calcium excretion [64]. The previously reported study by Skov et al published a separate paper on the effect of their weight loss study on bone mineral content (BMC) using DEXA [110]. BMC declined after six months by 4% and 3% respectively, and was correlated with loss of fat mass. Protein sources were mainly dairy and meat products. Once loss of fat mass was adjusted for, the low protein group lost significantly more BMC than the high protein group.
There is some evidence that protein may be protective of bone as higher protein diets increase the production of IGF-1, which in turn promotes bone formation [111].

In conclusion, while observational studies have shown possible detrimental effects of a high intake of protein on bone, which may be more relevant if from animal protein, intervention studies have failed to demonstrate such effects. The observational studies however were cross-sectional and therefore cannot account for active weight loss. As weight loss results in a reduction in bone mineral content regardless of diet, a higher protein level may ameliorate the effects of this.

2.3.3 Cancer

There have been no reported risks for protein itself in regards to cancer. Red and processed meat consumption however, which may constitute a significant amount of protein intake, is associated with colorectal cancer in particular, and less consistently with stomach, pancreas, lung, oesophagus, prostate and endometrium [112, 113].

The World Cancer Research Fund (WCRF) report gives the highest level of evidence to the link between red and processed meat and colorectal cancer, labelling the link “convincing” [112]. The meta-analysis they conducted on ten cohort studies estimated an effect of 1.43 (1.04-1.60) per number of times a week red meat was eaten, and 1.29 (1.04-1.60) per 100g of red meat consumed per day. Suggested mechanisms for the link between red meat and cancer include the production of carcinogenic agents from gut microbiota, high cooking temperatures and haem iron. For processed meat there were only five studies suitable for meta-analysis, producing an estimated effect of 1.21 (1.04-1.42) per 50g processed meat per day. The mechanisms for processed meat causing cancer are the same as those of red meat, with the added mechanism of nitrate preservatives which produce N-nitroso compounds, suspected carcinogens [112].

Another recent meta-analysis of both red and processed meat confirmed the WCRF findings, with relative risks of 1.28 (1.15-1.42) per increase of 120g per day of red meat and 1.09 (1.05-1.13) per increase of 30g per day of processed meat [114].
The WCRF report also concludes there is limited evidence linking red meat to cancer of the oesophagus, lung, pancreas and endometrium, and processed meat to cancer of the oesophagus, lung, stomach and prostate [112].

On the other hand, a meta-analysis of thirty prospective studies examining the impact of obesity on colorectal cancer demonstrated that for every 5 point increase in BMI, risk of colon cancer increased in both men and women [115]. The association was stronger in men, with a risk ratio of 1.30 (95% CI: 1.25, 1.35) compared with a risk ratio of 1.12 (95% CI: 1.07, 1.18) in women. Risk of rectal cancer was also increased in men only. This suggests that obesity itself may contribute significant risk to this type of cancer, and therefore any weight loss that can be achieved may reduce the risks of colorectal cancer.

2.4 Conclusion

Overall from current evidence there may be a small advantage of a high protein diet on weight loss, fat loss, preservation of lean body mass and triglyceride levels relative to a high carbohydrate diet. Currently there is not enough evidence to comment on the effect of a high protein diet on glucose and insulin metabolism or glycaemic control in those with type 2 diabetes. Furthermore there appears to be no consistent effect on LDL, HDL or total cholesterol concentrations. Current studies are also generally short in duration and limited evidence exists for long-term effects on weight and weight-related morbidity and mortality.

All successful dietary weight loss interventions reviewed included a significant amount of intensive dietary counselling, and many provided food for the participants. Whilst in the context of a clinical trial this may contribute to a higher participant retention rate and therefore a more successful study, it does not help translate the findings to a free-living community population. Moreover it also dramatically increases the cost of implementation if the intervention is successful. This highlights the difference between an efficacy trial and an effectiveness trial.
It appears that there may be minimal risk of renal damage and bone loss with a high protein diet, but there may be a real risk of colorectal cancer if red and processed meat consumption increases as protein intake increases.

There is a clear need for further research into the effects of high protein diets in type 2 diabetes on weight loss, blood lipids and glycaemic control with follow up greater than one year duration. When considering the successful trials to date in order to design an intervention, available resources must be balanced with the desired sample size, number of measures and the applicability of the result to real world practise. With a higher sample size comes the necessity of more financial restraint, making provision of food and individual counselling less viable options. Although several successful trials did provide food, others did not [51-53, 56], making no food provision a feasible option. Most studies used individual dietary counselling, but two studies used group sessions [50, 52] and both of those reported greater weight loss for the high protein diet, demonstrating that this method of intervention delivery can also be successful.

The primary aim of the DEWL study was to assess whether a high-protein:moderate-carbohydrate (30% protein, 30% fat, 40% carbohydrate) diet was more effective than a low-fat:high-carbohydrate (15% protein, 30% fat, 55% carbohydrate) diet in reducing weight and maintaining weight loss in subjects with type 2 diabetes over two years. It is the hypothesis of this thesis that a high protein diet would result in better outcomes for all variables of interest.
3. Methods

3.1 Design of the Diabetes Excess Weight Loss Trial (DEWL)

The DEWL study was a two-year, community-based randomised controlled trial, conducted over three sites. The primary aim was to assess whether a high-protein:moderate-carbohydrate (30% protein, 30% fat, 40% carbohydrate) diet was more effective than a low-fat:high-carbohydrate (15% protein, 30% fat, 55% carbohydrate) diet in reducing weight and maintaining weight loss in subjects with type 2 diabetes over two years. The secondary aim was to assess whether a high-protein:moderate-carbohydrate diet was more effective than a low-fat:high-carbohydrate diet in improving glycaemic control, insulin sensitivity, lipid profile and blood pressure without adverse effects in subjects with type 2 diabetes over 2 years. The third aim was to assess the impact of the higher protein diet on renal function and hence the safety of use of such diets in those with type two diabetes. The DEWL trial was funded by a grant from the New Zealand Health Research Council (HRC 06/337) and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12606000490572). Ethical approval was granted by the Multi-Regional Ethics Committee on 25th October 2006 (MEC/06/08/081).

Primary outcomes measured were weight and waist circumference. Secondary outcomes included were HbA1c, systolic and diastolic blood pressure, lipid profiles (LDL, HDL and total cholesterol, triglycerides), dietary compliance, body composition (bio-impedance), renal function (urinary albumin/creatinine ratio and serum creatinine (sCr)), and quality of life.

3.1.1 Sample Size Calculation

The sample size was calculated on the basis of differences in key outcomes demonstrated in a similar intervention trial, and data from an unselected group of people with diabetes in New Zealand [56, 116]. Information regarding expected changes in HbA1c were derived from Samaha et al investigating the effects of a low carbohydrate diet on weight loss in obese subjects [22]. The attrition rates for long term dietary intervention studies can be high. Factors influencing this include duration
of study, intensity of follow up and extent of dietary change required. On the basis of
studies carried out at the Department of Human Nutrition, University of Otago, it was
decided to assume a possible attrition rate of 20%. Given the sample size calculations
presented in Table 3.1 and resulting rate of attrition it was decided to aim for between
390 and 450 participants.

**Table 3.1** Sample size calculations for chosen outcome variables, based on expected
change over two years

<table>
<thead>
<tr>
<th>Variable</th>
<th>Estimated difference in change*</th>
<th>Standard Deviation (SD)*</th>
<th>Correlation†</th>
<th>Adjusted SD</th>
<th>Number per group</th>
<th>Total 20% attrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, kg</td>
<td>2.2</td>
<td>15.3</td>
<td>0.97</td>
<td>3.7</td>
<td>45</td>
<td>90</td>
</tr>
<tr>
<td>Waist, cm</td>
<td>2.8</td>
<td>11.5</td>
<td>0.75**</td>
<td>8.13</td>
<td>133</td>
<td>266</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>0.6@</td>
<td>1.43#</td>
<td>0.57</td>
<td>1.33</td>
<td>78</td>
<td>156</td>
</tr>
<tr>
<td>HDL, mmol/l</td>
<td>0.07</td>
<td>0.29</td>
<td>0.71</td>
<td>0.22</td>
<td>156</td>
<td>312</td>
</tr>
<tr>
<td>Systolic BP mmHg</td>
<td>3.0</td>
<td>10.3</td>
<td>0.42</td>
<td>11.3</td>
<td>224</td>
<td>448</td>
</tr>
</tbody>
</table>

Formula: Adjusted SD = Sqrt(2(1-corr)) x SD

*source: difference in change at 12 months comparing high carbohydrate diet with
high protein diet, and SD at 12 months (average SD of HP and HC groups)
McAuley et al, 2006 [56]

†source: 2003 and 2004 diabetes register for people with HbA1c>7 [116]
@ HbA1c change estimate from Samaha et al 2003 [22]
**Waist correlation estimated from McAuley et al, 2006 [56]

3.1.2 Subject Recruitment

A total of 419 subjects were recruited across three centres (186 in Wellington, 131 in
Auckland and 100 in Christchurch). Recruitment was achieved over eleven months by
targeted letters to both hospital and general practice clinic patients, flyers in
newsletters (Diabetes Society, industry mail-outs, churches), posters in general
practices and hospital departments, advertisements (Diabetes Magazine) and press
releases.

All three of the following inclusion criteria were required to be met:

1. Previous confirmed diagnosis of Type 2 Diabetes Mellitus of either:

a. A fasting plasma glucose greater than 7.0 mmol/l on more than one
   occasion; or
b. A two hour, 75g oral glucose tolerance test in excess of 11.1 mmol/l
2. BMI ≥ 27kg/m²
3. Aged 30-75 years

The following exclusion criteria applied:
1. HbA1c > 9.5% (chosen as it was considered major changes in medication would be required with such levels)
2. Weight > 200 kg (the upper limit of the Tanita Scales)
3. Current or recent unexplained weight change (>3kg) in 3 months. If a participant had lost weight voluntarily they were asked to cease weight loss efforts.
4. Pregnancy or lactation
5. Diabetic nephropathy (urinary albumin/creatinine ratio >70, sCr >160 μmol/L) or other chronic renal failure resulting in glomerular filtration rate of <30.
6. Abnormal liver enzymes (AST, ALT or GGT >3 x upper limit of normal)
7. Active gallbladder disease (Cholecystitis in last 12 months, ongoing biliary colic)
8. Myocardial infarction in the last 6 months
9. Severe heart failure (New York Heart Association class III or IV)
10. Known malignancy, other than squamous cell or basal cell carcinoma of the skin, that has not been in full remission for at least 5 years prior to screening
11. Ongoing oral steroid use
12. Use of duramine, sibutramine or orlistat
12. Other reasons why taking part would be practically difficult e.g. vegan

Figure 3.1 describes the recruitment process. Potential participants were screened by telephone (pre-baseline questionnaire: Appendix A) by the research nurses (or the candidate in Wellington). Blood results were obtained for HbA1c, serum creatinine and liver function. Figure 3.2 describes the process of obtaining and interpreting blood results for inclusion in the study. Once all blood results and relevant medical information had been obtained from the pre-baseline questionnaire, those that were eligible were invited to attend a consent meeting. At the consent meeting the study was explained in more detail by the investigating physician, the research nurse and
dietitian at each centre (the candidate in Wellington). If the participant was still willing to take part and all criteria had been satisfactorily met, the consent form (Appendix B) was signed at the consent meeting. The participant then attended a baseline visit where all other study measurements were taken, the participant was randomised to a diet and subsequently enrolled in a group meeting.

3.1.3 Development of Intervention Resources

All dietary intervention materials were developed by the candidate. The control (high carbohydrate) and intervention (high protein, moderate carbohydrate) diets were developed based on a portion system of 15g of both protein and carbohydrate. Table 3.2 illustrates the nutrient composition of the diets. The control diet consisted of 55% total energy from carbohydrate, with predominantly low glycaemic index, whole-grain foods and a high fibre intake (≥25g/day). The balance of the diet was composed of 30% fat, with no more than 10% being saturated fat, and approximately 15% protein. This diet was based on recommendations for people with diabetes from the European Association for the Study of Diabetes [39]. Recipes for the control diet were provided with permission from the following recipe books; “Diabetes Eat and Enjoy”, 3rd Edition by Christine Roberts, Jennifer McDonald and Margaret Cox, “The Low GI Diet Cookbook” by Professor Jennie Brand-Miller, Kaye Foster-Powell and Joanna McMillan Price and The Best of Food for the Heart, National Heart Foundation cookbook. A sample diet plan was provided specific to the combination of protein and carbohydrate portions, along with food charts to enable easy portion choices.

The intervention diet consisted of 40% total energy from carbohydrate also with a focus on whole-grains and low glycaemic index foods, high fibre (≥25g/day) and 30% total energy from protein. The balance of the diet was composed of 30% fat, with no more than 10% being saturated fat. This diet was based on the high protein “Total Wellbeing Diet” developed at the Commonwealth Scientific and Industrial Research Organisation (CSIRO) of Australia [68]. Recipes for the intervention diet were provided from the following recipes books with permission; “The CSIRO Total Wellbeing Diet Book” by Manny Noakes and Peter Clifton, “Diabetes Eat and Enjoy”, 3rd Edition by Christine Roberts, Jennifer McDonald and Margaret Cox, “The Low GI Diet Cookbook” by Professor Jennie Brand-Miller, Kaye Foster-Powell and
Joanna McMillan Price and The Best of Food for the Heart, National Heart Foundation cookbook.

*Table 3.2* Nutrient composition of the diets

<table>
<thead>
<tr>
<th></th>
<th>High Carbohydrate</th>
<th>High Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbohydrate</td>
<td>55% of total energy</td>
<td>40% of total energy</td>
</tr>
<tr>
<td>Protein</td>
<td>15% of total energy</td>
<td>30% of total energy</td>
</tr>
<tr>
<td>Total fat</td>
<td>30% of total energy</td>
<td>30% of total energy</td>
</tr>
<tr>
<td>Saturated fat</td>
<td>10% of total energy</td>
<td>10% of total energy</td>
</tr>
<tr>
<td>Dietary fibre</td>
<td>25g per day</td>
<td>25g per day</td>
</tr>
</tbody>
</table>

For each participant, energy requirements were estimated based on Harris Benedict predictions (Women - [655 + (9.6 x weight) + (1.7 x height) – (4.7 x age)] x 1.3, Men - [66 + (13.7 x weight) + (5 x height) – (6.8 x age)] x 1.3[117]) taking into account diet induced thermogenesis but assuming subjects were sedentary (no physical activity factor). It was anticipated that weight loss would be achieved by not taking physical activity into account and making a reduction of 2000kJ/day for those weighing less than 150kg or a reduction of 4000kJ/day for those weighing 150kg – 200kg. The rationale for the greater reduction for those of higher weight was to reduce the prescribed food intake to more manageable levels, particularly for the HC diet which was high in bulk. The number of 15g protein and carbohydrate portions allocated was then calculated from the energy requirement and specific to the allocated diet.

While the highest eligible weight for a participant was 200kg, which gives an estimated energy requirement of 14,000kJ, it was decided that the sample menu plans would be written up to 10,000kJ. This is the level of food intake which was decided to be reasonable for participants to consume, particularly given the bulk of the high carbohydrate diet (10MJ entailed 21 carbohydrate portions on the high carbohydrate diet). Participants with an estimated energy requirement greater than this were given the amount of carbohydrate and protein portions that related to their energy requirement, but the 10,000kJ sample menu. They were encouraged to eat from the 10,000kJ plan, with the option of adding up to their allocation of carbohydrate and/or protein portions if they were still hungry.
Participants were instructed to limit added fats to three teaspoons per day and to choose low fat foods and cooking methods. Recommended types of fat and lower fat choices were discussed in several group sessions. The macronutrient breakdowns of selected sample meal plans are shown in Table 3.3.

Table 3.3 Macronutrient composition of selected sample meal plans

<table>
<thead>
<tr>
<th></th>
<th>Goal Energy (kJ)</th>
<th>Goal Carbohydrate (g)</th>
<th>Goal Protein (g)</th>
<th>Goal Fat (g)</th>
<th>Actual Energy (kJ)</th>
<th>Actual Carbohydrate (g)</th>
<th>Actual Protein (g)</th>
<th>Actual Fat (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Carbohydrate Diet</td>
<td>5442</td>
<td>176</td>
<td>48</td>
<td>44</td>
<td>5229</td>
<td>160</td>
<td>71</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>5860</td>
<td>183</td>
<td>52</td>
<td>47</td>
<td>5427</td>
<td>174</td>
<td>73</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>6698</td>
<td>217</td>
<td>59</td>
<td>54</td>
<td>6180</td>
<td>222</td>
<td>97</td>
<td>24</td>
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<tr>
<td></td>
<td>7116</td>
<td>230</td>
<td>63</td>
<td>57</td>
<td>6500</td>
<td>237</td>
<td>100</td>
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<td></td>
<td>7535</td>
<td>244</td>
<td>66</td>
<td>61</td>
<td>6813</td>
<td>252</td>
<td>103</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>8372</td>
<td>271</td>
<td>74</td>
<td>68</td>
<td>7746</td>
<td>282</td>
<td>106</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>9209</td>
<td>298</td>
<td>81</td>
<td>74</td>
<td>8048</td>
<td>299</td>
<td>128</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>10046</td>
<td>325</td>
<td>89</td>
<td>81</td>
<td>9178</td>
<td>328</td>
<td>144</td>
<td>35</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Goal Energy (kJ)</th>
<th>Goal Carbohydrate (g)</th>
<th>Goal Protein (g)</th>
<th>Goal Fat (g)</th>
<th>Actual Energy (kJ)</th>
<th>Actual Carbohydrate (g)</th>
<th>Actual Protein (g)</th>
<th>Actual Fat (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>128</td>
<td>96</td>
<td>44</td>
<td>44</td>
<td>5247</td>
<td>128</td>
<td>108</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>138</td>
<td>103</td>
<td>47</td>
<td>47</td>
<td>5914</td>
<td>137</td>
<td>123</td>
<td>42</td>
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<tr>
<td></td>
<td>158</td>
<td>118</td>
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<td>54</td>
<td>6622</td>
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<td>138</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>167</td>
<td>125</td>
<td>57</td>
<td>57</td>
<td>6966</td>
<td>169</td>
<td>141</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>177</td>
<td>133</td>
<td>61</td>
<td>61</td>
<td>7548</td>
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<td>162</td>
<td>48</td>
</tr>
<tr>
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<td>197</td>
<td>148</td>
<td>68</td>
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<td>7887</td>
<td>197</td>
<td>163</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>217</td>
<td>162</td>
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<td>74</td>
<td>8495</td>
<td>216</td>
<td>176</td>
<td>53</td>
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<td>236</td>
<td>177</td>
<td>81</td>
<td>81</td>
<td>9075</td>
<td>229</td>
<td>196</td>
<td>53</td>
</tr>
</tbody>
</table>

3.1.4 Intervention Pre-testing

Intervention materials were pre-tested on a sample of seven healthy volunteers, six females and one male. The volunteers were treated as if they were enrolled in the
study, given their energy requirements minus 500kcal and corresponding protein and carbohydrate portions – four pre-tested the intervention diet and three pre-tested the control diet. Volunteers were given the initial advice package and asked to follow the diet for three days and maintain a diet record. They were then asked to submit their diet record along with feedback about the initial advice package. From this pre-testing changes were made to the initial advice package to make it easier to comprehend and more useful to participants. The feedback given included a list of suggestions of other commonly eaten foods to be added to the protein or carbohydrate portion lists (fruit, sugar in drinks, nuts and seeds). It was also requested by several volunteers that weights be added to the meat section of the protein portion list, and the portion size of cheddar cheese be clarified. One suggestion was to have a sample diet plan for each combination of carbohydrate and protein so there was an easy menu plan to follow while learning how to use the portion system.

3.2 Intervention Delivery

The package of dietary advice (Appendices C and D) consisted of individualised energy and portion allocations, portion lists, information and advice on fibre, fat, treat foods, free foods and alcohol, recipes and a sample menu plan. Table 3.4 illustrates a sample menu plan for both diets for one day. The initial information was presented in a folder to which participants added all subsequent material. Participants were also given a laminated fridge magnet of the food “pyramid” of their allocated diet (Appendix E) and an optional booklet to record daily food diaries if they so chose (Appendix F). These were designed by the candidate and the layout and printing done by a fourth year design student from the Otago University Design Studies program.

The portion system allowed participants to keep close to their usual food choices while controlling the amount they ate. If a food was not included on the exchange list the group dietitian could provide the information from food composition tables issued to each centre.
Table 3.4 Sample one day menu from 1200kcal sample meal plans

<table>
<thead>
<tr>
<th></th>
<th>High Carbohydrate</th>
<th>High Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td>2 slices wholegrain toast with tomato</td>
<td>2 eggs, 2 slices toast</td>
</tr>
<tr>
<td>Morning Tea</td>
<td>2 crackers with 45g cheese</td>
<td>Pear</td>
</tr>
<tr>
<td>Lunch</td>
<td>Toasted sandwich with 1/3 cup baked beans</td>
<td>Tuna salad sandwich (3/5 cup tuna)</td>
</tr>
<tr>
<td></td>
<td>Orange</td>
<td>1 cup berries</td>
</tr>
<tr>
<td>Afternoon Tea</td>
<td>Apple</td>
<td>45g edam cheese and 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>wholegrain crackers</td>
</tr>
<tr>
<td>Dinner</td>
<td>2 low fat sausages</td>
<td>1 chicken breast</td>
</tr>
<tr>
<td></td>
<td>1 cup potato</td>
<td>1/2 cup cooked rice</td>
</tr>
<tr>
<td></td>
<td>1.5 cups free vegetables</td>
<td>1.5 cups free veges</td>
</tr>
</tbody>
</table>

After randomization, all participants were allocated to a group session, which met fortnightly for the first six months and then monthly for the second six months. The sessions were run by a dietitian or suitably qualified nutritionist and consisted of both intervention specific and general weight loss advice. Participants were given a handout of information at each of the first twelve sessions (Appendix G). These were based on weight loss material used in two previous studies and developed by Principal Investigator Dr Jeremy Krebs, with additional nutrition related material added by the candidate. The outline of the group sessions is listed in Table 3.5. The second six months of group sessions were loosely organized, and more participant directed. Options were given for further education or opportunities for participants to present information they had collected, including recipes, meal ideas and articles. Some groups opted to bring in healthy dishes and recipes to share. For groups that were not willing to direct their own monthly sessions, the dietitian organized activities such as a food safety quiz, discussing articles from newspapers or magazines and guessing portion sizes.
**Table 3.5 Outline of group sessions**

<table>
<thead>
<tr>
<th>Session</th>
<th>Topics Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction to the diet, keeping a food diary, group dynamics</td>
</tr>
<tr>
<td>2</td>
<td>The glycaemic index, converting recipes, sticking to the diet</td>
</tr>
<tr>
<td>3</td>
<td>Fat – types of fat, reducing fat, effect on blood lipids</td>
</tr>
<tr>
<td>4</td>
<td>Label reading and shopping</td>
</tr>
<tr>
<td>5</td>
<td>Types of thinking about weight and diets, fibre</td>
</tr>
<tr>
<td>6</td>
<td>Dealing with pressures to eat, suitable drinks</td>
</tr>
<tr>
<td>7</td>
<td>Special occasions, fruit and vegetables</td>
</tr>
<tr>
<td>8</td>
<td>Takeaways, meal ideas, calcium and iron</td>
</tr>
<tr>
<td>9</td>
<td>Using herbs for flavour, managing stress</td>
</tr>
<tr>
<td>10</td>
<td>Balancing life, artificial sweeteners</td>
</tr>
<tr>
<td>11</td>
<td>Alcohol</td>
</tr>
<tr>
<td>12</td>
<td>Maintaining your weight in the long term, salt and sodium</td>
</tr>
</tbody>
</table>

Culturally appropriate recipes were available for Maori, Pacific Island and Indian cultural groups (Appendix H) and were made available at the first or second group session. The Maori recipes were sourced from a Maori website (www.maori-in-oz.com), and the karengo recipes from the personal collection of Wendy Nelson, NIWA seaweed scientist. Culturally specific foods for Maori were also included in the lists of carbohydrate and protein portions, in consultation with Te Hotu Manawa Maori. Pacific Island recipes were used with permission from the “Pacific Recipes for the Heart” cookbook and food advice was sought from the Pacific Heartbeat group at The National Heart Foundation. Indian recipes were used from the book “Margaret Gee’s Low Cholesterol Cuisine” by Bay Books, now out of print.

Four dietitians/nutritionists were employed to deliver the intervention along with the candidate, one in Christchurch and Wellington and two in Auckland. A Dietary Intervention Manual was produced by the candidate to provide support and information to the dietitians and to ensure the delivery was consistent across all three sites (Appendix I). The employed nutrition staff attended a training day run by the candidate where the study, interventions and procedures were explained and there was
an opportunity to ask questions. The nutrition staff referred to the candidate for all primary queries and concerns regarding the intervention. The Christchurch and Auckland nutrition staff reported to a site manager for site specific concerns.

3.2.1 Exercise
Changes in physical activity have important effects on the primary outcome measures in a study of this nature. As this was a dietary intervention trial specific information about exercise was not given to participants. However it would not be ethical or possible to ensure that participants did not make any changes to their activity levels. If asked about exercise the dietitians gave handouts on walking, swimming, running and exercising with a health condition from Sport and Recreation New Zealand. Specific individual advice was not offered and participants were referred back to their general practitioner. This advice was consistent between centres and dietary groups therefore any impact of change in exercise should be randomly distributed across both intervention and control groups. Physical activity was measured by questionnaire (see section 3.3.1) at each time point.

3.2.2 Vegans/Vegetarians
Prospective participants following a vegan diet were excluded from the study as the amount of protein required for the high protein diet was not achievable without animal products. In the pre-baseline screening questionnaire prospective participants were asked if they were vegetarian, and if so they were given an example of the amount of protein required should they be randomised to the high protein diet. The prospective participant had the opportunity to decide then if this was feasible for them, and if not, they did not proceed with screening.

3.2.3 Additional Support
As adherence to the prescribed dietary profile was important to the study outcome it was considered that additional support in the form of text messaging or e-mails might improve adherence. Therefore additional support was provided using these media to convey short motivational or educational messages of support to study members who chose to receive them. At baseline screening, participants were given the option to receive weekly messages of encouragement by text message or email. A total of 307 participants (73%) opted to receive these messages. One message was sent per week
for one year excluding holidays (46 messages in total), and were a mixture of nutrition, weight loss and diabetes tips and motivational quotes (Appendix J). Participants could reply to both text and email messages if they had questions or comments and these were answered by the candidate. Emails were sent in plain text in blind carbon copy to ensure privacy of addresses using the Mozilla Thunderbird email programme on the Otago University server. Text messages were sent using SMS Messenger software from Message Media and the recipient could not access any other participant’s phone numbers.

3.3 Data Collection

3.3.1 Quantitative Data

Data was collected at four time points: baseline, 6 months, 12 months and 24 months. Dietary intake was assessed from a validated University of Otago Human Nutrition Department estimated three day diet record, using common household measures and diet assessment photos (Appendix K and L). The diet assessment photo booklet consisted of photographs of common foods in different serving sizes, with a corresponding interpretation sheet for the researcher with gram and litre measures for the different serves. Satiety was assessed using a seven point Likert scale before and twenty minutes after eating main meals (1 = extremely hungry, 7 = extremely full). The satiety scale had previously been used in a weight loss trial in exactly the same way as for this trial [118]. Satiety scores were coded and recorded by the candidate. Three day diet records were entered by research assistants into Diet Cruncher for Windows (version 1.6.0, 1999-2003, Way Down South Software, Dunedin, New Zealand) and all checking was completed by the candidate. Training was provided to each research assistant and all had previous experience with the programme. Entered records on return were checked according to the error rate of the assistant who had entered them. To determine an error rate, 200 lines of entry were checked for each data enterer, and the number of errors recorded. For those with an error rate less than 1%, one record in five was checked. For error rates above 1% every record was checked. Table 3.6 below lists the error rates for all research assistants.
Table 3.6 Error rates of diet record entry by research assistants

<table>
<thead>
<tr>
<th>Assistant</th>
<th>Error Rate</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS</td>
<td>3.8%</td>
<td>Check every record</td>
</tr>
<tr>
<td>LB</td>
<td>0%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>HT</td>
<td>0.4%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>SH</td>
<td>0.7%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>RS</td>
<td>0.4%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>AD</td>
<td>0.4%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>SW</td>
<td>0.3%</td>
<td>Check 1 in 5 records</td>
</tr>
<tr>
<td>RK</td>
<td>0.7%</td>
<td>Check 1 in 5 records</td>
</tr>
</tbody>
</table>

Quality of life was measured using the SF-36 Health Survey from QualityMetric (Appendix M). It is a validated, generic thirty-six question tool measuring functional health and wellbeing. The SF-36 health survey was designed for the Medical Outcomes study in 1992 [119] and validated two years later by McHorney et al [120].

Physical activity was measured using the Auckland Heart Study (AHS) Physical Activity Three Month Recall questionnaire (Appendix N). A subset of participants also wore pedometers at each time point to verify the questionnaire. The pedometer instructions for participants and recording sheets were written by the candidate (Appendix O). The AHS physical activity questionnaire was designed for use in the Auckland Heart Study [121]. The questionnaire was first validated in a sample of 113 adults [122] and then again by Elley et al [123] who concluded the questionnaire was appropriate for use in primary care.

Weight and bioimpedance were measured on a TBF 300 Tanita scale throughout the study. The accuracy of the scale was assessed each week by the study nurse using a 10 kg weight. Scales were recalibrated if a deviation of +/- 0.1 kg was detected. The bioimpedance was calculated using the manufacturer’s equations. Participants were instructed to wear minimal clothing, no shoes or socks, and have an empty bladder. Clothing weight was entered as 300g and weight was recorded to the nearest 10g. Waist circumference was measured in duplicate and taken as the smallest
circumference measured between the lower ribs and the iliac crest to the nearest 0.5cm (World Health Organisation Method) [124]. Blood Pressure was measured using a mobile Welsh Allen Tycos, model 767 manual sphygmomanometer. Blood pressure was measured in triplicate with no time gap between measurements, after participants had rested for at least 10 minutes in the sitting position. Final recorded blood pressure was taken as the mean of the second and third measures. Height was measured at the top of the head using a fixed stadiometer with vertical backboard and movable headboard, to the nearest millimetre.

A fasting blood sample was collected by the research nurse using standard phlebotomy techniques at each measurement point. Samples were prepared by centrifuging at 2000g for 15 minutes, serum and plasma separated then stored at -20° C. Analysis was performed by the Diabetes and Lipid Laboratory at the University of Otago for HbA1c, creatinine, lipids and glucose. A sample was also sent to a local laboratory at each time point for serum creatinine analysis for renal monitoring.

Participants completed a 24hr urine collection prior to each investigation day (baseline, six, twelve and 24 months). The sample was mixed, total volume recorded and a 2ml sample transferred into a microcentrifuge tube and frozen until analysis at -20° C. This was analysed by the Diabetes and Lipid Laboratory at the University of Otago for serum creatinine and albumin:creatinine ratio. A subsample of urine specimens was sent to Gribbles Laboratory at the Invermay Research Centre Mosgiel, for analysis of 24 hour urinary nitrogen using a micro-kjeldahl method due to low volumes of available urine. The lab provided a 95% confidence limit of ±0.06 for this test. Table 3.7 lists the coefficients of variation provided by the University laboratory for the blood and urine tests.

<table>
<thead>
<tr>
<th></th>
<th>CHOL</th>
<th>HDL</th>
<th>Glucose</th>
<th>Serum Creatinine</th>
<th>Urine Creatinine</th>
<th>HbA1c</th>
<th>MALB</th>
<th>TAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>interassay</td>
<td>2.94</td>
<td>5.43</td>
<td>2.63</td>
<td>5.22</td>
<td>4.09</td>
<td>6.17</td>
<td>5.66</td>
<td>2.69</td>
</tr>
<tr>
<td>intraassay</td>
<td>2.2</td>
<td>3.86</td>
<td>0.82</td>
<td>5.27</td>
<td>2.98</td>
<td>1.85</td>
<td>2.02</td>
<td>1.79</td>
</tr>
</tbody>
</table>
The research nurses completed all measurements for weight, height, bioimpedance, blood pressure and waist circumference, took blood and urine samples and administered the quality of life and physical activity questionnaire. Weight was measured monthly, in the first year by the candidate/dietitian at group sessions using the same scales, and by the research nurses in the second year. Some baseline weight and height measures were taken by the candidate or dietitian depending on the centre. The research nurses followed guidelines in the Investigators Brochure (Appendix P) to ensure consistent techniques and advice. The Investigators Brochure was written by the head research nurse with contributions regarding the intervention from the candidate. All measurements were recorded at baseline, six, 12 and 24 month visits (Appendix Q).

The research nurses were asked to undertake a clinical measurements standardisation exercise, where they measured three different people (normal weight, overweight and obese) three times each for weight, height and waist circumference. This was to ensure consistent accuracy of use of the measuring apparatus. Acceptable variation was considered to be less than 1.5% for intra-examiner error as elucidated in a recent publication [125]. Table 3.8 lists the measurement variation for the research nurses. Waist circumference resulted in the most variation, but all results were considered to be within acceptable limits.

Table 3.8 Results of clinical measurements standardisation exercise for intra-examiner error – variation in repeated measures

<table>
<thead>
<tr>
<th>Nurse</th>
<th>Measurement</th>
<th>Healthy Wt (%)</th>
<th>Overweight (%)</th>
<th>Obese (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP</td>
<td>Weight</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Height</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Waist</td>
<td>1.52</td>
<td>0</td>
<td>0.49</td>
</tr>
<tr>
<td>CR</td>
<td>Weight</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Height</td>
<td>0.12</td>
<td>0.06</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>Waist</td>
<td>0.63</td>
<td>0.10</td>
<td>0.46</td>
</tr>
<tr>
<td>IM</td>
<td>Weight</td>
<td>0</td>
<td>NA</td>
<td>0.09</td>
</tr>
</tbody>
</table>
### 3.3.2 Food Cost Survey

A small survey was undertaken to determine the relative costs of following the diets compared to baseline eating habits. This was undertaken by a dietetic student, supervised by the candidate, and statistical analysis was completed by the candidate using two-tailed Student’s t tests. Baseline and six month diet records were costed for three participants from each diet group, along with a sample menu plan (seven days) from each diet. Participants were chosen from group one and were the first participants to complete their six month visit. Food prices (including beer and wine) were calculated using the retail prices from the online store Woolworths (www.woolworths.co.nz), and spirits from the online store Liquorking (www.liquorking.co.nz). Cost per 1000kJ was also calculated to adjust for differing energy intakes, and cost of protein alone was reported separately.

### 3.3.3 Qualitative Intervention Evaluation

A questionnaire was administered anonymously to participants at 12 months (conclusion of the intervention) to determine the value of the resources used in the intervention (Appendix R). This questionnaire was not intended to elicit responses about the specific diets, only the materials provided. The test-retest reliability was determined by administering the questionnaire twice, one month apart, to the participants of Group 1. As the questionnaire was Likert scale based (scale 1-5), one point was considered acceptable variability. For the participants who returned both questionnaires, 88.8% of their answers were within one point of the original choice. This was considered repeatable within reasonable parameters.
An exit interview was administered to participants at the time of withdrawal from the study, whether early or at the two year completion date (Appendix S). This questionnaire recorded the date of withdrawal from the study if early, and gave all participants the opportunity to make short comments on what they liked and disliked about the diet.

Four focus groups (two per diet group) were conducted in one centre (Christchurch) by a dietetic student, supervised by the candidate, to ascertain barriers to dietary change. Focus groups were conducted in the usual group session, after the education component had been delivered. Participants were asked for their consent to take part in this aspect of the project and for the sessions to be audio-taped. Participants were asked the following semi-structured open-ended questions:

1. What is the first thing that comes to mind when you hear the phrase “healthy eating costs more?”
2. What were (or still are) some of the barriers you faced (or are still facing) in following the diet?
3. When you think of all these barriers do any others come to mind?
4. Of all the barriers we have discussed, which has been the largest barrier you have faced?

Responses were transcribed using denaturalism and collated by the student and analysed to identify common themes.

3.3.4 Statistical Analysis

Statistical analyses of variables were performed by the candidate using the xtreg procedure in STATA 9.2 (Statacorp, Stata Statistical Software, Release 9.2 College Station, TX, Stata Corporation: 2007). The data were analysed according to intention to treat and followed the procedures outlined in the consort statement [126].

A mixed model analysis (random effects GLS regression with baseline as a covariate) was used for the main analyses, which assumes an underlying covariance due to the multiple time point measures for the same person. This method provides appropriate standard error and accounts for baseline differences. Mixed models are the
recommended way to analyse randomised-controlled trials as they consider relative change [127]. A p-value of less than 0.05 was considered significant. Within diet changes were assessed using two-tailed Student’s t tests.

The SF-36 quality of life questionnaire was coded according to the software provided by the developer and analysed by the study statistician.

Ethnicity data was handled according to the Total Response Output Method preferred by Statistics New Zealand for using the census ethnicity question. This entails counting a person once for every ethnicity identified with, hence the total number of responses is higher than the total number of participants [128].

Exploratory analyses were undertaken under the guidance of a biostatistician, using both categorical and continuous variables, and pooled data. The data were divided into three categories, according to dietary intake levels of interest. Linear regression was used to analyse both categorical and continuous variables at six months and two years. A univariate analysis was run for each variable of interest and adjusted for baseline value, energy, age, sex and centre. A multivariate analysis was then run, adjusted for baseline value, energy, age, sex, centre with %TE protein, %TE total fat and dietary fibre in the same model.
4. Results

4.1 Recruitment and Retention

A total of 419 participants were randomized to participate in the intervention from a total enquiry pool of 884. By the end of the two year intervention, 294 participants remained, resulting in a 70% retention rate. This is lower than anticipated in our sample size calculation, where 80% retention was estimated. Figure 4.1 illustrates the numbers recruited, withdrawn and retained over the course of the study. A total of 207 participants were randomised to the intervention diet and 212 to the control diet. Of the 125 who dropped out of the trial, most (58%) dropped out during the active weight loss phase (first six months). A further 30% of the drop outs occurred by twelve months with only 12% of drop outs withdrawing in the second year of the intervention. Few differences were observed between those who dropped out and those who completed the study. Those who dropped out of the trial tended to be older than those that completed the trial (59 versus 55 years, p<0.001) and had worse diabetes control at baseline (HbA1c 8.24% versus 7.99%, p=0.04). There was no difference in gender or baseline weight between completers and non-completers.

4.1.1 Demographics

Tables 4.1 and 4.2 illustrate the demographics of the study population. The sample was predominantly New Zealand (NZ) European, with more females and an average age of 57.9 years. Although small differences were observed in the ethnic distribution of the participants between centres, overall the ethnic distribution was similar to the general population of New Zealand [129].
Table 4.1 Study demographics by centre

<table>
<thead>
<tr>
<th>Centre</th>
<th>Gender</th>
<th>Mean Age</th>
<th>NZ European</th>
<th>Maori</th>
<th>Pacific Island</th>
<th>Asian</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Standard Dev.</td>
<td>(min-max)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auckland</td>
<td>80 F</td>
<td>58.5</td>
<td>92</td>
<td>12</td>
<td>11</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>(n = 133)</td>
<td>53 M</td>
<td>SD = 10.1</td>
<td>(31.6-76.0)</td>
<td>(9%)</td>
<td>(8%)</td>
<td>(8%)</td>
<td>(6%)</td>
</tr>
<tr>
<td>Wellington</td>
<td>108 F</td>
<td>57.4</td>
<td>133</td>
<td>22</td>
<td>3</td>
<td>6</td>
<td>27</td>
</tr>
<tr>
<td>(n = 186)</td>
<td>78 M</td>
<td>SD = 8.7</td>
<td>(32.3-74.4)</td>
<td>(12%)</td>
<td>(2%)</td>
<td>(3%)</td>
<td>(15%)</td>
</tr>
<tr>
<td>Christchurch</td>
<td>61 F</td>
<td>57.9</td>
<td>87</td>
<td>7</td>
<td>0</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>(n = 100)</td>
<td>39 M</td>
<td>SD = 10.3</td>
<td>(31.1-75.7)</td>
<td>(87%)</td>
<td>(7%)</td>
<td>(1%)</td>
<td>(7%)</td>
</tr>
<tr>
<td>Overall</td>
<td>249 F</td>
<td>57.9</td>
<td>312</td>
<td>41</td>
<td>14</td>
<td>18</td>
<td>42</td>
</tr>
<tr>
<td>(n = 419)</td>
<td>170 M</td>
<td>SD = 9.5</td>
<td>(31.1-76.0)</td>
<td>(73%)</td>
<td>(10%)</td>
<td>(4%)</td>
<td>(10%)</td>
</tr>
</tbody>
</table>

Table 4.2 Study demographics by diet

<table>
<thead>
<tr>
<th>Centre</th>
<th>Gender</th>
<th>Mean Age</th>
<th>NZ European</th>
<th>Maori</th>
<th>Pacific Island</th>
<th>Asian</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Standard Dev.</td>
<td>(min-max)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control (HC)</td>
<td>139 F</td>
<td>58.0</td>
<td>162</td>
<td>19</td>
<td>6</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>(n = 212)</td>
<td>73 M</td>
<td>SD = 9.2</td>
<td>(31.1-76.0)</td>
<td>(76%)</td>
<td>(9%)</td>
<td>(3%)</td>
<td>(4%)</td>
</tr>
<tr>
<td>Intervention</td>
<td>110 F</td>
<td>57.7</td>
<td>150</td>
<td>22</td>
<td>7</td>
<td>10</td>
<td>19</td>
</tr>
<tr>
<td>(HP) (n = 207)</td>
<td>97 M</td>
<td>SD = 9.9</td>
<td>(31.6-75.7)</td>
<td>(72%)</td>
<td>(11%)</td>
<td>(3%)</td>
<td>(5%)</td>
</tr>
</tbody>
</table>

4.1.2 Attendance

Attendance at group sessions is illustrated in Tables 4.3 and 4.4 and Figures 4.2 and 4.3 (facing page). A total of twelve sessions were offered in the first six months and six sessions in the second six months. Attendance dropped off markedly in the second six months, with participants attending substantially fewer sessions in the second six months than was observed at the start of the intervention. Overall, average attendance was 9.7 sessions (54%), with an average of 7.3 sessions (61%) in the first six months.
and 2.4 sessions (40%) in the second six months. No differences were observed in attendance either by diet or centre. In the second year a voluntary monthly weigh in clinic was held but attendance not recorded.

**Table 4.3 Attendance rates at group sessions by centre**

<table>
<thead>
<tr>
<th>Centre</th>
<th>First Six Months</th>
<th>Second Six Months</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (Std Dev)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auckland</td>
<td>7.1 (3.5)</td>
<td>2.4 (2.3)</td>
<td>9.5 (5.5)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>59</td>
<td>40</td>
<td>53</td>
</tr>
<tr>
<td>Wellington</td>
<td>7.2 (3.5)</td>
<td>2.1 (2.2)</td>
<td>9.3 (5.4)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>35</td>
<td>52</td>
</tr>
<tr>
<td>Christchurch</td>
<td>7.5 (3.1)</td>
<td>2.7 (2.3)</td>
<td>10.2 (5.4)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>63</td>
<td>45</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8.5 (5)</td>
<td>3 (5)</td>
<td>12 (8)</td>
</tr>
</tbody>
</table>

**Table 4.4: Attendance rates at group sessions by diet**

<table>
<thead>
<tr>
<th>Diet</th>
<th>First Six Months</th>
<th>Second Six Months</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (Std Dev)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High carbohydrate</td>
<td>7.2 (3.4)</td>
<td>2.4 (2.3)</td>
<td>9.6 (5.4)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>60</td>
<td>40</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (6)</td>
<td>2 (5)</td>
<td>10 (10)</td>
</tr>
<tr>
<td>High protein</td>
<td>7.3 (3.5)</td>
<td>2.3 (2.3)</td>
<td>9.6 (5.3)</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>61</td>
<td>38</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 (5)</td>
<td>2 (5)</td>
<td>10 (9)</td>
</tr>
</tbody>
</table>

### 4.2 Anthropometric Measurements

#### 4.2.1 Weight, body mass index, waist circumference

Both diet groups lost modest amounts of weight and reduced their waist circumference from baseline. However, no differences were observed in change over time between groups for weight, body mass index or waist circumference, as
illustrated in Table 4.5 (facing page). Overall, participants lost on average 2.6kg (±4.4) by six months, but this had diminished to 1.8kg (±7.3) at two years. Considering the raw data, there appears to be more substantial reductions in weight, but once drop outs were taken into account by the analysis, the actual losses were much smaller.

