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

Date of this baseline visit

Ethnicity:
Which ethnic group(s) do you belong to?
Mark the space(s) that apply

a. New Zealand European
b. Maori
c. Samoan
d. Cook Island Maori
e. Tongan
f. Niuean
g. Chinese
h. Indian
i. Other (such as Dutch, Japanese, Tokelauan) (Please specify)

Smoking status: (Enter the number that describes the participants smoking status)
1 = Current; 2 = ex smoker; 3 = Never

Do you have a community services card:
Yes ☐ No ☐

Do you have a high user card:
Yes ☐ No ☐

How much would your household spend each week on food? $ ☐

How many adults (>14 yrs) live in your household?

How many children (≤14 yrs) live in your household?

On average how many hours per week do you spend in paid employment?

If employed: how many days off work have you had in the previous 12 months due to sickness or injury?
Medical Review:

Do you have any allergies?        Yes  No
If yes, list:
.................................................................................................................................
.................................................................................................................................
What is your current blood sugar testing regime?
.................................................................................................................................
.................................................................................................................................

How many episodes of symptomatic hypoglycaemia have you had in the last month?:
(Tick)        0  1 – 10  > 10

How many episodes of gout have you had in the last 12 months?

How many public hospital outpatient clinic visits have you had in the last 12 months?

How many private specialist visits have you had in the last 12 months?

How many visits to a general practitioner have you had in the last 12 months?

How many visits to an after-hours medical centre have you had in the last 12 months?

How many visits to an Emergency department have you had in the last 12 months (not counting hospital admissions)?

Have you been admitted to hospital in the last 12 months?        Yes  No
If YES: What for?

Admission 1: ___________________________________________________ Days: □
Admission 2: ___________________________________________________ Days: □
Admission 3: ___________________________________________________ Days: □
Admission 4: ___________________________________________________ Days: □

Have you had any illness or injury in the last 10 days (eg: a cold, any infection, trauma)
If yes, explain:.................................................................................................................................
.................................................................................................................................

Review past medical history and current medications recorded on Pre- Baseline questionnaire.
(update as necessary)
Baseline Questionnaire Version #16: 26.03.07
Primary outcome measures:

Date of measures:
Time of measures:
Weight (kg)
Height (cm)
BMI
Waist Circumference (cm)

Bio-impedance: (place printout from scales in patients source document folder)

   Impedance
   Fat %
   Total Body Fat (kg)
   Fat Free Mass (kg)
   Total Body Water (kg)

Blood Pressure: (Sitting, use RIGHT arm if possible, after 10 minutes rest)

   Recorded in: L/R arm
   Systolic Blood Pressure 1
   Diastolic Blood Pressure 1
   Systolic Blood Pressure 2
   Diastolic Blood Pressure 2
   Systolic Blood Pressure 3
   Diastolic Blood Pressure 3

Pulse Rate (beats/minute):

Assessment completed by: .............................................
Blood test results: (place lab forms in patient's source document folder)

Fasting blood sample collected?  Yes  No

Any problems with sample collection (eg difficult access)  Yes  No

Date of blood test
Time of blood test
Time last ate
Total volume of 24 hr urine collection (mls)

Glycaemic control:
HbA1c (%)
Fasting plasma glucose (mmol/L)
Insulin sensitivity
  OGTT 2 Hour glucose (mmol/L)

Lipids:
Total cholesterol (mmol/L)
LDL (mmol/L)
HDL (mmol/L)
Triglycerides (mmol/L)

Uric acid (mmol/L)

Renal:
Serum creatinine (µmol/l)
Est GFR

Urine sample:
Urine albumin concentration
Urine creatinine concentration
Urine albumin: creatinine ratio

24 Hour urine:
24 hour urine protein
24 hour urine creatinine
24 hour urine sodium
24 hour urine nitrogen

hsCRP

Baseline Questionnaire Version #16: 26.03.07
**LFT's:**
ALT (mmol/L)  
AST (mmol/L)  
GGT (mmol/L)  
Albumin (mmol/L)  
Bilirubin (mmol/L)