Within the HC group, significant reductions in weight were observed from baseline to six (-2.5kg ± 4.5kg, p<0.001) and twelve (-1.7kg ± 6.8kg, p<0.001) months. While a similar trend was apparent at 24 months, the difference was no longer significant (-1.3kg ± 7.0kg, p = 0.063). For the HP group the reductions in weight were also highly significant and in contrast with the HC group, remained so for all time points, from baseline to six (-2.6kg ± 4.4kg, p<0.001), 12 (-2.3kg ± 6.5kg, p<0.001) and 24 months (-2.2kg ± 7.5kg, p = 0.004).

Participants also lost on average 2.4cm (±5.9) from the waist by six months, which had increased to 2.7cm (±8.9) by two years. The HC group sustained significant reductions from baseline to all time points (6 months -2.7cm ± 6.4cm, p<0.001, 12 months -2.7cm ± 7.4cm, p<0.001 and 24 months -3.1cm ± 8.4cm, p<0.001). Within the HP group significant reductions were seen from baseline to six months (-2.1cm ± 4.5cm, p<0.001) and 12 months (-1.6cm ± 6.1cm, p = 0.002) and again sustained until 24 months (-2.3cm ± 9.5cm, p = 0.015).

Thus overall there were considerable improvements in weight and particularly waist circumference in both groups, regardless of which diet was prescribed.

4.2.2 Body fatness, lean body mass and blood pressure
Changes in body composition, as measured by bio-impedance, are shown in Table 4.5. Overall, fat mass reduced by 1.9kg (±5.3) by six months, which had reduced to 1.5kg (±7.2) by two years. There was no difference between diet groups in change over time. Overall, there were no significant changes in either systolic or diastolic blood pressure, and no differences between the groups in change over time.
4.3 Dietary Intake

4.3.1 Three day diet record results
Dietary intakes of the HP and HC groups over the four time points are shown in Table 4.6 (facing page). Both groups reported a decrease in energy intakes from baseline, with the reduction sustained across all time points. The HC group however reported a significantly greater decrease in energy intake than the HP group, of 500kJ per day. This suggests that both groups reported eating less compared with baseline, but the HC group reported eating less again compared with the HP group. This decrease in energy intake for the HC group appears to have come predominantly from a decrease in fat intake, with a small reduction in carbohydrate and protein intake. The HP group achieved small decreases in fat and carbohydrate, with a small increase in protein intake (approximately 1g/kg).

Neither group reached the intended targets for %TE for protein or carbohydrate, but the HC group did achieve 30% TE from fat. Carbohydrate intakes as a percentage of total energy did increase in the HC group and fall in the HP group, leaving a significant difference between the two groups, although the difference was small (3.7% over the two years). Actual carbohydrate intakes (grams/day) changed very little and were not significantly different between the groups.

The HP group significantly increased their protein intake by approximately 14g of protein greater than the HC group. However, the proportion of protein as a percentage of TE only reached 22% at the highest in the HP group. At six months, 12 of the 207 participants allocated the high protein diet achieved a protein intake of 30% of TE or higher.

The HC group had significantly lower intakes of both fat and saturated fat, which contributed to the lower total energy intake. No differences between groups were observed for fibre or alcohol.

4.3.2 Urinary Nitrogen
Urinary nitrogen was measured in a subsample (n = 123) at baseline, six and twelve months. Despite differences in reported protein intakes, there was no difference
between groups for the change in percent nitrogen over time. There were also no significant differences within groups from baseline to six months, or between six and 12 months, and no differences between groups at any time point.

*Table 4.7* Percent nitrogen content of urine in the first year of study (mean and standard deviation)

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>High carbohydrate</td>
<td>71.7 (49.2)</td>
<td>61.9 (38.2)</td>
<td>72.6 (41.9)</td>
<td>3.21 (-7.44, 13.86)</td>
<td>0.56</td>
</tr>
<tr>
<td>High protein</td>
<td>79.6 (77.4)</td>
<td>80.2 (76.5)</td>
<td>78.3 (65.2)</td>
<td>(-7.44, 13.86)</td>
<td></td>
</tr>
</tbody>
</table>

4.3.3 Satiety

*Table 4.8* Likert scale measures of hunger and satiety (mean and standard deviation)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Carbohydrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hunger</td>
<td>2.9 (0.69)</td>
<td>3.0 (0.85)</td>
<td>2.9 (0.75)</td>
<td>3.1 (0.90)</td>
</tr>
<tr>
<td>High Protein</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hunger</td>
<td>2.9 (0.86)</td>
<td>3.0 (0.87)</td>
<td>3.0 (0.76)</td>
<td>3.0 (0.85)</td>
</tr>
<tr>
<td>P value</td>
<td>0.78</td>
<td>0.88</td>
<td>0.69</td>
<td>0.47</td>
</tr>
<tr>
<td>High Carbohydrate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satiety</td>
<td>5.7 (0.55)</td>
<td>5.7 (0.66)</td>
<td>5.6 (0.72)</td>
<td>5.7 (0.74)</td>
</tr>
<tr>
<td>High Protein</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satiety</td>
<td>5.7 (0.64)</td>
<td>5.7 (0.63)</td>
<td>5.8 (0.53)</td>
<td>5.7 (0.65)</td>
</tr>
<tr>
<td>P value</td>
<td>0.31</td>
<td>0.84</td>
<td>0.06</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Satiety was measured on the 3-day diet record using a Likert scale of 1-7 (1 = extremely hungry, 7 = extremely full) before and 20 minutes after eating main meals. Pooled satiety data were analysed using paired t-tests. No significant differences occurred in either hunger or satiety between the intervention and control groups. There was a non-significant increase in satiety at 12 months in the high protein group.
Despite eating less energy than at baseline, participants did not report significantly more hunger on either diet.

4.4 Glycaemic Control and Blood Lipids
Data for glycaemic control and blood lipids are presented in Table 4.9 (facing page). Despite reported differences in fat intake, no differences between groups in change over time were noted for any blood lipid measurement. No consistent trends were observed here, with several measurements increasing above baseline, although all changes were small and not clinically significant.

No differences were noted between diet groups in change over time for HbA1c or fasting blood glucose. Similar small, but not clinically significant, reductions were observed in each group over the first twelve months, but had increased again by two years.

4.5 Measures of Kidney Function

4.5.1 Urinary Albumin:Creatinine Ratio (ACR) and Serum Creatinine
Also presented in Table 4.9 are the data showing no difference in change over time between the groups for either serum creatinine or ACR. Variations in both measurements are within expected normal parameters.

4.5.2 Local Serum Creatinine and Renal Surveillance
Seven participants triggered the renal protocol due to increases in creatinine, but were evenly distributed over the two diet groups. Two of these resolved with no intervention, one was withdrawn from the diet (but continued with the study measurements) and the other four were referred to their usual general practitioner for review. All were included in the analysis under the intention to treat principle.

4.6 Quality of Life and Exercise

As illustrated in Table 4.10, there was no difference in quality of life as measured by the SF-36 questionnaire for either physical or mental health.
Table 4.10 Quality of life summary outcomes from SF-36 questionnaire

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline (SD)</th>
<th>6 months (SD)</th>
<th>12 months (SD)</th>
<th>24 months (SD)</th>
<th>Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF36 physical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>44.74 (9.10)</td>
<td>46.05 (9.36)</td>
<td>45.46 (9.39)</td>
<td>45.78 (9.27)</td>
<td>-0.20 (-1.44, 1.04)</td>
<td>0.59</td>
</tr>
<tr>
<td>HP</td>
<td>44.80 (9.62)</td>
<td>46.20 (8.69)</td>
<td>46.13 (8.98)</td>
<td>43.93 (9.93)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF36 mental</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>52.43 (9.28)</td>
<td>50.75 (11.12)</td>
<td>52.26 (9.17)</td>
<td>52.07 (11.04)</td>
<td>1.67 (0.25, 3.09)</td>
<td>0.65</td>
</tr>
<tr>
<td>HP</td>
<td>52.03 (10.04)</td>
<td>52.98 (9.08)</td>
<td>53.36 (9.17)</td>
<td>52.66 (9.21)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There was no difference in exercise levels between the groups (Table 4.11) as measured by either the physical activity questionnaire or the pedometer recordings. The pedometer recordings were undertaken in a subsample, with 96 participants taking part.

Table 4.11 Exercise as measured by total activity from AHS physical activity questionnaire and pedometer recordings

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline (SD)</th>
<th>6 months (SD)</th>
<th>12 months (SD)</th>
<th>24 months (SD)</th>
<th>Difference (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHS Questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>634.82 (846.49)</td>
<td>699.96 (759.49)</td>
<td>762.95 (1887.37)</td>
<td>591.01 (573.40)</td>
<td>43.70 (204.38, 291.77)</td>
<td>0.73</td>
</tr>
<tr>
<td>HP</td>
<td>699.93 (804.97)</td>
<td>863.17 (2198.86)</td>
<td>814.90 (2551.69)</td>
<td>571.11 (538.13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pedometers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(total steps over 7 days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>39667.41 (18753.67)</td>
<td>41662.54 (22211.94)</td>
<td>40017.46 (21357.02)</td>
<td>41638.06 (23662.33)</td>
<td>-508.94 (-8906.77, 7888.90)</td>
<td>0.91</td>
</tr>
<tr>
<td>HP</td>
<td>40654.33 (21617.71)</td>
<td>48365.68 (26731.19)</td>
<td>43177.91 (23711.12)</td>
<td>37294.19 (20563.77)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.7 Exploratory Analyses

The exploratory analyses included multiple tests with a high risk of statistically significant results being due to chance (i.e. 1 in 20 results due to chance at p <0.05).
To minimise drawing inappropriate conclusions from these analyses, results which were significant for both univariate and multivariate analyses were accepted. Table 4.12 presents an abridged version of this data for protein only, for all other analyses please refer to Appendix T.

Overall, small but perhaps important benefits were observed for those with higher protein intakes, for example a protein intake of 15-25% was associated with lower triglycerides (-0.37 (-0.67, -0.06) at two years. A higher protein intake was also linked to better preservation of lean body mass (0.17kg per 1% increase in total energy from protein (0.04, 0.30) at two years. An increase of protein from 15 to 25% of total energy for example, would be expected to result in retention of lean body mass of 1.7kg. The preservation of muscle tissue is an important factor in weight loss.

Serum creatinine was lower at two years (-7.97(-13.64, -2.30) and -8.89 (-16.03, -1.75)) in both higher protein categories. However, a disadvantage of a higher protein intake appeared to be its effect on systolic blood pressure, which at six months was higher in both of the higher protein categories (6.41 (0.75, 12.07) and 6.53 (0.00, 13.05)).

4.8 Food Cost Survey

The average daily costs, calculated using the seven day sample menu plans, (Table 4.13 facing page) shows significantly increased costs for the HP group. The average daily cost on the HP menu plan was significantly higher than that on the HC menu (p = 0.001). As expected therefore, the cost of protein was also significantly higher on the HP menu (p = 0.003). The cost per 1000kJ trended towards significance at p = 0.06, again showing the HP menu to be more expensive.

Food costs for the participant three day diet records at baseline and six months and per 1000kJ are reported in Table 4.14 (facing page). There were no significant changes in total cost for either diet from baseline to six months, or for cost per 1000kJ from baseline to six months. There was however a significant increase in the cost of protein on the HP diet from baseline to six months that was not seen in the HC group. This increase of $2.90 on average per day for protein represents a significant cost increase.
for this group. This was a small sample size and significant results may have been seen for the HP group for total cost with a larger sample.

4.9 Diet Materials Questionnaire

A total of 172 questionnaires were received, which were coded and entered into Microsoft Excel, with the comments sections recorded separately. These questionnaires were not separated into diet groups as they were done anonymously at twelve months, before unblinding took place. The questions in sections one to three involved Likert scale ratings from 1 to 5, with 1 being very useful and 5 being not at all useful.

4.9.1 Dietary Advice Materials

<table>
<thead>
<tr>
<th>Question</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folder</td>
<td>1.4</td>
<td>0.7</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Menu Plan</td>
<td>2.1</td>
<td>1.0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Fridge Magnet</td>
<td>2.3</td>
<td>1.0</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Recording Book</td>
<td>2.0</td>
<td>1.5</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Weekly messages</td>
<td>2.1</td>
<td>1.0</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Each participant was given a folder of initial dietary advice which included a list of portions, some general dietary information and recipes. They were also given a menu plan specific to their energy intake, a fridge magnet and a recording book. Participants indicated that they found the folder of advice most useful, followed by the recording book, menu plan and finally the fridge magnet was considered least useful.

Out of the 172 questionnaires received, 136 (79%) received the weekly text or email messages. The messages were considered relatively useful, not as useful as the dietary advice folder or the recording book, but as useful as the menu plan.
4.9.2 Group Sessions

Participants found the group sessions contributed new diabetes and nutrition knowledge, but less weight management knowledge. Most participants reported getting on well with other people in their group.

*Table 4.16* Likert scale rating of group sessions

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Std Dev</th>
<th>Median</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes knowledge</td>
<td>1.8</td>
<td>0.9</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nutrition Knowledge</td>
<td>1.6</td>
<td>0.8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Weight Management</td>
<td>2.0</td>
<td>0.9</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Knowledge</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group dynamic</td>
<td>1.3</td>
<td>0.7</td>
<td>1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

The responses to questions three and four of this section (“What did you find most/least useful about the group sessions?”) were grouped into categories according to common themes. Please see Appendix U for the full transcript of comments. For the most useful question, four common themes were identified: education, support, discussion/idea sharing and accountability. Education covered all comments about learning, gaining knowledge, advice from the dietitian and asking questions. Support refers to comments about sharing personal stories, problems, issues and experiences, camaraderie and the feeling of not being alone. Discussion or idea sharing encompasses sharing tips, recipes and group problem solving. Finally accountability referred to weighing in, maintaining motivation and focus.

*Table 4.17* Number of comments referencing common positive themes for group sessions

(n = 154)

<table>
<thead>
<tr>
<th>Education</th>
<th>Support</th>
<th>Discussion/Idea Sharing</th>
<th>Accountability</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>91</td>
<td>60</td>
<td>20</td>
</tr>
</tbody>
</table>
“Friendly atmosphere, everyone had the same issues. Dietitian fantastic, informative and approachable.”

“Being able to share and knowing other people are going through the same”

“Group talks invigorating and amusing, fun times, supportive of one another”

For the least useful section, 42 people (24%) wrote negative comments. Again four common themes were identified, being the group size/dynamic, time/venue/traffic, some aspect of content and motivation. The group size or dynamic mainly referred to people who had an issue with one particular person in a group and the dwindling number of some groups as attendance fell over time. The time/venue/traffic category refers to complaints about the logistics of the group sessions, the venue was too far away or took too long to get to in peak hour traffic. An aspect of content mainly referred to a particular topic or sessions that people didn’t find useful (for example “I didn’t like the recipes”). Finally, some people admitted that it took motivation to get to the group sessions that they found difficult to find.

**Table 4.18** Number of comments referencing common negative themes for group sessions (n = 42)

<table>
<thead>
<tr>
<th>Group Size/Dynamic</th>
<th>Time/Venue/Traffic</th>
<th>Aspect of Content</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>14</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

“Insufficient individual accountability”

“Whole group dropped out by 2nd 6 months I was only one left”

“Participants partner present – patronising, changed dynamic”
4.9.3 Rating of Dietary Support Resources

Participants were asked to rate the usefulness of the five specified diet resources from one to five – from one being the most useful and five being the least useful. The group sessions were by far considered the most useful, followed by the folder of materials, weekly messages, menu plan and then the recording book.

Table 4.19 Respondent comparative ranking of diet materials (%)

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group Sessions</td>
<td>70</td>
<td>18</td>
<td>7</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Weekly Messages</td>
<td>16</td>
<td>17</td>
<td>21</td>
<td>17</td>
<td>29</td>
</tr>
<tr>
<td>Folder of Materials</td>
<td>32</td>
<td>35</td>
<td>23</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Recording Book</td>
<td>17</td>
<td>20</td>
<td>14</td>
<td>24</td>
<td>25</td>
</tr>
<tr>
<td>Menu Plan</td>
<td>17</td>
<td>17</td>
<td>23</td>
<td>29</td>
<td>15</td>
</tr>
</tbody>
</table>

4.9.4 Changes Made to Diet or Lifestyle

Participants were asked to state the three most significant changes they have made to their diet or lifestyle as a result of the programme (Table 4.20). This was open-ended, with no list of options to choose from being provided. The three most commonly stated changes were decreased portion size, increased exercise and more awareness of food. These reported changes are interesting to compare with the goals and aims of the education sessions. The main reported change was a reduction in portion size. This fits very nicely with the education sessions, where considerable focus was placed upon reducing total energy intake by decreasing portion size. However, interestingly increasing their exercise was the second most reported behaviour change. Exercise was not a target of the intervention and participants were instructed to keep their exercise levels the same. However, participants often asked exercise questions and basic resources were provided if they did so as outlined in the methods (section 3.2.1).

Participants commonly reported having more awareness of food, and this was repeated in the exit interviews, but the exact meaning of this is very vague. Similarly more label reading may or may not translate into real change in buying or eating
behaviour. Reducing fat intake was also a study aim and was achieved particularly by the HC group. Only twelve participants listed controlling carbohydrate and nine participants listed increased protein in their top three changes, despite these being the other main aims of the study. Increased fruit and vegetable intake was an encouraging reported change. Although this was not measured in this study specifically, this dietary change potentially provides benefits by displacing higher energy foods and increasing antioxidant intakes.

Table 4.20 Changes made to diet or lifestyle as a result of programme

<table>
<thead>
<tr>
<th>Change Made</th>
<th>Number Listing Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased portion size</td>
<td>64</td>
</tr>
<tr>
<td>Increased exercise</td>
<td>61</td>
</tr>
<tr>
<td>More awareness of food</td>
<td>56</td>
</tr>
<tr>
<td>Label Reading</td>
<td>35</td>
</tr>
<tr>
<td>Less fat</td>
<td>31</td>
</tr>
<tr>
<td>Increased fruit and vegetables</td>
<td>19</td>
</tr>
<tr>
<td>Controlling Carbohydrate</td>
<td>12</td>
</tr>
<tr>
<td>Increased protein</td>
<td>9</td>
</tr>
<tr>
<td>No snacks</td>
<td>8</td>
</tr>
<tr>
<td>Higher motivation</td>
<td>5</td>
</tr>
<tr>
<td>Less alcohol</td>
<td>5</td>
</tr>
<tr>
<td>Regular Meals</td>
<td>4</td>
</tr>
<tr>
<td>Less meat</td>
<td>3</td>
</tr>
<tr>
<td>More fibre</td>
<td>2</td>
</tr>
<tr>
<td>Less sugar</td>
<td>2</td>
</tr>
<tr>
<td>Testing blood glucose more often</td>
<td>1</td>
</tr>
<tr>
<td>Less salt</td>
<td>1</td>
</tr>
<tr>
<td>Low GI</td>
<td>1</td>
</tr>
</tbody>
</table>
4.10 Exit Interview Questions

At their final visit (at two years or earlier if withdrew early) each participant was administered an exit interview. In this they were asked about likes and dislikes of the diet they were allocated to, and whether they wanted to make a short comment. Many left this section blank, but the opportunity was taken up by 226 participants. Not all participants answered all three questions. The likes, dislikes and comments were then analysed for common themes, and are presented by diet group. More than one theme was sometimes represented in a comment.

Table 4.21 Common themes reported by participants when asked “What did you like about the diet?”

<table>
<thead>
<tr>
<th></th>
<th>HC (n = 116)</th>
<th>HP (n = 98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liked the diet itself, food choices and amounts</td>
<td>35 (30%)</td>
<td>30 (31%)</td>
</tr>
<tr>
<td>Liked having more vegetables</td>
<td>6 (5%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Liked the amount of protein</td>
<td>0</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Liked the amount of carbohydrate</td>
<td>5 (4%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Liked the group sessions – including dietitian, education, learning about food</td>
<td>41 (35%)</td>
<td>36 (37%)</td>
</tr>
<tr>
<td>The diet was easy to follow</td>
<td>22 (19%)</td>
<td>10 (10%)</td>
</tr>
<tr>
<td>Liked losing weight</td>
<td>1 (1%)</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>Recording food intake</td>
<td>2 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Liked nothing about the diet</td>
<td>2 (2%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2%)</td>
<td>6 (6%)</td>
</tr>
</tbody>
</table>

As illustrated in Table 4.21, a significant proportion of respondents in both groups were happy with the diet that they were prescribed and how it was presented. Also the experience of, and knowledge gained in the group sessions was a popular positive comment in both groups. Similar numbers also specifically liked the major macronutrient for their diet group, carbohydrate or protein. However, more people found the high carbohydrate diet easy to follow than the high protein diet.
“Enjoyed the variety + group meetings + dietitian”
“Enjoyed the discussions and new foods”
“Keeping a diary & meetings good for motivation”

**Table 4.22** Common themes reported by participants when asked “What did you dislike about the diet?”

<table>
<thead>
<tr>
<th>Theme</th>
<th>HC (n = 63)</th>
<th>HP (n = 58)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too much food</td>
<td>3 (5%)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Too many carbohydrates/too much fibre</td>
<td>14 (22%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Too much protein</td>
<td>0</td>
<td>13 (22%)</td>
</tr>
<tr>
<td>Too little food</td>
<td>4 (6%)</td>
<td>3 (5%)</td>
</tr>
<tr>
<td>Too little carbohydrate</td>
<td>0</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Too little protein</td>
<td>11 (17%)</td>
<td>0</td>
</tr>
<tr>
<td>Not losing weight</td>
<td>5 (8%)</td>
<td>0</td>
</tr>
<tr>
<td>Wanted more group meetings</td>
<td>3 (5%)</td>
<td>0</td>
</tr>
<tr>
<td>Wanted more structured diet</td>
<td>1 (2%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Didn’t suit/like particular foods</td>
<td>7 (11%)</td>
<td>9 (16%)</td>
</tr>
<tr>
<td>Wanted the other diet group</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Too difficult to follow</td>
<td>8 (13%)</td>
<td>12 (21%)</td>
</tr>
<tr>
<td>No family support</td>
<td>5 (8%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Cost too much</td>
<td>1 (2%)</td>
<td>3 (5%)</td>
</tr>
</tbody>
</table>

As presented in **Table 4.22**, a similar number from each diet group thought the key macronutrient for their group was too high, and the target amounts too difficult to consume. Interestingly, only four people in the HP group mentioned there being too little carbohydrate, whereas eleven in the HC group mentioned there being too little protein. Similar numbers of participants found the diet difficult to follow in both groups, along with high cost and no family support.

“Sometimes difficult to eat required protein”
“Too many carbs & not enough protein”
“Not having pies, cake, dessert etc”
Table 4.23 Common themes from participants when asked “Any comments you would like to make?”

<table>
<thead>
<tr>
<th></th>
<th>HC</th>
<th>HP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 74)</td>
<td>(n = 58)</td>
</tr>
<tr>
<td>Not lost weight</td>
<td>3 (4%)</td>
<td>0</td>
</tr>
<tr>
<td>Diet similar to what already eating</td>
<td>2 (3%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>More aware of healthy food choices</td>
<td>6 (8%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Liked group sessions and overall “programme”</td>
<td>41 (55%)</td>
<td>34 (59%)</td>
</tr>
<tr>
<td>Had specific difficulties – health etc</td>
<td>8 (11%)</td>
<td>10 (17%)</td>
</tr>
<tr>
<td>Didn’t like the restrictions</td>
<td>2 (3%)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>12 (16%)</td>
<td>5 (9%)</td>
</tr>
</tbody>
</table>

The general comments as listed in Table 4.23 mainly repeated what had already been noted in the “likes” and “dislikes” sections of the exit interview. Similar numbers in each group reiterated liking the group sessions, becoming more aware of food choices and listing specific reasons why they were unable to comply with the diet.

“Great guideline, has changed my eating patterns”
“Well run programme, education useful”
“Wanted to be on high protein diet”

4.11 Focus Group Research – Barriers to Following the Prescribed Diets

4.11.1 Cost of Healthy Eating
The first question put to the focus groups was whether they agreed with the statement that healthy eating costs more. All of the participants in the HC group disagreed with this statement. The most common comment was that meal planning was the key to keeping cost down as it reduced waste and the purchase of less healthy food items.

“You plan more so you seem to be buying less. I know I buy a cauliflower and that will be for so many meals.”
“I’m spending less as I’ve cut out all the junk – biscuits and all that. I was amazed when I started to shop. I couldn’t believe that was all the groceries cost me.”
In contrast, a few in the HP group agreed with the statement that healthy eating costs more.

“On a low budget, it definitely cost more because you can’t just go and buy the cheapest thing.”

“It’s easier and cheaper to buy junk food. You need to be able to shop around to make savings. Fruit and vegetables are expensive.”

Many of the participants reported that healthy options for breads (wholegrain, high fibre), breakfast cereals (low fat and sugar) and meat (low fat mince and skinless chicken breasts) were expensive, although most stated that they were buying these items prior to following the diet.

A few of the HP participants reported that certain food items were expensive.

“White bread’s always cheap.”

“I like Vogels™ – but it’s more expensive. For the rest of the family I can buy three loaves for the price of one.”

“Milk. Double calcium – always paying more for this which is recommended for the high protein group.”

“Diabetic products are expensive. I now buy the reduced sugar jam. I tend to buy a few items just for me which increases the cost.”

When asked to prioritize factors influencing food selection, nutritional content and taste appeared to be more important than cost alone. All participants considered buying budget brands as long as they were ‘healthy’ and ‘tasty’.

“I see no point in eating food I don’t like because it’s cheap.”

“I buy on taste and I do read the labels.”

“I buy on the label.”
4.11.2 Barriers to following a prescribed diet - Internal factors

Most participants reported issues with special occasions as they were often linked with favourite/treat foods. Many felt that they were missing out if they didn’t consume these foods and that these foods were difficult to resist.

> “Easter comes once a year and I want hot cross buns and Easter eggs. I love my hot cross buns and I have to find the ones that are the nicest, and they come in packs of six.”

> “Christmas. It was a nuisance having Christmas. Plus we have had three weddings so far this year. It is a killer.”

A number of participants found self control/willpower the most significant barrier to following the diet. It was also evident that nutrition knowledge alone was not enough to change eating behaviour.

> “It’s all in my head. I know perfectly well what I should be doing but my head still wants something else.”

> “It’s my willpower. I associate nice food with feeling better and having a good time and enjoying myself”.

It also appeared that eating out was linked with self control. A few associated eating out with having a good time which meant eating foods they enjoy rather than healthier foods.

> “The only trouble I have with eating out is my state of mind. Cos I think oh, an outing – wine, beautiful chocolate desserts and I want to have a good time. That’s how I regard it – as having something really nice to eat and having a good time. So to me having a low calorie food is not worth going out as you can have that at home”.

An equal number of participants in both groups reported that the sample food plans used for the study were difficult to follow. A few in the higher protein groups had
trouble consuming enough protein portions whilst others found it difficult to work out the portions they should be consuming.

“I’ve found it hard to eat the right amount of portions. It was too much so I cut it in half, then it wasn’t enough.”
“I found it difficult to work out. I’m getting older and it’s difficult to follow.”
“I’ve struggled with the portions of protein right from the start and I still do. I’m just not having enough. You say you have more energy. I don’t. I’m tired.”

4.11.3 Barriers to following a prescribed diet - External factors
External factors such as people and social occasions were reported as major barriers to following their respective food plans. When asked about the barriers to following their diets, every focus group discussed family and friends. Most felt the pressure of having to make food choices that were different to others.

“I find my workmates push food on me. That’s a big barrier having to say no all the time. They all know I’m diabetic at work, yet they still bring big chocolates cakes when they know I can’t eat it. They don’t consider other people and sometimes get a little piggy when you say no I don’t want it.”
“My husband makes me stressed. I always have to think about - I don’t want it, I shouldn’t have it. I’m under quite a bit of pressure all the time because of his eating.”
“I have a husband with a sweet tooth and he takes it as a rejection if I don’t take what he offers me because he thinks he’s doing something nice for me.”

Eating out was consistently reported as a major barrier to following the diet. Most found it difficult to access healthy foods when eating out and felt a sense of lack of control over what they were eating. However, a few participants stated that it
depended on where they ate out. Some participants felt confident in asking for healthy options such as dressing on the side and no fries, whilst others did not.

“You have no control over what’s being served.”
“So many of them put dressings all over them, so I’ve given up on those.”
“What they bring me out has always got white bread and not enough filling.”
“There is always something I can have. Most places have variety now, they cater for everybody.”
“We just go to Subway.”

When prompted about food cost, time involved in following their prescribed diet, taste, nutrition knowledge, food preparation and convenience, all focus groups did not consider these to be barriers to following their diets. A few participants thought their food costs had increased but this was not regarded as a barrier.
5. Discussion

5.1 Anthropometric Measurements

Prescribing either a HC or a HP diet resulted in equal amounts of weight loss, suggesting that dietary composition of the diet does not influence weight loss. However, given the inability of participants to follow the prescribed diets, an alternative view is that adherence to a high protein diet is not practical. The lack of any effect of dietary composition is in agreement with eleven other studies, only one of which was in a population with T2DM [57, 58, 60-68], that have reported similar results, and in contrast to the nine studies that did find a difference between groups for weight loss [47-54, 69]. None of these studies demonstrated a significantly greater weight loss for the HC diet as compared with the HP diet. There are no clear reasons as to why some studies demonstrated a difference in weight loss for the high protein group and others did not, but a successful outcome appears to be linked to a high level of support and counselling, food provided by the study and short duration (less than six months) which is likely to encourage a higher compliance rate. Adequate power is also likely to affect trials, and this is difficult to compare between studies as it is often not reported.

There have been five weight loss studies to date considering the effect of a HP diet in individuals with T2DM, similar to the present study [51, 58, 62, 63, 66]. Only one of these trials found a significant effect for the HP diet on weight loss [51] (compared to 8 out of 15 trials in the general population). These studies, taken together with the present trial, suggest the population with diabetes is different to the general population, and a high protein diet may not be the answer for this particular group.

The present study is important for its large sample size, long duration, and the aim to deliver only what could be replicated in a primary care setting. The magnitude of weight loss achieved was similar to four other studies [47, 49, 61, 62] but on the lower end of the range (-1.09 to -9.9kg for HP diets) for the studies presented in Table 2.2 of the literature review. Interestingly, two of the four studies achieving similar small levels of weight loss did demonstrate a difference between the groups, as although
total weight losses were small, the differences between groups were similar to studies achieving greater total weight loss [47, 49].

In the present study however, weight loss at six months was almost identical, at -2.5 and -2.6kg in the HC and HP groups respectively. Three other studies also demonstrated nearly identical weight loss in both groups [57, 62, 67]. These studies differed in study population, but were all of short duration at six, eight and 12 weeks. The fact that the present study maintained similar weight losses to six months lends support to the comparable effect of the diets.

The study was powered to detect a difference of 2.2kg in weight with only 112 participants, less than half the number that completed the study. The difference between the groups at six months however was only 0.1kg; it would have required a very large sample indeed to find a statistically significant difference of that size, and it would not have been clinically significant. This more likely means that there is no true difference between the effects of the diets. The anticipated attrition rate was 20% and the study experienced a slightly higher attrition of 30%, which is still within reasonable limits of expectation for this duration of study. Brinkworth et al experienced a 42% attrition rate, and Clifton et al 34% attrition [66, 130]. Studies with lower attrition rates were much shorter, such as Te Morenga et al, who retained 91% of participants after a ten-week intervention [47]. However even some of the short-term studies experienced relatively high attrition rates; Meckling et al had a 27% drop out rate after only 12 weeks [53]. Those who dropped out of the present study did tend to be older, and because of this may have experienced more health problems. This in turn may have reduced their ability or willingness to stay in the study. On balance the attrition rate likely illustrates the difficulty for participants of committing to such a long study and to sustained dietary change. At two years this has been the longest study of its type, with the nearest similar study being Brinkworth et al at 68 weeks [66].

It was encouraging that although only modest weight, body fat and waist circumference losses were obtained, these were sustained throughout the length of the study. Participants were on the whole better off than when they started the study. The usual pattern for weight loss is for weight to drop in the first few months, then slowly
increase again either to baseline, or even higher. A meta-analysis of weight loss studies showed a net weight gain of 0.03 BMI units per month once studies moved to weight maintenance phases [131]. The National Weight Loss Registry recently reported that only 20% of those who lose weight will be able to maintain the weight loss for more than one year [132]. When weight is tracked in the general population over time (i.e. not specifically those trying to lose weight) average weight gains of 0.5-1kg are observed each year [133]. The support provided by the study through group sessions, weigh in clinics and text or email contact was obviously beneficial regardless of diet. This has also been demonstrated in other studies, for example Dale et al, where weight loss maintenance was achieved through weigh-in clinics and phone calls, regardless of the diet used [118]. Also beneficial was the long duration of the intervention, involving one year of regular contact. The fact that weight losses were sustained in the second year was testament to the skills learned in the group sessions, and that long term behaviour changes were made. For some individuals, large behaviour changes were made and sustained, with 61 people losing 5kg or more by 12 months. The largest individual weight loss was 54kg at 24 months. Conversely, not all individuals were able to make such changes, and at the other extreme eight participants had gained 10kg or more at 12 months. The largest individual weight gain by 24 months was 26kg.

It is also worthy of note that when the groups were examined separately, the HP group maintained their significant weight loss right throughout the study, whereas in the HC group weight loss was no longer significant by 24 months. This may suggest a small advantage for the HP diet, in that weight maintenance is better over the long term. Potentially those that were still following a high protein diet by 24 months had adjusted to the concept and found compliance to the sustained energy reduction easier than those on the high carbohydrate diet. On the contrary however, the significant weight loss at 24mths in the HP group exists despite any difference in energy intake and urinary nitrogen, and probably highlights again the inaccuracy of diet records for measuring energy intake.
5.2 Dietary Intake, Urinary Nitrogen and Satiety

Our study clearly demonstrates the difficulty participants had in meeting the high protein targets. The HP group did not meet the target of 30% of TE from protein, reaching only a maximum intake of 22% (at six months), from a baseline intake of 19%. In absolute amounts, this was an increase of 8g protein (equivalent to one egg or 50g of ham), from 87.8 to 95.3g at six months. Only 12 of the 207 participants allocated the high protein diet achieved a protein intake of 30% of TE or higher. The inability of most to adequately increase protein intake was confirmed by the urinary nitrogen findings, which did not change from baseline even with a small reported increase in protein intake. This limited the ability of the study to comment on the true effect of high protein intakes on any variable including renal safety, as this was only a small increase above baseline levels of intake.

Generally speaking, studies that provided at least half the participants required protein foods reported the highest protein intakes. In studies that also demonstrated no difference in weight loss between the diets, protein intakes varied from 24 to 31% of total energy from protein. Three studies provided key foods that made up around 60% of participants energy intake, and the HP groups achieved 27%, 31% and 28% of TE from protein respectively [64, 65, 68]. Providing study food appears critical to maintaining high protein intakes, as demonstrated by Brinkworth et al, where protein intakes fell in the HP group to just 21% after three months, once the supply of food ceased [65]. Whilst these studies can inform as to whether a high protein intake can have specific metabolic effects, it is clearly not possible to provide food to patients in the “real world”. The only study that did achieve high protein intakes (27%) without supplying food (and was in a population with T2DM) gave participants individual nutrition counselling, rather than group sessions which may have assisted compliance [62]. In contrast, in the study by Gardner et al where no food was provided and information delivered in group sessions, intakes only reached 24% of TE at two months and dropped to 20% by six months [61].

Where studies did find a beneficial effect of protein on weight loss, protein intakes were slightly higher than the above, ranging from 24 to 35% of total energy from protein. Claessons et al provided casein supplements and achieved 35% TE from
protein [49]. Two studies provided all food in a research department grocery store, and the protein intakes reached 25% and 24% of TE respectively [50, 54]. Te Morenga et al provided pre-prepared main meals and dietary advice, and protein intakes reached 25% TE [47]. Protein levels of 24% and 28% were reached in two studies without providing food, but again individual dietary counselling was employed which may have assisted compliance [48, 53].

All studies examined achieved a higher protein intake than the present trial. The majority however were much shorter in duration, with either the whole study or the intervention phase completed between 6 and 16 weeks. In the study by Gardner et al for example, by six months the protein intake was lower than that of the present trial at the same time point [61]. Also once the Brinkworth and Due studies ceased to provide key protein foods, protein intakes fell to the same level as observed in the present trial [50, 65]. The DEWL trial did not undertake any measurements at three months, which may well have shown a higher protein intake. In the only two trials that took measurements at six months (while still in the intervention phase) and did not provide protein foods, protein intakes reached 28% in one, and were not reported in the other [48, 60].

The sample menu plans were acceptably close to the macronutrient recommendations for protein and carbohydrate but the fat content varied more. The protein contents were slightly higher in both diets than the goal, but as they were equally higher this was not considered to be a problem. The fat contents were lower in the HC diet than the HP diet, as sources of protein are also commonly sources of fat. This is a difficulty with prescribing a HP diet and extra effort must be undertaken to keep fat intakes to a minimum. However even in the HP diet fat intakes in the sample plans were lower than the 30% of total energy, which then allowed for added fats and spreads.

Considering the difference in reported energy intake between the HP and HC groups, one might have expected the HC group to have lost twice the weight they did lose. Both groups lost the same amount of weight, despite the HC group having a lower reported caloric intake. Exercise levels were unchanged, so this did not account for the imbalance in weight and caloric intake. It is likely however that this was not a true difference, but due to under-reporting of intake in the HC group. Other studies have
reported similar findings, the study by Te Morenga for example reported the HC group eating 580kJ less than the HP group but yet the HP lost significantly more weight [55]. Under-reporting of energy intake in three day diet records has been associated predominantly with reporting lower fat intakes, but also lower protein intakes [134, 135]. This could well explain the reported difference in both fat and energy intakes between the HC and HP groups. It also illustrates however the difficulties of increasing protein intakes without increasing fat intakes, as the two nutrients are often present in food together. While some trials exclude energy data considered to be under-reported (by the Goldberg cutoff), in this trial intention to treat was considered to mean that all data should be included as reported. All diet record data was therefore used with none excluded. While under-recording is certain to have occurred, it is difficult to distinguish this from under-eating, which is desirable in a weight loss study. As this was a randomised trial, it was assumed that under-reporting would occur equally in both groups. As this did not happen, it would be useful to examine this phenomena more closely in future studies. This is important as all indirect methods of determining dietary intake are flawed and increasing our understanding of this can assist in using the most appropriate method for the question being addressed.

Another strength of the study was that both groups achieved the same fibre intake, hence difference in fibre intake was not a confounder. Dietary fibre is known to positively influence weight loss as it contributes to satiety. Randomised controlled trials using both fibre rich foods and supplementary fibre have consistently demonstrated greater weight losses than that observed when following lower fibre diets [136]. In the study by Te Morenga et al, fibre intake was increased along with protein in the intervention group, hence it is unknown how much of the observed difference between diets was due to increased fibre or increased protein [47].

As the target protein intake was not reached, the conclusion one must draw is that it is difficult to motivate people to change their diets significantly. Other studies have overcome this by providing food to participants, either all of their grocery requirements, protein supplements, key protein foods or ready-made main meals [47, 49, 50, 54, 64-66, 68]. This however makes these studies less applicable to free-living participants in the community, who when deciding to undertake a diet, must shop for
and prepare all their own meals themselves. Perhaps a key question that these findings raise, is what are the barriers to this change and therefore what intervention could overcome these barriers. The other possible explanation is that the food pattern of a high protein diet is unacceptable to consumers. As a number of participants disliked the diet after embarking on it, high protein intakes may be difficult to sustain over the long term, particularly low fat high protein options which may be less palatable.

Protein is hypothesized to provide greater satiety, hence limiting the amount of total energy consumed. No difference was found between the diet groups for either hunger before meals, or satiety following meals in this study. The tool used, the visual analogue scale, has provided consistently positive results for protein and satiety in other studies [25, 26, 33, 81, 82]. It is likely that the protein intake at each meal was not increased enough to observe any effect on satiety. The lowest amount of protein used in other studies to demonstrate higher satiety was 5g extra per meal [26], whereas the daily protein increase in the HP group only amounted to 8g, an average of 2.6g extra per meal. In other studies the HP test meals were up to 30g higher in protein than the low protein meals [81, 82].

5.3 Glycaemic control, blood lipids and kidney function

No differences were observed between the diets for glycaemic control, blood lipids and measures of kidney function. This is likely reflecting the fact that there was no difference in weight loss, and that the dietary targets were not achieved. The small changes that occurred in each variable were not clinically significant. With the 294 completers the study was powered to detect a difference between groups in HbA1c of 0.6%. It was not powered however to detect the projected difference in HDL of 0.07mmol/L, meaning that potential differences in HDL would not have been identified. The lack of significant changes despite a three kilogram weight loss may also be due to medication use. With the use of lipid lowering and hypoglycaemic medications a much larger weight loss may be required in order to see clinically meaningful changes in HbA1c and blood lipid markers. Medication use was monitored over the study. An interesting point to note was the deterioration in blood pressure and lipids over the two years, indicating a need for more follow up of patients in primary care to ensure better management of these risk factors. While it
appeared that there was a gradual deterioration in kidney function over time, especially in ACR, the changes are well within normal expected day-to-day variation.

Conflicting results have been reported from the three weight loss studies that were conducted in individuals with T2DM. Two of the studies found no difference between the diets on measures of glycaemic control, in agreement with the present study, although one of these was only 12 weeks long [51, 66]. The results of the third study favoured the HC diet, with significant changes in HbA1c, fasting glucose concentrations and insulin sensitivity [62]. Sargrad et al also measured serum creatinine as a marker of kidney function, and reported no change on either diet [62].

One of the points of interest for this study was the potential effect on renal function, as this is often cited as a reason for not increasing dietary protein in patients with T2DM. As the participants did not reach the goal of 30% of TE from protein, no conclusion is able to be drawn about the safety of this level of protein intake in those with diabetes. However, this study does show that intakes of 22% of TE from protein are safe to consume for people with T2DM, and that in the general population it is unlikely that protein levels higher than this will be reached using similar diets without intensive dietary counseling or protein supplementation.

5.4 Exploratory Analyses

The difficulties of undertaking such analyses, where multiple tests are involved, are acknowledged and the results viewed with some caution. While the exploratory analyses (refer to Table 4.12) were undertaken with pooled data (i.e. regardless of diet allocation), they were intended to demonstrate what might have been the result had the dietary targets, in particular the protein level of 30%, been achieved. This analysis enabled the consideration of the subgroup who did comply with a higher protein intake, with intakes of 25% of total energy from protein and above. Three of the variables (lean body mass, triglycerides and serum creatinine) were only significant at two years, probably due to better compliance at this point with others having dropped out.
The ability of protein to preserve lean body mass has been hypothesized as a potential benefit of a high protein diet. This analysis suggested a retention of lean body mass of 0.15kg for every 1% increase in total energy from protein. This is in agreement with a meta-analysis of protein intakes above 1.05g/kg, where a retention of 0.6kg lean body mass was demonstrated compared with diets containing less protein [137]. This increased to 1.21kg in studies of longer than twelve weeks duration. In the present study an intake of 30% protein equates to 1.8g/kg protein for a 75kg participant consuming 8000kJ per day. Initially it was thought that protein had a nitrogen sparing effect on lean body mass, however studies investigating the nitrogen sparing effect of different macronutrients have not found this to be the case [138, 139]. Other studies have demonstrated that at protein intakes above 1.5g/kg of body weight, tissue proteolysis is suppressed and hence lean body mass is spared [140, 141]. Farnsworth et al did demonstrate that lean body mass was significantly better preserved on the high protein diet (-0.1 ± 0.3kg), but only in women, who may need less protein for the same effect than men due to fundamental differences in body composition [64].

The analysis of triglycerides indicated that only protein at 15-25% of total energy had an effect of reducing triglycerides. However the >25% category did show a trend towards significance (p = 0.09 and 0.07) which was consistent across the univariate and multivariate analyses. Larger numbers achieving the category of >25% TE than the n = 62 in this study would be needed to be certain of this observation. Taking this into account therefore indicates a possible positive effect of increased protein on triglycerides. The effect of protein on triglycerides has been remarkably consistent in other studies, with six demonstrating a greater decrease in triglycerides with a high protein diet and none demonstrating the opposite [48, 51, 52, 64, 68, 73].

The exploratory analyses reported an increase in systolic blood pressure at six months for both the higher protein categories. This does not agree with the literature, where the three weight loss studies that found a difference in blood pressure reported favourable results for the high protein diet [47, 62, 66]. Two of these studies found no greater weight loss for the HP diet, hence changes in BP were not influenced by greater changes in weight [62, 66]. It is possible that this is a consequence of the type of protein that was consumed, for example from animal versus plant sources. New Zealand does not have a tradition of legume consumption and several people
commented that they didn’t like beans. Another possibility is that sodium and potassium intakes also increased, as both are associated with certain types of high protein foods. Potassium intakes were not measured in the dietary survey, but sodium intakes were able to be retrospectively analysed. On the HC diet sodium intakes decreased significantly from baseline to six and 12 months, but the decrease was no longer significant by two years. On the HP diet sodium intakes also decreased from baseline, but the decrease was significant only at six months. Urinary sodium excretion was not measured and would have provided an objective measure of sodium intakes. It appears unlikely though that sodium intake was responsible for the increase in blood pressure. It is also possible that a confounder exists here that was not controlled for, for example weight and height.

5.5 Qualitative Research – Group Sessions, Focus Groups and Diet Materials

On the whole, group sessions were relatively poorly attended, at just over fifty percent, with attendance consistent across centres. Motivation was clearly higher in the first six months, where attendance reached 61%, and waned substantially by the second six months. There are likely several reasons for this, the most important being the time commitment required. Participants made several comments about the group sessions, including waning numbers, personality clashes, traffic, location and time. The reduction of the group sessions to monthly in the second six months rather than fortnightly also affected motivation for some people. While many people mentioned weigh-ins at group sessions as positive motivators, it is possible that many people who were not losing weight found this de-motivating and chose not attend. In the Diabetes Prevention Programme, attendance at group sessions was linked to better weight loss maintenance, even though the successful weight maintainers only attended on average one more session than those who did not maintain their weight [142].

Group sessions were chosen as a cost effective way of delivering health education to large numbers of people. Group education has been shown to be effective for patients with T2DM in improving health behaviours, quality of life and diabetes knowledge compared with individual care [40]. While the group setting is effective for imparting knowledge, it may not be the most appropriate setting for individual responsibility in order to achieve weight loss. The group setting did not allow for the dietitian to work
individually with participants to check that they were following the diet correctly, or to examine individual diet records for advice. This does however reflect the reality of a primary care setting, where resources are limited and group settings are a necessity to best utilize scarce financial resources. Two studies that did use individual counseling, did achieve a much higher protein intake in the HP group without the use of supplementary food [48, 62].

It was interesting that participants reported the group sessions contributed new diabetes and nutrition knowledge, but less weight management knowledge. This would have been interesting to explore further to see whether they felt they knew it all already, or that the group sessions did not contain enough information on weight management. Part of this could have been the conspicuous absence of detailed information on exercise, which was not covered in the group sessions as the trial did not include a physical activity component and participants were encouraged to maintain constant physical activity levels.

For those that did attend the group sessions, the experience was mainly positive, with most of the comments appreciating the support the sessions provided followed by the opportunity for idea sharing. The support was certainly more important to people than the knowledge gained. For many this was possibly the first time they had been in the company of others with diabetes who were actively trying to lose weight, and this psychological support was a positive outcome, even if it did not directly support weight loss.

The weekly text and email messages were a novel form of motivation that aimed to increase compliance. The idea was that by receiving a message from the study team each week, the participants would be prompted to think about their diet and the study. While three quarters of the participants opted to receive the messages, they were not rated as particularly useful. Whether or not they achieved their motivational goal however was not explored, and would make a good basis for another study. In this study subjects were able to choose to receive the messages, and because the majority did choose this option, it was not possible to compare compliance with those that did not. A study where participants were randomized either to receive messages or not would be better placed to assess the motivational success of this idea. A review of the
few studies using this technology has indicated promising results, with two weight loss studies demonstrating greater weight loss in the text messaging group [143].

When asked what changes had been made to their diet or lifestyle as a result of the programme, the three most commonly stated changes were decreased portion size, increased exercise and more awareness of food. The fact that decreased portion size, and thus reduced energy intake, was the most common change is reassuring that one of the aims of the education sessions came to fruition. And this was also borne out by the fact that participants did reduce their energy intake and lose weight. Increased exercise however was not something that was explicitly encouraged by the study. It is likely that participants were well aware of the benefits of exercise however, and being part of a programme provided motivation to increase this. The increased awareness of food also featured in the comments made in the exit interviews and is more vague. While no doubt well meaning, an increased awareness of food does not necessarily translate to any concrete changes in behavior.

The dietary support materials were mostly well received, but a number of participants thought the diets were too difficult to follow. The decision was made to use a portion system as it was a way of providing quantitative guidelines for protein and carbohydrate intakes while still providing flexibility for individual food preferences and choices. It was acknowledged that this would not suit some people, and hence the sample menu plans were distributed as well to provide a simpler option. In the exit interviews, some people remarked that they wanted a menu plan written with their own food preferences, which would have required more individualization of the diet than was able to be provided in this group based setting. This approach may not encourage long term change however, as participants must still be empowered to make their own appropriate food choices.

The focus groups conducted with study participants showed that the influence of family and friends, eating out and lack of self control were the major barriers participants faced in following their prescribed diet, whereas nutrition knowledge, cost and time were not. At the beginning of the study, cost was perceived to be a potential barrier as protein containing foods are potentially more expensive than other options. However this did not turn out to be an actual barrier as participants felt they
had made savings in other areas and planned meals more efficiently. As protein intake was not increased as prescribed, it may be that cost would still be a barrier if recommended levels were consumed.

It is interesting that participants were willing to absorb any increased costs of protein, as the food cost survey of the study diets did clearly show the HP diet was more expensive than the HC diet. Taking the cost per 1000kJ, and assuming an energy intake of 8000kJ per day, the HP diet was potentially $13.44 more expensive than the HC per week. As participants hinted however, it may not have been more expensive than their usual diet, once less healthy foods were no longer being purchased. It is also likely that participants were not consuming the amount of protein prescribed, and hence the costs were lower than expected.

Other studies have shown similar results; Holgado et al identified that time constraints and will power were the perceived barriers to healthy eating in 1000 European Union citizens [144]. Biloukha et al in the Ukraine listed cost, lack of time and lack of self control as the main barriers to healthy eating [145]. The support of family and friends, food costs and time constraints were the top three barriers in the study by Cox et al [146]. These findings suggest that it is not enough to choose to follow a diet, one must overcome significant barriers in order to be successful. More studies are needed on the types of support that could help people to achieve success, potentially focussed on these common barriers.

A number of participants commented that they wanted to be on the other diet, or that the macronutrient content of the diet they were allocated to was not to their liking. While there were some comments about the high protein diet being too much protein, more consistently this applied to the high carbohydrate diet, with participants complaining it was too high in carbohydrate. Perhaps this could partly be explained by the sheer amount of publicity reduced carbohydrate diets have received, influencing the perception of the general public about what is a healthy level of carbohydrate. It also suggests that the bulk and volume of the high carbohydrate diet is alien to most people, who are used to more energy dense diets higher in fat. The idea that more food does not always equal more energy was very difficult to grasp for some people. It would be interesting to see whether compliance to a diet was better if
the participants were allowed to choose the diet that suited them best. As randomised controlled trials are considered the gold standard for assessing success of a diet, this is unlikely to be an idea easily explored in research.

The suggested reasons why people cannot adhere to a diet and achieve weight loss vary from genetics [147] to motivation [148] to complex psychological assessments [149]. Kruger et al reported that those reporting significant dietary barriers were 48-64% less likely to lose weight than those who did not report barriers [150]. In the Diabetes Prevention Programme, those who did not maintain weight loss at follow up were significantly more likely to report emotional eating, stress, work and coping as barriers [142].

When one considers the characteristics of successful weight loss interventions, common themes do emerge. Self monitoring of food intake and regular weighing are both linked with successful weight loss [150, 151]. This study provided both options, with food recording diaries issued to every participant and more available if required. While it was not noted on an individual level whether these were used, the qualitative survey reported that people found this very useful, secondary only to the dietary advice itself. All participants were encouraged to use their diaries to record food intake and monitor their eating. Weight was taken every group session, and monthly weigh in clinics were offered in the second year. Successful interventions must also increase dietary restraint and decrease disinhibition (loss of control of eating – binge eating and eating in response to non-hunger cues) [142, 149]. The education material delivered in group sessions did try to address some of these issues, for example session nine discussed eating in response to stress and potential ways participants could deal with this. Goal setting has also been associated with better weight loss outcomes [131], and this was encouraged at every group session, with space on the session handouts for specific goals to be written in, and time allocated for discussing goals.

Three approaches are often used to elicit behaviour change in individuals to achieve weight loss. The transtheoretical model of behaviour change (TTM) suggests that in order to change a behaviour, an individual must progress through six “stages of change”, which are precontemplation, contemplation, preparation, action,
maintenance, and termination [152]. This model is best suited to individual consultations, as it involves determining where the individual is currently at in terms of the behaviour of interest, and what intervention might move that individual towards the “action” stage. Johnson et al have shown this method to be successful for achieving weight loss, but it requires detailed personal assessment and intervention [148]. Motivational interviewing is also a personalised approach, described by its creators as ‘directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence’ [153]. This has been shown to be effective in initiating behaviour change that results in weight loss when compared with traditional ways of giving advice [154, 155].

Behaviour therapy is the practice of identifying problem behaviours and providing skills for changing these behaviours [156]. This is more suited to group sessions as common behaviours can be identified and discussed and problem solving techniques employed with a small group of people. It is on this theory that much of the education component of the group sessions in this study was based. Problems were identified such as dichotomous thinking, pressures to eat, special occasions and understanding ‘wants’ versus ‘needs’. These were then discussed as a group and problem solving techniques employed to find possible solutions for participants to try. Along with problem solving, behavioural substitution and stimulus control are advocated to avoid situations when eating usually occurs outside of meal times and not triggered by hunger. Cognitive restructuring is also employed to change negative thought patterns like all-or-nothing thinking [156]. All of these techniques were employed in the group sessions run during the study. Behaviour therapy also encourages self monitoring and goal setting as previously mentioned.

Despite the evidence that individual consultations may allow for better use of some behaviour change techniques, meta-analysis has shown that both group and individual settings are effective in changing diet in order to achieve weight loss [131]. The challenge is to effectively design group settings that provide enough individual accountability and make use of different behaviour change theories to best support participants to make dietary changes.
5.6 Limitations

The major limitation of this study was that the HP group participants did not reach the intended dietary target of 30% of total energy from protein. Whether more intensive dietary counselling, individual monitoring or a different way of presenting the information would have made a difference to compliance is not known.

It would have been preferable to have analysed all available urine for the urinary nitrogen analysis, but unfortunately time and financial constraints did not allow this. The urinary nitrogen analysis therefore is reliant on the subsample chosen being of sufficient size and distribution to be representative of the whole population.

The use of three day diet records to assess self reported food intake remains a limitation due to the prevalence of under-reporting. This was illustrated in this trial as energy intake (and likely fat intake) was probably under-reported by the HC group as the energy difference between groups did not translate into a difference in weight. In the future, analysis of the relationship between reported energy intakes and weight loss for individuals would go some way to understanding this better.

The limitation of the diet materials questionnaire was that only those who completed the year of dietary intervention participated. It is likely that more negative comments would have been collated if we had been able to capture the whole participant population including those who had dropped out by this point. The focus groups were also small and limited to one centre, which may not be representative of the study population. The food cost survey was again limited by small sample size and a more representative picture would have been gained had a larger number of diet records been included.
6. Conclusions and Recommendations

Prescription of a high-protein:moderate-carbohydrate diet was not more effective than a low-fat:high-carbohydrate diet in reducing weight and optimising glycaemic control, lipid profile and blood pressure in this large trial of free living adults with type 2 diabetes. Both diets resulted in a modest reduction of weight and waist circumference, but little or no differences were observed for glycaemic control, blood lipids and blood pressure. Either macronutrient composition thus presents an effective option for people with T2DM wishing to lose weight. No adverse effects of the high protein diet were noted on renal function at the achieved level of intake.

In this free-living population target protein intakes were not met on the high protein diet, leading to the conclusion that it is difficult for people to change their dietary habits, and sustain a weight loss programme. It also suggests reaching a level of 30% of total energy from protein in the general population is not practical. This trial highlights what is possible to achieve in a primary care setting, when supplementary protein is not supplied. It appears from other studies that more intensive individual counseling may be more effective than group sessions in reaching dietary targets for weight loss, and this should be the subject of further research.

As modest weight losses were sustained by both groups over two years, it can be suggested that either diet is suitable for weight management in individuals with T2DM. The choice should be made by the individual as to which diet will better suit them, and the role of the health professional is then to determine how best to support that individual to adhere to their chosen diet.

The following recommendations are offered for future research:

- Further studies are required to ascertain whether it is possible to substantially increase the protein consumption of free-living individuals without supplementary assistance. Clarification on whether group or individual counseling is the best way to achieve this in the context of weight loss is also important.
• It is still a priority to assess whether an actual intake of 30% of total energy from protein has a detrimental impact on renal function in individuals with T2DM.
• It is important to continue research into the barriers to dietary change. This includes ways to support whole families to eat healthier and changing the food environment so that better choices exist when eating out.
• Sending text and email messages as a motivational and compliance tool is a novel use of technology that has much potential, but requires further research to ascertain the success of this approach.
7. References


80. Parker BA, Sturm K, McIntosh CG, Feinle C, Horowitz M, et al. Relation between food intake and visual analogue scale ratings of appetite and other sensations


8. List of Appendices

A. Pre-baseline screening questionnaire
B. Information sheet and consent form
C. Sapphire diet information package (Sample diet plans on CD)
D. Topaz diet information package (Sample diet plans on CD)
E. Food pyramids
F. Recording book
G. Group session participant material (CD)
H. Recipes – Maori, Pacific Island and Indian Food
I. Dietary intervention manual
J. Text/email support messages
K. 3-Day diet record
L. Diet assessment photos
M. SF-36 Quality of life questionnaire
N. AHS Physical activity questionnaire
O. Pedometer recording sheet and instructions
P. Investigators brochure (CD)
Q. Baseline, 6, 12 and 24 month questionnaires (CD)
R. Diet materials questionnaire
S. Exit interview
T. Exploratory analyses
U. Comments from diet materials questionnaire
APPENDIX A – Pre-baseline Screening Questionnaire

The Diabetes Excess Weight Loss (DEWL) Trial:
High Protein vs Low Fat Diets

* This information needs to be collected and entered into the database for study audit purposes even if the person is ineligible.

* Date of this phone call: __/__/__
* Surname:……………………………….  * First Name:
……………………………………

Preferred name:………………………..  * Title: Mr / Mrs / Miss / Ms
(Circle)

* Date of birth: __/__/__
* Sex : □ (M/F)

* Full Address:
………………………………………………………………………….
…………………………………………………………………………
………………
……………………………………………………Postcode………………
………………

* Phone:  Home .............................................□  Tick Preferred

工作  ............................................. □

Mobile .............................................□

E mail address:  .............................................

Fax no:  .............................................

* NHI: □
Explain that throughout the study we may use email or text to provide encouragement to participants once a week for the first year.

Preferred method of contact:

- Text [ ]
- Email [ ]
- Neither [ ]

* Year diagnosed with diabetes:

* Proof of diabetes diagnosis:

Participants must meet the WHO criteria for diabetes. This needs to be confirmed by the participant’s primary carer if they are on diet alone, metformin alone with an HbA1c < 6.5% or it is uncertain whether they have Type 1 diabetes.

- Diagnosis confirmed (tick) [ ]

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<thead>
<tr>
<th>LAST KNOWN: (SELF REPORTED)</th>
<th>CONSENT MEETING:</th>
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<td>DATE [ ]/ [ ]/ [ ]</td>
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<th>WEIGHT:</th>
<th>WEIGHT:</th>
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<th>BMI:</th>
<th>BMI:</th>
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**Blood / Urine Test Results:**

(* If last test not within the last 3 months you will need to send a lab form to the participant)

1st Serum Creatinine:

(If last test is over 140mmol/L you will need to send a lab form to the patient)

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<tr>
<th>DATE OF TEST</th>
<th>RESULT µMOL/L</th>
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<thead>
<tr>
<th>HbA1c:</th>
<th>DATE OF TEST:</th>
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<td>[ ]/ [ ]%</td>
<td>[ ]/ [ ]/ [ ]</td>
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<tr>
<th>Albumin / Creatinine Ratio:</th>
<th>DATE OF TEST:</th>
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<td>[ ]/ [ ]/ [ ]</td>
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| DATE OF MEETING: |
|-----------------|----------------|
| DATE: [ ]/ [ ]/ [ ] |
### LFTs:

<table>
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<tr>
<th>TEST</th>
<th>Result</th>
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<tbody>
<tr>
<td>ALT (mmol/L)</td>
<td></td>
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<tr>
<td>AST (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>GGT (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>Albumin (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>Bilirubin (mmol/L)</td>
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</table>

### Are you happy for us to obtain copies of these blood tests?

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
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<tbody>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>No</td>
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<tr>
<td>N/A</td>
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</table>

### Consent Meeting:

**2ND Serum Creatinine:**

<table>
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<tr>
<th>TEST</th>
<th>Result</th>
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<td>DATE OF TEST</td>
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<tr>
<td>DATE OF TEST</td>
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<td>DATE OF TEST</td>
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<tr>
<th>µMOL/L</th>
<th>µMOL/L</th>
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### Are you vegetarian?

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<thead>
<tr>
<th>Option</th>
<th></th>
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<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
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</tbody>
</table>

**If yes:** Explain – If you are randomised to the high protein group, an example of the amount you may need to eat each day is:

- 2 cups milk
- 45g cheese
- ½ cup nuts
- 1 cup beans
- 1 cup yoghurt

Is this amount feasible for you?

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
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<tbody>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>No</td>
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</tbody>
</table>
**INCLUSION CHECKLIST:** (If “No” ticked the person is ineligible)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>Type 2 diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age between 30 and 75 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI ≥27kg/m² (Self reported)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI ≥27kg/m² (Consent meeting)</td>
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</table>

**Exclusion checklist:** (If “Yes” ticked the person is ineligible)

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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</thead>
<tbody>
<tr>
<td>HbA1c &gt; 9.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight &gt; 200 kg</td>
<td></td>
<td></td>
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<tr>
<td>Current or recent weight change (&gt;3kg) in 3 months</td>
<td></td>
<td></td>
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<tr>
<td>Pregnancy or lactation</td>
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<td></td>
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<tr>
<td>An eating disorder or active psychiatric illness</td>
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<tr>
<td>Diabetic nephropathy (urinary albumin/creatinine ratio &gt;70, sCr &gt;160 mmol/L)</td>
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<tr>
<td>Or other chronic renal failure</td>
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<tr>
<td>Abnormal liver enzymes (AST, ALT or GGT &gt;3 x upper limit of normal)</td>
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<tr>
<td>Active gallbladder disease (cholecystitis in last 12 mths, ongoing biliary colic)</td>
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<tr>
<td>Myocardial infarction in the last 6 months</td>
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<tr>
<td>Heart failure (New York Heart Association class III or IV)</td>
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<tr>
<td>Known malignancy, other than squamous cell or basal cell carcinoma of the skin, that has not been in full remission for at least 5 years prior to screening</td>
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<tr>
<td>Ongoing oral steroid use</td>
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<tr>
<td>Other reasons why taking part would be practically difficult</td>
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</table>
Does the patient still meet the eligibility criteria and wish to continue?

Yes □  No □

If Yes: explain the:  Consent meetings / Dieticians meetings / 4 x clinic visits

Appointment date for consent meeting ________________________

Availability for group sessions:

Would you prefer:  Daytime □  Evening □

The days / times that I will never be available are:

..................................................................................................................
..................................................................................................................
..................................................................................................................

* If No: What is the reason:

□ Declined after receiving the study information
□ Serum creatinine > 160μmol/L
□ LFT’s > 3x ULN
□ BMI out of the range
□ Weight > 200 kg
□ Unable to confirm diabetes
□ Other (please state reason)

..................................................................................................................
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* Would they like us to contact them in the future regarding other relevant studies? (Tick)

YES □  NO □
**FOR THOSE ELIGIBLE AND INTERESTED IN PARTICIPATING IN THE DEWL TRIAL:**

**Current medical conditions:**

<table>
<thead>
<tr>
<th>Diabetes-related:</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Peripheral Vascular Disease</td>
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<td>Neuropathy</td>
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<td>Retinopathy</td>
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<tr>
<td>Depression</td>
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<tr>
<td>Other Diabetes-related:</td>
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<table>
<thead>
<tr>
<th>Cardiovascular-related:</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Ischemic Heart Disease (e.g. heart attack, angina, angioplasty, CABG)</td>
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<tr>
<td>Cerebrovascular Disease (CVA or TIA)</td>
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<tr>
<td>Diagnosed Hypertension</td>
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<tr>
<td>Dyslipidaemia</td>
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<tr>
<td>Other CVD-related:</td>
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**Other Medical Conditions:**

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</table>
Current medications and doses:
from: 1=medical notes, 2=self-report, 3=viewed

Diabetes treatment: (Record insulin on the treatment chart, next page)
(Fill in drop-down menu when entering or text field if not available)

………………………………………………………..
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Cardiovascular treatment: (Fill in drop-down menu when entering or text field if not available)

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Other prescribed treatment: (Fill in drop-down menu when entering or text field if not available)

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OTC/ Herbal/ Vitamins: …………………

………………………………………………………..
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**INSULIN TREATMENT CHART**

**WHAT IS THE USUAL DOSE THAT YOU ARE TAKING?**
*(If the participant cannot give exact doses then record the average dose at each time point)*

<table>
<thead>
<tr>
<th>AM (u)</th>
<th>NOON UNITS</th>
<th>PM UNITS</th>
<th>BEDTIME UNITS</th>
<th>TOTAL DAILY DOSE</th>
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<tr>
<td>Lisopro (Humalog)</td>
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<td>Aspart (NovoRapid)</td>
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<tr>
<td>Neutral (Actrapid, Humulin R)</td>
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<td>Isophane (Insulatard, Humulin NPH, Protophane)</td>
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<td>Glargine (Lantus)</td>
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<td>Insulin detemir (Levemir)</td>
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<tr>
<td>Humulin Mixture 30/70</td>
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<td>Mixtard 30</td>
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<tr>
<td>Mixtard 50</td>
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<tr>
<td>Penmix 10</td>
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<td>Penmix 20</td>
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<td>Penmix 30</td>
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<tr>
<td>Penmix 40</td>
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<tr>
<td>Penmix 50</td>
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</table>

**TOTAL DAILY DOSE**
Name of General Practitioner: ...........................................

Medical Centre: ........................................................................
..........................................................................................
..........................................................................................
..........................................................................................

Postcode .................................................................

Phone Number: .............................................................

- **Alternative contact:** (name and phone number of a family member or friend, in case you move away or change contact details)

..........................................................................................
..........................................................................................
..........................................................................................

- Collect at the end of the conversation if the person still meets the criteria and wishes to continue

How did you hear about the study:
..........................................................................................
APPENDIX B – INFORMATION SHEET AND CONSENT FORM

INFORMATION SHEET

The Diabetes Excess Weight Loss (DEWL) Trial:
‘High Protein’ compared with ‘Low Fat’ Diets

LEAD RESEARCHER: DR JEREMY KREBS, WELLINGTON SCHOOL OF MEDICINE & HEALTH SCIENCES

Funded by the New Zealand Health Research Council

If you are eligible, you are invited to take part in a 2-year study that compares two diets for reducing weight in people with diabetes. Please take your time deciding whether or not you would like to participate and feel free to discuss with family or friends first. Your participation is entirely voluntary (your choice). You do not have to take part and if you choose not to take part you will receive your usual care. You can withdraw at any time without having to give a reason and this will not affect your future health care. If you agree to take part, the investigators may withdraw you from the trial if for any reason they feel it would not be appropriate for you to continue. All information collected for this study is confidential and kept secure and no material that could personally identify you will be used in any reports on this study.

People between the ages of 30 and 75 who have type-2 diabetes, are overweight and would like to lose weight are invited to take part. All participants will have measurements done by a research nurse at the beginning of the study, then after 6 months, 1 year and 2 years to see if any changes have taken place. The measurements will take about 1 hour each time and include weight, height, waist measurement, blood pressures, body fat, a 24-hour urine test, fasting blood test and questionnaire. A few participants will also be invited to have blood sugar levels monitored for three days, and a few participants will be invited to wear a pedometer for one week. Participants will be asked to keep a record of food consumed over 3 days before each visit with the research nurse. The first assessment will also check to see if each person is suitable for the study, for health and safety reasons and will include at least 2 extra blood tests in the first 1-2 months to check kidney function. With your consent, blood samples will be stored for 5 years after completion of the study, and may be used to measure other relevant factors to this study, with ethics committee approval. If you would prefer, blood samples will be destroyed after the end of the study.

Half the 450 participants from around New Zealand will be chosen by chance to use a low fat diet and the other half will use a high protein diet to lose weight. All participants will be invited to join small groups that will meet for 1-2 hours fortnightly for the first 6 months and monthly for the second 6 months. An experienced dietitian will lead and support the group and provide information about how to achieve the diet.

If you participate, you will benefit by having the support of a dietitian and participation in a small group in the first year to help you stick to the diet and lose weight. Weight loss will be good for many aspects of your health and for your diabetes control. You will also have the benefit of regular measurements by the research nurse over two years. Participants will have to buy their own food but the diet options have been designed to be low cost and probably no more expensive then your usual diet. You can choose whether you continue the diet after the study and you may stop the diet and group attendance at any time. Even if you don’t continue the diet, we are still interested in taking the research measurements and we will not mind if you have stopped the diet. A change in diet and weight loss sometimes leads to a lowering of blood sugar so those using insulin or certain tablet medications (these will be discussed with you) to control blood sugar will need to test blood sugar regularly to watch for low readings.
The long-term effects of high protein diets on kidney function are not clear, but we expect the diet to help. We will be monitoring kidney function to ensure there is no harm.

If you agree, your usual GP or other carer will be informed of your participation and results of the study. You will be offered a copy of the results at the end of the study. Please feel free to contact the researchers if you have questions or need more information, Cecilia Ross / Tess Clarke / Ingrid McEnaney, ph 385 5999 ext. 4703.

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. If you have any questions about ACC, contact your nearest ACC office or the investigator. This study has received ethical approval from the Multi-regional Ethics Committee. If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate, telephone 0800 42 36 38 (4 ADNET)
CONSENT FORM

The Diabetes Excess Weight Loss (DEWL) Trial:
‘High Protein’ compared with ‘Low Fat’ Diets

LEAD RESEARCHER: DR JEREMY KREBS, WELLINGTON SCHOOL OF MEDICINE & HEALTH SCIENCES

I have read and I understand the information sheet dated 20/02/07 for volunteers taking part in the study designed to assess the effects of low fat and high protein diets for weight-loss over 2 years. I have had the opportunity to discuss this study and I am satisfied with the answers I have been given. I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study. I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care. I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study. I understand that I will be advised to stop if the diet should appear harmful to me. I understand the compensation provisions for this study.

I would like to participate providing initial assessments confirm I am eligible for the study. I know who to contact if I have any side effects to the study. I know who to contact if I have any questions about the diet or the study.

<table>
<thead>
<tr>
<th>Language</th>
<th>English</th>
<th>Maori</th>
<th>Cook Island</th>
<th>Fijian</th>
<th>Niuean</th>
<th>Samoan</th>
<th>Tokelaun</th>
<th>Tongan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I wish to have an interpreter.</td>
<td>E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.</td>
<td>Ka inangaro au i tetai tangata uri reo.</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td>Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.</td>
<td>Ou te mana’o ia i ai se fa’amatala upu.</td>
<td>Ko au e fofo kia he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika</td>
<td>Oku ou fiema’u ha fakatoneula.</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

I consent to blood samples being stored at the end of the study for five years, for the purpose of additional tests directly related to this study. I understand that any additional tests will only be performed with prior approval of the ethics committee. I also understand that my blood samples will be destroyed at the end of five years.

YES/NO

I agree to my GP and/or diabetologist being informed of any abnormal personal results in this study

YES/NO

I wish to receive a copy of the results

YES/NO
I _____________________________ (full name) hereby consent to take part in this study.

Date:

Signature:

Full names of Researchers: Jeremy Krebs, Helen Lunt, Paul Drury, C. Raina Elley, Amber Strong, Damon Bell, Jim Mann, Elizabeth Robinson

Local Contact Phone Number for researchers: (04) 385 5999 ext. 4703 or 021 244 6630

Project explained by:

Project role:

Signature:

Date:
Welcome to the DEWL diabetes study! You have been allocated to the sapphire diet plan. This plan is high in carbohydrate, low glycaemic index and low fat. This plan is also lower in energy than you usually eat so that you can lose weight.

My energy requirements are: kJ or kcal per day

My Carbohydrate Portions per day are:

My Protein Portions per day are:

I need to eat at least 2 pieces of fruit each day

I need to eat 3 or more serves of vegetables each day

I need to have high fibre and low glycaemic index foods

We will help you fill this table in at group session one:

My Day Plan:

<table>
<thead>
<tr>
<th>Meal</th>
<th>Carbohydrate Portions</th>
<th>Protein Portions</th>
<th>Vegetables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lunch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dinner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snacks</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Protein Portions: P

On your goals page you will have been given the number of protein and carbohydrate portions you need to eat each day. Below is an exchange list of the foods that make up one portion. You need to spread your portions out over the day, for an example see your sample diet plan.

<table>
<thead>
<tr>
<th>Food</th>
<th>1 protein portion (1P) =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mince</td>
<td>¼ cup</td>
</tr>
<tr>
<td>Chicken Drumstick</td>
<td>1 drumstick</td>
</tr>
<tr>
<td>Chicken Breast</td>
<td>½ breast (52g)</td>
</tr>
<tr>
<td>Chicken Leg</td>
<td>¾ leg</td>
</tr>
<tr>
<td>Sliced Ham</td>
<td>2 slices (100g)</td>
</tr>
<tr>
<td>Sliced Beef eg roast</td>
<td>1 slice (47g)</td>
</tr>
<tr>
<td>Steak</td>
<td>⅜ of a steak (57g)</td>
</tr>
<tr>
<td>Hamburger Pattie</td>
<td>1 pattie</td>
</tr>
<tr>
<td>Sliced Lamb</td>
<td>2 slices (47g)</td>
</tr>
<tr>
<td>Lamb Chop</td>
<td>2 chops (80g)</td>
</tr>
<tr>
<td>Egg</td>
<td>2 eggs</td>
</tr>
<tr>
<td>Sausage</td>
<td>1 sausage</td>
</tr>
<tr>
<td>Brisket</td>
<td>2 slices (90g)</td>
</tr>
<tr>
<td>Tinned Corned Beef</td>
<td>2 slices (56g)</td>
</tr>
<tr>
<td>Bacon</td>
<td>2 rashers (45g)</td>
</tr>
<tr>
<td>Pork diced</td>
<td>⅛ cup (50g)</td>
</tr>
<tr>
<td>Pork Steak</td>
<td>⅜ steak (63g)</td>
</tr>
<tr>
<td>Fresh Fish</td>
<td>1 fillet</td>
</tr>
<tr>
<td>Tinned Tuna</td>
<td>½ cup</td>
</tr>
<tr>
<td>Tinned Salmon</td>
<td>⅛ cup</td>
</tr>
<tr>
<td>Tinned Sardines</td>
<td>5 sardines</td>
</tr>
<tr>
<td>Oysters</td>
<td>8 oysters</td>
</tr>
<tr>
<td>Mussels</td>
<td>⅛ cup</td>
</tr>
<tr>
<td>Pipi</td>
<td>36 pipis</td>
</tr>
<tr>
<td>Prawn</td>
<td>15 prawns</td>
</tr>
<tr>
<td>Tuatua</td>
<td>9 tuatua</td>
</tr>
<tr>
<td>Cheddar Cheese</td>
<td>½ cup grated or 45g sliced</td>
</tr>
<tr>
<td>Calci-trim/Calci-xtra Milk only</td>
<td>250ml</td>
</tr>
<tr>
<td>Cottage/Paneer Cheese</td>
<td>½ cup</td>
</tr>
<tr>
<td>Yoghurt</td>
<td>300ml</td>
</tr>
<tr>
<td>Nuts – limited to 3 x per week</td>
<td>½ cup</td>
</tr>
<tr>
<td>Tofu</td>
<td>¾ cup</td>
</tr>
<tr>
<td>Kidney Beans (cooked)</td>
<td>1 cup</td>
</tr>
<tr>
<td>Baked Beans</td>
<td>1 cup</td>
</tr>
<tr>
<td>Chickpeas (cooked)</td>
<td>1.5 cups</td>
</tr>
<tr>
<td>Lentils (cooked)</td>
<td>1 cup</td>
</tr>
<tr>
<td>Sunflower Seeds</td>
<td>½ cup</td>
</tr>
</tbody>
</table>
### Carbohydrate Portions: C

<table>
<thead>
<tr>
<th>Food</th>
<th>1 Carbohydrate Portion (1C) =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheatmeal/Multigrain Bread</td>
<td>1 slice</td>
</tr>
<tr>
<td>Round Bun Wholemeal</td>
<td>½ bun</td>
</tr>
<tr>
<td>Long Roll</td>
<td>½ roll</td>
</tr>
<tr>
<td>Fruit Bread</td>
<td>1 slice</td>
</tr>
<tr>
<td>Pita Bread</td>
<td>1 small pita</td>
</tr>
<tr>
<td>Bagel</td>
<td>½ bagel</td>
</tr>
<tr>
<td>Crumpet</td>
<td>1 crumpet</td>
</tr>
<tr>
<td>Scone</td>
<td>1 small scone</td>
</tr>
<tr>
<td>Muffin (Bran or fruit)</td>
<td>1 small muffin</td>
</tr>
<tr>
<td>Crackers (ryvita)</td>
<td>2 ryvita crackers</td>
</tr>
<tr>
<td>Tortilla</td>
<td>½ tortilla</td>
</tr>
<tr>
<td>Porridge (made with ½ milk + ½ water)</td>
<td>½ cup cooked ¤</td>
</tr>
<tr>
<td>Weetbix</td>
<td>1½ biscuits ¤</td>
</tr>
<tr>
<td>Cereal - Cornflakes</td>
<td>¾ cup</td>
</tr>
<tr>
<td>Muesli</td>
<td>¼ cup ◇</td>
</tr>
<tr>
<td>Special K</td>
<td>½ cup</td>
</tr>
<tr>
<td>Pasta Cooked</td>
<td>½ cup</td>
</tr>
<tr>
<td>Rice Cooked</td>
<td>½ cup</td>
</tr>
<tr>
<td>Vermicelli/rice noodles cooked</td>
<td>1 cup</td>
</tr>
<tr>
<td>Potato/kumara Cooked</td>
<td>½ cup</td>
</tr>
<tr>
<td>Pumpkin</td>
<td>1 cup</td>
</tr>
<tr>
<td>Corn kernels</td>
<td>¾ cup ◇</td>
</tr>
<tr>
<td>Parsnip</td>
<td>1 medium parsnip</td>
</tr>
<tr>
<td>Taro</td>
<td>½ cup</td>
</tr>
<tr>
<td>Cassava/ Pacific Island Giant Yam</td>
<td>½ cup</td>
</tr>
<tr>
<td>Banana</td>
<td>½ large banana/1 bobby</td>
</tr>
<tr>
<td>Apple/ Orange/ Pear</td>
<td>1 apple/1 orange/1 pear</td>
</tr>
<tr>
<td>Kiwifruit/mandarin/plums</td>
<td>2 medium sized</td>
</tr>
<tr>
<td>Tinned fruit</td>
<td>½ cup</td>
</tr>
<tr>
<td>Berries</td>
<td>1 cup</td>
</tr>
<tr>
<td>Dried Apricots</td>
<td>10 halves</td>
</tr>
<tr>
<td>Flour Dumplings Kopai</td>
<td>1 dumpling</td>
</tr>
<tr>
<td>Breadfruit</td>
<td>½ cup</td>
</tr>
<tr>
<td>Green Banana</td>
<td>½ banana</td>
</tr>
<tr>
<td>Giant Taro - Kape</td>
<td>½ cup</td>
</tr>
<tr>
<td>Plantain</td>
<td>½ cup</td>
</tr>
<tr>
<td>Kidney Beans/lentils (cooked)</td>
<td>½ cup ◇</td>
</tr>
<tr>
<td>Baked Beans</td>
<td>½ cup ◇</td>
</tr>
<tr>
<td>Chickpeas cooked)</td>
<td>1 cup ◇</td>
</tr>
<tr>
<td>Milk</td>
<td>300ml</td>
</tr>
<tr>
<td>Yoghurt</td>
<td>150ml</td>
</tr>
<tr>
<td>Sugar in drinks – not recommended</td>
<td>3 teaspoons</td>
</tr>
</tbody>
</table>

¤ means high fibre option - see page 5 for explanation

Remember at least two of your carbohydrate portions need to be fruit
## Glycaemic index of common carbohydrate foods:

<table>
<thead>
<tr>
<th>High GI foods – eat least</th>
<th>Moderate GI foods – eat some</th>
<th>Low GI foods - eat most</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breads:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bagels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baguettes, French bread</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gluten free bread</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cereals:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cornflakes™</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puffed/shredded Wheat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rice Bubbles™</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sultana Bran™</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bran Flakes™</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pasta / Rice:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rice – Calrose, Instant,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sunbrown quick, white,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>medium and short grain,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jasmine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pasta – brown rice pasta</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fruit:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watermelon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lychee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dates</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Vegetables:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parsnip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potato – instant, baked,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mashed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pumpkin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kumara</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Cereals:**              |                             |                        |
| Mini Wheats               |                             |                        |
| Just Right™, Sustain™     |                             |                        |
| Weetbix™, Vita Brits™     |                             |                        |
| Instant porridge          |                             |                        |
| **Pasta / Rice:**         |                             |                        |
| Rice – Basmati, brown,    |                             |                        |
| long-grain, Arborio,      |                             |                        |
| Doongara                  |                             |                        |
| Couscous, gnocchi         |                             |                        |
| Instant noodles           |                             |                        |
| **Fruit:**                |                             |                        |
| Figs                      |                             |                        |
| Paw paw (papaya)          |                             |                        |
| Rockmelon                 |                             |                        |
| Pineapple                 |                             |                        |
| Raisins                   |                             |                        |
| Sultanas                  |                             |                        |
| **Vegetables:**           |                             |                        |
| Beetroot                  |                             |                        |
| Potato – new              |                             |                        |
| Taro                      |                             |                        |
| Green banana              |                             |                        |

| **Cereals:**              |                             |                        |
| All Bran™, Porridge       |                             |                        |
| Unsweetened, untoasted    |                             |                        |
| muesli                    |                             |                        |
| Special K™                |                             |                        |
| **Dairy Foods:**          |                             |                        |
| Milk, yoghurt, custard    |                             |                        |
| **Rice/Pasta:**           |                             |                        |
| Pasta – white, wholemeal  |                             |                        |
| Rice – Parboiled          |                             |                        |
| **Legumes / Grains:**     |                             |                        |
| Beans – Baked beans,      |                             |                        |
| haricot, Kidney, soy,     |                             |                        |
| butter beans              |                             |                        |
| Chickpeas, split peas,    |                             |                        |
| lentils, Barley bulgur,   |                             |                        |
| dhal, buckwheat           |                             |                        |
| **Fruit:**                |                             |                        |
| Apples                    | Grapefruit                  |
| Pears                     | Grapes                      |
| Cherries                  | Peaches                     |
| Oranges                   | Plums                       |
| Apricots                  | Strawberries                |
| Grapes                    | Mango                       |
| Banana (firm)             | Kiwifruit                   |
| **Vegetables:**           |                             |                        |
| Yams                      |                             |                        |
| Corn                      | Carrots                     |
| Green banana              |                             |                        |
Fat

Fat comes in different forms as oils or fats. It is found mainly in animal based foods (e.g. meat, milk, lard, egg yolks) and in other foods such as nuts, seeds, avocados, olives and some grains. In the DEWL study we need to try to lower our fat intake because:

- Fat contains more calories than other foods
- Eating too much fat may cause you to put on weight, or make it hard for you to lose weight
- Certain types of fat can raise your blood cholesterol levels
- Eating too much fat may make your body resistant to the action of insulin
- Fat can delay your blood glucose levels from coming down after a meal

It is important to include a small amount of fat in your food plan, as it provides your body with valuable nutrients. However some fats are much healthier choices than others.

**Saturated fats**: These are the fats mainly found in animal fats (eg fat in meats, butter or cream), palm oil or coconut oil. Saturated fats tend to either increase, or give you unhealthy, cholesterol levels. It is wise to limit or reduce the amount of saturated fat that you eat.

**Polyunsaturated fats and monounsaturated fats**: These are the fats found in fish, nuts, seeds, olive oil, avocados and canola oil. They are a healthier choice of fat. Use small amounts of these good types of fats - eg canola or olive oil based margarine, some of the vegetable oils (canola, olive, peanut, soy, sunflower, avocado), peanut butter, avocado and nuts.

---

**TRY TO LIMIT ADDED FATS TO ABOUT 3 TEASPOONS PER DAY POLYUNSATURATED OR MONOUNSATURATED FATS.**

Trans Fatty Acids: These fats are formed when fat is processed or repeatedly heated to high temperatures. Trans fatty acids may increase your risk of heart disease. By limiting processed and fast foods, you can limit your intake of trans fatty acids.

<table>
<thead>
<tr>
<th>Foods containing large amounts of fat:</th>
<th>Cream cheese</th>
<th>Cream cheese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep fried food, fish and chips</td>
<td>Dripping, lard, Chefafe</td>
<td>Dripping, lard, Chefafe</td>
</tr>
<tr>
<td>Salami, luncheon, pate, some bacon</td>
<td>Mayonnaise, salad dressing</td>
<td>Mayonnaise, salad dressing</td>
</tr>
<tr>
<td>Sausages, saveloys</td>
<td>Butter, ghee</td>
<td>Butter, ghee</td>
</tr>
<tr>
<td>Pies, pastry, croissants</td>
<td>High fat takeaways e.g. burgers, pizza</td>
<td>High fat takeaways e.g. burgers, pizza</td>
</tr>
<tr>
<td>Potato chips</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cream</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Fibre

Fibre is the collective term for parts of carbohydrate foods that don't get digested. Common foods high in fibre are:

- Fruit and vegetables
- Some breakfast cereals such as weetbix, muesli and porridge
- Bran, oat bran, wheat germ, barley, linseed, brown rice
- Beans, chickpeas and lentils

Making sure you have plenty of fibre in your food improves your health in many ways. It is particularly beneficial when you have diabetes.

Fibre helps to keep your digestive system moving and working properly. It can help to improve your cholesterol levels and it may prevent you from absorbing all the fat you eat. fibre is not digested; therefore it is not broken down into glucose. However it can help to slow the breakdown of carbohydrate foods in your body, and therefore help you to achieve more steady blood glucose levels. Eating foods that are high in fibre can also help you to feel less hungry and therefore less likely to snack on extra foods.

Look for the DEWL diamond ◆ next to foods on the carbohydrate portions list, which shows you which foods are high in fibre. Try to use more of these foods than others.
DEWL Free Foods List

You can eat as many of the foods off this list as you like. These foods should make up the rest of your diet.

**Vegetables:**
Asparagus     Mushroom
Beetroot      Onion
Broccoli      Parsley
Brussel Sprouts Peas
Butter beans   Peppers
Cabbage       Puha
Carrot        Radish
Cauliflower   Silverbeet
Celery        Spinach
Choko         Snowpeas
Cucumber      Spring Onion
Egg plant     Swede
Green Beans   Taro leaves
Kamokamo      Tomato
Leeks         Watercress
Lettuce       Zucchini
Marrow

**Condiments:**
Herbs
Spices
Garlic
Marmite/vegemite
Vinegar
Worcester sauce
Soy sauce
Tomato sauce and paste
Lemon
Rhubarb

**Soups:**
Clear soup
Soup made from tinned tomatoes
Soup made from free vegetables
**Foods High In Sugar And Fat**

These foods are treat foods and while you are on this diet they should be kept to only once or twice a week in total.

- Lollies
- Fruit leathers
- Chocolate
- Carob
- Ice blocks
- Ice cream
- Cakes
- Sausages
- Fried chicken
- Liquorice
- Thick shakes
- Sports drinks
- Doughnuts
- Fa'apapa or to'okutu/manioke tama
- Preserved muttonbird

- Biscuits
- Slices
- Sweet or chocolate muffins
- Muesli bars
- Fizzy drinks
- Chippies/potato crisps
- Battered fish
- Cordials
- Deep fried chips/hot chips
- Hamburgers
- Pastries
- Pies
- Roll ups
- Kokolaisa
The DEWL Guide to Alcohol

Alcohol in moderation is fine for those who choose to drink, but remember to have at least two alcohol free days each week.

The American Diabetes Association recommendation for those who choose to drink alcohol is 0-1 standard drinks per day for women and 0-2 standard drinks per day for men. That means a maximum of one drink per day for women and maximum two drinks per day for men if you choose to drink.

Remember that alcohol can affect those people with diabetes who take insulin or sulphonylurea tablets so always eat some carbohydrate food with your alcohol.