**Local Serum Creatinine Monitoring for Adverse Events:**

**Week 4:**
Date of blood test  
Serum creatinine (µmol/l)

NB: If Creatinine >160µmol/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. (Ref: DEWL Renal surveillance protocol)

**Repeat test if required:**
Date of blood test  
Serum creatinine (µmol/l)

Action taken (if any required):
…………………………………………………………………………………………
…………………………………………………………………………………………
…………………………………………………………………………………………

**Repeat test if required:**
Date of blood test  
Serum creatinine (µmol/l)

**Repeat test if required:**
Date of blood test  
Serum creatinine (µmol/l)
The Diabetes Excess Weight Loss (DEWL) Trial:
High Protein vs Low Fat Diet

Date of this 6 month visit

Smoking status: (Enter the number that describes the participants smoking status)
1 = Current; 2 = Ex smoker; 3 = Never

How much would your household spend each week on food?

How many adults (>14 yrs) live in your household?
How many children (≤14 yrs) live in your household?

On average how many hours per week do you spend in paid employment?
If employed: how many days off work have you had since your last visit due to sickness or injury?

How satisfying have you found the diet? (Tick one)
Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

3 Day Diet Record sighted by nurse

Medical Review:
How many episodes of symptomatic hypoglycaemia have you had in the last month?
(Tick) 0 1 – 10 > 10

How many episodes of gout have you had since your last visit?

How many public hospital outpatient clinic visits have you had since your last visit?

How many private specialist visits have you had since your last visit?

How many visits to a general practitioner have you had since your last visit?
How many visits to an after-hours medical centre have you had since your last visit? □□

How many visits to an Emergency department have you had since your last visit? □□

**Adverse Events:**

Have you experienced any change in the following medical problems since your last visit?

- More than the usual amount of Flatulence / Farting
  - Yes □  No □
- Constipation
  - Yes □  No □
- Diarrhoea / loose bowel motions
  - Yes □  No □
- Abdominal bloating
  - Yes □  No □
- Halitosis / bad breath
  - Yes □  No □
- Gout
  - Yes □  No □

Have you had any new diagnosis related to your diabetes, cardiovascular or other related medical conditions since your last visit? □□

……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………

*Does the wording of this question make sense? Should we just be asking about diabetes and cardio as we ask about other adverse events in the next question but 1?*

Have you been admitted to hospital since your last study visit? □□

If YES: What for?

Admission 1: ____________________________ Days: □

Admission 2: ____________________________ Days: □

Admission 3: ____________________________ Days: □

Admission 4: ____________________________ Days: □

Any other adverse events since the last visit:

……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………
Have you had any illness or injury in the last 10 days (eg: a cold, any infection, trauma)
Yes ☐ No ☐
If yes, explain: ________________________________________________________________

Current medications:
Review current medications and record any changes since the last visit.
______________________________________________________________________________

Primary outcome measures:
Date of measures: __________________________________________
Time of measures: ___________________________________________
Weight (kg) ________________________________________________
BMI _________________________________________________________
Waist Circumference (cm) _____________________________________
Bio-impedance: (place printout from scales in patients source document folder)
   Impedance _________________________________________________
   Fat % _____________________________________________________
   Total Body Fat (kg) _________________________________________
   Fat Free Mass (kg) _________________________________________
   Total Body Water (kg) ______________________________________
Blood Pressure: (Sitting, use RIGHT arm if possible, after 10 minutes rest)
   Recorded in: L/R arm ________________________________________
   Systolic Blood Pressure 1 __________________________________
   Diastolic Blood Pressure 1 _________________________________
   Systolic Blood Pressure 2 __________________________________
   Diastolic Blood Pressure 2 _________________________________
   Systolic Blood Pressure 3 __________________________________
   Diastolic Blood Pressure 3 _________________________________
Pulse Rate (beats/minute): ________________________________
Assessment completed by: ……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………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24 hour urine creatinine
24 hour urine sodium
24 hour urine nitrogen
hsCRP
**LFT’s:**
- ALT (mmol/L)
- AST (mmol/L)
- GGT (mmol/L)
- Albumin (mmol/L)
- Bilirubin (mmol/L)

**Local Serum Creatinine Monitoring for Adverse Events:**

Date of blood test
Serum creatinine (µmol/l)