A standard drink is:

120 ml wine
200 ml beer
30 ml nip of spirits such as whiskey, brandy, gin, vodka
60 ml sherry, vermouth, port

Alcohol also has a calorie content and can contribute significantly to energy intake. Hence for those wanting to lose or maintain weight, keeping alcohol to a minimum can help. For example by reducing your alcohol intake by just two glasses a week you could save 4kg of weight over a year.

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If you don’t drink alcohol then that’s fine, we don’t want you to start!
Sapphire Recipes:

These recipes are from the book: Diabetes Eat and Enjoy, 3rd Edition by Christine Roberts, Jennifer McDonald and Margaret Cox. Published by New Holland Publishers NZ Ltd. Look for it at a book store or order with the ISBN number: 1 877246 59 X

Golden Chicken Risotto – Serves Four

2 tablespoons water
1 large onion, chopped
1 clove garlic, crushed
1 and ½ cups basmati rice
6 cups chicken stock
4 skinless chicken breasts, diced
1 tspn powdered turmeric
20 almonds blanched and halved
3 tablespoons raisins

Oven Method:

Place all the ingredients in a casserole dish. Cover and cook at 180 degrees for one hour, or until rice has absorbed all the stock and is tender.

Stove top method:

1. Boil the water in a saucepan and cook the onion in it until softened.
2. Add the garlic and cook for 2 minutes
3. Add the rice and ¼ of the chicken stock. Bring to the boil. Reduce heat and simmer for 20 minutes, stirring occasionally and adding more stock as necessary to prevent sticking.
4. Add the diced chicken breasts, turmeric, almonds and raisins.
5. Continue simmering for a further 20-25 minutes, adding remaining stock as necessary, until the rice is tender. There should be no liquid in the finished risotto.

Portions per Serve:

Carbohydrate: 4
Protein: 2
Seafood Pasta – Serves 4

300g pasta
2 tablespoons water
½ medium onion, chopped
1 clove garlic, crushed
1 cup trim milk
2 teaspoons cornflour
1 ½ cups cooked seafood – fish, oysters, calamari, shrimps, mussels, scallops, cockles etc
1 tablespoon parsley, chopped
black pepper to taste

Method:

1. Fill a large saucepan two-thirds full with water and bring to a rapid boil. Add pasta and boil rapidly for 10-12 minutes until al-dente (tender but still firm to bite).
2. While the pasta is cooking, prepare the sauce. In a medium saucepan, boil the 2 tablespoons of water. Add the onion and garlic and cook until tender.
3. In a small bowl, blend 1 tablespoon of the milk with the cornflour to make a smooth paste. Then stir in the remainder of the milk. Add mixture to the onion and garlic and stir constantly over medium heat until sauce thickens.
4. Over medium heat add all the remaining ingredients and stir to combine and heat through.
5. Drain the pasta and add to the sauce. Toss gently to combine.

Portions per Serve:

Carbohydrate: 3
Protein: 2
Green Pork Curry – Serves 4

1 spanish (red) onion, chopped
2 teaspoons fresh chopped ginger or ginger paste
2 hot green chillies, de-seeded and chopped
2 tablespoons chopped fresh coriander
grated rind and juice of 1 lime
1 stem fresh lemongrass, chopped or rind of 1 lemon
½ teaspoon salt
1 ½ tablespoons cornflour
1 cup light evaporated skim milk
¾ teaspoon coconut essence
500g lean pork fillet, cut into bite sized pieces
200g French beans, topped, tailed and halved
½ red capsicum de-seeded and diced
250g fresh bean sprouts
sprigs of fresh basil

Method:
1. Blend onion, ginger, chillies, coriander, lime rind and juice, lemongrass and salt together until almost smooth. Alternatively use 2 tablespoons of a low fat commercial green curry paste.
2. Mix cornflour with a little evaporated milk to form a smooth paste, add remaining milk and coconut essence and set aside.
3. Sauté pork until tender and just beginning to brown, set aside.
4. Add curry paste, beans and capsicum and toss for about 2 minutes.
5. Add cornflour and milk mixture and stir until sauce thickens and cooks.
6. Add bean sprouts and pork and stir until heated through.
7. Serve on a bed of rice or noodles (remember to count these portions) garnished with basil leaves.

Portions per Serve:

Carbohydrate: 1 (remember to add on for your rice/pasta)
Protein: 2.5
**Chilli Con Carne – Serves Four**

500g beef topside  
1 large onion, chopped  
4 large tomatoes, chopped  
150g can tomato paste  
300ml water  
425g can red kidney beans  
1-2 teaspoons Tabasco sauce  
¼ teaspoon ground black pepper  
1 tablespoon cornflour

**Method:**
- Trim off all fat from the meat and cut into cubes (or you could use lean mince)
- Brown meat in pan until well browned
- Spoon into casserole dish
- Add onion to frying pan and sauté until lightly browned
- Add tomatoes and cook over medium heat until soft, stirring occasionally
- Stir in tomato paste and 1 cup water. Mix well
- Rinse kidney beans, drain well and add to the mixture
- Add Tabasco sauce and pepper, pour over meat and combine
- Mix cornflour into remaining water (50ml). When smooth. Stir into mixture
- Cover casserole and cook in a 180C oven until meat is tender (approx 1 ½ hours)

**Portions per Serve:**

Carbohydrate: 2  
Protein: 2.5
Mogul Lamb – Serves 6

6 large ripe tomatoes or 440g tin tomatoes
½ cup water
4 cloves garlic, chopped
2 teaspoons finely chopped ginger
3 fresh chillies, chopped
1 teaspoon ground black pepper
½ teaspoon each of ground cardamom, cloves, fennel, cinnamon and fenugreek
4 tablespoons chopped coriander
1 tablespoon each of chopped fresh basil, mint, dill
1 x 1/5kg leg of lamb, boned and trimmed of visible fat

Method:
1. Place tomatoes, water, garlic, ginger, chillies and pepper into a saucepan and simmer, stirring occasionally for 15 minutes
2. Add all other ingredients but the lamb and mix well and set aside
3. Place lamb into a casserole dish, spread well with tomato mixture, cover and stand for 20 minutes in refrigerator to marinate
4. Place, uncovered, in a preheated 180C oven and bake for 1 hour 15 minutes or until cooked
5. Serve accompanied by rice and vegetables

Portions per Serve:

Carbohydrate: O – but add rice and count this as C portions
Protein: 2.5
Jumping Bean Bake – Serves 4

4 cups tinned beans – eg lima, borlotti, kidney, soy or haricot
1 cup tomato puree
¼ teaspoon cayenne pepper
2 cloves garlic, crushed
1 teaspoon dried oregano
1 bay leaf
500g tomatoes (or 1 tin)
2 medium onions, sliced
½ cup fresh wholegrain breadcrumbs
4 tablespoons grated low fat cheese

Method:
1. Drain beans and rinse well
2. In a bowl combine the tomato puree, cayenne pepper, garlic and herbs
3. Lightly grease a casserole dish and place a layer of beans on the base. Cover with a layer of tomatoes and a layer of onions. Repeat layers until ingredients are used.
4. Pour tomato mixture over, top with breadcrumbs and cheese
5. Cover and bake in a preheated oven 180C for one hour, then remove the cover and bake for another hour, or until beans start to break apart. Alternatively, cover and microwave on medium for 45 minutes, then remove the cover and microwave for another 30 minutes or until the beans start to break apart.

Portions per Serve:

Carbohydrate: 3.5
Protein: 2
Vegetarian Lasagne – Serves 4-6

2 medium onions, chopped
3 large tomatoes, chopped
150g tomato paste
2 cups water
1-2 teaspoons crushed garlic
1 teaspoon mixed herbs
¼ teaspoon black pepper
¼ teaspoon salt
750g can three bean mix, or kidney beans
250g frozen spinach
9 sheets instant lasagne
½ cup grated low fat cheese
2 tablespoons grated parmesan cheese
½ cup cottage cheese

Method:
1. Wipe or spray a frying pan lightly with oil, heat it and sauté the onions until lightly browned, stirring to prevent burning
2. Add tomatoes and cook for about 5 minutes until soft
3. Add tomato paste and water and mix thoroughly
4. Add seasonings
5. Rinse and drain beans add to tomato mixture, combine well.
6. Simmer gently, covered, until you are ready to assemble the lasagne. If sauce becomes too thick, add a little water.
7. Place spinach in saucepan. Cook very gently, uncovered, until it is fairly dry.
8. Spoon a thin layer of tomato and bean sauce over base of dish
9. Arrange a layer of lasagne on top
10. Spoon on more sauce, sprinkle with half the low fat cheese and half the parmesan
11. Top with another layer of lasagne and cover this with spinach, cottage cheese and the remaining parmesan
12. Place the last layer of lasagne over this, cover with the remaining sauce and lastly sprinkle with the remaining grated low fat cheese.
13. Cover with foil and bake in a preheated 180C oven for 30 minutes. Remove the foil and bake for a further 30 minutes or until lasagne is tender.

Portions per Serve:

Carbohydrate: 3
Protein: 2
Baked Apples with Orange and Strawberry Sauce – Serves 4

4 granny smith apples
Cinnamon
1 cup orange juice
1 punnet strawberries
Liquid artificial sweetener
2 tablespoons slivered almonds or chopped pecans
Orange slices

Method:

1. Peel and core apples. When peeling, leave some peel on to create a striped effect.
2. Place in a small baking dish. Sprinkle with cinnamon, then pour on the orange juice.
3. Bake, covered, in a pre-heated 180C oven for 30-35 minutes, until the apples are tender but still retain their shape. Baste occasionally to prevent drying out.
4. While apples are cooking, wash, hull and puree strawberries. Add sweetener to puree.
5. When apples are cooked, lift gently onto individual serving dishes.
6. Reduce cooking liquid by boiling if necessary and pour into strawberry puree. Mix and pour over apples.
7. Decorate with slivered nuts and orange slices.
8. Serve warm or chilled.

Portions per Serve:

Carbohydrate: 1
Protein: 0
Lentil, Spinach and Feta Salad – Serves 4

1 cup brown lentils
2 garlic cloves, flattened
2 red capsicums
150g baby spinach
90g reduced fat feta cheese, cubed
1 tablespoon olive oil
2 teaspoons balsamic vinegar
1 teaspoon sugar

Method:
- Put the lentils in a saucepan, cover with water, add the garlic cloves and bring to the boil. Reduce the heat and simmer for 25 minutes, or until lentils are soft (but retain their shape). Remove the garlic and drain.
- Quarter the capsicums and remove the seeds. Place the capsicum pieces skin-side up under a grill and cook until the skins are completely black. Allow to cool for 6-8 minutes, then remove the skins. Slice the flesh into strips.
- Combine the lentils, capsicum, spinach and feta in a serving bowl. Pour over the oil and balsamic vinegar, sprinkle the sugar over and mix well.

Portions per Serve:

Carbohydrate: 1.5
Protein: 1
Linguine with Salmon and Peas – serves 4

350g linguine
2 salmon fillets, or other white fish
1 tablespoon olive oil
300g fresh or frozen peas
250ml fish or vegetable stock
2 tablespoons parsley, chopped
juice of 1 lemon
1 teaspoon finely grated lemon zest

Method:
1. Bring a large saucepan of water to the boil and cook the pasta.
2. Take any bones/skin off the fish then cut into bite sized pieces. Cook fish in the oil in a frying pan for about 5 minutes, until it is cooked through. Add the peas, stock and parsley and cook for 1-2 minutes. Season with plenty of pepper and add the lemon juice and zest, stirring gently to combine all ingredients.
3. When the pasta is cooked, drain well and add to the sauce, tossing gently to coat in the sauce.

Portions per Serve:

Carbohydrate: 4
Protein: 2
Beef Stroganoff – Serves 4

300g basmati rice
500g lean beef, cut into strips
1 tablespoon olive oil
1 red onion, sliced thinly
1 brown onion, sliced thinly
2 garlic cloves, crushed
250g mushrooms, sliced
60ml brandy (optional)
zest and juice of 1 orange
½ teaspoon dried dill
250g low fat natural yoghurt

Method:

• Wash the rice and put it in a large saucepan with 500ml water. Cover with a lid and bring to the boil, then reduce the heat and simmer for 10 minutes. Turn off the heat and leave to stand, with the lid on, until ready to serve.
• Meanwhile, heat a large non-stick frying pan over medium heat and dry fry the meat, in small batches, for 2 minutes. Remove the meat and set aside.
• Using the same pan, heat the oil over medium heat, add the onions and garlic and fry for 5 minutes or until the onions are soft. Add the mushrooms and fry for 3 minutes. Return the meat to the pan.
• If using brandy, pour it into the pan and flambé, then dowse the flames with the orange zest and juice. Add the dill and season with pepper. Turn off the heat before mixing with the yoghurt.
• Spoon the steamed rice onto plates and top with the stroganoff. Serve with salad or mixed vegetables.

Portions per Serve:

Carbohydrate: 4.5
Protein: 3
Spinach and Ricotta Cannelloni – Serves 4

300g packet frozen spinach, defrosted
400g low fat ricotta cheese
¼ teaspoon ground nutmeg
2 tablespoons pine nuts, toasted
30g parmesan cheese, finely grated
4 fresh lasagne sheets
300g tomato pasta sauce
pepper and basil leaves to serve

Method:
1. Preheat the oven to 180 degrees C. Put the spinach in a colander and squeeze out the excess liquid.
2. Combine the ricotta, nutmeg, pine nuts and half the parmesan in a large bowl and mix with a wooden spoon. Lay one sheet of lasagne on a flat surface and spoon a quarter of the ricotta mixture along the long edge of the sheet. Roll lengthways to make a long sausage shape and place into an oblong lasagne dish, cutting the lasagne to fit if necessary. Repeat until mixture is used up.
3. Spoon the pasta sauce over the cannelloni and season with pepper. Cover with foil and bake for 25-30 minutes, or until the pasta is tender and the sauce is bubbling.
4. Divide the lasagne into 4 and serve. Spoon any tomato sauce left on the top and sprinkle with parmesan cheese and basil.

Portions per Serve:

Carbohydrate: 3
Protein: 1.5
Roasted Pumpkin and Mushroom Lasagne – Serves 8

400g pumpkin, cubed
400g kumara, cubed
2 sprigs rosemary
3 garlic cloves, crushed
1L trim milk
1 onion, sliced
3 tablespoons plain flour
250g ricotta cheese
250g lasagne sheets
200g mushrooms, sliced
1 spring onion, sliced
50g edam cheese, grated

Method:

- Preheat oven to 200 degrees C. Mix the pumpkin, kumara, rosemary and garlic in a bowl and season with pepper. Lightly spray a baking tray with olive oil and bake the vegetables on for 20 minutes.
- Put the milk and onion in a saucepan over medium heat. Heat until just below boiling point and then turn off the heat and let sit for 10 minutes. Mix the flour with a little water and then add to the milk, bring to a simmer and cook for 5 mins, then add the ricotta cheese.
- Spray a lasagne dish with olive oil. Add a layer of lasagne sheets, then a quarter of the sauce, a quarter of the vegetables (including mushroom and spring onion). Continue until everything is used up and the sprinkle with grated cheese.
- Bake for 35-45 minutes or until cooked through and golden on top. Rest for 5 mins before cutting. Serve with a green salad.

Portions per Serve:

Carbohydrate: 3
Protein: 1
**Chicken Pasta with Caramelised Onions – Serves 6**

2 tablespoons olive oil  
2 red onions, sliced  
2 teaspoons sugar  
1 capsicum  
2 chicken breasts, sliced  
4 spring onions, sliced  
2 teaspoons crushed garlic  
1 cup low fat evaporated milk  
1 cup chicken stock  
2 tablespoons tomato paste  
350g pasta spirals  
basil and black pepper to serve

**Method:**

1. To make the caramelized onions, heat 1 tablespoon of the oil in a frying pan and add the onions and sugar. Cook over medium heat, stirring occasionally for 10 minutes, until the onions are soft and golden brown. Remove to a bowl and cover to keep warm.

2. Quarter the capsicums and remove the seeds. Place the capsicum pieces skin-side up under a grill and cook until the skins are completely black. Allow to cool for 6-8 minutes, then remove the skins. Slice the flesh into strips.

3. Meanwhile, heat the remaining tablespoon of oil in a large frying pan. Add the chicken and cook for 4-5 minutes, or until the chicken is browned and cooked through. Add the spring onions and garlic and cook for a further minute. Stir in the evaporated milk, stock, tomato paste and capsicum strips. Bring to the boil, then reduce the heat and simmer for 1-2 minutes. Remove to a boil and cover to keep warm.

4. Cook the pasta, drain it and return to saucepan. Stir in the chicken mixture and onions and heat through. Serve with the basil and black pepper.

**Portions per Serve:**

Carbohydrate: 3  
Protein: 1.5
Curried Chicken - Serves 4-6

1 whole chicken
3 bay leaves
1 Tbsp oil
2 large carrots, finely chopped
1 large onion, peeled and finely chopped
1 Tbsp curry powder
1 1/2 Tbsp flour
1/2 cup low fat milk
1/4 cup sultanas
black pepper

Method:

- Remove giblets and any excess fat from the chicken. Place the chicken and bay leaves in a large saucepan. Cover with water and simmer for 45-50 minutes, or until juices run clear when a skewer is inserted. Reserve 1 1/2 cups of the cooking liquid.
- Discard the chicken skin and bone and cut the meat into bite-sized pieces. Heat the oil in a large saucepan. Add the carrots, onion and curry powder. Sauté until lightly browned. Add the flour and mix well. Gradually add the reserved cooking liquid, stirring continuously, and heat until thickened. Add the chicken, milk and sultanas.
- Serve with rice or pasta or over baked kumara

Portions per Serve:

Carbohydrate: 0 – but remember to add your rice/pasta/kumara
Protein: 2 - depending on what chicken is eaten – check!
Welcome to the DEWL diabetes study! You have been allocated to the topaz diet plan. This plan is high in protein with moderate carbohydrate, low glycaemic index and low fat. This plan is also lower in energy than you usually eat so that you can lose weight.

My energy requirements are: kJ or ______ kcal ______ per day

My Protein Portions per day are: ______

My Carbohydrate Portions per day are: ______

I need to eat at least 2 pieces of fruit each day

I need to eat 3 or more serves of vegetables each day

I need to have high fibre and low glycaemic index foods

We will help you fill this table in at group session one:

My Day Plan:

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Topaz Recipes

Recipes reproduced with permission from THE LOW GI DIET COOKBOOK by Professor Jennie Brand-Miller, Kaye Foster-Powell and Joanna McMillan Price, Hachette Livre Australia, 2005. Look for it at a book store or order with the ISBN number: 0-7336-1945-2

Lentil, Spinach and Feta Salad – Serves 4

1 cup brown lentils
2 garlic cloves, flattened
2 red capsicums
150g baby spinach
90g reduced fat feta cheese, cubed
1 tablespoon olive oil
2 teaspoons balsamic vinegar
1 teaspoon sugar

Method:
- Put the lentils in a saucepan, cover with water, add the garlic cloves and bring to the boil. Reduce the heat and simmer for 25 minutes, or until lentils are soft (but retain their shape). Remove the garlic and drain.
- Quarter the capsicums and remove the seeds. Place the capsicum pieces skin-side up under a grill and cook until the skins are completely black. Allow to cool for 6-8 minutes, then remove the skins. Slice the flesh into strips.
- Combine the lentils, capsicum, spinach and feta in a serving bowl. Pour over the oil and balsamic vinegar, sprinkle the sugar over and mix well.

Portions per Serve:

Carbohydrate: 1.5
Protein: 1
Pork Vindaloo – Serves 4

750g diced pork
2 tablespoons olive oil
2 onion, sliced
4 garlic cloves, sliced
4cm piece ginger, sliced
3 ripe tomatoes
2 green chillies, de-seeded and chopped
1 teaspoon brown sugar
1/2 cup chopped coriander leaves

Marinade:
2 tablespoons vindaloo curry powder
4 tablespoons white wine vinegar
1 tspn malt vinegar

350g steamed basmati rice to serve

Method:
5. To make the marinade combine the curry powder and vinegar and mix well.
6. Add the pork and toss to coat in the marinade. Cover and leave to marinate in the refrigerator for 1 hour or more.
7. Heat the oil in a casserole dish and over low heat gently cook the onions until soft and golden. Add the garlic, ginger, tomatoes, chillies and sugar and stir well to combine. Add the pork (reserve the marinade), increase the heat and cook for 1-2 minutes until meat is starting to brown. Add 1 cup water and the marinade, cover and simmer for 1-1 1/2 hours stirring occasionally until the meat is very tender. Stir in the coriander just before serving.
8. Serve with steamed rice and plain yoghurt.

Portions per Serve:

Carbohydrate: 2
Protein: 3
Green Pork Curry – Serves 4

1 spanish (red) onion, chopped
2 teaspoons fresh chopped ginger or ginger paste
2 hot green chillies, de-seeded and chopped
2 tablespoons chopped fresh coriander
grated rind and juice of 1 lime
1 stem fresh lemongrass, chopped or rind of 1 lemon
½ teaspoon salt
1 ½ tablespoons cornflour
1 cup light evaporated skim milk
¾ teaspoon coconut essence
500g lean pork fillet, cut into bite sized pieces
200g French beans, topped, tailed and halved
½ red capsicum de-seeded and diced
250g fresh bean sprouts
sprigs of fresh basil

Method:
6. Blend onion, ginger, chillies, coriander, lime rind and juice, lemongrass and salt together until almost smooth. Alternatively use 2 tablespoons of a low fat commercial green curry paste.
7. Mix cornflour with a little evaporated milk to form a smooth paste, add remaining milk and coconut essence and set aside.
8. Saute pork until tender and just beginning to brown, set aside.
9. Add curry paste, beans and capsicum and toss for about 2 minutes.
10. Add cornflour and milk mixture and stir until sauce thickens and cooks.
11. Add bean sprouts and pork and stir until heated through.
12. Serve on a bed of rice or noodles (remember to count these portions) garnished with basil leaves.

Portions per Serve:

Carbohydrate: 1 (remember to add on for your rice/pasta)
Protein: 2.5
Chilli Con Carne – Serves Four

500g beef topside
1 large onion, chopped
4 large tomatoes, chopped
150g can tomato paste
300ml water
425g can red kidney beans
1-2 teaspoons Tabasco sauce
1/4 teaspoon ground black pepper
1 tablespoon cornflour

Method:
- Trim off all fat from the meat and cut into cubes (or you could use lean mince)
- Brown meat in pan until well browned
- Spoon into casserole dish
- Add onion to frying pan and sauté until lightly browned
- Add tomatoes and cook over medium heat until soft, stirring occasionally
- Stir in tomato paste and 1 cup water. Mix well
- Rinse kidney beans, drain well and add to the mixture
- Add Tabasco sauce and pepper, pour over meat and combine
- Mix cornflour into remaining water (50ml). When smooth. Stir into mixture

Cover casserole and cook in a 180C oven until meat is tender (approx 1 1/2 hours)

Portions per Serve:

Carbohydrate: 2
Protein: 2.5
Mogul Lamb – Serves 6

6 large ripe tomatoes or 440g tin tomatoes
1/2 cup water
4 cloves garlic, chopped
2 teaspoons finely chopped ginger
3 fresh chillies, chopped
1 teaspoon ground black pepper
1/2 teaspoon each of ground cardamom, cloves, fennel, cinnamon and fenugreek
4 tablespoons chopped coriander
1 tablespoon each of chopped fresh basil, mint, dill
1 x 1/5kg leg of lamb, boned and trimmed of visible fat

Method:

- Place tomatoes, water, garlic, ginger, chillies and pepper into a saucepan and simmer, stirring occasionally for 15 minutes
- Add all other ingredients but the lamb and mix well and set aside
- Place lamb into a casserole dish, spread well with tomato mixture, cover and stand for 20 minutes in refrigerator to marinate
- Place, uncovered, in a preheated 180C oven and bake for 1 hour 15 minutes or until cooked
- Serve accompanied by rice and vegetables

Portions per Serve:

Carbohydrate: O – but add rice and count this as C portions
Protein: 2.5
These recipes are from *The CSIRO Total Wellbeing Diet Book* by Manny Noakes and Peter Clifton. Published by Penguin.

**Cajun Fish Fillets – Serves 4**

60g skim milk powder  
1 cup water  
1 tablespoon paprika  
2 teaspoons ground cumin  
1 teaspoon turmeric  
1 teaspoon chilli powder  
800g white fish fillets  
2 tablespoons olive oil  
500g natural yoghurt  
1 small cucumber, diced

Method:
4. Preheat oven to 200 degrees C. Line a baking tray with baking paper.
5. Mix milk powder and water in a small bowl. In a separate bowl mix ground spices. Dip fish fillets in milk, then in spices.
6. Heat oil in frying pan over high heat. Rapidly fry the fish, in batches, for 2 mins each side or until golden. Be careful not to overcrowd the pan, or the fish will stew. Place the fish on the baking tray and bake for 5 mins.
7. Mix yoghurt and cucumber and serve with the fish.

**Portions per Serve:**

Carbohydrate: 1  
Protein: 2
Stir-fried Ginger Chicken with Sesame Bok Choy – Serves 4

2 teaspoons sesame seeds
2 small bunches bok choy, halved and washed
1 tablespoon sesame oil
800g chicken breast, cut into strips
1 piece ginger, sliced
1 small red chilli, sliced
1 onion, quartered
½ red capsicum, sliced
1/3 cup sherry (optional)
2 tablespoons soy sauce

Method:
15. Bring a little water to simmer in a wok or large frying pan. Simmer bok choy until wilted and set aside. Add 1 tablespoon sesame oil to the pan and heat then add chicken. Stir-fry for 6-8 mins until chicken is cooked and golden. Remove from pan and set aside, wipe pan with paper towel.
16. Return pan to heat and add the remaining oil. Add ginger, garlic, chilli, onion and capsicum and stir fry for 2 minutes. Return chicken to wok, add sherry and soy sauce and stir. Add bok choy and toss through. Serve sprinkled with the toasted sesame seeds and rice.

Portions per Serve:

Carbohydrate: 0 – but remember to add your rice
Protein: 2
Baked Yoghurt Chicken with Tomato, Mint and Cucumber Salad – Serves 4

½ teaspoon Chinese 5 spice
1 teaspoon chilli powder
2 teaspoons soy sauce
1 clove garlic, crushed
1 tablespoon olive oil
200g natural low fat yoghurt
800g skinless chicken breast

Salad:
2 small cucumbers, sliced
4 tomatoes, sliced
½ red onion, sliced
¼ cup mint leaves
1 tablespoon olive oil
1 teaspoon lemon juice

Method:
5. In a bowl mix five spice, chilli powder, soy sauce, garlic and yoghurt. Coat chicken with the mixture and allow to stand for 4 hours.
6. Preheat oven to 180 degrees C. Line a baking dish with baking paper.
7. Heat a non-stick frying pan over medium heat. Add chicken and cook for 2 mins each side. Transfer to baking dish and bake for 6-8 minutes or until cooked through. Remove and allow to rest before carving into thick slices.
8. To make the salad gently toss all ingredients. Divide between 4 serving plates and then add the chicken. Serve with a slice of crusty wholegrain bread to make up your carbohydrate portions.

Portions per Serve:

Carbohydrate: 0 – but remember to add your bread
Protein: 2
Chicken and Tarragon Meatloaf – Serves 5

1 ½ tablespoons olive oil
1 small granny smith apple, peeled and diced
1 onion, chopped
1 tablespoon tarragon
1 clove garlic, chopped
2 slices bread, crumbled
1 egg, lightly beaten
3 spring onions, sliced
1 small zucchini, grated
1 tablespoon chutney
1kg minced chicken

Method:
7. Preheat oven to 150 degrees C, lightly grease a loaf tin
8. Heat oil in a large frying pan over medium heat. Add apple, onion and garlic and cook for 8 minutes, or until soft and golden.
9. In a large bowl combine the onion mixture from above with the tarragon, breadcrumbs, egg, spring onion, zucchini, chutney and chicken.
10. Spoon into prepared loaf tin and bake for one hour.
11. Allow to cool in the tin then turn out and cut into 5 slices.

Portions per Serve:

Carbohydrate: 1
Protein: 2
Beef and Potato Pie – Serves 4

800g lean minced beef
2 tablespoons olive oil
2 onions, finely chopped
1 carrot, chopped
1 stick celery, chopped
2 cloves garlic
1 beef stock cube
½ cup hot water
1 tablespoon flour
½ cup red wine
4 ripe tomatoes, diced
1 tablespoon chopped rosemary
2 tablespoons chopped parsley
2 kumara, peeled, boiled and drained
300g pumpkin, peeled, boiled and drained

Method:
10. Heat the remaining oil over medium heat and add onion, carrot, celery and garlic and cook for 4 mins or until soft. Dissolve stock cube in water and then add to pan with the cooked mince along with vegetables, wine, flour, tomato and herbs. Bring to the boil, then simmer for 25 mins.
11. Preheat oven to 180 degrees C.
12. In a bowl, roughly mash kumara and pumpkin with a fork.
13. Spoon mince filling into a casserole dish or 4 individual dishes and top with mash. Bake for 20 mins.

Portions per Serve:

Carbohydrate: 1
Protein: 2
Burgers – Serves 4

4 wholegrain bread roll
1 tomato, sliced
1 small cucumber, sliced
Salad leaves
8 slices beetroot
2 tablespoons tomato sauce

Patties:
400g mince
½ onion
2 teaspoons oregano
1 tablespoon dijon mustard
1 tablespoon tomato paste
1 tablespoon parsley chopped
1 egg

Method:
8. Heat a grill or non stick frying pan to hot. Cook patties for 6 mins each side, until cooked through.
9. Meanwhile, cut bread rolls in half and add salad vegetables, then patty and top with tomato sauce.

Portions per Serve:

Carbohydrate: 2
Protein: 1
Italian Lamb Casserole – Serves 4

800 lamb, cut into cubes
2 tablespoons olive oil
1 onion, chopped
1 carrot, chopped
1 stick celery, chopped
2 cloves garlic, crushed
¼ cup red wine – optional
2 tablespoons tomato paste
2 cups chicken stock
1 bay leaf
2 sprigs rosemary
water
2 parsnips, peeled and chopped
2 tablespoons parsley

Method:
8. Preheat oven to 180 degrees C
9. Heat a large pan over high heat, cook lamb in the oil until browned. Remove from pan and set aside.
10. Add onion, carrot and celery to pan and cook until soft.
11. Return lamb to the pan and add garlic, red wine and tomato paste and cook for a further 5 mins
12. Add stock, bay leaf, rosemary and enough water to ensure lamb is covered. Cover and bake in the oven for 1 hour.
13. Add parsnip and cook for a further 40 mins

Portions per Serve:

Carbohydrate: ½
Protein: 2
**Sesame Tofu with Mushrooms – serves 2**

2 teaspoons sesame seeds  
400g firm tofu  
2 tablespoons olive oil  
2 cups mushrooms  
1 clove garlic, sliced  
¼ cup soy sauce  
¼ cup vegetable stock  
½ cup sliced spring onion  
1 teaspoon cornflour  
1 tablespoon water  
1 tablespoon chopped coriander leaves

**Method:**

6. Preheat oven to 150 degrees C  
7. Heat a nonstick frying pan over medium heat, add sesame seeds and toss for 5 mins, until lightly toasted. Set aside.  
8. Cut tofu into slices and dab with a paper towel to absorb as much water as possible. Heat half the oil and cook the tofu for 3 mins each side. Transfer to a serving plate and keep warm in the oven.  
9. Add the rest of the oil to the pan over medium heat. Add mushrooms and garlic and cook for 5 mins or until tender. Add soy sauce and stock and bring to a boil. Add spring onion. Mix cornflour with water and pour into pan, stir until sauce has thickened. Add coriander.  
10. Spoon mushroom mixture over tofu and sprinkle with toasted sesame seeds.

**Portions per Serve:**

Carbohydrate: 0  
Protein: 1
Baked Mediterranean Vegetables with Ricotta – Serves 4

1 red capsicum, halved
1 yellow capsicum, halved
4 zucchini, sliced lengthways
1 eggplant, sliced
1 tablespoon olive oil
1 clove garlic, crushed
2 red onions, sliced
4 tomatoes, diced
½ cup basil leaves
200g low fat ricotta cheese

Method:
1. Heat oven to 180 degrees C
2. Place capsicums, skin side up in a baking dish and roast for 20 mins. Remove from oven, cover with foil and cool. Peel off skin and slice flesh into strips.
3. Preheat oven grill. In a bowl, toss the zucchini and eggplant with half the oil. Grill vegetables until soft.
5. Arrange vegetables, including tomato and basil, in layers in a baking dish. Crumble ricotta over the top and bake for 30mins. Allow to cool a little before serving.

Portions per Serve:

Carbohydrate: 0
Protein: 1
Curried Chicken - Serves 4-6

1 whole chicken
3 bay leaves
1 Tbsp oil
2 large carrots, finely chopped
1 large onion, peeled and finely chopped
1 Tbsp curry powder
1 1/2 Tbsp flour
1/2 cup low fat milk
1/4 cup sultanas
black pepper

Method:

• Remove giblets and any excess fat from the chicken. Place the chicken and bay leaves in a large saucepan. Cover with water and simmer for 45-50 minutes, or until juices run clear when a skewer is inserted. Reserve 1 1/2 cups of the cooking liquid.

• Discard the chicken skin and bone and cut the meat into bite-sized pieces. Heat the oil in a large saucepan. Add the carrots, onion and curry powder. Sauté until lightly browned. Add the flour and mix well. Gradually add the reserved cooking liquid, stirring continuously, and heat until thickened. Add the chicken, milk and sultanas.

• Serve with rice or pasta or over baked kumara

Portions per Serve:

Carbohydrate: 0 – but remember to add your rice/pasta/kumara
Protein: 2-3 depending on what chicken is eaten – check!
DEWL Healthy Kai Recipes

These recipes have been sourced from the website www.maori-in-oz.com and then modified to make them healthier.

Puha:

Preparation of Puha - Cut the heads off the puha, any flowers and the bottom of the stems. Rinse thoroughly several times and change the water with each rinse. I prefer to wash individual stems, but that will be dependant on how much puha one is preparing. At a hui sacks of puha can be prepared in one go. Under running cool water place all cleaned puha into the sink and rub together really well; this helps to take the bitterness out of the puha. Repeat this 2-3 times. Cover with a cloth and set aside. Puha can be boiled, stir fried (with soy sauce is good!) or cooked in soups/boil up.

• Puha and Mussels

Ingredients:
Puha – 2 bunches prepared as above
Mussels – 600gms shelled & cut into pieces
Olive Oil – 1 tablespoon

Method:
Boil puha in a pot of salted water for 1 hour.
Lightly cook the shelled mussels in olive oil.
Add mussels to the pot of puha and retain in the juices.
Refrigerate and serve the following day.

½ cup mussels = 1P
Watercress:

Preparation of Watercress:
Prepare Watercress immediately before use to maintain their freshness. Cut away & discard the bottom of the stems then wash the remaining stalks thoroughly, set aside.

Watercress Soup – Serves 4:

Ingredients:
Watercress - 2-3 bunches rinsed and roughly chopped
Potatoes - 250gms peeled and chopped into pieces
Olive oil – 1 tablespoon
Low fat milk - 600ml
Pepper – Freshly ground to taste

Method:
Peel and cut potatoes into small pieces and boil until cooked.
Drain and mash with olive oil.
Pour in the milk and chopped watercress and cook through on a low heat.
Add seasoning and stir well.

Protein portions per serve: 1
Carbohydrate portions per serve: 1

• Pipi, Tuatua, Toheroa, Tuangi, Hehari, Mussels, Oysters

Pipi can be eaten raw; straight from the shell, tossed on an open fire or barbecue until their shells open or cooked in a variety of ways. There are a variety of Pipi which are found close to the shore on a low tide just beneath the surface of the seabed (sand): the Tuatua and Pipi are much smaller than their cousin the Toheroa which is generally found on the West Coast of the Far Northern areas of New Zealand. They are identified by their oblong shape and rounded ends with the apex in the middle. Where as the Tuangi and Hehari are more rounded and commonly known as the cockle.

• Pipi Soup – serves 2

Ingredients:
Pipi - 1 Cup freshly shelled (or other seafood)
Nutmeg - ½ tsp
Onion - 1 diced
Water - 2 Cups
Parsley - 2 Tblspns
Pepper - to taste
Cornflour - 2 Tblspns
Low fat milk - 1 Cup
Method:
Mince the Pipi and place in a saucepan with the water, onion and parsley and simmer gently for 30 minutes.
Press through a sieve or puree in a blender and return to pan.
Blend 2 Tbspns of milk with cornflour and add to Pipi puree with remaining milk and nutmeg and bring to the boil while stirring continuously.
Add black pepper to taste.

Protein portions per serve: ½

• Mussel Soup – Serves 2

Ingredients:

• Mussels - ½ Dozen chopped
• Ginger Ground - 1 Tbspn
• Onion - 1 diced
• Water - 1 Cup
• Parsley - 2 Tbspns
• Olive oil - 1 Tbspn
• Cornflour - 2 Tbspns
• Low fat milk - 1 Cup

Method:

• Sautee onion in oil, add chopped mussels, water, parsley, ground ginger and milk.
• Cook until almost at boiling point, turn heat right down and simmer.
• Mix Cornflour with a little milk to make a smooth paste, add into soup mix and stir until it thickens.

Protein portions per serve: ½

• Oyster Sauce – serves 2

Ingredients:

• Oysters - 1 ½ Dozen Bottled Oysters
• Margarine - 2 Tbspns
• Flour - 3 Tbspns
• Paprika - ½ tspn
• Cayenne - ¼ tspn
• Low fat milk - 300ml
• Lemon - 1 squeezed juice
• Pepper - to taste
Method:

• Melt margarine with seasonings.
• Blend in flour.
• Gradually add milk stirring consistently until thick and smooth.
• Add strained oysters and a little oyster juice from the bottle.
• Add lemon juice and seasoning to taste.

Protein portions per serve: 1

• **Toheroa Fritters – serves 2**

**Ingredients:**

• Toheroa - 1 Dozen minced
• Eggs - 2 beaten
• Onion - 1 finely chopped
• Low fat milk - ½ cup
• Flour - 1 Cup
• Baking Powder - 1 tsp
• Pepper - to taste
• Cooking Oil

**Method:**

• In a bowl add Toheroa, eggs, onion and milk and mix together.
• Stir in flour, baking powder and pepper to taste and mix well.
• Heat non stick pan with a spray of oil and carefully drop spoonfuls of batter into pan
• Turn regularly until golden.
• Drain on absorbent paper.

Protein portions per serve: ½

**Creamed Paua and Bacon – serves 4**

**Ingredients:**

• Paua - 500gm minced
• Vegetable oil - 1 Tblspns
• Flour - 2 Tblspns
• Onion - 1 large finely chopped
• Garlic - 2 Tblspns
• Bacon - 2 rashes cooked, rind removed and finely chopped
• Parsley - 2 Tblspns
• Low fat milk - 1 Cup
• Pepper - to taste

**Method:**
• Sauté onion and garlic in oil.
• Add flour and mix well.
• Gradually add milk stirring consistently.
• Add bacon, seasoning, parsley and Paua while continuously stirring.
• Bring to boil and immediately turn down heat to simmer until Paua is cooked through.

Protein portions per serve: 2

Tips for a Healthy Boil Up

• Use leaner cuts of meat
• Add more vegetables!
• Let the boil up cool so the fat solidifies on the top, scoop off the fat then reheat to eat
• Cut down on salt – use herbs for flavour instead

Wholemeal Seed Rewena Bread

Step One - Original Starter Plant/Bug:

Ingredients:

• Flour - 2 Cups - one cup plain, one cup wholemeal
• Potatoes - 3 Medium
• Water - 1 Cup
• Sugar - 1 tspn

Method:

Day One:

• To make Starter Plant, Peel, slice and boil potato in 1 cup of water to mashing consistency.
• Mash potato thoroughly with any remaining water in pot & set aside.
• When lukewarm add flour and sugar, mix all ingredients together to a fairly firm texture. Mixture should be a dough-like resemblance.
• Cover and leave in a warm place to prove/ferment.
• Warm Tropical Weather - Place uncovered plant on a bench in a warm sunny place. Due to warmer conditions, plant may require only 1 day of feeding (Step Two - Day Two) if Starter plant begins to rise and bubble it is ready to make into Rewena Paraoa (Step Three).
• Cold Winter Weather - Place uncovered plant inside a hot water cupboard. I have found storing your plant on the bench in cool conditions does not allow for a suitable rise in the plant where the hot water cupboard does. It may take 2-3 days of daily feeds (Step Two - Day Two) until the starter plant is ready for Step Three.
Step Two - Feeding your Original Starter Plant Daily:

Ingredients:

- Potato - 1 medium size
- Water - 1 Cup
- Sugar - 1 teaspoon

Method:

Day Two & Three:

- To feed the above plant daily, peel, cut and boil potato in 1 cup of water.
- When boiled remove the potatoes and retain the liquid, set liquid aside until lukewarm.
- Pour 1 cup of warm liquid mixed with 1 teaspoon of sugar into the starter plant (made the day before) and mix well.
- Store again in a warm place to continue in the proving/fermenting process.
- Repeat this process on Day Three.
- On days 2 & 3 starter plant should resemble a thick creamy consistency similar to batter. The plant should rise and form bubbles, this is a good indicator the plant is ready for Step Three. It is ok if plant has a sour odor to it, do not discard it is fermenting well.

Step Three - Making Rewena Paraoa from the Starter Plant

Ingredients:

- Flour - 5 Cups - 1 cup wholemeal, 3 ½ cups plain, ½ cup mixed seeds – sunflower, linseeds, sesame seeds
- Salt - 1 teaspoon
- Baking Soda - 2 teaspoons
- Water - 1 Cup (approx)

Method:

- Pre-heat oven to 200c.
- Grease and lightly flour 2 Baking Trays (Pizza Trays are ideal) or 2 medium size (approx 20cms in diameter) Round Baking Tins and/or Loaf Tins- set aside.
• In a large bowl sift flour and salt and make a well in the centre, pour in all of the Starter Plant and sprinkle baking soda over starter plant. Mix ingredients until combined adding extra water if required.
• Turn out onto floured bench and knead lightly for approximately 10 minutes.
• Take out a scoop (approx 2 dessertspoons) and use this to make another plant, following through with daily feeding as to Step Two - Day Two & Three. May require an additional cup (or 2) of sifted Plain Flour added to mixture to maintain a thick batter like consistency. By continuing this process you can always have a plant handy to make Rewena Paraoa every few days.
• With the remaining dough, split in ½ and shape into baking tins or onto trays.
• Bake in pre-heated over for approximately 30-40 minutes or until golden.

1 thin slice rewena bread = 1 carbohydrate portion

Karengo

These recipes were kindly supplied by Wendy Nelson at NIWA.

Karengo is a seaweed that is known to the Japanese (and most westerners) as nori. It has long been eaten by Maori and is very nutritious. Karengo is collected off rock pools at low tide and then either eaten fresh or dried for storing. It can be dried out in the sun or in the oven on a low temperature. Fresh karengo can be used in soups and stir frys – make sure you wash the sand out first. Dried karengo can be pounded to make flour, added to soups and casseroles and salads. It can also be eaten as a snack.

Fish and Rice with Karengo
(From the Portobello Marine Laboratory in Dunedin)

Ingredients:

• 2 cups rice
• 3 cups water
• 6 tablespoons white wine or sherry – optional
• 4 tablespoons soy sauce
• 1 tablespoon honey
• ½ pound fish eg hapuka
• ¼ cup dried karengo chopped

Method:

• Boil rice with 2 tablespoons soy sauce, 3 cups water and ½ the sherry until cooked
• Cook the fish in water, drain, remove skin and bones and rub the flesh until it flakes.
• Place fish in pan with the rest of the soy sauce and sherry and the honey and stir over medium heat until fish becomes dry.
• Crisp the karengo in the oven on low heat for 20 mins.
• Arrange the rice on the bottom, then the fish and sprinkle karengo on top – and serve

Carbohydrate portions per serve: 3

Karengo Soup
(From the Portobello Marine Laboratory in Dunedin)

Ingredients:

• 1 tablespoon oil
• 1 small onion, chopped
• ½ cup chopped celery
• ¼ cup fresh ginger, chopped
• 1 tblspn soy sauce
• 350ml beef stock (either ready made or use 350ml water with 1 tspn beef stock powder)
• 1 cup water
• ½ cup dried karengo
• ½ cup fresh karengo

Method:

• Stir fry onion and celery in oil until cooked through.
• Stir in all other ingredients, bring to the boil then simmer for 5 mins
**Beef Curry – Serves 8**

1 tablespoon vegetable oil  
3 cloves garlic, peeled and crushed  
1 onion, chopped  
1 dessertspoon masala powder  
1 dessertspoon curry powder  
2 cups water  
1kg blade steak, cubed  
3 medium potatoes, peeled and diced  
2 medium carrots, peeled and diced  
1 cup frozen green beans  

**Method:**  
Heat the oil in a large saucepan and add the garlic and onion. Cook on high heat until softened.  
Add the masala powder and curry powder and cook for a further 2 minutes, stirring. Add the water and bring to the boil.  
Add the meat and boil for 5 minutes. Reduce the heat and simmer for 20 minutes. Stir in the potatoes and carrots and cook for another 15-20 minutes until softened.  
Add the beans and simmer for a further 5 minutes.  