**Repeat test if required:**
Date of blood test
Serum creatinine (µmol/l)

Action taken (if any required):

………………………………………………………………………………
………………………………………………………………………………
………………………………………………………………………………
………………………………………………………………………………

**Repeat test if required:**
Date of blood test
Serum creatinine (µmol/l)

**Repeat test if required:**
Date of blood test
Serum creatinine (µmol/l)
The Diabetes Excess Weight Loss (DEWL) Trial: High Protein vs Low Fat Diet

Date of this 12 month visit

Smoking status: (Enter the number that describes the participants smoking status)
1 = Current; 2 = Ex smoker; 3 = Never

How much would your household spend each week on food?

How many adults (>14 yrs) live in your household?
How many children (≤14 yrs) live in your household?

On average how many hours per week do you spend in paid employment?

If employed: how many days off work have you had since your last visit due to sickness or injury?

How satisfying have you found the diet? (Tick one)
Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

3 Day Diet Record sighted by nurse

Medical Review:
How many episodes of symptomatic hypoglycaemia have you had in the last month?
(Tick) 0 □ 1 – 10 □ > 10 □

How many episodes of gout have you had since your last visit?

How many public hospital outpatient clinic visits have you had since your last visit?

How many private specialist visits have you had since your last visit?

How many visits to a general practitioner have you had since your last visit?
DEWL Trial
12 Month Questionnaire

Study number:              .
Participant initials:  

How many visits to an after-hours medical centre have you had since your last visit?  

How many visits to an Emergency department have you had since your last visit?  

**Adverse Events:**

Have you experienced any change in the following medical problems since your last visit?

- More than the usual amount of Flatulence / Farting
- Constipation
- Diarrhoea / loose bowel motions
- Abdominal bloating
- Halitosis / bad breath
- Gout

Have you had any new medical conditions since your last visit?  Yes  No  

Have you been admitted to hospital since your last study visit?  Yes  No  

If YES: What for?

Admission 1: _______________________________ Days:  

Admission 2: _______________________________ Days:  

Admission 3: _______________________________ Days:  

Admission 4: _______________________________ Days:  

Any other adverse events since the last visit:  

Have you had any illness or injury in the last 10 days (eg: a cold, any infection, trauma)  Yes  No  

If yes, explain:  


12 Month Questionnaire Version 3 12.12.06
Current medications:
Review current medications and record any changes since the last visit.

……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………

Primary outcome measures:
Date of measures:   
Time of measures:   
Weight (kg)   
BMI   
Waist Circumference (cm)   
Bio-impedance: (place printout from scales in patients source document folder)
    Impedance   
    Fat %   
    Total Body Fat (kg)   
    Fat Free Mass (kg)   
    Total Body Water (kg)   
Blood Pressure: (Sitting, use RIGHT arm if possible, after 10 minutes rest)
    Recorded in: L/R arm   
    Systolic Blood Pressure 1   
    Diastolic Blood Pressure 1   
    Systolic Blood Pressure 2   
    Diastolic Blood Pressure 2   
    Systolic Blood Pressure 3   
    Diastolic Blood Pressure 3   
    Pulse Rate (beats/minute):   
Assessment completed by:
Blood test results: (place lab forms in patient’s source document folder)

Fasting blood sample collected?  
Yes ☐  No ☐  
Any problems with sample collection (eg difficult access)  
Yes ☐  No ☐

Date of blood test  ☐/☐/☐  
Time of blood test  ☐/☐:☐ ☐  
Time last ate  ☐/☐/☐  
Total volume of 24 hr urine collection (mls)  ☐/☐/☐ ☐

Glycaemic control:
HbA1c (%)  ☐/☐/☐  
Fasting plasma glucose (mmol/L)  ☐/☐/☐  
Insulin sensitivity
   OGTT 2 Hour glucose (mmol/L)  ☐/☐/☐  

Lipids:
Total cholesterol (mmol/L)  ☐/☐/☐  
LDL (mmol/L)  ☐/☐/☐  
HDL (mmol/L)  ☐/☐/☐  
Triglycerides (mmol/L)  ☐/☐/☐  
Uric acid (mmol/L)  ☐/☐/☐  