**Portions:**  
Protein: 2  
Carbohydrate: 0.5
**Corned Beef Pie- Serves 5**

- 600g tapioca, grated to crumbs
- ½ cup light coconut cream
- 340g corned beef
- 1 onion chopped
- 1 can creamed corn
- 2 courgettes, sliced
- 1 tomato, sliced
- pepper

**Method:**

Mix the tapioca and coconut cream thoroughly. Press the tapioca mixture into a 20cm diameter pie dish to form a thin crust.

Immerse the can of corned beef in boiling water for 5 minutes to melt the fat. Open the can and drain off the fat.

Combine the corned beef, onion, corn and half the courgettes. Pour into the crust. Arrange the remaining tomato and courgette slices on top, sprinkle with pepper.

Bake at 180 degrees celsius for 40 minutes or until the crust is lightly browned.

**Portions:**
- Protein: 1
- Carbohydrate: 7
Hearty Beef Rissoles – Makes 16 Rissoles

1kg lean mince
2 medium potatoes, peeled and grated
3 cups crushed weetbix
2 eggs
1 large onion, chopped
2 cloves garlic, peeled and crushed
2 tablespoons soy sauce

Method:

Place all ingredients into a bowl and mix thoroughly. Divide the mixture into 16 portions and shape into balls then flatten. Cook in a non-stick frying pan for 10-15 mins or bake in the oven at 180 degrees Celsius for 30 minutes or until browned. Turn halfway during cooking to brown on each side.

Portions:
Carbohydrate: 0.5 per rissole
Protein: 1 per rissole
**Pork and Pumpkin – Serves 6**

3-4 teaspoons fresh ginger grated  
2-3 cloves garlic peeled and crushed  
1 ½ tablespoons soy sauce  
1 teaspoon sugar  
1kg lean pork chopped  
1 ½ kg pumpkin  
1 tablespoon cooking oil  
2 cups water

Method:

Combine the garlic, ginger, soy sauce and sugar. Rub on the pork pieces and leave for 20 mins.

Peel the pumpkin and cut into small cubes. Place in a saucepan and cover with water. Cook for 15-20 mins or until the pumpkin is tender but not overcooked. Drain and set aside.

Heat the oil in medium-sized saucepan, add the pork and cook until browned, stirring frequently. Add the water, bring to the boil and cook for 10 minutes, stirring regularly. Reduce the heat and simmer for a further 15-20 minutes or until pork is tender.

Add the pumpkin to the pork and heat through.

Portions:
Carbohydrate: 1.5  
Protein: 3.5
Lamb and Banana Casserole – Serves 6

6 green bananas
1 tablespoon cooking oil
1kg lamb, diced
2 cloves garlic, peeled and crushed
2 medium onions, chopped
2 large tomatoes, chopped
1 large green pepper, chopped
1 tablespoon peanut butter
1 cup water
½ cup coconut cream, light
½ cup water

Method:

Peel the bananas and chop into small pieces. Immerse in a bowl of water and set aside.

Heat the oil in a large saucepan, add the lamb and garlic and cook on high until brown, stirring frequently. Remove the meat from the saucepan and set aside.

Add the onion, tomatoes and green pepper to the saucepan and cook for 5 minutes. Mix the peanut butter with the first measure of water. Add to the saucepan, together with the bananas and cook for 10 mins. Return the meat to the saucepan and simmer on low heat.

Combine the coconut cream, the second measure of water and some pepper and add to the meat and vegetables. Cook for a further 10 mins. Transfer to a casserole dish and bake at 150 degrees C for 30 minutes.

Portions:
Carbohydrate: 2
Protein: 2.5
Sapasui – Chicken Chop Suey – Serves 6

250g vermicelli
2 large carrots, finely chopped
2 cups cauliflower, chopped
2 sticks celery, chopped
1 chicken
1 tablespoon vegetable oil
5 cloves garlic, peeled and crushed
2 teaspoons ginger, chopped
½ cup low salt soy sauce
1 ½ cups water

Method:

Place the vermicelli in a large bowl and cover with hot water. Soak for 20-30 minutes or until expanded.

Lightly steam or half cook the carrots, cauliflower and celery. Drain and set aside.

Remove the skin from the chicken. Cut the flesh from the bones and cut into small pieces.

Heat the oil in a pan and add the garlic and ginger and cook on high for 2-3 minutes. Add the chicken and stir fry until chicken is white and cooked through.

Drain any remaining water from the vermicelli and cut into short lengths. Add to the chicken along with the soy sauce and water and bring to the boil. Add the vegetables and simmer for a further 5 mins.

Portions:
Carbohydrate: 2
Protein: 1-2 depending on what meat is eaten
**Smoked Fish Supreme – Serves 6**

1 whole smoked kahawai  
1kg kumara, cooked and sliced  
3 tablespoons parsley  
1 ½ cups crushed weetbix  
1 cup grated edam cheese  
2 tomatoes, sliced

**White Sauce:**

1L low fat milk  
1 med onion, chopped  
1 teaspoon pepper  
2 tablespoons cornflour  
½ cup more milk

**Method:**

Remove the skin and bones from the flesh of the fish. Flake the flesh into small pieces.

Make the white sauce:  
Place the first measure of milk, onion and pepper into a saucepan. Bring to the boil and remove from the heat. Mix the cornflour to a smooth paste with the second measure of milk. Gradually stir the cornflour mixture into the saucepan of milk. Return to a medium heat and stir until thickened.

Add half the cheese and all the fish to the sauce and heat through for 5-10mins.

Layer a casserole dish with half the kumara slices, then with half the fish and sauce mixture, then with parsley. Repeat the layers again then sprinkle the crushed weetbix on top and then the rest of the cheese. Arrange the tomato slices on top. Bake for 30-40 mins at 180 degrees C.

**Portions:**
Carbohydrate: 4  
Protein: 2-4 depending on how much fish is used
Curry Lolo with Tuna – Serves 6

2L water
2 taro, peeled and cubed
1 cup light coconut cream
4 cups water
2 onions, chopped
2 teaspoons curry powder
2 x 170g cans tuna, flaked

Method:

Bring the first measure of water to boil in a pot, add the taro and cook until taro is softened when tested with a skewer. Drain and leave in the saucepan.

Combine the coconut cream, second measure of water and onions in a bowl. Use a little of this mixture to mix the curry powder to a paste.

Add the curry powder paste to the coconut mixture and pour over the taro. Return the saucepan to the heat and bring to the boil.

Stir in the tuna and simmer for 5-10 mins on low heat. Season with pepper before serving.

Portions:
Carbohydrate: 4
Protein: 1
Fish and Banana Bake – Serves 6

6 small fish fillets
4 ripe bananas, sliced lengthways
2 spring onions, chopped
2 rashers of lean bacon, chopped
800g pumpkin, sliced
1½ cups low fat milk
1½ cups light coconut cream
2 teaspoons chopped parsley
pepper

Method:

Rinse the fish fillets and arrange them in the bottom of a casserole dish. Add a layer each of half the bananas, spring onions, bacon and pumpkin. Repeat the layers again. Mix together the milk and coconut cream and pour over. Sprinkle with parsley and black pepper. Cover and bake at 180 degrees C for 45 mins or until everything is cooked.

Portions:
Carbohydrate: 1
Protein: 1
Fish and Taro Patties – Makes 12 patties

2L water
1 large taro, peeled and cut into pieces
425g can fish in water
3 spring onions, chopped
1 onion, chopped
pepper
2 cups breadcrumbs, wholemeal if possible
2 tablespoons vegetable oil

Method:

Bring the water to boil in a pot, add the taro and cook until taro is softened when tested with a skewer. Drain and leave to cool.

Grate the cooked taro and place in a large bowl. Add the fish, spring onions and onion and mix thoroughly. Season with pepper. Shape small handfuls of mixture into patties and coat with breadcrumbs.

Cook in a non-stick frying pan for 30 minutes or bake on a tray in the oven for 30 mins at 180 degrees C. Turn halfway to brown on both sides.

Portions:
Carbohydrate: 1 per pattie
Protein: 1 per pattie
HEALTHY DISHES FROM INDIA

The following recipes are from the book “Margaret Gee’s Low Cholesterol Cuisine” by Bay Books, which is out of print.

TANDOORI CHICKEN
This is one of India’s most celebrated dishes. Traditionally, it is cooked in a tandoor, or clay oven, which gives the chicken a very special, slightly smoky flavour. However, you can produce a delicious result in your own oven. This recipe can be used for meat or seafood, and it is recommended you use freshly ground spices to create a genuine tandoori paste. Tandoori chicken can also be cooked on the barbecue.

Ingredients:
1.5 kg (3 lb) chicken pieces, on the bone
1 tablespoon vinegar
1 cup low-fat yoghurt
lemon wedges, for garnish

TANDOORI PASTE
3 fresh red chillies
1 onion
6 cloves garlic
1 tablespoon chopped fresh ginger root
2 tablespoons lemon juice
1 teaspoon ground cumin
1 teaspoon freshly ground black pepper
2 teaspoons ground coriander
2 whole cloves
small piece cinnamon stick
1 bay leaf
dash turmeric
dash nutmeg
dash paprika
1 teaspoon paprika

Remove all skin from chicken and prick pieces with a fork. To make tandoori paste, puree chillies, onion, garlic, ginger and lemon juice. Place in a bowl. Preheat non-stick fry-pan and dry-fry remaining tandoori paste spices until smoking vigorously. Combine with the puree and mix to form a paste. Rub this paste thoroughly into chicken pieces. Sprinkle over vinegar and pour over yoghurt. Combine well and marinate in refrigerator for at least 24 hours, stirring mixture occasionally.

Preheat oven to 190C (375F). Place chicken pieces on rack in roasting pan. Bake for 35—40 minutes until tender. Baste during cooking process with any remaining marinade. Garnish with lemon wedges and serve with salad and wholemeal chapatis (see recipe).

Note: Tandoori Chicken can also be grilled instead of roasted.

Serves 4—6
Carbohydrate Portions: 1/2
Protein portions: 1 drumstick = 1P, 3/4 leg = 1P
CAULIFLOWER WITH YOGHURT
1 small cauliflower, divided into florets
½ teaspoon turmeric
generally ground black pepper
2 teaspoons mustard seeds
1½ cups low-fat yoghurt
1 teaspoon finely chopped fresh ginger root
2 garlic cloves, finely chopped
½ fresh red or green chilli, finely chopped

Steam or boil cauliflower until tender. Drain and set aside. Preheat non-stick
fry-pan and dry-fry turmeric, pepper and mustard seeds. When seeds begin to
pop, add yoghurt. Stir in ginger, garlic and chilli. Add cauliflower florets and
mix well. Refrigerate one hour and serve.
Serves 6

PAKORAS
800 g (1½ lb) mixed free vegetables
(broccoli, cauliflower, capsicum,
eggplant, onions)
BATTER
2 cups wholemeal or besan (chick
pea) flour
½ teaspoon baking powder
2 cups water
2 egg whites, lightly beaten
½ teaspoon ground turmeric
1 teaspoon cumin seeds
freshly ground black pepper

Preheat oven to 190C (375F). Chop vegetables into bite-sized pieces and
set aside. To make batter, sift flour and baking powder. Add water and combine
well. Add all other batter ingredients. Dip in vegetable pieces and place on non-
stick baking tray. Bake for 25 minutes until brown. Serve with low-fat yoghurt or
chutney dip.
Serves 6

Carbohydrate Portions: 1.5
Protein portions: ½

DHAL
2½ cups red lentils
6 cups water
5 cloves garlic, finely chopped
2.5 cm (1 in) piece cinnamon stick
6 black peppercorns
8 cardamom pods, slightly bruised
2 teaspoons turmeric  
3 teaspoons cumin seeds

Wash lentils in colander. Discard any that float to the surface. Place lentils in a heavy-based saucepan with water and all ingredients except cumin seeds. Bring to the boil. Reduce heat, cover and simmer for 45—60 minutes. Stir at regular intervals. If mixture becomes too thick, add a little more water. The consistency can vary according to your preference for a thick or thin dhal. Allow to cool. Remove cardamom pods, peppercorns and cinnamon stick. For a smoother texture, blend or mash lentils. Just before serving, heat a non-stick fry-pan and dry-fry cumin seeds until they start to smoke. Sprinkle heated cumin seeds over dhal. Serve with curry and brown rice.  
Serves 4

Carbohydrate Portions: 1  
Protein portions: ½

VEGETABLE SAMOSAS

1½ cups wholemeal flour  
pinch baking powder  
½ cup water  
1½ tablespoons skim milk  
lemon wedges and chutney to garnish

SAMOSA FILLING
3—4 potatoes (about 800 g), peeled and chopped  
¾ cup water  
1 large onion, finely sliced  
2 cloves garlic, finely chopped  
1 cup fresh or frozen peas  
1 small carrot, grated  
1 teaspoon finely chopped fresh ginger root  
1 teaspoon ground cumin  
½ teaspoon ground coriander  
½ teaspoon ground turmeric  
freshly ground black pepper  
1 fresh green chilli, finely chopped or blended  
½ cup finely chopped fresh coriander  
2 tablespoons lemon juice

To make dough, sift flour and baking powder. Add water and milk, combine and knead for 10 minutes. Wrap in plastic and set aside.  
To make filling, steam or boil the potatoes and mash. Bring water to the boil. Add onion and garlic. Reduce heat, cover and simmer for 5 minutes. Add peas, carrot and ginger. Cover and simmer for 5 minutes. Drain well. Combine with mashed potato and mix thoroughly. Preheat non-stick fry-pan and dry-fry cumin, ground coriander, turmeric and pepper until they smoke. Add to filling mixture with chilli, fresh coriander and lemon juice. Mix well and allow to cool. Preheat oven to 190°C (375F). Take small amounts of dough and form into
balls. Roll these out into very thin circular pancakes. Cut pancakes in half. Place 1 ½ teaspoons of filling on one side of half a pancake. Fold over to form a triangular shape. Seal edges and brush top with extra skim milk. Bake for 25 minutes until brown. Garnish with lemon wedges and chutney and serve.

Note: Instead of cutting circular pancakes in half, you can form pastie shapes. For a crowd, I sometimes make one large pastie and serve the samosas in thick strips. (if there is any samosa mixture over, form into balls, brush with egg white and bake in the oven — easy Indian rissoles!)

Serves 4

Carbohydrate Portions: 3
Protein portions: ½

PRAWN CURRY
1 kg fresh uncooked prawns, shelled and deveined; leave tails on ½ cup water or stock
2 large white onions, finely sliced lemon wedges, for garnish
CURRY MARINADE
1 teaspoon ground turmeric
2 tablespoons ground coriander
4 cardamom pods, ground freshly ground black pepper
1 tablespoon finely chopped fresh ginger root
4 garlic cloves, finely chopped
3 fresh red or green chillies
¼ cup brown vinegar
1 tablespoon fresh tomato paste, mixed with 1 tablespoon water
1 bunch fresh coriander, finely chopped

Preheat non-stick fry-pan. Dry-fry turmeric, coriander, cardamom and pepper until they are heated through and smoking. Remove from fry-pan and mix with other curry marinade ingredients. Marinate prawns in marinade for at least 1 hour — preferably overnight. Bring water to the boil and add onion. Reduce heat, cover and simmer for 10 minutes. Add prawns with marinade and simmer for 5—10 minutes. Garnish, with lemon wedges and serve with brown rice.
Serves 6

Carbohydrate Portions: 0
Protein portions: 3

FAVOURITE FISH CURRY
This is a ‘wet’ curry and the delicious gravy is poured over rice.
1 teaspoon ground turmeric
1 tablespoon ground coriander
2 teaspoons ground cumin seeds freshly ground black pepper
1½ cups water
2 large white onions, finely sliced
4 cloves garlic, finely chopped
2 teaspoons finely chopped fresh ginger root
2 fresh red or green chillies, chopped
2 large very ripe tomatoes, roughly chopped
1 teaspoon tomato paste
1 kg firm fish fillets, chopped into thick slices
½ cup chopped fresh coriander
lemon wedges, for garnish

Preheat non-stick fry-pan. Dry-fry turmeric, coriander, cumin and pepper until they are heated through and smoking. Remove from heat and set aside. Pour 1 cup water into pan. Bring to the boil and add onions, garlic, ginger and chillies. Reduce heat, cover and simmer for 5 minutes. Add the spices, tomato pieces and tomato paste. Stir until well combined, then cover and simmer for a further 3 minutes. Add fish pieces and remaining ½ cup water. Gently stir until combined. Cover and simmer on a low heat for 20 minutes. Before serving, stir in chopped coriander. Garnish with lemon wedges. Squeeze juice over fish curry before eating. Serve with brown rice and accompaniments.

Serves 6

Carbohydrate Portions: 0
Protein portions: 3

**TAJ MAHAL CHICKEN**
1¼ cups liquid chicken stock
2 large white onions, thinly sliced
2 fresh red or green chillies, finely chopped
4 cloves garlic, finely chopped
1 tablespoon finely chopped fresh ginger root
1.5kg (3 lb) chicken pieces, skinned
1 cup low-fat yoghurt
1 cup finely chopped fresh coriander
2 tablespoons finely chopped fresh mint leaves

**SPICES**
2 cardamom pods
2 teaspoons ground turmeric
1 bay leaf
1 teaspoon black mustard seeds
1 teaspoon cumin seeds
1 small piece cinnamon stick
1 clove
3 peppercorns

Preheat non-stick fry-pan. Add spices and dry-fry. Remove from heat when spices smoke. Bring 1 cup stock to the boil and add onions. Reduce heat, cover and simmer for 4 minutes. Add chillies, garlic and ginger and cook for a further 2 minutes. Stir in dry-fried spices until well combined. Remove this
spicy mixture from fry-pan.
Add chicken pieces to fry-pan and sauté until lightly browned all over.
Combine all ingredients except coriander and mint. Cover and simmer on a
low heat for 40 minutes. Stir in coriander and mint and serve with brown rice.
Serves 4—6

Carbohydrate Portions: 0
Protein portions: 1 drumstick = 1P, ¾ leg = 1P

PUNJAB POTATO PUREE
1 kg potatoes, peeled and chopped
1 tablespoon black mustard seeds
1 teaspoon ground coriander
1 teaspoon ground cumin
freshly ground black pepper
½ cup water
1 onion, finely chopped
1 clove garlic, finely chopped
1 teaspoon finely chopped fresh ginger root
¼ cup low-fat yoghurt
1 fresh red or green chilli, finely chopped
½ cup finely chopped fresh coriander
lemon wedges and chopped fresh coriander, for garnish

Steam or boil potatoes until tender, and reserve. Preheat non-stick fry-pan.
Dry-fry mustard seeds, coriander, cumin and pepper until smoking and
mustard seeds pop; set aside.
Bring water to the boil. Add onion, garlic and ginger. Reduce heat, cover and
simmer for 5 minutes. Drain and combine with dry-fried spices.
Mash potatoes with yoghurt and add in all other ingredients.
Garnish with lemon wedges and fresh coriander
Serves 4

Carbohydrate Portions: 3
Protein portions: 0

RAJASTHANI RICE
3 cardamom pods, slightly bruised
1 small piece cinnamon stick
3 whole cloves
6 black peppercorns
3 cups brown rice, well rinsed and drained
1 teaspoon grated orange zest
1 teaspoon grated lemon zest
3 cups water
1 cup fresh orange juice
½ cup mixed dried fruit, rinsed under cold water and drained

Preheat non-stick fry-pan and dry-fry cardamom, cinnamon, cloves and
peppercorns until they begin to smoke. Add to rice with all ingredients except
dried fruit.
Stir until well combined and bring to boil. Reduce heat, cover and simmer slowly until cooked — about 40 minutes. Mix through dried fruit and serve with curry and accompaniments.
Serves 6

Carbohydrate Portions: 5
Protein portions: \( \frac{1}{2} \)

HOT BEEF VINDALOO
1.5 kg (3 lb) topside beef, trimmed of all visible fat and diced
1 cup liquid chicken stock
4 medium-sized white onions finely sliced
3 fresh red or green chillies, finely chopped
5 cloves garlic, finely chopped
1 tablespoon finely chopped fresh ginger root
CURRY PASTE
1 teaspoon ground turmeric
1 tablespoon ground coriander
1 teaspoon ground peppercorns
1 teaspoon ground cumin
1 teaspoon ground fenugreek
\( \frac{1}{4} \) cup brown vinegar
1 tablespoon tomato paste

To make curry paste, preheat non-stick fry-pan and add ground spices. Heat through; remove from heat when they are smoking. Mix with vinegar and tomato paste until smooth. Pour over meat and marinate for at least 1 hour. Bring \( \frac{1}{2} \) cup stock to the boil and add onions. Reduce heat, cover and simmer for 5 minutes. Add chillies garlic and ginger and cook a further 3 minutes. Remove from fry-pan and set aside.
Add marinated meat and sauté for 10 minutes. Add remaining stock. Cover and simmer on a low heat for 1 hour, until meat is tender. Serve with brown rice.
Serves 6

Carbohydrate Portions: 0 but remember to count your rice
Protein portions: 4

WHOLEMEAL CHAPATIS
2\( \frac{1}{2} \) cups wholemeal flour
1 cup water
1 tablespoon skim milk

Sift flour and gradually add water and milk. Combine well and knead for 10 minutes on a lightly floured board. Wrap in plastic wrap or slightly damp cloth and allow to stand for 2 hours.
Form small pieces of dough into balls and roll out as thinly as a crepe.
Preheat non-stick fry-pan, cook chapatis for 1 minute. Press edges with a cloth to make the chapatis light and bubbly. Turn over and cook for another
minute.
Wrap cooked chapatis in clean tea towel and serve with curries and chutney.
Serves 4

Carbohydrate Portions: 3
Protein portions: ½

AVIYAL MIXED VEGETABLES
2 fresh green chillies
1 onion
1 teaspoon grated fresh ginger root
2 cloves garlic
1 cup water
1 teaspoon cumin seeds
2 teaspoons black mustard seeds
½ teaspoon ground turmeric
freshly ground black pepper
1 kg mixed free vegetables (carrots, beans, capsicum, broccoli, cauliflower)
1 cup low-fat yoghurt
½ cup finely chopped fresh coriander
lemon wedges, for garnish

Puree chillies, onion, ginger and garlic. In a casserole, bring water to the boil and add pureed mixture. Cover, reduce heat and simmer for 5 minutes. In a pan, dry-fry cumin and black mustard seeds, turmeric and pepper until seeds pop. Add to casserole, cover and simmer for a further 2 minutes. Then add vegetables; cover and simmer for 8—10 minutes. Stir in yoghurt and coriander. Garnish with lemon wedges and serve.
Serves 4—6

PEAS AND BEANS IN SPICY TOMATO SAUCE
1 onion
1 clove garlic
1 teaspoon grated fresh ginger root
1 fresh red chilli, chopped
¼ cup water
1 heaped teaspoon cumin seeds
1 teaspoon ground turmeric
freshly ground black pepper
3 very ripe tomatoes
2 tablespoons lemon juice
250 g (8 oz) fresh shelled peas
500 g (1 lb) snake or French beans, cut into short lengths
Blend onion, garlic, ginger and chilli. Add puree to a pan of boiling water. Cover, reduce heat and simmer for 5 minutes. Dry-fry cumin, turmeric and pepper. Add to pan and cook for a further minute. Puree tomatoes and lemon juice and add to pan with peas and beans. Cover and simmer for 10—12 minutes and serve.
Serves 4—6
BRAISED CABBAGE WITH CUMIN

1 1/4 cups water
1 large onion, finely sliced
2 teaspoons finely chopped fresh ginger root
2 cloves garlic, finely chopped
1/2 cabbage, finely shredded
2 fresh green chillies, finely chopped or blended
1 teaspoon ground turmeric
2 teaspoons cumin seeds
1/4 cup lemon juice

Bring water to the boil. Add onion, ginger and garlic. Reduce heat, cover and simmer for 5 minutes. Add cabbage, chillies and turmeric and mix well. Cover and simmer for 15—20 minutes. Dry-fry cumin seeds until they smoke. Sprinkle over cabbage. Pour over lemon juice and Serve.

Serves 4—6
Dietitians:

Amber Parry Strong – PhD Candidate, dietary intervention supervisor, Wellington.

Auckland: Fiona McKechnie, Carolyn Cairncross

Wellington: Gemma Bishop, Eirean Kiely

Christchurch: Kristen Corselius White
Background to the Study

Four hundred and fifty overweight (BMI >25kg/m²) individuals with type 2 diabetes will be randomised to one of two dietary protocols. Subjects will be recruited in multiple centres throughout New Zealand (Auckland, Wellington, Christchurch) through diabetes research databases, diabetes centres and clinics, through primary care databases and PHOs and by general public advertisements. Subjects will be screened by initial contact over the telephone and subsequently by blood tests and physical examination. Subjects will be included if they have established type-2 diabetes requiring oral hypoglycaemic agents and/or insulin, or are diet-controlled and meet the WHO criteria for diabetes and are aged between 30 and 75 yrs.

Active consultation with local Maori and Pacific peoples in each of the participating centres has been undertaken in the development of this study. Through the support and participation of local Maori and Pacific peoples, we aim to maximise recruitment of Maori and Pacific participants.

Exclusion criteria: Current or recent weight change >3kg in previous three months, pregnancy or lactation, an eating disorder or active psychiatric illness, diabetic nephropathy (Creatinine >160umol/l or urinary albumin >300mg/24hr) or other chronic renal failure, chronic liver disease other than non-alcoholic fatty liver disease (AST, ALT or GGT >3xULN), active gallbladder disease, NYHF class 3 or 4 heart failure, myocardial infarction in last 6 months, known malignancy, ongoing oral steroid use, or other reasons why taking part would be practically very difficult e.g. institutional care.

Interventions:
Dietitian supervised diets using one of two protocols:

Group 1. “Conventional- current best advice”
Subjects in this group will be prescribed an energy-restricted diet based on current recommended macronutrient composition. This will be 55% carbohydrate, with predominantly low glycaemic index, whole-grain foods with high fibre intake (25-30g/day), and minimal refined carbohydrates. The balance of the diet will be composed of 30% fat, with no more than 10% being saturated fat, and approximately 15% protein. The diet prescription will aim for a reduction in total energy intake of 500kcal/day, using an initial dietary prescription based on estimation of energy requirements minus 500kcal.

Both the carbohydrate and protein recommendations will use 15g portions with the carbohydrate being low glycaemic index and the protein being low fat. Specific fat recommendations will not be given but advice on low fat cooking and preferred types of fat will be given in the initial advice package, and more in the group sessions. Recipes will be provided using the “Low GI” and National Heart Foundation cookbooks. It is hoped that a low glycaemic index diet with high fruit and vegetables, wholegrains and legumes will achieve the fibre goal. A sample diet plan will be provided along with food charts to enable easy portion choices.
Sample calculation – Subject A weighs 100kg and her energy requirement calculation indicates she requires 2100kcal per day. Recommendations would be:

Energy: 1600kcal
55% Carbohydrate: 880kcal or 220g = 14 portions
15% Protein: 240kcal or 60g = 4 portions

Group 2. “High-Protein:Reduced-Carbohydrate”
Reduced carbohydrate (40% total energy) with a focus on wholegrains and low glycaemic index foods, high fibre (25-30g/day), increased protein (30% total energy) and moderate total fat (30% total energy) and SAFA (<10% total energy as part of the 30%). The diet prescription will aim for a reduction in total energy intake of 500kcal/day, using an initial dietary prescription based on estimation of energy requirements minus 500kcal.

Recommendations for carbohydrate and protein in this group will also use 15g portions with low glycaemic index carbohydrate, and low fat protein. Recipes will be provided using the “CSIRO Total Wellbeing Diet” cookbook. Again the fibre intake will be monitored and more intensive individualized advice or a fibre supplement will be provided to those who are not meeting the fibre goal.

Sample calculation – Subject A weighs 100kg and her energy requirement calculation indicates she requires 2100kcal per day. Recommendations would be:

Energy: 1600kcal
40% Carbohydrate: 640 kcal or 160g = 10 portions
30% Protein: 480kcal or 120g = 8 portions

All participants will be allocated to a group session, which will meet fortnightly for the first 6 months and then monthly for the second 6 months. These sessions will be run by a dietitian and consist of both intervention specific and general weight loss advice.
Pre-baseline Preparation:

The following will need to be put together and photocopied before the study (all files on the CD and examples in your folder):

3 Day Diet Record:
- DEWL 3 day diet record with satiety scores
- If you can give these out with the diet assessment photos in a large envelope so that people can add recipes and packages to the envelope which will make data entry easier. The whole envelope will be collected back in, with the diet assessment photos booklet so that we minimize how many of these get lost.

Participant Folders:
- Topaz and sapphire DEWL study sheets with the sweeteners and suitable drinks handouts and corresponding recipes into the folders
- Paste the corresponding pyramid poster on the front of the folder

Session Handouts:
- Photocopy the handout for that session and suggest participants add them to their folders

Randomisation Procedure for Dietitians

All numbers will sent by Elizabeth (the statistician) to Amber – then the process will happen:

1. Amber will make up all randomisation envelopes for all centres with the envelope number on the outside

2. Numbers randomised to wear pedometers will have a P on the envelope

3. Inside the envelope will be a sheet of paper telling the participant which diet they have been randomised to

4. Amber will send envelopes to auckland and christchurch dietitians with 2 lists – one for the dietitian with the envelope numbers matched to the intervention and control allocations, and one for the research nurse with the envelope number and space for the study ID, name and contact phone number to be filled in.

5. The research nurse will fill out the sheet with the participants study ID next to the envelope number, name and phone number and give it back to you.

6. You will then be able to phone people to put them into group sessions

7. You will then type only the study ID into the original list with the envelope numbers and email to Amber when the list is finished, who will send on to Elizabeth.
Baseline

Interested participants will be screened at baseline by the research nurses and included or excluded depending on whether they meet the inclusion criteria. All participants will be asked to complete a 3 day estimated food record. Once they are accepted into the study, they will be randomized into either the Sapphire or Topaz study groups and you will need to complete a Diet Manual for them.

- Fill in participants name

- Calculate daily energy requirements using the following equation:

  Women:
  \[655 + (9.6 \times \text{weight in kg}) + (1.7 \times \text{height in cm}) - (4.7 \times \text{age in years})\] \(\times\) 1.3

  Men:
  \[66 + (13.7 \times \text{weight}) + (5 \times \text{height in cm}) - (6.8 \times \text{age})\] \(\times\) 1.3

  *Then, take off 500kcal for weight loss for every participant under 150kg. Note the lowest energy we will go down to is 1200kcal, so if taking off 500kcal gives you less than 1200 – use 1200kcal. For those who weigh 150kg and above take off 1000kcal.*

This gives you the energy requirement (ER) in calories (kcal), multiply by 4.2 to get kJ.

- Once you have the daily energy requirement (ER) in kJ, you can work out the protein and carbohydrate portions:

  **Topaz Diet Group:**

  Energy from protein: ER x 0.3 = X

  Grams of protein: \(X ÷ 17\) = Y grams

  Protein portions: \(Y ÷ 15\) = \(Z\) portions

  Rounding – round numbers up to the nearest portion

  Energy from carbohydrate: ER x 0.4 = X

  Grams of carbohydrate: \(X ÷ 17\) = Y grams

  Carbohydrate portions: \(Y ÷ 15\) = \(Z\) portions

  Rounding – round numbers down to the nearest portion

  **Sapphire Diet Group:**
Energy from protein: ER x 0.15 = X

Grams of protein: X ÷ 17 = Y grams

Protein portions: Y ÷ 15 = _________Z portions

Rounding – round numbers down to the nearest portion

Energy from carbohydrate: ER x 0.55 = X

Grams of carbohydrate: X ÷ 17 = Y grams

Carbohydrate portions: Y ÷ 15 = _______Z portions

Rounding – round numbers up to the nearest portion

Once you have worked out their carbohydrate and protein portions, please find the corresponding sample diet plan and put a copy in their folder. If the portions are higher than the largest sample plan given, please use the largest sample diet plan.

Making up Groups

You will need to set up groups of each intervention arm as people come through. The minimum in a group is 12 people. Once you fill in their diet manual, phone the person and let them know when their group session will take place. Fill in a group list for each group session to use as a roll, and to double check that everyone has been placed in a group. At the end of the intervention, please fax the rolls to Amber.

Weigh In’s at Group Sessions

Weights are required to be recorded monthly, so for the first 6 months weights of participants will need to be taken every second session, then every session in the second six months. Weight must be taken by either the dietitian or the research assistant to ensure the nurses remain blinded. Each centre will need to work out how best this will work.

Weight will be measured on a TBF 300 Tanita scale (or other Tanita Scale if calibrated with a 10kg weight regularly) throughout the study, note bio-impedance is not required.

Participants should be wearing minimal clothing (no jerseys or jackets) and NO shoes. Ensure the participant has an empty bladder. Weight should be measured and recorded to the nearest 10g.
Group Sessions

The following information is designed to help you lead all the group sessions. The sessions for the first six months are quite prescriptive and educational, whereas the sessions in the second six months will be more supportive. For your assistance you have been provided with a copy of the food composition tables in case you are asked the protein or carbohydrate content of foods not on the exchange list, measuring cups to illustrate portion sizes and a set of scales so participants can weigh food at group meetings if they don't have scales at home.

You will need to take a roll for each group session, so make sure you bring your group list with you and tick off names each time.

Session One:

Session one is an introduction to the diets and a chance for participants to plan their carbohydrate and protein portions across the day and ask any questions they might have. The suggested order for you to run the evening is:

- Welcome – introduce yourself and invite participants to introduce themselves. Hand out folders.
- Go through the timetable with them so they understand when the medical investigations will occur
- Go through each page of the participant manual to ensure they understand what it means. Ask if there are questions. Ensure you discuss the portions system for protein and carbohydrate and that they understand which foods are in each category. Briefly cover fat, fibre, treats, free foods, alcohol, drinks and sweeteners.
- Menu Planning: reproduce this table on the whiteboard and help people to allocate their portions over the day. Remember to include fruit and free vegetables, but fruit needs to be counted as carbohydrate portions. A guideline is to divide the portions by three and allocate a third for each meal. Then if they wish to allow for snacks they can take some portions from a meal and re-allocate them as snacks.

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<th>Carbohydrate Portions</th>
<th>Protein Portions</th>
<th>Vegetables</th>
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<td>Snacks</td>
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- Discuss the section in the session handout on keeping food diaries. Most of this they can read through themselves at home. Please ask them to fill in the section on weight as homework to be discussed briefly in session 2.
- Please encourage the high protein topaz group to use calci trim or calci-xtra milk!
• Finish up by reminding them of the date of the next meeting and ask them to bring some of their favourite recipes next time.

Session Two:

• Review how the first 2 weeks went
• Ask how they went with the weight exercise and emphasise that 10% weight loss is their goal and make sure everyone has filled in that box. 10% weight loss provides significant improvements in insulin sensitivity and is more likely to be achieved and maintained.
• Explain the concept of GI and point out the GI of some different foods from the chart. Discuss easy substitutions eg basmati rice, breakfast cereal
• Recipe Conversion. Help the participants to alter some of their usual recipes to suit the diet by asking the following questions:
  o How much protein is in the recipe? Can I increase or decrease it to suit?
  o How much carbohydrate is in the recipe? Do I need to add extra carbohydrate to make this a meal? What sort of carbohydrate could I add?
  o Does the recipe already contain vegetables or do I need to add them in or increase the amount?
  o Does the recipe contain ingredients that I could swap for lower fat or lower GI ingredients?

Session Three:

• DEWL Diamond – put a copy of the group’s diamond on the white board and talk through each section and how it differs from the usual pyramid – i.e. more protein for the topaz group, Low GI, high fibre, potato is a carbohydrate not a vegetable etc.
• Fat – put the three categories on the board (saturated, mono and poly) and put different fats into each group. Discuss merits of mono and poly in terms of cholesterol (mono may increase HDL, poly is cholesterol neutral). Discuss merits of different oils i.e. olive has antioxidants, canola has omega-3 fats.

Composition per 100g

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Sunflower        11.9    20.2    63.0    5.3       0       49.0
Safflower        10.2    12.6    72.1    7.1       0       40.68
Canola           5.3    64.3    24.8    4.7       0       22.21

- Nuts - Nuts are high in fat but contain vitamin E and unsaturated fats and are recommended in small doses for heart protection. Discuss better types of nuts (unsalted, not roasted) (Also brazil nuts contain more saturated fat than other types of nuts). And quantity – 1 tablespoon. Suggest ways of including nuts eg salads, stir frys, muesli. One large study showed two serves of nuts a week can cut heart attack risk by 11%. But stress the calorie content and in large amounts will inhibit weight loss.

- Omega-3 fat – explain this is a type of fat that also has protective qualities for heart disease.

Approximate EFA content in grams per 100 grams

<table>
<thead>
<tr>
<th>Omega-3s (100g)</th>
<th>(g)</th>
<th>Omega-6s (100g)</th>
<th>(g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flax / Linseed oil</td>
<td>58</td>
<td>Safflower oil</td>
<td>74</td>
</tr>
<tr>
<td>Flax / Linseeds</td>
<td>15-30</td>
<td>Grapeseed oil</td>
<td>68</td>
</tr>
<tr>
<td>Walnut oil</td>
<td>11.5</td>
<td>Sunflower oil</td>
<td>63</td>
</tr>
<tr>
<td>Canola / Rapeseed oil</td>
<td>7</td>
<td>Walnut oil</td>
<td>58</td>
</tr>
<tr>
<td>Soybean oil</td>
<td>7</td>
<td>Soybean oil</td>
<td>51</td>
</tr>
<tr>
<td>Wheatgerm oil</td>
<td>5</td>
<td>Corn oil</td>
<td>50</td>
</tr>
</tbody>
</table>

Ask people to bring in packets and food labels for next weeks label reading session.

**Session Four:**

- Food labels – bring in some packages for people to practice label reading with. Use an example and then ask them to get into small groups to read labels. You can also help them to convert food labels into portions by telling them that 1 carbohydrate portion = 15g carbohydrate and 1 protein portion = 15g protein. The per serve column will be useful for this.

- Shopping – ask people to share tips and advice they have for shopping

**Session Five:**

- Go through the attitude traps section and see if people want to volunteer examples. If they don’t, ask some of their food downfalls eg cheese, beer and use these as examples.

- Fibre – discuss the info on fibre and then ask participants to use the fibre counter to count up how much fibre they had the day before, their goal is 25-30g so if they have not reached that find ways to help them increase their fibre intake.
Session Six:

- Eating pressures – go through this section and ask if anyone has examples to discuss. If no examples, try asking what people would do in different situations e.g.:
  - A friend tells you she heard about this new diet you should try
  - Work morning teas where food is provided
  - Going away to a conference and staying in a hotel
  - Child wanting to do baking at home
  - Your mother telling you can't lose weight – you are just like her

- Drinks – use drinks handout in the diet manual as well as the info in the handout. Ask people to calculate how much they drank the day before. Discuss caffeine, put some of the following info up:

The upside

Caffeine stimulates the central nervous system, leading to many positive changes.

- **Mental performance:** Around 40mg of caffeine (one cup of tea) has been reported to enhance mood and increase energy, alertness and concentration. You feel less tired and your reaction times are shorter. However, this improved performance may be the result of relief of withdrawal symptoms.

- **Physical performance:** The theory is that caffeine increases the availability of fat for fuel, so glycogen, your muscles' main fuel, can last longer. This may help with endurance, but not intense short-term exercise. However, because caffeine increases urine output and the risk of dehydration, caffeine drinks are not suitable for sport. People with high blood pressure should avoid caffeine before a workout as it can further increase the usual exercise-induced rise in blood pressure.

- **Parkinson's disease:** A reduced risk has been shown in men who drink at least two cups of coffee a day. Other studies found caffeine seemed to protect brain cells from the depletion of dopamine, which is the problem underlying Parkinson's.

- **Cancer:** The association is very weak. It has been argued that because caffeine is an antioxidant it may help prevent the development of some cancers.

The downside

There are several possible risks from taking caffeine.

- **High blood pressure:** Ingesting even normal doses of caffeine before exercise or during stressful periods could be dangerous for people who have high blood pressure (hypertension).

- **Raised blood cholesterol levels:** Unfiltered coffee can raise blood cholesterol. Coffee brewed in a plunger or boiled using coarse grains contains cafestol and kahweol. These fat-containing substances have been implicated in raising blood cholesterol levels.
• **Osteoporosis**: The more caffeine you consume, the more calcium you'll lose in your urine. But there does seem to be a compensating decrease in the calcium you lose via the gut. So moderate consumption probably shouldn't increase your risk of osteoporosis.

• **Birth and pregnancy problems**: Some research suggests women who regularly consume more than 300mg (about three cups of coffee) per day may reduce their chances of becoming pregnant and increase their chances of having a miscarriage or delivering an underweight baby. Caffeine may also make its way into breast milk and make your baby jittery. To be on the safe side, pregnant or breastfeeding women should restrict their caffeine intake or avoid it altogether.

• **Insomnia**: This is a common symptom. It takes about an hour for caffeine levels to be absorbed in the body and between four and seven hours to be metabolised. So caffeine taken before bedtime usually delays sleep onset, shortens overall sleep time and reduces the depth of sleep.

• **Anxiety**: Some evidence suggests that people who suffer from anxiety problems tend to feel better when they avoid caffeine. Large doses can trigger panic attacks in some people.

• **Drug interactions**: Some drugs - including birth control pills, and ulcer and heartburn drugs - can hamper your body's ability to dispose of caffeine. Medications that stimulate the nervous system - certain appetite suppressants, asthma drugs and thyroid hormones - can add to the caffeine hit. Check with your doctor or pharmacist about any adverse effects of mixing your medication with caffeine.

**Public health bodies recommend no more than 300mg caffeine per day.**

**How much caffeine in common drinks?**

**Soft Drinks**

<table>
<thead>
<tr>
<th>366ml beverage (can)</th>
<th>milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Bull</td>
<td>80.0</td>
</tr>
<tr>
<td>Jolt</td>
<td>71.2</td>
</tr>
<tr>
<td>Pepsi One</td>
<td>55.5</td>
</tr>
<tr>
<td>Mountain Dew</td>
<td>55.0</td>
</tr>
<tr>
<td>Diet Mountain Dew</td>
<td>55.0</td>
</tr>
<tr>
<td>Diet Coke</td>
<td>45.6</td>
</tr>
<tr>
<td>Pepsi-Cola</td>
<td>37.5</td>
</tr>
<tr>
<td>Diet Pepsi</td>
<td>36.0</td>
</tr>
<tr>
<td>Coca-Cola Classic</td>
<td>34.0</td>
</tr>
</tbody>
</table>

**Other Beverages**
<table>
<thead>
<tr>
<th>250ml Beverage (cup)</th>
<th>milligrams</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coffee, Drip</td>
<td>115-175</td>
</tr>
<tr>
<td>Coffee, Brewed</td>
<td>80-135</td>
</tr>
<tr>
<td>Coffee, Espresso</td>
<td>100</td>
</tr>
<tr>
<td>Coffee, Instant</td>
<td>65-100</td>
</tr>
<tr>
<td>Tea, iced</td>
<td>47</td>
</tr>
<tr>
<td>Tea, brewed, imported brands (avg.)</td>
<td>60</td>
</tr>
<tr>
<td>Tea, instant</td>
<td>30</td>
</tr>
<tr>
<td>Tea, green</td>
<td>15</td>
</tr>
<tr>
<td>Hot cocoa</td>
<td>14</td>
</tr>
<tr>
<td>Coffee, Decaf, brewed</td>
<td>3-4</td>
</tr>
<tr>
<td>Coffee, Decaf, instant</td>
<td>2-3</td>
</tr>
</tbody>
</table>

**Session Seven:**

- Eating out – ask people to share experiences and tips, where are good places to go or not go? Good meals to order?
- Fruit and vegetables – rainbow of colours needed to get all phytochemicals. Suggest ways of getting more vegetables in – soups, casseroles, sandwiches, salads, grated etc

**Session Eight:**

- Takeaways – discuss differences between low and high fat takeaways and ask them to share tips and experiences. Also discuss quick meals from the supermarket rather than takeaways – e.g. a roll, coleslaw and cooked chicken, homemade hamburgers, oven fries (discuss how many is a CHO portion), homemade pizza and doner kebabs or tortillas.
- Encourage them to add ideas for different meals
- Discuss calcium and iron and answer questions, encourage people to discuss how much calcium they get on a daily basis if they don’t have dairy and iron if they don’t have meat.