Renal:
Serum creatinine (µmol/l)  ☐/☐/☐  
Est GFR  ☐/☐/☐  

Urine sample:
Urine albumin concentration  ☐/☐/☐  
Urine creatinine concentration  ☐/☐/☐  
Urine albumin: creatinine ratio  ☐/☐/☐  

24 Hour urine:
24 hour urine protein  ☐/☐/☐  
24 hour urine creatinine  ☐/☐/☐  
24 hour urine sodium  ☐/☐/☐  
24 hour urine nitrogen  ☐/☐/☐  
hsCRP  ☐/☐/☐  

12 Month Questionnaire Version 3 12.12.06
LFT's:
ALT (mmol/L)  
AST (mmol/L)  
GGT (mmol/L)  
Albumin (mmol/L)  
Bilirubin (mmol/L)  

Local Serum Creatinine Monitoring for Adverse Events:
Date of blood test  
Serum creatinine (µmol/l)  

NB: If Creatinine >160µmol/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. (Ref: DEWL Renal surveillance protocol)

Repeat test if required:
Date of blood test  
Serum creatinine (µmol/l)  
Action taken (if any required):

Repeat test if required:
Date of blood test  
Serum creatinine (µmol/l)  

Repeat test if required:
Date of blood test  
Serum creatinine (µmol/l)  

Repeat test if required:
Date of blood test  
Serum creatinine (µmol/l)
The Diabetes Excess Weight Loss (DEWL) Trial:
High Protein vs Low Fat Diet

Date of this 24 month visit

Smoking status: (Enter the number that describes the participants smoking status)
1 = Current; 2 = Ex smoker; 3 = Never

How much would your household spend each week on food? $ 

How many adults (>14 yrs) live in your household?

How many children (≤14 yrs) live in your household?

On average how many hours per week do you spend in paid employment?

If employed: how many days off work have you had since your last visit due to sickness or injury?

3 Day Diet Record sighted by nurse

Medical Review:
How many episodes of symptomatic hypoglycaemia have you had in the last month?
(Tick) 0 1 – 10 > 10

How many episodes of gout have you had since your last visit?

How many public hospital outpatient clinic visits have you had since your last visit?

How many private specialist visits have you had since your last visit?

How many visits to a general practitioner have you had since your last visit?

How many visits to an after-hours medical centre have you had since your last visit?

How many visits to an Emergency department have you had since your last visit?
Adverse Events:
Have you experienced any change in the following medical problems since your last visit?

- More than the usual amount of Flatulence / Farting
  - Yes ☐ No ☐
- Constipation
  - Yes ☐ No ☐
- Diarrhoea / loose bowel motions
  - Yes ☐ No ☐
- Abdominal bloating
  - Yes ☐ No ☐
- Halitosis / bad breath
  - Yes ☐ No ☐
- Gout
  - Yes ☐ No ☐

Have you had any new medical conditions since your last visit?  ☐ Yes ☐ No ☐

……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………

Have you been admitted to hospital since your last study visit?  ☐ Yes ☐ No ☐
If YES: What for?
Admission 1: ____________________________ Days: ☐
Admission 2: ____________________________ Days: ☐
Admission 3: ____________________________ Days: ☐
Admission 4: ____________________________ Days: ☐

Any other adverse events since the last visit:
……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………

Have you had any illness or injury in the last 10 days  ☐ Yes ☐ No ☐
(eg: a cold, any infection, trauma)
If yes, explain: __________________________________________________________
……………………………………………………………………………………………
Current medications:
Review current medications and record any changes since the last visit.

……………………………………………………………………………………………
……………………………………………………………………………………………
……………………………………………………………………………………………

Final visit questions:
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, used a personal trainer)
   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: ……………………………
h. Has anyone diagnosed you as having obstructive sleep apnoea?  
1 = Yes  2 = No  
If Yes, Have you had any treatment for this over the two years of the study?  
(eg. C-PAP, mandibular advancement device)  
1 = Yes  2 = No  
If Yes, What is the duration of the treatment?  