**Session Nine:**

- Discuss the herbs and what they can be used with, if you are able bring in some examples or ask participants to bring in. Encourage participants to grow herbs at home.
- Discuss stress

**Session Ten:**

- Discuss the “shoulds” and “wants” exercise
• Discuss the Diabetes NZ sweeteners handout – if you have packets and samples bring them along! For samples try:
  o www.splenda.co.nz

Session Eleven:

• Alcohol – discuss the alcohol culture that many people live in and how it affects us. It is not uncommon for business people to be in situations several times a week involving heavy alcohol use – functions, entertaining clients, work lunches, shouts etc. Males in particular may have a weekly alcohol consumption in excess of 20 units. A binge is defined as more than 4 units in one time period (eg evening, afternoon). Discuss ways of reducing alcohol consumption at functions and over a week e.g. drink non-alcoholic drinks, be sober driver, light beer etc. Discuss the impact alcohol has on weight. The alcohol page in the participants manual will be useful here, and use the standard wine glass to illustrate.

Session Twelve:

• Discuss the material on lapses and the benefits of weight loss
• Salt – ask people to estimate their salt intake each day. Do people use it in cooking and/or on food? Discuss the difference between iodised salt and other types eg rock salt. Go through these “salt myths” – ask the question with true or false and then read the answer!

**Salt myths**

I don't add salt to my food, so I can't be eating too much sodium
About 65 to 70 percent comes from processed food such as cereals, bread, sauces, and processed meats and sodium also occurs naturally in foods. So, before you assume you don't eat much salt, take a look at what you're buying.

Food has no flavour without salt
If you're used to salty foods, you may miss it when you first cut down. But our taste buds get used to eating less salt in a few weeks - so then you'll enjoy food with less salt. To add flavour, you can also replace salt with lemon juice, herbs and spices.

Only older people need to watch their salt intake
Eating too much salt at any age can raise your blood pressure. It's true you have less of a risk of heart disease or strokes if you're younger. But if you have high blood pressure when you're young, you're at greater risk of these problems.

Sea salt and other designer salts are better for you than regular table salt
Salt is made up of sodium and chloride. It's the sodium in salt that can raise your blood pressure. It doesn't matter how expensive it is, where it's from, or whether it's in grains or flakes - it still contains sodium.

If I cut back on salt I won't have enough
It's actually very difficult to eat too little salt. It's in so many ready-to-eat foods such as bread, cereals, sauces, and crackers.
I’m keeping my iodine levels up if I eat salt
That's only true if you use iodised salt in cooking or add it to your food. Most of our sodium intake comes from processed food, which doesn't contain iodised salt.

The next 6 Sessions….
After the first 6 months, the sessions become monthly rather than fortnightly. These will run more like support groups and are much less directed. You can discuss with each group how they would like these to run. Always have a time at the beginning for discussion of problems and answering questions. Suggested ideas are:
• Recipe swaps
• Vegetable profiles – split the group into 6 small groups and allocate a session to each group. That group has to choose a vegetable for their session and introduce it, say what good stuff it contains and provide some recipes for cooking it. Make sure you make a list so that each group covers a different vegetable.
• Gardening – have people share vegetable gardening ideas – what can be grown easily, in pots, which vegetables to plant when etc.
• Health topics – are there other questions they would like to cover? For example cholesterol, heart disease or blood pressure?

Exercise
As this study is a nutrition trial we are unable to specifically mention exercise. If participants ask about exercise please give them a SPARC handout on exercise. You have been given 20 of each of the following pamphlets:
● Running
● Cycling
● Walking
● Medical conditions and exercise
● Water activities
● Stretching
More of these can be ordered from: www.sparc.org.nz

Vegetarian Diets
Vegans are necessarily excluded from the study as it is not possible to reach the protein levels required for the topaz diet without animal products. Vegetarians however can reach the required levels with planning. If fish is eaten this is much easier to achieve the protein levels. Some examples of portions are:

<table>
<thead>
<tr>
<th>7 Protein Portions</th>
<th>9 Protein Portions</th>
</tr>
</thead>
<tbody>
<tr>
<td>45g cheddar cheese</td>
<td>¾ cup tofu</td>
</tr>
<tr>
<td>½ cup cottage cheese</td>
<td>½ cup cottage cheese</td>
</tr>
<tr>
<td>1 cup calci trim milk</td>
<td>1 cup calci trim milk</td>
</tr>
</tbody>
</table>
1/2 cup nuts
1 cup beans
2 eggs
½ cup sunflower seeds
½ cup sunflower seeds
2 cups lentils
45g cheddar cheese

Smoothies are an easy way to increase the protein content – yoghurt, milk and silken tofu can be blended together to make an excellent high protein smoothie. Adding skim milk powder also adds extra protein – 1 tablespoon skim powder = 3g protein. Hence 250ml yoghurt + 1 tablespoon milk powder = 1 P.

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Dept Medicine
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PO Box 7343
Wellington South
1. No one can make you feel inferior without your consent. -- *Eleanor Roosevelt*
1 Aug 07

2. The hardest challenge is to be yourself in a world where everyone is trying to make you be somebody else. -- *E. E. Cummings* 5 July 07

3. Begin doing what you want to do now. We have only this moment, sparkling like a star in our hand -- and melting like a snowflake. -- *Marie Beyon Ray* 3 May 07 1 May 08

4. My dad always used to say, "If you're falling off a cliff, you may as well try to fly. You have nothing to lose." -- *Captain John Sheridan, Babylon* 5 6 June 07

5. Things turn out the best for the people who make the best of the way things turn out. -- *John Wooden* 20 Sept 07 9 April 2007

6. Always bear in mind that your own resolution to succeed is more important than any one thing. Abraham Lincoln (1809 - 1865) 11 April 2007 9 April 2008

7. An apple a day may keep the doctor away, they contain antioxidants and phytochemicals which lower cholesterol, fight cancer, keep our lungs healthy and our brains young. 16 May 07 15 May 08

8. Add bananas, berries, or raisins to your morning cereal to get an extra serving of fruit today. We all need 2-3 servings of fruit each day. 26 Mar 08

9. Frozen and canned vegetables and fruit still count towards your servings each day and are often convenient and tasty!! 26 April 07 23 April 08

10. Mussels are a good source of iron and have a good dose of calcium and selenium. Try cooking in a tin of tomatoes and serve with pasta. 16 Nov 07 29 Oct 08

11. DEWL Vege ideas: Steam asian greens eg bok choy in a pan with a little water, then add soy sauce, ginger and chilli for flavour. 30 Jan 08

12. DEWL vege ideas: Lightly stir fry celery and add toasted sesame seeds 12 Dec 07

13. Asparagus is one of the best natural sources of folate and in season now. Keep your asparagus in a vase of water in the fridge. 10 Oct 07 24 Sept 08

14. Fresh beetroot is available now and a great source of antioxidants. Roast or steam and put the leaves in your stir fry 21 Nov 07 12 Nov 08

15. Brussels sprouts have anti cancer properties due to their sulphur compounds,
chopped and stir fried they taste much better than your childhood memory! 13 Feb 08

16. Cooking cabbage for less than 7 mins reduces their gas causing effects, so a quick stir fry is best or use the large leaves as wraps for chicken or mince 20 June 07 11 June 08

17. Try making a whole cucumber into soup with 2 onions, 2 cups chicken stock, 1 cup milk and 1 tblspn curry powder. Simmer until cooked. 20 feb 08

18. Tried eggplant? Bake a whole eggplant in the oven until soft (about 20mins), then slice and mix with natural yoghurt and 1 tspn allspice 18 July 07 18 June 08

19. Watercress makes lovely soup, wilt with onion then simmer with 2 cups chicken stock, 1 tspn nutmeg and 1 tspn chilli 30 May 07 9 May 08

20. The puha that grows wild is high in iron and potassium - steam then add a dash of soy sauce for flavour or blanch and use in salads 28 Feb 08

21. To cook a whole pumpkin without chopping – pierce the skin with a knife in several places and microwave for 15-20 mins 7 Nov 07 23 Oct 08

22. The humble silverbeet is very nutritious, cook with a small amount of water and plenty of garlic 17 Oct 07 8 Oct 08

23. Try spinach soup – stir fry an onion then add 1kg spinach, 1 clove garlic, ½ cup rice and 1L water. Cook until rice is cooked then add 2 cups plain yoghurt 16 jan 08

24. The southland swede is great source of fibre, mash with carrot and parsley and plenty of black pepper or roast with a sprinkle of nutmeg 3 Sept 07 29 July 08

25. Tomatoes contain lycopene, an antioxidant that can protect skin and prevent cancer. Try tomato paste on crackers for an extra hit 9 Jan 08

26. Yams are a good source of vitamin A, microwave them for 50 seconds as a quick snack with a little lemon juice 25 Sept 07 10 Sept 08

27. Capsaicin, which makes chillies hot, can be neutralised by the casein in milk so drink milk with your next hot curry 28 Nov 07 5 Nov 08

28. Green tea has excellent antioxidant properties but can taste bitter – use tea leaves and only infuse for 10 seconds to stop the bitterness coming out. 3 Oct 07 17 Sept 08

29. Including chickpeas in your diet each week may help fight insulin resistance and high cholesterol. 23 Jan 08

30. Researchers have found steaming vegetables not only keeps the nutrients
inside but enhances the antioxidant compounds in them compared to other cooking methods. 4 March 08

31. Support is the best motivation, you can share stories, good times and bad times and know that other people understand what you are going through. 8 Aug 07 23 July 08

32. Boredom is one of the biggest enemies – if you stay busy and occupied your mind won’t turn to food. 3 April 2008

33. Reward yourself with non-food treats – try a movie, bath, new book, holiday, outing or hair cut instead 13 June 07 5 June 08

34. Food actually makes a poor comforter, phoning a friend or family member and talking things through will be more helpful – and more sympathetic 11 July 07 3 July 08

35. Eating after dinner is too easy, especially in front of TV. Take up a craft or hobby to keep your hands occupied, take a night class, write a novel or put your photos in albums! 9 May 07 21 May 08

36. A recent study found that people who ate an apple before a meal then went on to eat 190 calories less at the meal – an apple a day keeps the calories at bay? 31 Oct 07 1 Oct 08

37. Don’t downplay the positives – if you lose 5kg that’s the equivalent of 10 blocks of butter gone from your body! 12 Mar 08

38. Life with diabetes is a team effort – you, your family and friends and your medical team – and you are the team leader 18-4-07 16 April 08

39. Managing stress is an important part of managing diabetes – remember to take time out for yourself this week 23 May 07 29 May 08

40. Information is the key to understanding diabetes – arm yourself with the facts about diabetes and your care and the battle is half won 27 June 07 17 July 08

41. Diabetes has ups and downs, and they’re not all your fault. When you have a good day, take credit. Be realistic, not perfectionistic. 19 Mar 08

42. A recent study has shown that sprinkling a few chopped pistachios on a carbohydrate rich meal of rice or pasta may lower your blood glucose response. 24 Oct 07 15 Oct 08

43. Diabetes may (oddly) delay your eyebrows going grey, a survey of 100 men showed that more men with diabetes had stayed dark eyebrowed than men without diabetes. 14 August 07

44. One teaspoon of cinnamon sprinkled on your food may decrease the rise in blood sugar after a meal suggested a recent study in people with type 2
45. In a recent study diabetics eating brown rice had a 35% lower blood glucose response than ordinary white rice. Shorten cooking time by soaking brown rice first. 12 Sept 07 3 Sept 08

46. 4 teaspoons of vinegar or lemon juice with a meal slows the digestion of the meal and may reduce blood glucose levels after the meal by up to 30%. 5 Feb 08

47. New research has shown that people tend to eat more on weekends and this slows down weight loss. If you think this is you, planning ahead helps to beat this. 9 July 08
APPENDIX M – SF36 QUESTIONNAIRE

SF-36 HEALTH SURVEY

INSTRUCTIONS: This questionnaire asks for your views about your health, how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
   (circle one)
   
   Excellent ........................................................................................................... 1
   Very good .......................................................................................................... 2
   Good .................................................................................................................. 3
   Fair ..................................................................................................................... 4
   Poor .................................................................................................................... 5

2. Compared to one year ago, how would you rate your health in general now?
   (circle one)
   
   Much better now than one year ago ............................................................... 1
   Somewhat better now than one year ago ....................................................... 2
   About the same as one year ago ................................................................. 3
   Somewhat worse now than one year ago .................................................... 4
   Much worse now than one year ago ............................................................ 5
3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>ACTIVITIES</th>
<th>Yes, Limited A Lot</th>
<th>Yes, Limited A Little</th>
<th>No, Not Limited At All</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>c. Lifting or carrying groceries</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>d. Climbing several flights of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>e. Climbing one flight of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>f. Bending, kneeling or stooping</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>g. Walking more than one kilometre</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>h. Walking half a kilometre</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>i. Walking 100 metres</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>j. Bathing or dressing yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cut down on the amount of time you spent on work or other activities</td>
<td>1</td>
</tr>
<tr>
<td>b. Accomplished less than you would like</td>
<td>1</td>
</tr>
<tr>
<td>c. Were limited in the kind of work or other activities</td>
<td>1</td>
</tr>
<tr>
<td>d. Had difficulty performing the work or other activities (for example, it took extra effort)</td>
<td>1</td>
</tr>
</tbody>
</table>
5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cut down on the amount of time you spent on work or other activities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>b. Accomplished less than you would like</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>c. Didn't do work or other activities as carefully as usual</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>..........................................................1</td>
</tr>
<tr>
<td>Slightly</td>
<td>..........................................................2</td>
</tr>
<tr>
<td>Moderately</td>
<td>..........................................................3</td>
</tr>
<tr>
<td>Quite a bit</td>
<td>..........................................................4</td>
</tr>
<tr>
<td>Extremely</td>
<td>..........................................................5</td>
</tr>
</tbody>
</table>

7. How much bodily pain have you had during the past 4 weeks?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No bodily pain</td>
<td>..........................................................1</td>
</tr>
<tr>
<td>Very mild</td>
<td>..........................................................2</td>
</tr>
<tr>
<td>Mild</td>
<td>..........................................................3</td>
</tr>
<tr>
<td>Moderate</td>
<td>..........................................................4</td>
</tr>
<tr>
<td>Severe</td>
<td>..........................................................5</td>
</tr>
<tr>
<td>Very severe</td>
<td>..........................................................6</td>
</tr>
</tbody>
</table>
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all .................................................................1
A little bit .................................................................2
Moderately ...............................................................3
Quite a bit .................................................................4
Extremely .................................................................5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

(circle one number on each line)

<table>
<thead>
<tr>
<th>Question</th>
<th>All of the Time</th>
<th>Most of the Time</th>
<th>A Good Bit of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Did you feel full of life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>b. Have you been a very nervous person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>c. Have you felt so down in the dumps that nothing could cheer you up?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>d. Have you felt calm and peaceful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>e. Did you have a lot of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>f. Have you felt down?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>g. Did you feel worn out?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>h. Have you been a happy person?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>i. Did you feel tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time ..............................................................................................1
Most of the time ............................................................................................2
Some of the time ...........................................................................................3
A little of the time ..........................................................................................4
None of the time ............................................................................................5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

<table>
<thead>
<tr>
<th></th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>b. I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>c. I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>d. My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
APPENDIX O – PEDOMETER RECORDING INSTRUCTIONS

Instructions for Callibrating a Pedometer

1. The participant must walk a 10 meter line and the nurse will count the number of steps they take over this distance (eg. 13 steps).

2. The nurse will then divide 10 by the number of steps (eg. 10 divided by 13 = 0.769), this is the participants stride length.

3. Open a pedometer and press the ‘reset’ button so the number on the screen is ‘0’

4. Press the ‘mode’ button and the curser will move to point to ‘km’ and the display will read 0,00.

5. Press the ‘set’ button until you reach the stride length desired (eg. 76) (The stride length number starts at 30 and goes as high as 180. If you need to reduce the stride length you will need to continue pressing the set button until it reaches 180 and it then returns to 30)

6. Press the ‘mode’ button until the curser is pointing to ‘steps’

7. Close the pedometer on clip it onto your belt.

When the pedometer is returned to the clinic after use, reset the stride length to 30
12 Month Diet Materials Questionnaire

Now that you have finished the group diet sessions with your dietitian, we would like to ask you a few questions about what you found helpful on the diet. Please circle your response on the scale.

Initial Folder of Materials

1. Did you find the material in the folder you were given at the first session a year ago useful for starting the diet?

Very useful

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<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

2. Did you use the sample menu plan at all?

Yes ☐ No ☐

If yes, on the scale below how useful did you find this?

Very useful

<p>| | | | | |</p>
<table>
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<tr>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

3. Did you put the pyramid fridge magnet on the fridge or wall?

Yes ☐ No ☐

If yes, on the scale below how useful did you find this?

Very useful

<p>| | | | | |</p>
<table>
<thead>
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<tbody>
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<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

4. Did you use the diet recording book?

Yes ☐ No ☐

If yes, on the scale below how useful did you find this?

Very useful

<p>| | | | | |</p>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Weekly Text or Email Messages:

1. Did you opt to receive the weekly messages?  
   Yes ☐  No ☐

If yes, on the scale below how useful did you find this?

Very useful  1  2  3  4  5  not at all useful

Group Sessions with the Dietitian:

1. Do you feel the group sessions have improved your knowledge on the following topics:

   **Diabetes:**
   A lot of new knowledge  No new knowledge  
   1  2  3  4  5

   **Nutrition:**
   A lot of new knowledge  No new knowledge  
   1  2  3  4  5

   **Weight Management:**
   A lot of new knowledge  No new knowledge  
   1  2  3  4  5

2. Did you get along with the other people in your group?

   All of them  Most of them  None of them  
   1  2  3  4  5
3. What did you find most useful about the group sessions?

4. What did you find least useful about the group sessions?

5. Please rate the following in order from most 1 being the most useful to 5 being the least useful:

   - Group sessions
   - Weekly messages
   - Folder of materials
   - Recording book
   - Sample menu plan

6. What have been the three most significant changes you have made to your diet or lifestyle as a result of this programme?
APPENDIX S – EXIT INTERVIEW

Date interview completed: 

1. Why did you withdraw from the diet before 24 months?
   1 = disliked diet  4 = death
   2 = injury          5 = refused/no reason
   3 = health problem  6 = other

2. Date you finished the study diet: 

3. While on the DEWL Study have you:
   a. had bariatric surgery?
      1 = Yes  2 = No
   b. been on any specific/named diet or diet programme other than DEWL?
      (eg. Weight Watchers, Jenny Craig, SureSlim)
      1 = Yes  2 = No
      If Yes, provide details: ........................................
   c. used any prescribed weight loss products?
      (eg. Sibutramine)
      1 = Yes  2 = No
      If Yes, provide details: ........................................
   d. used any non-prescribed weight loss products?
      (eg. Optifast, Herbalife)
      1 = Yes  2 = No
      If Yes, provide details: ........................................
   e. used any other method of weight loss not mentioned above?
      (eg. Hypnosis, psychotherapy)
      1 = yes  2 = no
      If Yes, provide details: ........................................
   f. taken up and sustained a high intensity exercise programme?
      (eg. Marathon clinics, triathalons)
      1 = Yes  2 = No
      If Yes, provide details: ........................................
   g. been involved in any other research projects?
      including observational studies
1 = Yes 2 = No
If Yes, provide details: ........................................

4. For what reason did you miss a group session/s?
   1 = illness  5 = holiday
   2 = fall     6 = other…………………………
   3 = major surgery
   4 = death/serious illness to partner/family member

5. Did you have any unpleasant symptoms from the diet?
   ………………………………………………………………………
   ………………………………………………………………………
   ………………………………………………………………………

6. What did you like about the diet?
   ………………………………………………………………………
   ………………………………………………………………………
   ………………………………………………………………………

7. What did you dislike about the diet?
   ………………………………………………………………………
   ………………………………………………………………………
   ………………………………………………………………………

8. Any comments you would like to make?
   ………………………………………………………………………
   ………………………………………………………………………
   ………………………………………………………………………
   ………………………………………………………………………
APPENDIX U – COMMENTS FROM DIET MATERIALS QUESTIONNAIRE

Comments Recorded On Diet Questionnaire Sheet - Negative

1. Participants partner present – patronising, changed dynamic
2. Didn’t like recipes
3. Late dinners after sessions
4. Long stories
5. Small group
6. Insufficient individual accountability
7. Getting to the group
8. Awful venue, too short
9. People wandering off topic
10. Group session time didn’t suit
11. Getting to the group
12. Dwindling attendance
13. Small group
14. Time and travel
15. Traffic
16. 2\textsuperscript{nd} half of year not so useful
17. 2\textsuperscript{nd} half of the year was not useful
18. Personal motivation to get there
19. Difficult to get to meetings
20. Travel time
21. Numbers dropping off
22. Motivation dropped moving from fortnightly to monthly
23. Whole group dropped out by 2\textsuperscript{nd} 6 months I was only one left
24. Cooking demo – chch?
25. Time of session
26. Too many sessions
27. Recipes for families and I am a bachelor
28. Didn’t get the fridge magnet til the end
29. Dwindling numbers
30. Lack of interest of others not attending
31. Evening sessions in winter
32. Same old same old
33. Would have liked an exercise session
34. Missed ongoing attendance
35. The other people – not a joiner
36. Session time didn’t suit
37. Person in group took over and was distracting
38. Getting there on time and going back after missing one
39. Daytime sessions difficult to get to = attendance dropped
40. We had some problems (in group)
41. People not attending meetings
42. Lost something going from fortnightly to monthly
Comments Recorded On Diet Questionnaire Sheet Group Sessions – Positive

1. Friendly atmosphere, everyone had the same issues. Dietitian fantastic, informative and approachable.
3. Opportunity to discuss and ask questions
4. Sharing information, problems, overcoming hurdles
5. Discussion
6. Sharing ideas
7. Talking to others in the group with the same problems and finding the answer
8. Hearing others tips and experiences
9. Sharing info, problems and recipes
10. Being able to ask questions
11. Discussing everything, going away feeling more focussed
12. Support and tips from other members
13. Keeps you in touch and gives you a goal to reach at your next weigh in
14. Label information, support systems
15. Information sharing with others
16. Group Support
17. Other peoples experiences
18. Talking to a dietitian and others in group
19. Group accountability and support
20. Hearing about other peoples experiences, sharing tips and advice about new products etc
21. Sharing information with people in the same situation
22. Information sharing
23. Finding that others faced similar problems
24. (Getting) different ideas and opinions from everybody
25. Tutor confidant in relaying information, group friendly and willing to share
26. Interaction
27. Interesting to hear others experiences
28. Finding what problems others had and how they solved them
29. Dietitian’s endless knowledge and helpfulness and kindness
30. Weighing in and exchanging meal ideas and recipes
31. Others experiences to gauge where I am at
32. Kept you thinking about the programme
33. Interaction
34. Information, team progress
35. Collective support
36. Exchange of ideas and general support
37. Nutrition advice
38. Discussions
39. Question time, nutrition knowledge
40. Weigh ins, topics discusses
41. Weigh ins
42. Reinforcement and support
43. Discussions
44. Discussions and support
45. Support and learning
46. Experiences shared
47. Regular monitoring, sharing experiences, useful information
48. Help and advice
49. Group discussion
50. Information
51. Other members having the same problems and thoughts
52. Exchange of ideas
53. Support
54. Company, discussions and weigh in
55. Group discussions, menu ideas
56. Being able to share and knowing other people are going through the same
57. Sharing
58. Sharing ideas and recipes
59. Keeping focussed on weight loss
60. Interaction and discussions
61. Weighing in
62. Knowing you weren’t alone
63. Knowing everyone has the same downfalls
64. Talking with dietitian re diet
65. Listening to other people and knowing you are not alone
66. Sharing ideas/experiences/successes
67. Finding you are not the only one going through problems with diabetes
68. Realising I am one of many with these problems
69. Discussion of various topics
70. Find others had same problems
71. Ongoing support
72. Hearing how other people got along
73. Group talks invigorating and amusing, fun times, supportive of one another
74. Information
75. Guideline for diet, good teacher, great company in group
76. Listening and a lot of knowledge from the group
77. Knowledge and companionship
78. Sharing experiences, dietitian available, laughter
79. Variety of diverse opinions
80. Open chat, sharing of issues etc
81. Social contact and having a good laugh
82. Education on diet and diabetes
83. Group therapy
84. Sharing knowledge, ideas, strengths and weaknesses and the challenges we all face
85. Sharing experiences, nutritional advice, recipes
86. The feedback
87. Greater awareness of food type and make up
88. Share experiences, improved and updated nutritional knowledge
89. Support
90. Information sharing
91. Swapping suggestions and ideas
92. New ideas for meals and being able to talk to others
93. Varied discussion and group support
94. Able to focus on program, discussions
95. Discussion, questions answered
96. Keep on track and keep going
97. Meeting the group and talking about diabetes etc
98. Feeling connected to others doing the same thing
99. Swapped stories and information to help each other
100. Group discussions
101. Exchange of ideas
102. Learning about diabetes
103. Making new acquaintances, getting other opinions
104. Sharing
105. Others experiences
106. Greater understanding of what to eat
107. Discussion of different aspects of food and diabetes
108. Not only one to struggle with diet
109. Discussion – hints and ideas
110. Discussions and tips
111. Exchange of ideas, being able to discuss things
112. Sharing experiences, dietitian presentations
113. Sharing and accountability
114. Dietitian
115. Others sharing successes and difficulties, new ideas
116. Interchange of ideas
117. Improved knowledge of diabetes
118. Dietitian is great
119. Reminders to keep at it
120. Knowledge
121. Sharing knowledge
122. Knowing I’m not alone, exchange of ideas
123. Dietary information and support
124. Interchange of knowledge, peoples stories of how they were coping, what they were doing.
125. Sharing experiences
126. You are not alone
127. Support, regular weigh ins
128. Hearing about other peoples issues etc
129. Weigh in
130. Discipline, concentrate harder on the diet before weigh in
131. Connectedness, group dynamics, interesting food
132. Discussions
133. Improve diet, exercise, weight loss and gain
134. Talk about low fat and good healthy food
135. Interesting to talk and find out how the others were finding sessions
136. All here for the same reason
137. Listening to everybody else knowledge, learning different things
138. Comraderie
139. Support of the group
140. Listening and talking to others
141. Sharing information
142. Listening to everyone with their ideas
143. The support
144. Support when I felt things weren’t going well for me, morale boost
145. Hearing how each person was coping, dietitian was good
146. Getting weighed and getting results, catching up with the group
147. Ideas
148. Being able to talk to others honestly about the trials of not managing as well as one would have hoped
149. Being accountable
150. Other persons comments etc
151. Chance to discuss problems with others and dietitian
152. Companionship and encouragement to keep going
153. Advice on what not to eat
154. Sharing experiences informally, knowing other people had similar problems, ingredient exercise struck me as juvenile at the time but were very helpful

Other comments/suggestions

- Follow up session
- Electronic version of recording book
<table>
<thead>
<tr>
<th></th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>2 slices wholegrain toast with tomato</td>
<td>1 cup cooked porridge with 1 cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>½ cup muesli and ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3 slices wholegrain toast</td>
<td>½ cup cooked porridge, ½ cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>2 crackers with 45g cheese</td>
<td>Bobby banana</td>
<td>2 mandarins</td>
<td>1 slice fruit bread</td>
<td>Pear</td>
<td>1 small wholemeal scone</td>
<td>Bran and apple muffin</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Toasted sandwich with 1/3 cup baked beans</td>
<td>Orange Chicken (2 slices) and salad sandwich 2 kiwifruit</td>
<td>1 cup mixed bean salad with 1 slice toast</td>
<td>Ham (2 slices) and salad sandwich 2 plums</td>
<td>45g Edam cheese, onion, tomato toasted sandwich 20 grapes (1C)</td>
<td>Egg and salad sandwich Peach</td>
<td>2 slices toast with tuna (1/3 cup) Pear</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>Apple</td>
<td>1 pottle yoghurt</td>
<td>2 ryvita crackers with marmite/tomato</td>
<td>1 mini wholemeal pita pocket + tomato</td>
<td>1 slice fruit bread</td>
<td>Fruit smoothie – ½ cup berries + 250ml trim milk</td>
<td>1 pottle yoghurt</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>2 low fat sausages 1 cup potato 1.5 cups free vegetables</td>
<td>½ cup mince 2/3 cup cooked pasta 1.5 cups free vegetables</td>
<td>100g cooked chicken 1.5 cups salad 1 cup cooked basmati rice</td>
<td>1 cup casserole ½ cup potato 1.5 cups free vegetables</td>
<td>100g cooked beef 1 cup cooked basmati rice 1.5 cups stir fry vegetables</td>
<td>100g tinned tuna 2/3 cup cooked pasta 1.5 cups free vegetables</td>
<td>3 egg omelette 1 cup cooked basmati rice 1.5 cups stir fry vegetables</td>
</tr>
</tbody>
</table>
**Sapphire Sample Diet plan - 11C, 3P**

<table>
<thead>
<tr>
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<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 slices wholegrain toast with tomato</td>
<td>1 cup cooked porridge with 1 cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3/4 cup muesli and ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3 slices wholegrain toast</td>
<td>1 cup cooked porridge, ½ cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, with ½ cup tinned fruit, 1 cup green/light blue top milk</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>2 crackers with 45g cheese</td>
<td>Bobby banana</td>
<td>2 Fruit biscuits</td>
<td>1 slice fruit bread</td>
<td>Pear</td>
<td>1 small wholemeal scone</td>
<td>Bran and apple muffin</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Toasted sandwich with 1/3 cup baked beans</td>
<td>Chicken (2 slices) and salad sandwich 2 kiwifruit</td>
<td>1 cup mixed bean salad with 1 slice toast 2 mandarins</td>
<td>Ham (2 slices) and salad sandwich 2 plums</td>
<td>45g Edam cheese, onion, tomato toasted sandwich 20 grapes</td>
<td>Egg and salad sandwich Peach</td>
<td>2 slices toast with tuna (1/3 cup) Apple</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>Apple</td>
<td>1 pottle yoghurt</td>
<td>3 wholegrain crackers with marmite/tomato</td>
<td>1 mini wholemeal pita pocket + tomato</td>
<td>2 slices fruit bread</td>
<td>Fruit smoothie – ½ cup berries + 250ml trim milk</td>
<td>1 pottle yoghurt</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>2 low fat sausages 1 cup potato 1.5 cups free vegetables</td>
<td>½ cup mince 1 cup cooked pasta 1.5 cups free vegetables</td>
<td>100g cooked chicken 1.5 cups salad 1 cup cooked basmati rice</td>
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<td>100g cooked beef 1 cup cooked basmati rice 1.5 cups stir fry vegetables</td>
<td>100g tinned tuna 1 cup cooked pasta 1.5 cups free vegetables</td>
<td>3 egg omelette 11/2 cups cooked basmati rice 1.5 cups stir fry vegetables</td>
</tr>
<tr>
<td></td>
<td>Monday</td>
<td>Tuesday</td>
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</tr>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 slices wholegrain toast with tomato</td>
<td>1 cup cooked porridge with 1 cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3/4 cup muesli and ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3 slices wholegrain toast</td>
<td>1 cup cooked porridge, 1 cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>2 crackers with 45g cheese</td>
<td>Large banana</td>
<td>2 Fruit biscuits</td>
<td>1 slice fruit bread</td>
<td>Pear</td>
<td>1 small wholemeal scone</td>
<td>Bran and apple muffin</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Toasted sandwich with 1/3 cup baked beans Orange</td>
<td>Chicken (2 slices) and salad sandwich 2 kiwifruit</td>
<td>1 cup mixed bean salad with 2 slices wholegrain toast 2 mandarins</td>
<td>Ham (2 slices) and salad sandwich yoghurt pottle 2 plums</td>
<td>45g Edam cheese, onion, tomato toasted sandwich 20 grapes</td>
<td>Egg and salad sandwich Bobby banana</td>
<td>2 slices toast with tuna (1/3 cup) Peach</td>
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<td>2 slices fruit bread</td>
<td>Fruit smoothie – 1 cup berries + 250ml trim milk</td>
<td>1 pottle yoghurt with 10 dried apricots</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>2 low fat sausages 1.5 cups potato 1.5 cups free vegetables</td>
<td>½ cup mince 1 cup cooked pasta</td>
<td>100g cooked chicken 1.5 cups salad 1 cup cooked basmati rice</td>
<td>1 cup casserole ½ cup potato 1.5 cups free vegetables</td>
<td>100g cooked beef 1.5 cups cooked basmati rice 1.5 cups stir fry vegetables</td>
<td>100g tinned tuna 1 cup cooked pasta 1.5 cups free vegetables</td>
<td>3 egg omelette 1.5 cups cooked basmati rice 1.5 cups stir fry vegetables</td>
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<tr>
<td><strong>Breakfast</strong></td>
<td>3 slices wholegrain toast with tomato</td>
<td>1 cup cooked porridge with ½ cup tinned peaches, 1 cup green/light blue top milk</td>
<td>1 weetbix with 1 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3/4 cup muesli and ½ cup tinned fruit, 1 cup green/light blue top milk</td>
<td>3 slices wholegrain toast. 1/3 cup baked beans.</td>
<td>1 cup cooked porridge with ½ cup tinned peaches, 1 cup green/light blue top milk</td>
<td>2 weetbix with 2 tbspn all bran, ½ cup tinned fruit, 1 cup green/light blue top milk</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>2 crackers with 45g cheese</td>
<td>Large banana</td>
<td>2 Fruit biscuits</td>
<td>2 slices fruit bread</td>
<td>Pear</td>
<td>1 small wholemeal scone</td>
<td>Small bran muffin</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>2 slices wholegrain toast with 2/3 cup baked beans Orange</td>
<td>Chicken (2 slices) and salad sandwich 2 kiwifruit</td>
<td>1 cup mixed bean salad with 2 slices wholegrain toast 2 mandarins</td>
<td>Ham (2 slices) and salad sandwich 1 pottle yoghurt 2 plums</td>
<td>45g Edam cheese, onion, tomato toasted sandwich 20 grapes</td>
<td>1 Egg and salad sandwich Peach</td>
<td>2 slices toast with tuna (1/3 cup) Pear</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>Apple</td>
<td>1 pottle yoghurt</td>
<td>3 wholegrain crackers with marmite/tomato</td>
<td>1 mini wholemeal pita pocket + tomato</td>
<td>2 slices fruit bread</td>
<td>Fruit smoothie – 1 cup berries + 250ml trim milk</td>
<td>1 pottle yoghurt + 10 dried apricots</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>2 low fat sausages 1.5 cups potato 1.5 cups free vegetables</td>
<td>½ cup mince 1 cup cooked pasta 1.5 cups free vegetables</td>
<td>100g cooked chicken 1.5 cups salad 1.5 cups cooked basmati rice</td>
<td>1 cup casserole ½ cup potato 1.5 cups free vegetables</td>
<td>100g cooked beef 1.5 cups basmati rice 1.5 cups stir fry vegetables</td>
<td>100g tinned tuna 1 cup cooked pasta 1.5 cups free vegetables</td>
<td>3 egg omelette 1.5 cups cooked basmati rice 1.5 cups stir fry vegetables</td>
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<tr>
<td><strong>Breakfast</strong></td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>2 apricots</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 1 slice toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana</td>
<td>2 ham and salad sandwiches (1 slice ham each sandwich)</td>
<td>2 buns with 1 egg on each and salad filling</td>
<td>¾ cup creamed corn, 2 slices toast,</td>
<td>2 pita breads with 1/3 cup tinned salmon in each</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt</td>
<td>1 crumpet</td>
<td>1 slice fruit bread</td>
<td>1 small bran muffin</td>
<td>2 ryvita crackers with tomato</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>pear</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta, 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1.5 cups kumara, 2 slices roast beef</td>
<td>1.5 cups free vegetables, 1 cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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### Sapphire Sample Diet plan – 15C, 4P

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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit</td>
<td>1.5 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>2 apricots</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana 2 slices bread with ½ cup tuna</td>
<td>2 ham and salad sandwiches (1 slice ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling</td>
<td>¾ cup creamed corn, 2 slices toast,</td>
<td>2 pita breads with 1/3 cup tinned salmon in each 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt</td>
<td>1 crumpet</td>
<td>2 slices fruit bread</td>
<td>1 small bran muffin</td>
<td>2 ryvita crackers with tomato</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>Pear</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1.5 cups kumara, 2 slices roast beef</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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### Sapphire Diet Plan – 16C, 4P

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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana,</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, 1 cup tinned fruit, ½ banana</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>1 slice fruit bread</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana</td>
<td>2 ham and salad sandwiches (1 slice ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling, 2 apricots</td>
<td>¼ cup creamed corn, 2 slices toast, 2 apricots</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt</td>
<td>1 crumpet</td>
<td>2 slices fruit bread</td>
<td>1 small bran muffin</td>
<td>2 ryvita crackers with tomato</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>Pear</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta, 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1.5 cups kumara, 2 slices roast beef</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt, 1 slice toast</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon 150ml calcitrim milk, ½ banana, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
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</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>2 slices fruit bread</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana 2 slices bread with ½ cup tuna</td>
<td>2 ham and salad sandwiches (1 slice ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling, 2 apricots</td>
<td>¾ cup creamed corn, 3 slices toast, 2 apricots</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt</td>
<td>2 crumpets</td>
<td>2 slices fruit bread</td>
<td>1 small bran muffin</td>
<td>2 ryvita crackers with tomato</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>Pear</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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### Sapphire Diet Plan – 18C, 5P

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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk ½ banana 1 slice toast</td>
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<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>2 slices fruit bread</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana 2 slices bread with ½ cup tuna</td>
<td>2 ham and salad sandwiches (1 slice ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling, 2 apricots</td>
<td>½ cup creamed corn, 3 slices toast,</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt</td>
<td>2 crumpets</td>
<td>2 slices fruit bread</td>
<td>1 small bran muffin</td>
<td>2 ryvita crackers with tomato</td>
<td>250mls calcitrim milk</td>
<td>Pear</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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<tr>
<td><strong>Supper</strong></td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
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<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
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<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>2 mandarins</td>
<td>2 kiwifruit</td>
<td>2 slices fruit bread</td>
<td>2 plums</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana</td>
<td>2 ham and salad sandwiches (1 slice ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling, 2 apricots</td>
<td>¾ cup creamed corn, 3 slices toast, apple</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt, 10 dried apricot halves</td>
<td>2 crumpets, apple</td>
<td>2 slices fruit bread, 10 dried apricot halves</td>
<td>1 small bran muffin, apple</td>
<td>2 ryvita crackers with tomato, 10 dried apricot halves</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>2 slices fruit bread</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1 cup pasta, 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1.5 cups kumara, 2 slices roast beef</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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<tr>
<td><strong>Supper</strong></td>
<td>250mls calcitrim milk</td>
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### Sapphire Diet Plan – 20C, 5P

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<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana</td>
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<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear, 1 slice fruit bread</td>
<td>2 mandarins</td>
<td>2 kiwifruit, 1 slice fruit bread</td>
<td>2 slices fruit bread</td>
<td>2 plums, 1 slice fruit bread</td>
<td>orange</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 2 slices toast</td>
<td>2 bagels with smoked salmon and tomato</td>
<td>Banana</td>
<td>2 ham and salad sandwiches (1 slice ham each)</td>
<td>1 pottle yoghurt</td>
<td>¾ cup creamed corn, 3 slices toast, apple</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt, 10 dried apricot halves</td>
<td>2 crumpets, apple</td>
<td>2 slices fruit bread, 10 dried apricot halves</td>
<td>1 small bran muffin, apple</td>
<td>4 ryvita crackers with tomato, 10 dried apricot halves</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>2 slices fruit bread</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1+ ½ cup pasta, 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 2/3 cup diced pork</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
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<tr>
<td><strong>Supper</strong></td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
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<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ banana, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, 150ml yoghurt, 1 slice toast</td>
<td>3 slices wholegrain toast with 1 large banana sliced and cinnamon and ¼ cup cottage cheese</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 150ml yoghurt, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 banana, 1 slice toast</td>
<td>3 weetbix, ½ cup muesli, 250mls calcitrim milk, ½ cup tinned fruit, 1 banana, 1 slice toast</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear, 1 slice fruit bread</td>
<td>2 mandarins, 2 crackers with tomato</td>
<td>2 kiwifruit, 1 slice fruit bread</td>
<td>2 slices fruit bread</td>
<td>2 plums, 1 slice fruit bread</td>
<td>Orange, ¼ cup mixed nuts</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>1 cup baked beans with 3 slices toast + 45g edam cheese</td>
<td>2 bagels with smoked salmon and tomato, bobby banana</td>
<td>Banana 3 slices bread with ¼ cup tuna, 20g edam cheese and salad</td>
<td>2 ham and salad sandwiches (2 slices ham each) 1 pottle yoghurt</td>
<td>2 buns with 1 egg on each and salad filling, 2 apricots, 150ml yoghurt</td>
<td>¾ cup creamed corn, 3 slices toast, apple, ¼ cup cottage cheese</td>
<td>2 pita breads with 1/3 cup tinned salmon in each, 10 dried apricots</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 pottle yoghurt, 10 dried apricot halves</td>
<td>2 crumpets, apple</td>
<td>2 slices fruit bread, 10 dried apricot halves</td>
<td>1 small bran muffin, apple</td>
<td>4 ryvita crackers with tomato, 10 dried apricot halves</td>
<td>250mls calcitrim milk with 1 cup frozen berries in a smoothie</td>
<td>2 slices fruit bread</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>1+ ½ cup pasta, 1.5 cups free vegetables, 1 chicken breast</td>
<td>1.5 cups free vegetables, 1.5 cups basmati rice, 1 cup diced fish, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 1 fillet fish</td>
<td>1.5 cups free vegetables, 1 + ½ cup pasta, 2 chicken drumsticks</td>
<td>1.5 cups free vegetables, 1.5 cups rice, 2 low fat sausages</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
<td>1.5 cups free vegetables, 1.5 cups potato, 2 lamb chops</td>
</tr>
<tr>
<td><strong>Supper</strong></td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
<td>250mls calcitrim milk</td>
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# Topaz Sample Diet Plans

## Topaz Sample Diet Plan - 6P, 8C

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<tr>
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<th>Monday</th>
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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>1.5 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 eggs Scrambled, 2 slices toast</td>
<td>1.5 weetbix and ½ cup tinned fruit with 250ml calcitrim milk</td>
<td>1 slice toast with 1 cup baked beans</td>
<td>2 eggs Scrambled, 2 slices toast</td>
<td>1.5 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>1 slice toast with 1 cup baked beans</td>
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<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>2 plums</td>
<td>Peach</td>
<td>2 mandarins</td>
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<tr>
<td><strong>Lunch</strong></td>
<td>Slice self crusting quiche and salad 2 plums</td>
<td>⅓ cup Tuna and salad sandwich 1 cup berries</td>
<td>1 slice toast with ½ cup baked beans and ½ cup grated edam cheese</td>
<td>Chicken (¾ breast) salad with 1 apple</td>
<td>Ham (4 slices) and salad sandwich, apple</td>
<td>1 piece toast with 5 sardines, apple</td>
<td>2 egg Omelette with salad, 100g chicken and 1 slice toast</td>
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<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 slice fruit bread</td>
<td>45g edam cheese and 3 wholegrain crackers</td>
<td>1 pottle yoghurt</td>
<td>2 kiwifruit</td>
<td>3 crackers with 1/2 cup cottage cheese</td>
<td>⅓ cup cottage cheese on vege sticks</td>
<td>2 apricots</td>
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<tr>
<td><strong>Dinner</strong></td>
<td>Beef lasagne – ¼ cup mince 1.5 cups free veges 2/3 cup pasta</td>
<td>1 chicken breast ½ cup cooked rice 1.5 cups free veges</td>
<td>3 low fat sausages ½ cup cooked rice 1.5 cups free veges</td>
<td>150g roast beef 1 small potato 1.5 cups free veges</td>
<td>2 fillets fish ½ cup pasta 1.5 cups free veges</td>
<td>1 cup diced pork 1 cup kumara 1.5 cups free veges</td>
<td>4 slices roast lamb 1 medium potato 1.5 cups free veges</td>
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<td><strong>Breakfast</strong></td>
<td>1.5 weetbix and ½ cup</td>
<td>2 eggs Scrambled with 2</td>
<td>1.5 weetbix and ½ cup tinned fruit</td>
<td>1 slice toast with 1 cup</td>
<td>2 eggs Scrambled with 70g</td>
<td>1.5 weetbix and ½ cup special</td>
<td>1 slice toast with 1 cup</td>
</tr>
<tr>
<td></td>
<td>special K with 250ml</td>
<td>2 slices ham, 2 slices</td>
<td>with 250ml calcitrim milk</td>
<td>baked beans and 1 slice</td>
<td>smoked salmon, 2 slices</td>
<td>K with 250ml calcitrim milk</td>
<td>baked beans + 1 slice cheese</td>
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<td>calcitrim milk</td>
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<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>2 plums</td>
<td>Peach</td>
<td>2 mandarins</td>
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<tr>
<td><strong>Lunch</strong></td>
<td>Slice self crusting</td>
<td>¾ cup Tuna and salad</td>
<td>2 slices toast with ½ cup salmon and ½</td>
<td>Chicken (1 breast) salad</td>
<td>Ham (4 slices) and salad</td>
<td>2 pieces toast with 5 sardines,</td>
<td>2 egg Omelette with 100g</td>
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<tr>
<td></td>
<td>quiche and salad 2</td>
<td>sandwich</td>
<td>cup grated edam cheese</td>
<td>with 1 slice toast</td>
<td>sandwich, apple</td>
<td>apple</td>
<td>chicken, veges and 1 slice</td>
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<td></td>
<td>plums</td>
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<td>toast</td>
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<tr>
<td><strong>Afternoon Tea</strong></td>
<td>1 slice fruit bread</td>
<td>45g edam cheese and 3</td>
<td>1 pottle yoghurt</td>
<td>2 kiwifruit</td>
<td>3 crackers with 1/2 cup</td>
<td>½ cup cottage cheese on</td>
<td>2 tbspn Peanut butter on 3</td>
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<tr>
<td></td>
<td></td>
<td>wholegrain crackers</td>
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<td>cottage cheese</td>
<td>vege sticks</td>
<td>crackers, nectarine</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>Beef lasagne – 1 cup</td>
<td>1 chicken breast 1 cup</td>
<td>3 low fat sausages 1 cup cooked</td>
<td>150g roast beef 2 small potatoes</td>
<td>2 fillets fish ½ cup pasta</td>
<td>1 + ½ cup diced pork 1 cup</td>
<td>4 slices roast lamb 1 medium</td>
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<td></td>
<td>mince 1.5 cups free</td>
<td>cooked rice 1.5 cups free</td>
<td>cooked rice 1.5 cups free veges</td>
<td>1.5 cups free veges</td>
<td>1.5 cups free</td>
<td>kumara 1.5 cups free</td>
<td>potato 1.5 cups free veges</td>
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<td>veges 1 cup pasta</td>
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<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 eggs scrambled with 2 slices ham, 2 slices toast</td>
<td>3 weetbix and ½ cup tinned fruit with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans + 1 slice cheese</td>
<td>2 eggs scrambled with 70g smoked salmon, 2 slices toast</td>
<td>1.5 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans. 45g edam cheese</td>
</tr>
<tr>
<td>Morning Tea</td>
<td>Apple</td>
<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>2 plums</td>
<td>Peach, 250ml calcitrim milk</td>
<td>2 mandarins</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Slice self crusting quiche, 2 slices ham and salad 2 plums</td>
<td>1 cup tuna in green salad with 3 slices toast 1 cup berries</td>
<td>2 slices toast with ½ cup salmon and ½ cup grated edam cheese</td>
<td>Chicken (1 breast) salad with 1 slice toast</td>
<td>Ham (4 slices) and salad sandwich with 45g edam cheese, apple</td>
<td>2 pieces toast with 5 sardines, apple apple</td>
<td>2 egg Omelette with veges, 100g chicken and 1 slice toast</td>
</tr>
<tr>
<td>Afternoon Tea</td>
<td>1 slice fruit bread</td>
<td>45g edam cheese and 3 wholegrain crackers</td>
<td>1 pottle yoghurt</td>
<td>2 kiwifruit</td>
<td>3 crackers with 1/2 cup cottage cheese</td>
<td>½ cup cottage cheese on vege sticks</td>
<td>2 tablespoons Peanut butter on 3 crackers, nectarine</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>Beef lasagne – 1 cup mince 1.5 cups free veges 1 cup pasta</td>
<td>1 chicken breast 1 cup cooked rice 1.5 cups free veges</td>
<td>4 low fat sausages 1 cup cooked rice 1.5 cups free veges</td>
<td>200g roast beef 2 small potatoes 1.5 cups free veges</td>
<td>2 fillets fish 1 cup pasta 1.5 cups free veges</td>
<td>1 + ½ cup diced pork 1 cup kumara 1.5 cups free veges</td>
<td>4 slices roast lamb 1 medium potato 1.5 cups free veges</td>
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## Topaz Sample Diet Plan - 8P, 11C

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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 eggs Scrambled with 2 slices ham, 2 slices toast</td>
<td>3 weetbix and ½ cup tinned fruit with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans</td>
<td>2 eggs Scrambled with 70g smoked salmon, 2 slices toast</td>
<td>3 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans. 45g edam cheese</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>2 plums</td>
<td>Peach, 250ml calcitrim milk</td>
<td>2 mandarins</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Slice self crusting quiche, 2 slices ham and salad 2 plums</td>
<td>1 cup tuna + ¾ corn in green salad with 3 slices toast 1 cup berries</td>
<td>2 slices toast with ½ cup salmon and ½ cup grated edam cheese</td>
<td>Chicken (1 breast) salad with 2 slices toast</td>
<td>Ham (4 slices) and salad sandwich with 45g edam cheese, large banana</td>
<td>2 pieces toast with 5 sardines, apple</td>
<td>2 egg Omelette with 100g chicken, salad and 2 slices toast</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>2 slices fruit bread</td>
<td>45g edam cheese and 3 wholegrain crackers</td>
<td>1 pottle yoghurt</td>
<td>2 kiwifruit</td>
<td>3 crackers with 1/2 cup cottage cheese</td>
<td>½ cup cottage cheese on vege sticks</td>
<td>2 tablespoons Peanut butter on 3 crackers, nectarine</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>Beef lasagne – 1 cup mince 1.5 cups free veges 1 cup pasta</td>
<td>1 chicken breast 1 cup cooked rice 1.5 cups free veges</td>
<td>4 low fat sausages 1.5 cups cooked rice 1.5 cups free veges</td>
<td>200g roast beef 2 small potatoes 1.5 cups free veges</td>
<td>2 fillets fish 1 cup pasta 1.5 cups free veges</td>
<td>1 + ½ cup diced pork 1 cup kumara 1.5 cups free veges</td>
<td>4 slices roast lamb 1 medium potato 1.5 cups free veges</td>
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### Topaz Sample Diet Plan - 9P, 12C

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<tbody>
<tr>
<td><strong>Breakfast</strong></td>
<td>3 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 eggs Scrambled with 2 slices ham, 2 slices toast</td>
<td>3 weetbix and ½ cup tinned fruit with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans</td>
<td>2 eggs Scrambled with 70g smoked salmon, 2 slices toast</td>
<td>3 weetbix and ½ cup special K with 250ml calcitrim milk</td>
<td>2 slices toast with 1 cup baked beans. 45g edam cheese</td>
</tr>
<tr>
<td><strong>Morning Tea</strong></td>
<td>Apple</td>
<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>2 plums</td>
<td>Peach, 250ml calcitrim milk</td>
<td>2 mandarins</td>
</tr>
<tr>
<td><strong>Lunch</strong></td>
<td>Slice self crusting quiche, 2 slices ham and salad 2 plums</td>
<td>1 cup tuna + ¾ corn in green salad with 3 slices toast 1 cup berries</td>
<td>2 slices toast with ½ cup salmon and ½ cup grated edam cheese</td>
<td>Chicken (1 breast) salad with 2 slices toast</td>
<td>Ham (4 slices) and salad sandwich with 45g edam cheese, large banana</td>
<td>2 pieces toast with 5 sardines, apple</td>
<td>2 egg Omelette, 100g chicken with salad and 2 slices toast</td>
</tr>
<tr>
<td><strong>Afternoon Tea</strong></td>
<td>2 slices fruit bread</td>
<td>45g edam cheese and 3 wholegrain crackers</td>
<td>1 pottle yoghurt</td>
<td>2 kiwifruit</td>
<td>3 crackers with 1/2 cup cottage cheese</td>
<td>½ cup cottage cheese on vege sticks</td>
<td>2 tablespoons Peanut butter on 3 crackers, nectarine</td>
</tr>
<tr>
<td><strong>Dinner</strong></td>
<td>Beef lasagne – 1 cup mince 1.5 cups free veges 1 cup pasta</td>
<td>1 chicken breast 1 cup cooked rice 1.5 cups free veges</td>
<td>4 low fat sausages 1 cup cooked rice 1.5 cups free veges</td>
<td>200g roast beef 2 small potatoes 1.5 cups free veges</td>
<td>2 fillets fish 1 cup pasta 1.5 cups free veges</td>
<td>1 + ¼ cup diced pork 1 cup kumara 1.5 cups free veges</td>
<td>4 slices roast lamb 1 medium potato 1.5 cups free veges</td>
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<tr>
<td><strong>Supper</strong></td>
<td>1 cup calci trim milk</td>
<td>1 cup calci trim milk</td>
<td>1 cup calci trim milk</td>
<td>1 cup calci trim milk</td>
<td>1 cup calci trim milk</td>
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### Topaz Sample Diet Plan - 9P, 13C

|        | Monday                                                                 | Tuesday                                                                                      | Wednesday                                                                         | Thursday                                                                 | Friday                                                                 | Saturday                                                               | Sunday                                                                 |
|--------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------|
| **Breakfast** | 3 weetbix and ½ cup special K with 250ml calcitrim milk                | 2 eggs Scrambled with 2 slices ham, 2 slices toast                                           | 3 weetbix and ½ cup tinned fruit with 250ml calcitrim milk                        | 2 slices toast with 1 cup baked beans                                    | 3 weetbix and ½ cup special K with 250ml calcitrim milk                | 2 slices toast with 1 cup baked beans, 45g edam cheese                |
|        |                                                                        |                                                                                               |                                                                                  |                                                                         |                                                                        |                                                                        |
| **Morning Tea** | Apple                                                                  | Pear                                                                                         | Orange                                                                           | 1 pottle yoghurt                                                        | 2 plums                                                                | Peach, 250ml calcitrim milk                                            | 2 mandarins                                                          |
|        |                                                                        |                                                                                               |                                                                                  |                                                                         |                                                                        |                                                                        |
| **Lunch**     | Slice self crusting quiche, 2 slices ham and salad 2 plums             | 1 cup tuna + ¾ corn in green salad with 3 slices toast 1 cup berries                        | 2 slices toast with ½ cup salmon and ½ cup grated edam cheese                    | Chicken (1 breast) salad with 2 slices toast                            | Ham (4 slices) and salad sandwich with 45g edam cheese, large banana | 2 pieces toast with 5 sardines, apple                                 | 2 egg Omelette, 100g chicken with salad and 2 slices toast            |
|        |                                                                        |                                                                                               |                                                                                  |                                                                         |                                                                        |                                                                        |
| **Afternoon Tea** | 2 slices fruit bread                                                    | 45g edam cheese and 3 wholegrain crackers                                                  | 1 pottle yoghurt                                                                | 2 kiwifruit                                                            | 3 crackers with 1/2 cup cottage cheese                                 | ½ cup cottage cheese on vege sticks                                  | 2 tablespoons Peanut butter on 3 crackers, nectarine                   |
|        |                                                                        |                                                                                               |                                                                                  |                                                                         |                                                                        |                                                                        |
| **Dinner**   | Beef lasagne – 1 cup mince 1.5 cups free veges 1 cup pasta             | 1 chicken breast 1 cup cooked rice 1.5 cups free veges                                      | 4 low fat sausages 1 cup cooked rice 1.5 cups free veges                         | 200g roast beef 2 small potatoes 1.5 cups free veges                    | 2 fillets fish 1 cup pasta 1.5 cups free veges                         | 1 + ½ cup diced pork 1 cup kumara 1.5 cups free veges                | 4 slices roast lamb 1 medium potato 1.5 cups free veges               |
|        |                                                                        |                                                                                               |                                                                                  |                                                                         |                                                                        |                                                                        |
| **Supper**  | 1 cup calci trim milk + ½ banana                                      | 1 cup calci trim milk + ½ banana                                                            | 1 cup calci trim milk + ½ banana                                               | 1 cup calci trim milk + ½ banana                                        | 1 cup calci trim milk + ½ banana                                      | 1 cup calci trim milk + ½ banana                                      | 1 cup calci trim milk + ½ banana                                     |
| Time          | Monday                                                                 | Tuesday                                                                 | Wednesday                                                                 | Thursday                                                                 | Friday                                                                 | Saturday                                                                 | Sunday                                                                 |
|---------------|------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------|
| Breakfast     | 3 weetbix and ½ cup special K with 250ml calcitrim milk                | 2 eggs Scrambled with 2 slices ham, 2 slices toast                        | 3 weetbix and ½ cup tinned fruit with 250ml calcitrim milk                | 2 slices toast with 1 cup baked beans                                    | 2 eggs Scrambled with 70g smoked salmon, 2 slices toast               | 3 weetbix and 250ml calcitrim milk                                    | 2 slices toast with 1 cup baked beans. 45g edam cheese                 |
| Morning Tea   | Apple                                                                  | Pear                                                                    | Orange                                                                    | 1 pottle yoghurt                                                        | 2 plums, pottle yoghurt                                                | Peach, 250ml calcitrim milk                                          | 2 mandarins                                                            |
| Lunch         | Slice self crusting quiche, 2 slices ham and salad 2 plums             | 1 cup tuna + ¾ corn in green salad with 3 slices toast 1 cup berries    | 2 slices toast with ½ cup salmon and ½ cup grated edam cheese ½ cup mussels | Chicken (1 breast) salad with 2 slices toast and ½ cup cottage cheese   | Ham (4 slices) and salad sandwich with 45g edam cheese, large Banana, 4 oysters | 2 pieces toast with 5 sardines, apple, 1 cup plain custard             | 2 egg Omelette, 100g chicken with salad and 2 slices toast and 2 rashers bacon |
| Afternoon Tea | 2 slices fruit bread 45g edam cheese and 3 wholegrain crackers         | 1 pottle yoghurt                                                        | 2 kiwifruit                                                              | 2 crackers with 1/2 cup cottage cheese                                   | ½ cup cottage cheese on vege sticks                                   | 2 tablespoons Peanut butter on 3 crackers, nectarine                    |                                                                       |
| Dinner        | Beef lasagne – 1 + ¼ cup mince 1.5 cups free veges 1 cup pasta         | 3 chicken drumsticks 1 cup cooked rice 1.5 cups free veges              | 4 low fat sausages 1 cup cooked rice 1.5 cups free veges                  | 200g roast beef 2 small potatoes 1.5 cups free veges                     | 2 fillets fish 1 cup pasta 1.5 cups free veges                         | 1 + ½ cup diced pork 1 cup kumara 1.5 cups free veges                 | 4 slices roast lamb 1 medium potato 1.5 cups free veges                |
| Supper        | 1 cup calci trim milk + ½ banana                                       | 1 cup calci trim milk + ½ banana                                        | 1 cup calci trim milk + ½ banana                                         | 1 cup calci trim milk + ½ banana                                        | 1 cup calci trim milk + ½ banana                                      | 1 cup calci trim milk + ½ banana                                      | 1 cup calci trim milk + ½ banana                                      |
## Topaz Sample Diet Plan - 10P, 14C

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<td>Morning Tea</td>
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<td>Pear</td>
<td>Orange</td>
<td>1 pottle yoghurt</td>
<td>1 plum, pottle yoghurt</td>
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<td>2 mandarins</td>
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</table>
Sapphire DEWL

Eat most each day

- 3+ Free vegetables
- 2+ Fruit
- Low fat protein _____ portions
- Low fat dairy
- Plant fat (3 teaspoons per day)

Eat some each day

- Low GI carbohydrate _____ portions

Water
Eat most each day

3+ Free vegetables

Low GI carbohydrate _____ portions

Plant fat (3 teaspoons per day)

Water

2+ Fruit

Low fat protein _____ portions

Low fat dairy

Eat some each day

3+ Free vegetables

Low GI carbohydrate _____ portions

Plant fat (3 teaspoons per day)

Water

2+ Fruit

Low fat protein _____ portions

Low fat dairy
DEWL Study

3-Day Diet Record

Participant ID Number: 

Time Point: Baseline / 6 mth / 12 mth / 24 mth (circle)

Dates completed: (DD/MM/YYYY)

Data Entry:

Satiety: 

Diet Record: 

Checked:
SAMPLE RECORD SHEET

Please record all food and drink consumed during the whole day, including snacks and water. Remember to report all additions to each food or drink such as milk, sugar, salt, sauce or spreads. Remember also to mark the hunger scale immediately before eating a main meal and the fullness scale 20 minutes after eating a main meal.

<table>
<thead>
<tr>
<th>Time</th>
<th>Food or Drink</th>
<th>Brand and Details</th>
<th>Preparation/Cooking</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 am</td>
<td>Cereal</td>
<td>Kelloggs Just Right</td>
<td></td>
<td>1 cup</td>
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<tr>
<td></td>
<td>Milk</td>
<td>Meadowfresh, Trim</td>
<td></td>
<td>1/2 cup</td>
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<tr>
<td></td>
<td>Coffee</td>
<td>Greggs instant</td>
<td></td>
<td>1 tsp</td>
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<tr>
<td></td>
<td>Milk</td>
<td>Meadowfresh, Trim</td>
<td></td>
<td>1 Tbsp</td>
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</tbody>
</table>

Please circle your response to this question immediately before eating:

How do you feel?
- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full

Please circle your response to this question within 20 min after eating:

How do you feel?
- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full
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<tbody>
<tr>
<td>12 pm</td>
<td>Pasta with coriander</td>
<td>Recipe</td>
<td></td>
<td>1/4 recipe</td>
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<tr>
<td></td>
<td>pesto</td>
<td></td>
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<tr>
<td></td>
<td>Bread roll</td>
<td>New World, white</td>
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<td>50g</td>
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<td></td>
<td>Margarine</td>
<td>Flora lite</td>
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<td>1 tsp</td>
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<tr>
<td></td>
<td>Water</td>
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<td>250ml</td>
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</table>

Please circle your response to this question immediately before eating:

How do you feel?

- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full

Please circle your response to this question within 20 min after eating:

How do you feel?

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- extremely full
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Please circle your response to this question immediately before eating: How do you feel? 

- extremely hungry 
- hungry 
- semi-hungry 
- no particular feeling 
- semi-satisfied 
- satisfied 
- extremely full
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How do you feel?

- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full

Please circle your response to this question within 20 min after eating:

How do you feel?

- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full
<table>
<thead>
<tr>
<th>Day 2</th>
<th>Time</th>
<th>Food or Drink</th>
<th>Brand and Details</th>
<th>Preparation/Cooking</th>
<th>Quantity</th>
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</thead>
</table>

Please circle your response to this question within 20 min after eating:

How do you feel?

- extremely hungry
- hungry
- semi-hungry
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- satisfied
- extremely full

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Please circle your response to this question immediately before eating: 

How do you feel? 

 extremely hungry  hungry  semi-hungry  no particular feeling  semi-satisfied  satisfied  extremely full 

Please circle your response to this question within 20 min after eating: 

 extremely hungry  hungry  semi-hungry  no particular feeling  semi-satisfied  satisfied  extremely full 

Day 2 continued ______________________     Date _________________
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Please circle your response to this question immediately before eating: How do you feel?  
extremely hungry  hungry  semi-hungry  no particular feeling  semi-satisfied  satisfied  extremely full
Please circle your response to this question within 20 min after eating

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<td>hungry</td>
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<td>semi-hungry</td>
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<td>no particular feeling</td>
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<td>satisfied</td>
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<tr>
<td>extremely full</td>
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</table>

Day 3 ______________________       Date _________________
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- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full

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How do you feel? 
- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full

Please circle your response immediately before eating.

Please circle your response to this question within 20 min after eating.
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Please circle your response to this question immediately before eating:

How do you feel?
- extremely hungry
- hungry
- semi-hungry
- no particular feeling
- semi-satisfied
- satisfied
- extremely full
Please circle your response to this question within 20 min after eating.

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<tr>
<th>How do you feel?</th>
<th>extremely hungry</th>
<th>hungry</th>
<th>semi-hungry</th>
<th>no particular feeling</th>
<th>semi-satisfied</th>
<th>satisfied</th>
<th>extremely full</th>
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These questions are about your activities **during the last three months**.

1. During the last 3 months, did you engage in any **vigorous** leisure time activity long enough to make you **breathe hard** and **sweat**, at least once per fortnight? (eg: tennis singles, dancing, jogging, squash, soccer, swimming, aqua-aerobics, exercycle, gym workout etc.)

   YES [ ]     NO [ ]

   If YES, please record these below:

<table>
<thead>
<tr>
<th>Sport or recreation</th>
<th>times per fortnight</th>
<th>minutes per time</th>
<th>office use</th>
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2. During the last 3 months did you engage in any other regular leisure time activity? (**Moderate activity**, eg: **walking for exercise or pleasure**, bush walking, tabletennis, golf, bowling, tennis doubles, rebounder, biking etc) (excluding gardening)

   YES [ ]     NO [ ]

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<tr>
<th>Sport or recreation</th>
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3. How many hours do you usually rest and sleep each night?__________ hours

4. What is your current occupation?_________________________________

   (If household activities only, retired, or beneficiary, go straight to question 9)

5. How many hours do you work in an average week?__________ hours.

   (If more than one occupation, state how many hours at each job)

6. During the last 3 months, did you engage in any **vigorous** activity at work long enough to make you **breathe hard** and **sweat** on a regular basis? (eg. heavy carpentry, fencing or construction work, physical labour, chopping wood, etc)

   YES [ ]     NO [ ]

   If YES, please record these below:

<table>
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<tr>
<th>Work Activity</th>
<th>times per fortnight</th>
<th>minutes per time</th>
<th>office use</th>
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</table>
7. During the last 3 months did you engage in any moderate activity at work? (eg. delivering mail, milking cows, house painting, lifting, carrying light objects, brisk or farm walking etc.)

YES [ ] NO [ ]

<table>
<thead>
<tr>
<th>Work Activity</th>
<th>times per fortnight</th>
<th>minutes per time</th>
<th>office use</th>
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8. How many minutes per day would you spend walking to and from work? ____________ (eg. from home, car, bus). And how many days per week? ____________

9. Have you done any (other) brisk walking on a regular basis, (that is at least once per 2 weeks) in the last 3 months? e.g. to or around shops, library, or church?

YES [ ] NO [ ]

If YES, minutes per day : ____________ Number of days walked per week : ____________

10. How many hours did you spend on the following activities in an average week?

<table>
<thead>
<tr>
<th></th>
<th>HOURS</th>
<th>MINUTES</th>
<th>office use</th>
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</thead>
<tbody>
<tr>
<td>Hanging out clothes, light housework</td>
<td></td>
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<tr>
<td>Mopping, vacuuming, cleaning windows or car, moving furniture, clearing out garage, or heavier housework</td>
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<tr>
<td><strong>Gardening</strong>, weeding, pruning, lawn-mowing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home maintenance, light carpentry, painting</td>
<td></td>
<td></td>
<td>code hrs min</td>
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<tr>
<td>Other (specify)</td>
<td></td>
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</tbody>
</table>

11. Compared with 12 months ago, are you now :

less active [ ] more active [ ] the same [ ]

12. If more or less active, is there any reason? ____________________________________________
APPENDIX P – INVESTIGATORS BROCHURE

The Diabetes Excess Weight Loss (DEWL) Trial: High Protein vs Low Fat Diets

LEAD RESEARCHER: DR JEREMY KREBS, WELLINGTON SCHOOL OF MEDICINE & HEALTH SCIENCES
Funded by the New Zealand Health Research Council

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Study Personnel

HRC DEWL Study Investigators
Dr Jeremy Krebs
Dr Raina Elley
Dr Helen Lunt
Dr Paul Drury
Professor Jim Mann
Dr Damon Bell
Dr Elizabeth Robinson
Ms Amber Parry Strong

Wellington Diabetes Research Site
Dr Jeremy Krebs Principal Investigator
Dr Damon Bell Wellington Investigator
Ms Amber Parry Strong Ph D student. Dietary Intervention Manager
Cecilia Ross Project Manager
Cecilia Ross Research Nurse
Tessa Clarke Research Nurse
Ingrid McEnaney Research Nurse
Cheryl Maister Research Assistant
Gemma Bishop Dietitian

Auckland Diabetes Research Site
Dr Paul Drury Auckland Investigator
Dr Raina Elley Auckland Investigator
Cathrine Patten Research Nurse
Fiona McKechnie Dietitian

Christchurch Diabetes Research Site
Dr Helen Lunt Auckland Investigator
Flo Logan Research Nurse
…………………… Research Assistant
Kristen Corselius White Dietitian

University of Auckland
Dr Raina Elley
Dr Elizabeth Robinson Statistician

University of Otago
Professor Jim Mann Study Investigator
Rachael Taylor Ph D Supervisor
Background

Type 2 diabetes is reaching epidemic proportions in New Zealand, representing 80-90% of cases of diabetes. The Ministry of Health estimates that 200,000 people in New Zealand have diabetes and half are undiagnosed. These estimates represent 5% of the total population and exceed previous prevalence estimates from earlier New Zealand surveys. Accordingly, reducing the incidence and impact of diabetes has been identified as a priority health area in the New Zealand Health Strategy.

Obesity is the primary modifiable risk factor for glucose intolerance and type 2 diabetes and has also reached epidemic proportions worldwide including New Zealand. There are particular concerns in Maori and Pacific peoples. There has been a greater than 50% increase in the adult population with a body mass index (BMI) of greater than 30 kg/m², from 11% in 1988 to 21% in 2002. In 2002/03, 27 percent of Maori men and 27 percent of Maori women were obese and 36 percent of Pacific men and 47 percent of Pacific women were obese. The cost of obesity has been estimated to be $303 million in New Zealand (2-3% of annual health budget), based on World Health Organization (WHO) estimations.

Both obesity and type 2 diabetes have wide-ranging co-morbidities including hypertension, dyslipidaemia, obstructive sleep apnoea, increased rates of malignancies, osteoarthritis and others. There is a high rate of morbidity and cost associated with the complications of diabetes with nearly 7,000 diabetes-related admissions during 2002, and an average length of stay of 14 days. Of greatest concern is the increased rate of premature mortality largely secondary to cardiovascular disease. The effect of increased body mass index (BMI) was estimated to be responsible for 11.5 percent of all deaths in 1997. The New Zealand Health Strategy 2000 has three objectives that directly relate to obesity. These objectives are to improve nutrition, to increase physical activity, and to reduce obesity.

To address these stated aims of the Ministry of Health, strategies are required to reduce obesity and the adverse health consequences of obesity in both non-diabetic and diabetic individuals. As an integral component of this, there is an urgent need to establish optimal dietary strategies to facilitate weight loss and reduce the impact of diabetes that can be implemented successfully in a New Zealand context across a range of ethnic groups.

Current dietary recommendations for the reduction of obesity and the management of diabetes, endorsed by a variety of expert bodies, focus on an energy-reduced, low-fat diet with less than 10% of total energy derived from saturated fat. The implementation of this has largely been by substituting fat with predominantly carbohydrate. Recently there has been an emphasis on wholegrains and foods with a low glycaemic index, and high fibre, rather than more refined carbohydrate. Such an approach is associated with a reduction in total energy intake and modest weight losses, with associated improvements in insulin sensitivity. However, individuals find these goals hard to achieve and even harder to maintain with weight regain common following initial losses. Furthermore, despite widespread dissemination of public health messages to adopt a low-fat diet over the last 20 years, rates of obesity and diabetes continue to climb. Therefore, ‘alternative’ dietary approaches are popular. These ‘alternative’ diets are perceived to be easier to follow, encompass desirable food items, or are reported to achieve greater weight loss.

Such popular alternative diets include “Low Carb” diets such as the “Dr Atkins diet revolution” and “The Zone” diet. Despite considerable discussion in the lay press, there is remarkably little scientific evidence testing the efficacy or safety of these diets, particularly in patients with type 2 diabetes. Furthermore, while greater short-term weight loss has been demonstrated with low carbohydrate diets compared with conventional diets, longer-term sustainability and weight loss maintenance remains...
unclear. Some studies have shown that by 12-months, dietary compliance is reduced and weight loss is often similar in both types of diet. A recent New Zealand study showed benefit of the “Zone” diet (high protein/carbohydrate restricted) over the “Atkins” diet (high fat/ extreme carbohydrate-restricted diet) and a low-fat diet at 6 months in obese insulin resistant non-diabetic women. Encouragingly, at 12 months, the high-protein group in this study maintained their weight loss, in contrast to the high fat group.

Proponents of extreme carbohydrate-restricted diets suggest particular benefits in generating a ketotic metabolic state, whereas we and others have demonstrated that weight losses can be entirely explained on the basis of reduced total energy intake. The novelty of a different approach may aid in compliance in the short-term. However, in the long-term, subjects report the extreme nature of these diets limits adherence.

Weight loss requires a reduction in total energy intake relative to expenditure. The current evidence does not support one dietary approach over another for successful long-term weight loss. The best predictor of weight loss is, not surprisingly, adherence to the diet. From this it may be concluded that if weight loss per se is the goal, the type of diet adopted may be irrelevant, and that efforts should be directed to facilitating compliance. In support of this notion is the finding, by the investigators, that in obese insulin-resistant women, the addition of supplemental long chain n-3 PUFA had little impact over and above weight loss on a wide range of metabolic outcomes. Furthermore, that in obese women, maintenance of a minimum of 5% weight loss may be required to maintain the improvement in metabolic parameters and risk factors for cardiovascular disease. However, with regard to health outcomes in obesity and diabetes, this assumes that weight loss is the critical factor overwhelming and ignoring the impact of specific dietary factors for which there is abundant evidence of beneficial and detrimental effects. There are a number of specific concerns regarding carbohydrate-restricted and high protein diets that need to be considered, and may be of particular importance in individuals with type 2 diabetes, which would suggest the promotion of one dietary strategy over others.

**Potential detrimental effects of low carbohydrate diets:**

There are concerns that extreme carbohydrate restriction leads to abnormal metabolic functioning. It is postulated that elevated ketones will result in abnormal liver metabolism, abnormal glucose and insulin homeostasis, and dyslipidaemia. Furthermore, elevated ketones may result in salt and water depletion that in turn may cause postural hypotension. Reductions in dietary fibre may cause bowel dysfunction and increase risk of bowel malignancy. Possible excess saturated fat intake will promote dyslipidaemia and impair insulin sensitivity, while increased dietary protein may impair renal function. However, there is limited evidence to support these concerns, and the chosen carbohydrate level is far less restricted than those of more extreme diets.

**Potential benefits of low carbohydrate diets in type 2 diabetes:**

Circulating postprandial glucose concentration is largely determined by the digestion and absorption of glucose containing foods, with dietary fats and proteins having little effect. This is influenced by rates of hepatic glycogenolysis and glycogen storage. Therefore, reduction in dietary carbohydrate results in lower fasting and post-prandial glucose excursions. These effects were demonstrated in our pilot study of 14 subjects with diabetes, and were associated with improvements in glycaemic control measured by HbA1c.
Protein intake, weight management and glycaemic control:
In many existing diets, the proportion of protein remains relatively stable at 15-21% of total energy. (The proportion of protein intake in subjects in the U.K. Prospective Diabetes Study was 21%.) There is usually a reciprocal relationship between fat and carbohydrate dominating most changes in dietary intake. Thus, while much is known about the effects of changes in fat and carbohydrate intake, there is relatively little data on the effects of changes in protein intake on weight loss, insulin sensitivity, or glycaemic control, particularly in patients with diabetes.

There is evidence from highly controlled meal-test and short-term intervention studies that protein intake promotes greater satiety than does carbohydrate or fat. Furthermore, in a calorie-restricted diet, protein preserves lean body mass and maintains resting energy expenditure more than does carbohydrate or fat. Together, these findings suggest that, in free-living subjects, a diet with an increased proportion of protein may facilitate greater and more sustained weight loss while maintaining lean body mass, than diets high in carbohydrate or fat. This is supported by short-term studies in obese non-diabetic subjects.

Substitution of fat with carbohydrate may have an adverse effect on glucose and insulin homeostasis, because of the acute effects of carbohydrate intake on insulin release. Therefore, it is proposed that substitution of fat with protein may have a more favourable effect on insulin release and glucose metabolism. This has been demonstrated in obese subjects with test meals, and short-term interventions. However, data in those with diabetes is limited. In a short-term study in 54 obese subjects with type 2 diabetes, comparing a high protein with a low protein energy reduced diet over 12 weeks, Parker et al demonstrated greater loss of fat mass but not weight in women, although no differences in changes in body composition in men. There was also a greater reduction in LDL cholesterol in the high protein group, but no difference in improvements in fasting insulin, glucose, or HbA1c between groups. In contrast, in a crossover design trial, higher protein intakes have been associated with significant reductions in glucose, insulin, and HbA1c in weight stable patients with type 2 diabetes.

Impact of high protein intake on renal function, microalbuminuria and nephropathy:
The Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes has advised, for patients with type 1 diabetes and evidence of established nephropathy, that protein intakes should be at the lower end of the acceptable range (0.8g/kg normal body weight/day). This position is supported by evidence of reduced progression to end-stage renal failure or death in this population when protein intake is limited. However, in patients with no evidence of nephropathy or microalbuminuria, the ideal protein intake is less clear. It has been demonstrated that high protein intake increases kidney size and glomerular filtration rate (GFR), which are adaptive and produce no adverse effect on kidney function.

Evidence from the UK Prospective Diabetes Study (UKPDS) in type 2 diabetes and the Diabetes Control and Complications Trial (DCCT) in type 1 diabetes, supports the importance of achieving tight glycaemic and blood pressure control in reducing the incidence of nephropathy. Higher dietary protein intake has been related to improvements in glycaemic control in weight stable patients with type 2 diabetes over 5 weeks in a crossover trial. Similar benefits of increased protein intake have been observed in blood pressure. Thus, these improvements may translate into benefits in reduced microalbuminuria. Therefore, the impact of increased dietary protein on microalbuminuria and renal
function is an important issue in determining the optimal dietary advice for obese individuals with diabetes.

Taking a combination of the currently available evidence of the effect of macronutrient composition on weight and body composition, and on metabolic and cardiovascular factors in obese diabetic and non-diabetic patients, we propose that a diet with increased protein and reduced carbohydrate and moderate fat may be more efficacious in promoting weight loss and improved health outcomes compared with the common implementation of current guidelines for low fat diets. Such a strategy would also include a focus on low glycaemic index carbohydrate, wholegrain foods and fibre. Fat content would include mostly mono-unsaturated fatty acids (MUFA) and poly-unsaturated fatty acids (PUFA). Saturated fats would be restricted. It is proposed that this diet may increase satiety and compliance, while having beneficial effects on insulin/carbohydrate metabolism, glycaemic control, and cardiovascular disease risk.

A long-term randomised controlled trial is needed to further test this hypothesis. This study seeks to combine the above evidence from high-protein diets and carbohydrate-restricted diets in an alternative dietary strategy. It will test the effect of this strategy on weight, diabetes control, cardiovascular disease (CVD) risk and potential adverse effects in those with established type 2 diabetes, compared with current ‘low fat’ recommendations.
Study Design

A community-based randomised controlled trial, conducted over several sites.

Aim:

- To assess whether a high-protein:low-carbohydrate diet is more effective than a low-fat:high-carbohydrate diet in reducing weight and maintaining weight loss in subjects with type 2 diabetes over 2 years.
- To assess whether a high-protein:low-carbohydrate diet is more effective than a low-fat:high-carbohydrate diet in improving glycaemic control, insulin sensitivity, lipid profile and blood pressure without adverse effects in subjects with type 2 diabetes over 2 years.

Study Population and Intervention:

450 overweight and obese (BMI ≥27kg/m²) individuals with type 2 diabetes will be recruited in several centres throughout New Zealand (Wellington, Auckland, Christchurch) and randomised to one of two dietary protocols.

**Group 1 (Control) Conventional - “Low-fat”**: Subjects in this group will be prescribed an energy-restricted diet based on current recommended macronutrient composition. This will include 55-60% carbohydrate, with predominantly low glycaemic index, whole-grain foods with high fibre intake (30g/day), and minimal refined carbohydrates. The balance of the diet will be composed of 25-30% fat, with no more than 10% being saturated fat, and approximately 15% protein, aiming for a reduction in total energy intake of 500kcal/day.

**Group 2 (Intervention) “High-Protein:Reduced-Carbohydrate”**: Reduced carbohydrate (40% total energy) with a focus on whole grains, low glycaemic index foods, and high fibre (30g/day). The diet will also include increased protein (30% total energy) and moderate fat (30% total energy) with a focus on MUFA and PUFA and no more than 10% being saturated fat, aiming for a reduction in total energy intake of 500kcal/day.

All subjects will take part in a 12-month group-based programme which consists of, fortnightly meetings with a dietitian for the first six months to facilitate weight loss and adherence to the specific dietary protocol. This will be followed by a less intensive 6-month period with monthly sessions. Subjects will then be asked to maintain their weight loss by adhering to the dietary protocol, but will have no further dietitian input for a further 12 months, apart from monthly weighs.

Outcome Measures:

Outcomes will be assessed at baseline, 6, 12 and 24 months.

Primary outcomes include:

- **Obesity**: Assessed by weight and waist circumference
- **Glycaemic Control**: HbA1c and fasting plasma glucose
- **Blood Pressure**: Systolic and diastolic measured in triplicate.
- **Lipid profile**: Including triglycerides, LDL, HDL and total cholesterols

Secondary outcomes include:

- **Nutritional assessment**: Total energy intake and macronutrient composition, micronutrient intakes, dietary fibre, satiety questionnaire
- **Body Fatness**: Measured using Tanita foot-to-foot bioimpedence scales.
- **Insulin Sensitivity**: 
Area under insulin curve during OGTT (in subset with diet controlled or oral agents)

Glucose profile. Area under the glucose curve of continuous subcutaneous glucose monitor (CGMS) (in subset of patients with separate funding being sought for this outcome)

- Renal function and proteinuria. A blood sample will be collected for serum creatinine and a 24 hour urine sample for albumin:creatinine ratio.
- Inflammatory markers. A fasting blood test will be taken for high sensitivity C-reactive protein (hsCRP) and sialic acid.
- Quality of life (using the SF36)
- Medications: Insulin and oral antidiabetics, antihypertensive medication, lipid lowering therapy
- Cost variables: Cost components of the two interventions will be recorded prospectively from a health-funder and patient perspective. This data will be used in subsequent cost effectiveness and cost utility analyses, should the trial prove positive.
- Compliance comparison measures of text messaging and email

Eligibility:

Inclusion Criteria:

1. Type 2 diabetes
2. Age between 30 and 75 years
3. BMI ≥27kg/m²

Exclusion Criteria:

1. HbA1c > 9.5%
2. Weight > 200 kg
3. Current or recent weight loss (>5% of current weight) in 3 months
4. Pregnancy or lactation
5. Diabetic nephropathy (urinary albumin/creatinine ration >70, sCr >160 μmol/L) or other chronic renal failure
6. Abnormal liver enzymes (AST, ALT or GGT >3 x upper limit of normal)
7. Active gallbladder disease (Cholecystitis in last 12 mths, ongoing bilary colic)
8. Myocardial infarction in the last 6 months
9. Heart failure (New York Heart Association class III or IV)
10. Known malignancy, other than squamous cell or basal cell carcinoma of the skin, that has not been in full remission for at least 5 years prior to screening
11. Ongoing oral steroid use

12. If on Duramine, sibutramine, orlistat

13. Other reasons why taking part would be medically inappropriate or practically difficult

Final decisions about eligibility are to be made at the discretion of the study investigator and the potential study participant.

**Recruitment:**

Recruitment will begin once ethical approval, the necessary contractual documentation has been completed and research nurse staff have been appointed.

**Objectives:**

DEWL aims to recruit 450 participants over three sites.
Wellington 250  
Auckland 100  
Christchurch 100

It is envisaged that recruitment may begin in Wellington in Jan 2006 with a pilot group to test run the protocols and dietary intervention groups. Full recruitment drive in Wellington, Auckland and Christchurch is likely to be commenced in Feb 2007, with a target of full recruitment by June 2007.

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<thead>
<tr>
<th>Objectives</th>
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<tbody>
<tr>
<td>1 <strong>To gain multi-region ethics committee approval</strong></td>
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<tr>
<td>2 <strong>To assemble and train research staff and dietitians in three centres</strong></td>
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<tr>
<td>3 <strong>To recruit and conduct baseline assessments and randomisation of 450 overweight people with type 2 diabetes from three centres</strong></td>
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<tr>
<td>4 <strong>To deliver interventions</strong></td>
<td></td>
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<td>5 <strong>To undertake 6 month research assessments</strong></td>
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<td>6 <strong>To undertake 12 month research assessments</strong></td>
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<tr>
<td>7 <strong>To undertake 24 month research assessments</strong></td>
<td></td>
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<tr>
<td>8 <strong>Data entry and analysis</strong></td>
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<td>9 <strong>Write-up and dissemination</strong></td>
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Expand table as necessary by pressing enter at the end of a row outside of the table.

**Timeline for Objectives:**

(Gantt charts should be used – see guidelines)
Whilst the aim is for the proportion of participants in each centre as above, if recruitment is more difficult or easier in some centres this may be revised.

**Recruitment Strategy:**

Managing participant recruitment is the most important task for the first 6 months of the study. It is highly desirable that recruitment is completed as quickly as possible. We believe that a number of factors will strongly influence recruitment at each centre, these are:

- Continuity of staff, especially nurses and dieticians
- Allocation of adequate time and resources
- Sufficient time spent on training and learning the study procedures
- Setting, monitoring and regular review of realistic recruitment targets for each centre

Retention of the study participants in the study is a high priority over the entire two years. In order for the study to be successful participants must be encouraged to continue attending the investigation days even if they have stopped the diet. The most important factor to positively influence retention is the relationship the participant has with the study staff particularly the dietitian and research nurse, therefore continuity of staff remains a very important factor.

Recruitment strategies will include targeting:

- Diabetes clinics
- Diabetes research databases
  - Existing databases of willing participants from previous studies
- Local advertisement
A national press release of the DEWL study will be made once systems are in place. This will be likely to create considerable interest and it will be important to have capacity to field calls and at a minimum record contact details.

**Monitoring Recruitment:**

During the recruitment phase, research nurses in each centre will be required to update the project manager on a weekly basis of recruitment progress by completing a Recruitment Activity Log (see appendix 9). The information recorded will be the number of Initial Contacts (where the pre baseline questionnaire is filled out), the number of potential participants who signed a consent form and the number of participants who were randomised. This log will be faxed weekly to the project manager on (04) 385 5819 who will be in frequent contact with the study centres to review progress.

**Recruitment Process: (see flow chart)**

- **Initial Contact with Potential Participants**
  - The research nurse(s) at each site will be responsible for fielding enquiries from potential participants (PP), this will involve discussing the study with them and completing the Pre Baseline Questionnaire as fully as possible. If the PP wishes to continue with the study at the end of this phone call/meeting the nurse will make an appointment with them to attend a group consent meeting. If the PP does not wish to continue with the study, or is ineligible, the nurse must collect all the information marked with an * for study audit purposes.
  - Each person that is spoken to must be issued with a unique identification code which is 8 characters as follows: (eg. DJK1.0001)
    - D (for DEWL trial)
    - Participant first and last initials (eg. JK for Jeremy Krebs)
    - Site identification (1 Auckland, 2 Wellington, 3 Christchurch)
    - Four digit number in order of enrolment from 0001 – 9999
  - A record of codes matched to (potential) participants (Master Participant Log – see appendix 10) must be completed and will be held in each research site for the participants in that centre. It will be stored securely and available only to DEWL investigators and research nurses.
  - This code number will be used to identify all stored information and samples.

- **Follow-up from Initial Contact with Potential Participants**
  - If they do wish to continue the nurse will follow-up their eligibility blood/urine results (Serum Creatinine, LFT’s, HbA1c and Albumin/Creatinine Ratio) obtaining copies from the laboratory if they have results from within the last 3 months or sending a lab form to the PP to have which ever tests they do not have recent results for.
  - The nurse will also need to gather evidence of diabetes for those people who:
    1. are not using any diabetes treatment apart from diet
    2. use metformin alone and have an HbA1c of < 6.5%
    3. there is uncertainty about whether they have Type 1 diabetes
  - Participants need to meet the WHO criteria for diabetes:
1. Classical symptoms of diabetes and unequivocal hyperglycaemia; or
2. a fasting plasma glucose greater than 7.0 mmol/l on more than one occasion; or
3. a two hour, plus one other venous plasma glucose level in excess of 11.1 mmol/l in a formal 75g oral glucose tolerance test.

Evidence may take the form of copies of diagnostic laboratory tests or if these are not available the PP primary caregiver may complete a *GP Diabetes Source Document Form* (see appendix 11).