How satisfying have you found the diet? (Tick one)  
Very satisfied  
Satisfied  
Neither satisfied nor dissatisfied  
Dissatisfied  
Very dissatisfied  

Date of withdrawal from diet:  
(Todays date if participant is still following DEWL study diet)  

Reason for early withdrawal from diet: (If Required)  

What did you like about the diet?  

What did you dislike about the diet?  

Any comments you would like to make?
Primary outcome measures:

Date of measures: 
Time of measures: 

Weight (kg) 
BMI 
Waist Circumference (cm) 

Bio-impedance: (place printout from scales in patients source document folder)

Impedance 
Fat % 
Total Body Fat (kg) 
Fat Free Mass (kg) 
Total Body Water (kg) 

Blood Pressure: (Sitting, use RIGHT arm if possible, after 10 minutes rest)

Recorded in: L/R arm 

Systolic Blood Pressure 1 
Diastolic Blood Pressure 1 
Systolic Blood Pressure 2 
Diastolic Blood Pressure 2 
Systolic Blood Pressure 3 
Diastolic Blood Pressure 3 
Pulse Rate (beats/minute): 

Assessment completed by: ............................................
Blood test results: (place lab forms in patient’s source document folder)

Fasting blood sample collected?  
Yes □  No □

Any problems with sample collection (eg difficult access)  
Yes □  No □

Date of blood test  
\[ \text{mm/dd/yyyy} \]

Time of blood test  
\[ \text{HH:mm} \]

Time last ate  
\[ \text{HH:mm} \]

Total volume of 24 hr urine collection (mls)  
\[ \text{mls} \]
## Table 2.2 Loss of body and fat mass with high protein and high carbohydrate diets

<table>
<thead>
<tr>
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<th>Study Duration (wks)</th>
<th>BMI Range</th>
<th>Population Group</th>
<th>Carbohydrate: Protein (%TE)</th>
<th>Energy Intake (kJ)</th>
<th>Body Mass Change (kg)</th>
<th>P Value</th>
<th>Fat Mass Change (kg)</th>
<th>P Value</th>
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<td>[58] Brinkworth n = 58 (4 + 16 Mths) Individual counselling</td>
<td>68</td>
<td>27-43</td>
<td>M + W, HI</td>
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W = Women, M = Men, HI = Hyperinsulinemia, T2DM = type 2 diabetes mellitus, HC = High Carbohydrate, HP = High Protein
Results presented are actual, with targets in brackets where this was different, where reported
* Fixed energy intake
** Ad libitum energy intake
† p < 0.05 for difference between the diets
‡ Full sample – McAuley n = 93, Gardner n = 311 (Zone and LEARN arms), Meckling n = 60 (CON and HP arms)
## Table 2.3 High protein vs high carbohydrate diets - effect on blood lipids