When this information has been gathered and eligibility (up to this point) has been confirmed, the nurse will:

- send the information sheet and consent form to the PP (either by post, fax or e-mail)
- send a letter to the PP to confirm the group consent meeting appointment and give directions to the meeting.
- inform the PP’s primary caregiver of their intention to participate in the trial and check that there is no reason that it would be inappropriate for them to take part.

If, after the blood results have been viewed, the PP is now ineligible the nurse will explain this to the PP, cancel the group consent meeting appointment and inform the PP primary care giver.

**Consent Meeting**

At the consent meeting the study investigator for each site will present a summary of the study to the PP’s and answer any questions they may have. The investigator will then meet with each PP individually to complete a consent form, in duplicate, and give the PP one signed and dated copy to keep and ensure that they have a copy of the information sheet.

The nurse will then meet with each of the PP to:

- measure their weight & height and ensure they meet the BMI criteria
- give a laboratory form for their 2nd sCr or any other outstanding investigations needed to confirm eligibility (if required)
- give a 24 hr urine collection bottle with instructions (see appendix 14) to be returned at their baseline visit.
- give a 3 day food diary to be returned at their baseline visit (this will serve the purpose of collecting the baseline habitual dietary record).
- make an appointment for their baseline visit

**Pre Baseline Visit**

Before the baseline visit the nurse will obtain the results from any blood tests done after the consent meeting to confirm eligibility. If the PP is now ineligible the nurse will contact the PP to explain, cancel the baseline visit and inform the PP primary care giver.

**Baseline Visit**

At the baseline visit, the research nurse will complete any details in the Pre Baseline questionnaire that have not already been completed to confirm the eligibility status of the participant. If eligible, the nurse will:

- Complete the Baseline questionnaire and all other assessments and investigations required at this visit.
- At the end of the visit, if eligible, participants will be given their randomisation envelope.
- When the clinic is finished the nurse will fax the front page of the pre baseline questionnaire (contact details) to Amber Parry Strong in order that she can enrol people on the compliance sub study. (fax number: (04) 385 5819)
Putting Participants on ‘hold’:
If, after some initial contact with a PP they appear to meet the inclusion/exclusion criteria and are interested in continuing, but are either unable to commit to the fortnightly dietitians meetings at this time or would like to wait for the meetings to be on a different day/time, they may be put ‘on hold’. This must happen before the baseline visit and randomisation but can be before or after they have signed a consent form. Consideration should be given to the pre baseline blood tests, the serum creatinine tests must be done within 3 months of the baseline visit.

The nurse will keep a record of, and maintain contact with, all PP as they move through the screening process to randomisation or until exclusion from the trial.
Figure 1: PROCESS OF RECRUITMENT

Initial contact with participant
Complete pre baseline questionnaire & discuss study

Participant wishes to continue
Check blood results (see next page) & if appropriate:
- Send information sheet & consent form
- Make group meeting appointment
- Send letter to GP
- Send letter to patient to confirm group meeting date

Participant does not wish to continue

Group Meeting
Investigator to present study to group
Investigator to sign consents with participants individually

Participant wishes to continue
- Measure weight & height
- Give Lab form for 2nd S. Creat. (if required)
- Give 24 hr urine bottles to return at baseline visit
- Give food diary to return at baseline visit
- Make appointment for baseline visit

Participant does not wish to continue

Check 2nd s.Cr result (if required)

If result >160 μmol/L
- Exclusion from study and cancel baseline visit

If result ≤160 μmol/L
- Baseline Assessments & Investigations
  (Give randomisation envelope after all baseline assessments are completed and eligibility criteria reviewed)

6 Month Assessments & Investigations

Dietary Intervention
Group Sessions

12 Month Assessments & Investigations

24 Month Assessments & Investigations
**BLOOD RESULTS**

**No** Serum Creatinine, LFT’s, HbA1c &/or Albumin Creatinine Ratio (A/C Ratio) result available from ≤ 3 months

Send lab form for S. Creatinine, LFT’s, HbA1c &/or A/C Ratio

**RESULTS**

<table>
<thead>
<tr>
<th>S.Creat.</th>
<th>S.Creat.</th>
<th>S.Creat.</th>
<th>A/C Ratio</th>
<th>A/C Ratio</th>
<th>A/C Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;160 μmol/L</td>
<td>≤160 &amp; &gt;140 μmol/L</td>
<td>≤140 μmol/L</td>
<td>≤ 30</td>
<td>&gt; 30 - ≤ 70</td>
<td>&gt; 70</td>
</tr>
</tbody>
</table>

**Repeat test**

<table>
<thead>
<tr>
<th>LFT’s</th>
<th>HbA1c</th>
<th>LFT’s</th>
<th>HbA1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 3 x ULN</td>
<td>≤ 9.5%</td>
<td>&gt; 3 x ULN</td>
<td>&gt; 9.5%</td>
</tr>
</tbody>
</table>

Exclusion from study

Continue in study

Discuss with local invest.

Exclusion from study
Randomisation Process:

At the time of the potential participants initial phone call they would have been assigned a unique ID code. Amber Parry-Strong will provide the dietitian at each site with sealed, numbered envelopes containing the randomisation information along with a form listing all the envelope numbers in this batch. The dietitian will then pass them on to the research nurse(s) at each site. The sealed envelopes will be provided in batches of 40 and numbered sequentially. At the end of the baseline investigation day when it has been established that they are definitely eligible, each of the participants will be given an envelope (the next envelope in the sequence). The research nurse will record the participants unique ID code, name, telephone number, weight, height, age and gender against the number of the envelope on the form accompanying the batch of envelopes. A copy of this form will need to be given to the site dietitian at the end of each week in order that they can organise the group sessions, the original should always be retained by the research nurse. The site dietitians will forward the list to Amber Parry-Strong once the entire batch has been allocated, and Amber will forward the copies to Dr Elizabeth Robinson.

If more than one person from the same household/family is consented then they should be given the same envelope and their unique ID codes will all be written against that envelope number. Therefore all study ids will be unique but some people may have the same envelope number.

The research nurses are to remain blinded to the randomisations in order to prevent bias when carrying out the study assessments and investigations.

Study Visits:

General Information:

Fasting Prior to Scheduled Investigation Days
Participants should be asked to fast (no food or drink, except water) for at least 10 hours prior to the scheduled visit time. If they use insulin their appointment should be made at a time that will allow them to follow their usual nighttime / bedtime regime and then fast for the 10 hours. Participants should not take their diabetes medications on the morning of their investigation days, however, they may take all other medications as directed by the prescribing physician.

Scheduling Investigation Days
At the end of each study visit, the next study visit should be scheduled. The visits should be scheduled using calendar months (ie. if the baseline visit is on the 20th January then the 6 month visit should be scheduled for the 20th July) with a window of 7 days either side of the visits due date (see appendix 12 for Study Visit Schedule). Every effort should be made to adhere to the study schedule. If unavoidable, a visit may be outside the designated time point, but subsequent visits must be adjusted so that the total duration of the study is as close as possible to 24 months.

Visit Reminders
Prior to each investigation day, participants should be posted a reminder, or telephoned, to be reminded of:

- The date and time of their appointment
- The requirement to fast for at least 10 hours prior to their visit
- The requirement not to take diabetes medication on the morning prior to their visit (all other medication should be taken as directed by the prescribing physician). They should be reminded
to bring their diabetes medication with them to the visit (especially insulin) so that they can take it after their blood sample has been taken.

- The need to complete their 24 hour urine collection
- The need to carefully and accurately complete the 3 Day Diet Record

Breakfast
Participants should be offered breakfast on the four investigation days after all the assessments and investigations have been completed.

Early Withdrawal:

If a participant chooses to withdraw early from the diet they are to be encouraged to continue attending the investigation days. If the participant refuses to attend any more investigation days the study nurse should complete the Exit Interview and as much of the 24 month assessment as possible. It would be ideal if the participant would return to the clinic for final investigations, however, if they do not wish to do this the nurse should gather as much information on the telephone as possible, particularly the reason for their early withdrawal.

Visit 1 – Baseline Visit:

- Review Pre Baseline Questionnaire to confirm the eligibility of the participant
- Complete Baseline Questionnaire
- Complete the Menopausal Status questionnaire for all women
- Measure vital signs (blood pressure in triplicate), weight and height
- Measure bioimpedence
- Measure waist circumference
- Give the relevant hypoglycaemia information sheet depending on their diabetes treatment, discuss the information and study expectations with them.
- Administer SF-36 Questionnaire
- Administer AHS Physical Activity Questionnaire
- Obtain fasting blood samples
- Collect completed 24 hour urine collection
- Collect 3 day food diary and check for completeness
- Give laboratory form for sCr test to be done at their local laboratory 4 weeks after commencing the diet
- Give travel voucher
- Give randomisation envelope
- Make 6 month investigation day appointment

Post Baseline visit:

- Copy the front page of the prebaseline questionnaire and fax to Amber Parry Strong
- Check 4 week post diet commencement s.creatinine result and enter in database
Visit 2 – 6 Month Visit:

- Complete 6 Month Questionnaire
- Measure vital signs (blood pressure in triplicate) and weight
- Measure bioimpedence
- Measure waist circumference
- Review diabetes control and any episodes of hypoglycaemia and its management
- Monitor adverse events
- Review all medications
- Administer SF-36 Questionnaire
- Administer AHS Physical Activity Questionnaire
- Obtain fasting blood samples for central laboratory, and local sCr
- Collect completed 24 hour urine collection
- Collect 3 day food diary and check for completeness
- Give travel voucher
- Make 12 month investigation day appointment

Post 6 month visit:
- Check local s.creatinine result and enter in database

Visit 3 – 12 Month Visit:

- Complete 12 Month Questionnaire
- Measure vital signs (blood pressure in triplicate) and weight
- Measure bioimpedence
- Measure waist circumference
- Review diabetes control and any episodes of hypoglycaemia and its management
- Monitor adverse events
- Review all medications
- Administer SF-36 Questionnaire
- Administer AHS Physical Activity Questionnaire
- Obtain fasting blood samples for central laboratory, and local sCr
- Collect completed 24 hour urine collection
- Collect 3 day food diary and check for completeness
- Give travel voucher
- Make 24 month investigation day appointment

Post 12 month visit:
- Check local s.creatinine result and enter in database
Visit 4 – 24 Month Visit – Final Visit:

- Complete 24 Month Questionnaire
- Complete ‘Exit’ Questionnaire
- Complete the Menopausal Status questionnaire for all women who were not post menopausal at the baseline visit
- Measure vital signs (blood pressure in triplicate) and weight
- Measure bioimpedience
- Measure waist circumference
- Review diabetes control and any episodes of hypoglycaemia and its management
- Monitor adverse events
- Review all medications
- Administer SF-36 Questionnaire
- Administer AHS Physical Activity Questionnaire
- Obtain fasting blood samples for central laboratory
- Collect completed 24 hour urine collection
- Collect 3 day food diary and check for completeness
- Give travel voucher

Database:

General Information:

The database consists of two files, the first named ‘DEWL’ is the file that all the data must be entered into. The second named ‘DEWL_Data’ is where the data is stored, this is the file that will be copied onto a flash card and sent to the project manager in Wellington on request in order that the central database can be updated. The ‘DEWL_Data’ file must never be opened as this will jeopardise the data.

The ‘DEWL’ file consists of two screens, the first ‘Study Patients’ is where the pre baseline questionnaire must be entered. This screen is where the participants contact details will be held, the eligibility page will also remain in this screen, all the other pages on this screen will be replicated in the second screen, the ‘Study Data’ screen. The ‘Study Data’ screen is where all questionnaires, except pre baseline, will be entered, this includes the SF36 and AHS Physical Activity questionnaires.

It is very important that the DEWL Data file is backed up regularly by the research nurse to avoid losing the information.

‘Study Patients’ Screen:

If you are entering data on a new participant click the ‘new’ tab and enter the participants unique ID code in the box on the screen, click ‘enter’ and you can then begin entering data.

If you are updating data on an existing participant click on the drop down arrow under ‘study number’ if you know their unique ID code, otherwise click on ‘patient search’ to find their unique ID code. Once you have entered their unique ID code you can begin entering data. Work through all the 5 tabs (contact details, test results, eligibility, medical conditions, medications) entering as much information as possible. You can return to this screen to update the information as often as you wish. Once all the
information required for this participant has been entered in this screen click the ‘enroll patient in study’ tab, this replicates the information from the ‘test results’, ‘medical conditions’, and ‘medications’ pages into the ‘Study Data’ screen. Once you have used the ‘enroll patient in study’ tab you can no longer enter or change data for this participant in the ‘study patients’ screen, if you need to alter the data you will need to do this through the ‘study data’ screen.

‘Study Data’ Screen:

If you know the participants unique ID code click on the ‘study number’ drop down arrow, if you do not know their unique ID code you will need to go to the ‘patient search’ facility on the ‘study patients’ screen. You also need to enter the ‘questionnaire type’ (pre baseline, baseline, 6, 12, 24 month or exit interview). Once these two parameters have been entered you can start entering data. Work through all the relevant tabs entering all the required information. At each visit you will need to enter information under household stats, medical review, primary outcome measures, blood test results, creatinine monitoring, SF36 and activities. You will need to review the information under medical conditions and medications at each visit. The demographics page is only used at the pre baseline and baseline timepoints, the exit interview is only used when the participant finishes the study and the dietary variables are only used by the dietitians. On the ‘medical conditions’ and ‘medications’ pages there is an ‘import’ button, once you are sure that the information you have entered at each visit on these pages is correct you can click this tab and the information will be carried forward to the next visit. At the next visit you can then review the information with the participant and make changes as required.

Notes on entering data:

Only one screen can be open at a time, ‘Study Patients’ or ‘Study Data’. To move between questions in the database use ‘enter’ or ‘tab’
The participants unique ID code must be entered with a ‘.’ between the site number and the participants number eg. DJK1.0001
Dates must be entered as dd/mm/yyyy. Once one number has been entered in the box a prompt will appear to help you complete the rest of the date.
The time must be entered using the 24 hr clock.
When completing questions with tick boxes putting a tick in the box means ‘yes’, leaving the box empty means ‘no’. To put a tick in the box press the space bar, if you wish to take it out again press the space bar again.

Patient Search:

Having clicked the ‘patient search’ tab enter the participants first or last names (or both), click on the binoculars and the database will give you a list of the relevant matches for that search. If you then click on the appropriate participant to highlight their name and ‘OK’ their details will be brought up on the screen.
Questionnaires and Forms:

Completion of Questionnaires and Forms:

All questionnaires must be entered into the database. Ideally they will be entered directly into the database, however, the pre baseline questionnaire, SF36 & AHS Physical Activity Questionnaire will be completed on paper first, all the study logs will be completed on paper and any other questionnaires may be completed on paper first if necessary and entered into the database as soon as possible. Any questionnaires completed on paper first must be kept in the participants Source Document Folder.

The questionnaires can be found on the study website (http://www.compasshealth.org.nz/DEWL) and photocopied as required.
- Write clearly using a black ball point pen.
- Tick ‘yes/no’ boxes.
- Write numbers in spaces (if none, write 0).
- In the baseline questionnaire all the questions marked with an * must be completed for study audit purposes even if the person does not wish to continue or is ineligible.
- If you make an error when completing a log or questionnaire strike out the error with a single line (so that the incorrect data is still legible) and print the correction clearly alongside. Write your initials and date next to the correction.

Notes on Particular Questions:

Pre Baseline Questionnaire:

- **Proof of Diabetes Diagnosis:** Any participant who is on diet alone, Metformin alone with an HbA1c of less than 6.5% or it is uncertain whether they have Type 1 Diabetes needs to have proof that they meet WHO Criteria for Type 2 diabetes:
  1. Classical symptoms of diabetes and unequivocal hyperglycaemia; or
  2. a fasting plasma glucose greater than 7.0 mmol/l on more than one occasion; or
  3. a two hour, plus one other venous plasma glucose level in excess of 11.1 mmol/l in a formal 75g oral glucose tolerance test.

If the nurse is unable to find blood tests to prove this the participant’s primary caregiver can complete the GP Source Document Form (appendix 11).

Any participant for which there is uncertainty whether they have type 1 diabetes needs to have proof that their diabetes is type 2.

- **Are you vegetarian?** The example of food given relates to what the person would need to eat to cover the daily protein requirement of the high protein group.

Inclusion / Exclusion checklist:

- **HbA1c:** If the person has an HbA1c > 9.5% but believes that this will reduce to ≤ 9.5% they may be rescreened after 1 month. This may happen no more than 3 times at which point the person may not rescreen again.
- **Pregnancy or lactation:** A urine pregnancy test is only required if the participant believes that there is a chance she may be pregnant at this time. Ask each female participant:
  Is there any chance you are pregnant now?
  Are you planning a pregnancy within the next 2 years?
- **Diabetic Nephropathy:** 2 serum creatinine results >160 μmol/L and/or an Albumin/creatinine ratio >70 is a definite exclusion from the study. However, an Albumin/creatinine ratio > 30 - ≤ 70 needs
to be reviewed by the local study investigator and inclusion in the study is at their discretion. An Albumin/creatinine ratio < 30 is definite inclusion in the study (refer to the “Process of Recruitment” chart, page 16).

Current medical conditions:
Diabetes related:
● **Peripheral Vascular Disease**: This should only be ticked ‘yes’ if they have had an angioplasty or angiogram. Ask the participant:
  Have you ever had an angioplasty or an angiogram?
● **Neuropathy**: Ask the participant:
  Has anyone ever told you that you have nerve damage in your feet?
● **Retinopathy**: Ask the participant:
  Has anyone ever told you that you have damage to the back of your eyes?
  Have you ever had a retinal photograph reported as showing damage?
● **Depression**: Ask the participant:
  At this time do you have depression requiring treatment?
  Treatment includes medication as well as counseling
Cardiovascular-related:
● **Ischemic Heart Disease**: Ask the participant:
  Have you ever had a heart attack (MI) or has your GP ever told you that you have angina?
● **Cerebrovascular disease**: Ask the participant:
  Have you ever had a stroke or have you ever been told that you have had a mini stroke (TIA)?
● **Hypertension**: Ask the participant:
  Do you have or are you taking medication for high blood pressure?
● **Dyslipidemia**: This can be self reported or ticked ‘yes’ if they are on lipid lowering medication
  Ask the participant:
  Do you have or are you taking medication for high cholesterol?
● **Other Medical Conditions**: Include as detailed a medical and surgical history as possible as this will help when reporting adverse events later in the study. Particularly report any issues with flatulence, constipation, diarrhoea, abdominal bloating, halitosis and gout as these are all possible side effects of a change in diet.

Current medications and doses:
For diabetes (except insulin), cardiovascular and other treatments use the drop down menus as much as possible, putting in the usual total daily dose in the appropriate units (usually mgs). If the medication is only taken when needed (intermittently) put 999 for the dose (the field will not accept PRN). If they have a combination medication put the dose of the first component ie. Accuretic 10. If the medication is not on the drop down menus use the text fields including the generic name and usual total daily dose (as above). Insulin is recorded on the separate chart, if the participant cannot give exact doses of insulin then record the average dose at each time point in the day.
Ask if the participant uses any ‘recreational medications’ eg. Marijuana and record these under the OTC/herbal/vitamins section of the medications.

Baseline Questionnaire:
● **Smoking status**: This question is designed to gather information about the participants tobacco smoking history. That is cigarettes, cigars & pipes.
Medical Review:

- **Current blood sugar testing regime?:** This question and the following hypoglycaemia question are designed to give the nurse an insight into the participants' present routine and diabetes control. It should then be discussed with the participant what the study expectations are and the appropriate *Hypoglycaemia Information Sheet* (see appendix 29) can be given to the participant and discussed.

- **Symptomatic hypoglycaemia:** This is a documented Blood Sugar Level of less than 4 mmol/l accompanied by one or more of the following symptoms:
  - Sweating
  - Shakiness
  - Dizziness
  - Sudden moodiness
  - Clumsy or jerky movements
  - Tingling sensations around the mouth

- **Public hospital outpatient clinic visits:** This includes any public hospital outpatient visits eg. doctor, nurse, podiatrist etc

- **General Practitioner visits:** This includes visits to both the doctor and the nurse.

- **Illness or injury in the last 10 days:** Any illness or injury, even minor, can cause the hsCRP measurement to rise. This question is designed explain any rise in this measurement (or eliminate any other cause for it).

- **Review of medical conditions and medications:** The entries from the Pre Baseline questionnaire will appear here and can be updated if necessary.

**6, 12 & 24 Month Questionnaires:**

- **How satisfying have you found the diet?:** The participant is being asked to rate their overall satisfaction with the diet that they were on, this includes their level of hunger, amount of weight loss, ease of food preparation etc. The participant must be encouraged to answer this question without going into detail about the diet, as the nurses are to remain blinded to the randomization.

- **Diet record sighted by nurse:** The record should be briefly checked for completeness of information but not for content as the nurses are to remain blinded to the randomization. If the record does not appear to be complete the nurse will discuss with the participant what is required and ask them to add more detail before leaving the clinic.

**Adverse events:**

- **Change in the following medical problems:** This drop down list contains problems that may occur as a result of the participants' change in diet (flatulence, constipation, etc). Changes since the last visit need to be recorded.

- **New medical conditions:** Medical conditions for which the participant has sought medical advice and has received a diagnosis should be recorded here. The drop down list of medical conditions from the previous visit will appear here and should be updated as necessary.

- **Other adverse events:** Symptoms which the participant is experiencing but for which they have not sought medical advice or have not received a diagnosis should be recorded here.

**Current medications:**
The drop down list from the previous visit will appear here and should be updated as necessary. Add anything new that does not appear in the drop down list in the text section.
24 month visit questionnaire:

- **Date of withdrawal:** This question should be completed either when the participant completes the study at 24 months or if the participant withdraws early from the study (that is they refuse to attend any more investigation days).
- **Reason for early withdrawal:** This should be completed if the participant withdraws from the study early (that is they refuse to attend any more investigation days).

**Menopausal Status Questionnaire**

This questionnaire should be completed for all women at the baseline visit, and at the 24 month visit for all those women who were not post menopausal at the baseline visit.

Pre menopausal is defined as women who have regular periods.
Peri Menopausal is defined as women who have irregular periods (> 6 weeks apart), +/- hot flushes and other symptoms.
Post Menopausal is defined as women who have not had a period for > 6 months.

Exceptions to these definitions are for women who have:

- had a hysterectomy retaining the ovaries, for which pre menopausal is defined as women who are symptom free, have never had symptoms, and < 48 yrs; Peri Menopausal is defined as women who have symptoms or are 48 – 55 yrs; and Post Menopausal is defined as women who have had symptoms or are > 55 yrs
- Polycystic Ovary Disease for which Pre Menopausal is defined as < 48 yrs; Peri Menopausal is defined as 48 – 55 yrs and Post Menopausal is defined as > 55 yrs.

**Exit Interview**

This questionnaire should be completed when the participant finishes the study. This may be at 24 months or earlier if the participant chooses not to attend any more investigation days. The questionnaire may be completed over the phone if necessary. The nurses should follow the prompts on the questionnaire to ensure all relevant questions are answered.

**SF-36 Questionnaire:**

The SF-36 questionnaire is designed to take about 10 minutes to complete. The participant should be given a copy of the questionnaire to complete. At the completion of the clinic visit the nurse will enter the answers into the database. Once the questionnaire has been entered it must be kept in the participants source document folder.
The questionnaire should be completed at all four investigation days.

**AHS Physical Activity Questionnaire:**

The AHS Physical Activity Questionnaire will take approximately 15-20 minutes to complete. The study nurse will ask the participant each of the questions and continue questioning the participant until they ensure that enough detail has been provided to allow accurate coding of each activity.

At the completion of the clinic visit the nurse will enter the completed questionnaire into the study database. Once the questionnaire has been entered it must be kept in the participants source document folder.
The questionnaire should be completed at all four investigation days.

When entering the questionnaire into the database please refer to the ‘coding master’ sheet for help with the abbreviations. Using the ‘f5’ key on the computer will bring up all the activities and they can be entered into the database from this screen.
3 Day Diet Record:

The 3 Day Diet Record will be handed out to each of the participants before each of the four investigation days. The first time the 3 Day Diet Record is given out the participants will also be given a booklet of Diet Assessment Photos, participants should return these to the study nurse when they return the diet record and they will be kept in the participants file and reissued each time a diet record is to be completed.

At the consent meeting participants need to be informed the following:

- Participants must record everything they eat and drink for three days; two weekdays and one weekend day
- Give as much detail as possible including brand names, serving size, weight of serve if known, amount of food using common measures eg cups, tablespoons etc
- Use the booklet of Diet Assessment Photos to help estimate amounts and record the corresponding letter – eg marmite photo A

The participants will return the record at the investigation day, the nurse should briefly check the record for completeness of information but not for content as the nurses are to remain blinded to the randomization. If the record does not appear to be complete the nurse will discuss with the participant what is required and ask them to add more detail before leaving the clinic.

Study Procedures:

Blood Pressure:

Equipment
Blood Pressure will be measured using a mobile Welsh Allen Tyco’s, model 767 manual sphygmomanometer.

Preparation of the patient
- Ensure the participant is as relaxed as possible with an empty bladder.
- Participants should rest for at least 10 minutes in the sitting position before measurement.
- Participants should have neither smoked nor consumed alcohol in the 30 minutes before measurement.

Measuring the blood pressure
- Blood pressure should be measured on the same arm throughout the study.
- Ensure the arm is supported on a cushion or table top, so the cuff position is in line with the level of their heart.
- Blood pressure should be measured in triplicate with no time gap between measurements.

Weight:

Equipment
Weight will be measured on a TBF 300 Tanita scale throughout the study. The plate should be wiped before each participant with antibacterial wipes. This is to ensure good hygiene and also a good connection.

The accuracy of the scale will be assessed each week by the study nurse using a 10 kg weight. The nurse will first weigh her/himself, they will then weigh the 10 kg weight and finally weigh themselves.
PLUS the 10 kg weight. All these measurements will be recorded on the Tanita Scale – Weekly Quality Control Record (see appendix 13) If there is a deviation of +/- 0.1 kg they should contact the scales manufacturer to have the scales calibrated.
Scales should be serviced once a year with the local Wedderburn Service Centre (these can be found in the white pages).

Preparation of the patient
- Participants should be instructed to fast for at least 10 hours prior to the measurement.
- Participants should be wearing minimal clothing (no jerseys or jackets) and NO shoes. The amount of clothing worn by each participant should be consistent for each investigation day.
- Ensure the participant has an empty bladder.

Measuring the weight
Weight should be measured and recorded to the nearest 10g.
Please refer to the Tanita Scale instruction manual page 31 for scale operating instructions.

Height:

Equipment
Height will be measured using a fixed stadiometer with vertical backboard and movable headboard.

Preparation of the patient
- Hair ornaments should be removed from the top of the head before the measurement is taken.
- Participants should stand with the heels of their feet against the vertical backboard.
- Body weight should be distributed evenly with both feet flat on the floor.
- Participants should be looking straight ahead and asked to take a deep breath and stand tall.

Measuring the height
- Once the participant is positioned, the headboard will be placed on top of the head, with sufficient pressure to compress the hair.
- The measurement is recorded in cm, to the nearest mm.

Waist Circumference:
Waist circumference is the measurement of the circumference around the waist defined as the mid point between the lowest rib and the iliac crest. It should be measured with a flexible tape measure held next to the skin, and parallel to the floor. Care should be taken to ensure the subject is not holding their breath.

Bioimpedience:
Bioimpedience will be measured on a TBF 300 Tanita scale throughout the study. The plate should be wiped before each participant with antibacterial wipes. This is to ensure good hygiene and also a good connection. This measurement should be done before the participant has their breakfast. Participants should be wearing minimal clothing (no jerseys or jackets) and NO shoes or socks and have an empty bladder. The amount of clothing worn by each participant should be consistent for each investigation day. Clothing weight should be entered as 300 gms for each participant. Body type should be entered as ‘standard’ for each participant. Please refer to the Tanita Scale instruction manual page 28 for scale operating instructions.
Travel Vouchers:

Travel vouchers can be given to the study participants for each of the four investigation days that they attend the clinic. The study budget allows for an average of $10 per participant per investigation day. The nurses must keep a record of vouchers given with the participants signature of receipt. Travel vouchers are not provided for dietitian group visits as these are seen to be providing personal benefit for the participants.

Sample Handling:

Urine Sample:

Participants will complete a 24hr urine collection (see appendix 14 for Participants 24 hour Urine Collection Instructions) prior to each of the four investigation days and bring this with them to the research centre. The research nurse or assistant will combine any separate components of the collection and ensure the sample is well mixed. They will then measure and record, in the database, the total volume and transfer a 2ml sample into a microcentrifuge tube labelled as below. This will then be frozen at -20° C until analysis.

Blood Sampling:

A fasting blood sample will be collected by the research nurse or assistant using standard phlebotomy technique. Samples will be prepared and labelled as below and stored at -20° C until transported to the central laboratory.

<table>
<thead>
<tr>
<th>Tube</th>
<th>Tests</th>
<th>Preparation</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x Red Top</td>
<td>Lipid measurements</td>
<td>Stand @ least 1 hr room temp to allow clot to form</td>
<td>Freeze -20°C</td>
</tr>
<tr>
<td>10 mls</td>
<td>Insulin</td>
<td>Centrifuge @ 2000g for 15 mins</td>
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<tr>
<td></td>
<td>Serum Creatinine</td>
<td>Pipette 2 mls serum into microcentrifuge tube</td>
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<tr>
<td></td>
<td>hsCRP</td>
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<tr>
<td>1 x Gold Top</td>
<td>Local Serum Creatinine</td>
<td>Send to Local Laboratory for analysis</td>
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<tr>
<td>3.5 mls</td>
<td></td>
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<tr>
<td>1 x Lavendar Top</td>
<td>HbA1c</td>
<td>Pipette 0.5 mls of whole blood into a 2ml microcentrifuge tube BEFORE centrifuging &amp; replace vacutainer top. (for HbA1c)</td>
<td>Freeze -20°C</td>
</tr>
<tr>
<td>10 mls</td>
<td>LFT’s</td>
<td>Refrigerate vacutainer until centrifugue</td>
<td>Freeze -20°C</td>
</tr>
<tr>
<td></td>
<td>Uric Acid</td>
<td>Centrifuge within 2 hrs @2000g for 15 mins</td>
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<td>Pipette 2 mls plasma into microcentrifuge tube</td>
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</tr>
<tr>
<td>1 x Grey Top</td>
<td>Glucose measurements</td>
<td>Refrigerate until centrifugue</td>
<td>Freeze -20°C</td>
</tr>
<tr>
<td>4 mls</td>
<td></td>
<td>Centrifuge within 2 hrs @2000g for 15 mins</td>
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<tr>
<td></td>
<td></td>
<td>Pipette 2 mls plasma into microcentrifuge tube</td>
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</tbody>
</table>
Sample Labeling:

Write clearly on each microcentrifuge tube with a stabilo OHPen universal as below:

DEWL
Unique ID Code (eg. DJK1.0001)
Timepoint (Baseline, 6 mth, 12 mth, 24 mth)
Sample type (Serum, Plasma G, Plasma L, Whole Blood, Urine)
Date sample taken

On the cap of each tube write the last numbers of the participants unique ID code eg. DJK1.0001 should be recorded as “1”, DCR2.0244 should be recorded as “244”).

Sample Storage:

The microcentrifuge tubes will be stored in 81 plate freezer boxes (as shown).

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</tbody>
</table>

Starting at position A1 fill in all the gaps along row A and then row B etc. Therefore the first participant will use gaps A1 – A5, the second participant will use gaps A6 - B1 etc. If a sample is missing ie. no urine, then a gap should be left. As samples are put into the box the research nurse will fill in the Freezer Box Log (see appendix 15), writing the participants ID code, the date and any comments eg. missing samples, next to the box position. Each box should contain samples from only one time point (eg. Baseline, 6 month, 12 month or 24 month)

Using a stabilo OHPen universal write clearly on the lid of each box as below:

DEWL Study
Site number and name (1 Auckland, 2 Wellington, 3 Christchurch)
Box Number
Timepoint (Baseline, 6 mth, 12 mth, 24 mth)

All samples will be stored at -20°C in a monitored quality controlled freezer and sent once every two months on dry ice to the central laboratory. The temperature of the freezer will be monitored weekly by the research nurse or research assistant and recorded on the Freezer Temperature Log (see appendix 16)
**Central Laboratory:**

Samples will be batched at each site and sent once every two months to Ashley Duncan, Manager of the Diabetes and Lipid Laboratory at Otago University by the research nurse. Ashley Duncan’s Contact details are: Phone: 03 4797947  
Fax: 03 4797942  
Email: Ashley.Duncan@stonebow.otago.ac.nz

The address for couriering the samples to is: Ashley Duncan  
Manager, Diabetes and Lipid Laboratory  
Deliver to: Nutrition Undergrad Labs  
Science 1 Building  
700 Cumberland Street  
Dunedin

**Sample Transport:**

Samples will be sent overnight with NZ Couriers on a Monday, Tuesday or Wednesday. The research nurse should email Ashley Duncan on Thursday the week prior to sending the samples to tell him which day they plan to send the samples the next week. Prepaid tickets will be provided to each site, these are suitable for transport boxes no bigger than 43cm x 28cm x 21cm deep. The research nurse will pack the freezer boxes containing the samples into a transport box with adequate dry ice to ensure the samples remain frozen. They should photocopy the relevant Freezer Box Logs and send the copies with the samples to the lab, keeping the original at the site. When the samples have been collected by NZ Couriers the nurse should email Ashley Duncan with the date the samples were sent and the courier ticket numbers.

**Pedometer Substudy:**

In order to validate the information that participants provide on the AHS physical activity questionnaire a sub group of 100 people (50 in Wellington, 25 each in Auckland & Christchurch) will be randomised to wear a pedometer for 1 week (7 days) at every investigation timepoint. A ‘P’ will be written on the randomisation envelope next to the envelope number for these participants. The participant should record the total as they get into bed at night and reset the pedometer each morning before clipping it onto their belt. They must return the pedometer to the research nurse at the end of the week along with the Pedometer Recording Sheet. The research nurse must enter the participants daily totals and overall total into the Pedometer Recordings Master Form, this is an excel spreadsheet with 4 pages, one for each timepoint, which will be sent to Wellington at the conclusion of the study. See appendix 18 for Instructions for Callibrating a Pedometer.  
The pedometers are not participant specific, each participant must return the pedometer at the end of the week and they will be reissused to the next participant. The pedometers are numbered and the research nurse should record which pedometer is issued to each participant in order to keep track of the pedometers. Wellington will have a total of 20 pedometers, Auckland and Christchurch 10 each.
**Dietary Intervention Protocol:**
Dietitian-supervised diets using one of two protocols:

**Group 1. Conventional – “Low Fat” (Control):**
Subjects in this group will be prescribed an energy-restricted diet based on the currently recommended macronutrient composition. This will be 55-60% carbohydrate, with predominantly low glycaemic index, whole-grain foods with high fibre intake (25-30g/day), and minimal refined carbohydrates. The balance of the diet will be composed of 25-30% fat, with no more than 10% being saturated fat, and approximately 15% protein. The diet prescription will aim for a reduction in total energy intake of 500kcal/day, using an initial dietary prescription based on current energy intake and estimation of energy requirements minus 500kcal.

Both the carbohydrate and protein recommendations will use 15g portions with the carbohydrate being low glycaemic index and the protein being low fat. Specific fat recommendations will not be given but advice on low fat cooking and preferred types of fat will be given in the initial advice package, with further advice given in the group sessions. Recipes will be provided using the “GI Factor” cookbooks and similar. It is hoped that a low glycaemic index diet with high fruit and vegetables, wholegrains and legumes will achieve the fibre goal. Sample diet plans will be provided along with food charts to enable easy portion choices.

*Sample calculation – Subject A weighs 100kg and her baseline diet record indicates she eats an average of 2100kcal per day. Recommendations would be:*
  - Energy: 1600kcal hence –
  - 55% Carbohydrate: 880kcal or 220g = 14 portions
  - 15% Protein: 240kcal or 60g = 4 portions

**Group 2. “High-Protein:Reduced-Carbohydrate” (Intervention):**
Subjects in this group will be prescribed reduced carbohydrate (40% total energy) with a focus on wholegrains and low glycaemic index foods, and high fibre (25-30g/day). The diet will include increased protein (30% total energy) and moderate fat (30% total energy). The diet prescription will aim for a reduction in total energy intake of 500kcal/day, using an initial dietary prescription based on current energy intake and estimation of energy requirements minus 500kcal.

Recommendations for carbohydrate and protein in this group will also use 15g portions with low glycaemic index carbohydrate, and low fat protein. Specific fat recommendations will not be given but advice on low fat cooking and preferred types of fat will be given in the initial advice package, with further advice given in the group sessions. Recipes will be provided using the “CSIRO” diet cookbooks and similar.

*Sample calculation – Subject A weighs 100kg and her baseline diet record indicates she eats an average of 2100kcal per day. Recommendations would be:*
  - Energy: 1600kcal hence –
  - 40% Carbohydrate: 640 kcal or 160g = 10 portions
  - 30% Protein: 480kcal or 120g = 8 portions

**Delivery of the interventions:**
Dietitians will be employed at each centre to deliver the group-based dietary intervention, and will be trained by one dietitian (Amber Parry Strong) to ensure consistency across centres. The specific components of the dietary interventions, will be further developed by Amber Parry Strong as part of a
PhD programme, building on those already established by the pilot study. Groups will include 12-20 subjects.

All subjects will take part in a twelve-month group-based programme, attending fortnightly meetings with a dietitian for the first six months to facilitate weight loss and adherence to the specific dietary protocol. This will be followed by a less intensive 6-month period with monthly sessions facilitating weight loss maintenance. These sessions will comprise of nutrition education, goal setting and behaviour change management techniques as used by Krebs et al in the pilot study. These session components have already been developed and will be built on further for this study. Sessions will cover the same information for both study arms, but some of the nutrition education will be tailored to meet the specific diet guidelines. Nutrition education topics will include: macronutrients, micronutrients, fruit and vegetables, eating out, shopping, label reading, glycaemic index, fibre, low fat cooking ideas, recipes, cholesterol and types of fat, and the effect of food on blood glucose. Subjects will also be provided with detailed handouts. Subjects will be free-living making their own food choices based on these guidelines.

Subjects will then be asked to maintain their weight loss by adhering to the dietary protocol, but will have no further dietitian input for a further 12 months. Subjects will be asked to attend monthly for weight measurements with a research nurse, during the second 12 months.

No specific advise will be given regarding physical activity. Physical activity levels will be assessed and monitored by use of a validated physical activity questionnaire and triangulated by a random sample of participants wearing pedometers for a set period.

**Dietary Considerations for Maori and Pacific Island subjects:**

The development of the interventions has been a collaboration between the members of the investigating team and consultation with local Maori to ensure an approach which has the greatest likelihood of uptake by Maori and Non-Maori. Dr Bell, Maori researcher, will oversee the Maori participation in the study and will liaise with investigators, study nurses and Maori health providers in all centres to promote and facilitate Maori participation.

The portion food lists will also contain culturally appropriate foods for Maori and Pacific Island subjects. For example the food lists and recipes will also contain pork and bacon bones, boil up, puha and watercress for Maori participants and taro, breadfruit, green banana and corned beef for Pacific Island participants. Recipes will be used from the Pacific Island Heartbeat cookbook. Support will be provided for Maori subjects through Maori health providers and Maori community groups. Support will be provided for Pacific subjects through Pacific Health Services and churches, supported by the study.
Figure 1: Dietary Intervention Group Sessions
(Example only)

<table>
<thead>
<tr>
<th>Group</th>
<th>Nov</th>
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- **Yellow** indicates Fortnightly meetings
- **Red** indicates Monthly meetings
Renal Surveillance Protocol

The potential for an increase in protein intake to cause an impairment in renal function is identified by the investigators as an important safety aspect of this study. Therefore the following protocol will be followed for all participants in this study.

Baseline Serum Creatinine (mean of 2 samples separated by at least 7 days and within 3 months) and 24 Urine Protein prior to commencement of study diet. The volunteer will be excluded if they have diabetic nephropathy or serum creatinine >160µmol/L.

Serum Creatinine at 4 weeks after initiation of study diet. If Creatinine >160mmol/L or has increased by more than 30µmol/L from baseline then repeat sample. If repeated sample remains above criteria then withdraw patient from diet but retain person in study for study measurements. Report to principal investigator within 7 days. If patient is withdrawn from diet, a repeat blood sample will be taken after 2 weeks and patient advised to have review with usual diabetes clinician within 1 month. Usual carer will be informed.

Serum Creatinine and 24 Hour urine protein at 6, 12 and 24 months. If Creatinine >160mmol/L or has increased by more than 30µmol/L from baseline then repeat sample. If repeated sample remains above criteria then withdraw patient from diet but retain person in study for study measurements. Report to principal investigator within 7 days. If patient is withdrawn from diet, a repeat blood sample will be taken after 2 weeks and patient advised to have review with usual diabetes clinician within 1 month. Usual carer will be informed.

In the event that a participant is withdrawn from the diet due to deterioration in renal function, the local investigator will, with the consent of the participant, inform the participants General Practitioner and/or usual diabetes physician. Usual study follow-up measurements and blood tests will continue as per protocol. Withdrawals are only from the diet or intervention, not from the study.

It is recognised that there may be temporary reversible changes in renal function or proteinuria which may be secondary to for example concomitant medication use, dehydration or urinary infection. Therefore, at the clinical discretion of the local investigator after review of the patient, patients may be retained in the study.

If the rate of adverse events differs between treatment groups for the serious adverse events (substantial renal deterioration) by greater than 3 standard deviations (i.e. p-value < 0.003) at 3 or 6 months then this constitutes grounds for stopping the trial. Analyses will be carried out by the study statistician.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>6 Months</th>
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<th>24 Months</th>
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<td>Multivariate</td>
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<tr>
<td>%TE Protein</td>
<td>15-25 N = 240</td>
<td>1.09 (-0.67, 2.86)</td>
<td>0.22</td>
<td>1.16 (-0.62, 2.95)</td>
<td>0.20</td>
<td>0.22 (-1.65, 2.09)</td>
<td>0.23</td>
</tr>
<tr>
<td>Reference</td>
<td>&gt;25 N = 62</td>
<td>0.06 (-1.94, 2.07)</td>
<td>0.95</td>
<td>0.16 (-1.89, 2.22)</td>
<td>0.88</td>
<td>1.80 (-0.56, 4.16)</td>
<td>0.13</td>
</tr>
<tr>
<td>Category &lt; 15</td>
<td>Continuous</td>
<td>-0.09 (-0.19, 0.01)</td>
<td>0.07</td>
<td>-0.10 (-0.20, -0.00)</td>
<td>0.04</td>
<td>0.12 (-0.01, 0.25)</td>
<td>0.06</td>
</tr>
<tr>
<td>%TE Total Fat</td>
<td>20-30 N = 132</td>
<td>-0.31 (-1.31, 0.69)</td>
<td>0.54</td>
<td>-0.17 (-1.23, 0.88)</td>
<td>0.75</td>
<td>0.02 (-1.04, 1.08)</td>
<td>0.97</td>
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<tr>
<td>Reference</td>
<td>&lt;20 N = 20</td>
<td>-0.85 (-2.81, 1.10)</td>
<td>0.39</td>
<td>-0.65 (-2.67, 1.36)</td>
<td>0.52</td>
<td>1.36 (-1.02, 3.74)</td>
<td>0.26</td>
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<td>Category &gt;30</td>
<td>Continuous</td>
<td>-0.03 (-0.10, 0.03)</td>
<td>0.34</td>
<td>-0.06 (-0.13, 0.01)</td>
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<td>-0.01 (-0.09, 0.07)</td>
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<td>Dietary Fibre</td>
<td>20-30 N = 185</td>
<td>-0.12 (-1.25, 1.02)</td>
<td>0.84</td>
<td>-0.23 (-1.4, 0.94)</td>
<td>0.70</td>
<td>0.48 (-0.70, 1.66)</td>
<td>0.42</td>
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<tr>
<td>Reference</td>
<td>&gt;30 N = 60</td>
<td>-0.29 (-1.82, 1.24)</td>
<td>0.71</td>
<td>-0.28 (-1.88, 1.32)</td>
<td>0.73</td>
<td>-0.46 (-2.12, 1.20)</td>
<td>0.58</td>
</tr>
<tr>
<td>Category &lt; 20</td>
<td>Continuous</td>
<td>-0.02 (-0.09, 0.05)</td>
<td>0.53</td>
<td>-0.05 (-0.13, 0.03)</td>
<td>0.22</td>
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Lean Body Mass

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## Systolic BP

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### Diastolic BP

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Note: Values for %TE, Total Fat, and Dietary Fibre category are shown for reference categories.
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Univariate analyses adjusted for baseline, energy, age, sex and centre. Multivariate analyses adjusted for baseline, energy, age, sex, centre with %TE protein, %TE Fat and dietary fibre in the same model.