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<th>First Author</th>
<th>Study Duration (wks)</th>
<th>Carbohydrate: Protein (%TE)</th>
<th>Total Chol (mmol/L)</th>
<th>HDL (mmol/L)</th>
<th>LDL (mmol/L)</th>
<th>TAG (mmol/L)</th>
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<td>+0.37 +0.1 -0.35</td>
<td>-0.02 +0.03 +0.16 -0.18 -0.03</td>
<td>-0.42 +0.06 -0.18 -0.13</td>
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<td>68</td>
<td>40:30 HP 55:15 HC</td>
<td>0.0 +0.00 +0.60</td>
<td>0.0 +0.00 +0.15 -0.2 +0.04</td>
<td>-0.5 +0.00 -0.18 +0.00</td>
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<td>Claessons</td>
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<td>45:25 HP 55:15 HC</td>
<td>+0.58 +0.73</td>
<td>+0.2 +0.1 +0.36 +0.43</td>
<td>+0.06 +0.56</td>
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<td>+0.39† No change +0.08 +0.06</td>
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<td>-0.6 -0.3</td>
<td>+0.08 +0.06</td>
<td>-0.28 +0.10</td>
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<td>5 x-over</td>
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<td>4.4‡ 4.7‡</td>
<td>1.0‡ 1.0‡</td>
<td>2.6‡ 2.6‡</td>
<td>1.8‡ 2.2‡</td>
</tr>
<tr>
<td>Gardner</td>
<td>52</td>
<td>40:30 HP 52:18 HC</td>
<td>Not Reported</td>
<td>+0.09 +0.05 +0.09</td>
<td>+0.01 +0.00 +0.05 +0.02</td>
<td>-0.24 +0.04 +0.18 +0.16</td>
</tr>
<tr>
<td>Larsen</td>
<td>52</td>
<td>40:30 HP 55:15 HC</td>
<td>-0.23 -0.31 +0.01</td>
<td>0.00 +0.00 0.00 +0.00</td>
<td>-0.04 -0.05 -0.11 +0.04</td>
<td>-0.50 -0.47 -0.45 +0.30</td>
</tr>
<tr>
<td>Layman</td>
<td>10</td>
<td>41:30 HP 57:15 HC</td>
<td>-0.24 -0.55</td>
<td>-0.03† -0.10</td>
<td>-0.07 -0.45†</td>
<td>-0.3† -0.02</td>
</tr>
<tr>
<td>Lean</td>
<td>26</td>
<td>35:30 HP 58:20 HC</td>
<td>-0.12 -0.34</td>
<td>+0.05 -0.02</td>
<td>-0.03 -0.17</td>
<td>-0.25 -0.27</td>
</tr>
<tr>
<td>McAuley</td>
<td>52</td>
<td>40:30 HP 55:15 HC</td>
<td>-0.5 -0.6</td>
<td>+0.01 +0.05 +0.05 -0.2</td>
<td>-0.03 -0.2 -0.55† -0.66†</td>
<td>-0.34 -0.31</td>
</tr>
<tr>
<td>Noakes</td>
<td>12</td>
<td>44:31 HP 61:17 HC</td>
<td>-0.48 -0.33</td>
<td>-0.09 -0.09</td>
<td>-0.26 -0.19</td>
<td>-0.30† -0.11</td>
</tr>
<tr>
<td>Sargrad</td>
<td>8</td>
<td>40:30 HP 55:15 HC</td>
<td>-0.81 -0.81</td>
<td>-0.09 -0.05</td>
<td>-0.32 -0.36§</td>
<td>-2.00 -1.97</td>
</tr>
<tr>
<td>Te Morenga</td>
<td>10</td>
<td>50:30 HP 50:20 LP</td>
<td>+0.21† 0.16</td>
<td>-0.02 -0.01</td>
<td>-0.14† 0.06</td>
<td>-0.11 0.00</td>
</tr>
</tbody>
</table>

‡ Actual final result – no comparison given
† p < 0.05 for difference between the diets(2)
* % change only reported
§ p < 0.05 Different from baseline where between diet analysis was not reported
### Table 2.4 High protein diets in subjects with T2DM – changes in glycaemic control, insulin and renal function

<table>
<thead>
<tr>
<th>First Author</th>
<th>Duration (wks)</th>
<th>Carbohydrate: Protein (%TE)</th>
<th>Energy intake (kJ)</th>
<th>HbA1c (%)</th>
<th>Fasting glucose (mmol/L)</th>
<th>Fasting serum Insulin (pmol/L)</th>
<th>Serum Creatinine (μmmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brinkworth n = 66 (3 + 12 Mths)</td>
<td>64</td>
<td>40:30 HP 55:15 HC</td>
<td>6700/8700* 6700/8700*</td>
<td>-0.5 0.1</td>
<td>-0.5 0.4</td>
<td>-0.6 0.0</td>
<td>-15.6 1.2</td>
</tr>
<tr>
<td>Evangelista n = 14</td>
<td>12</td>
<td>40:30 HP 55:15 HC Normal diet</td>
<td>5040/6300* 5040/6300*</td>
<td>-0.7 0.8 0.5</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Gannon n = 12</td>
<td>5 (x-over With washout)</td>
<td>40:30 HP 55:15 HC</td>
<td>9387* 9517*</td>
<td>-0.8† -0.3</td>
<td>No change</td>
<td>No change</td>
<td>110† 104‡</td>
</tr>
<tr>
<td>Larsen n = 99 (3 and 12 mths)</td>
<td>52</td>
<td>40:30 HP 55:15 HC</td>
<td>6400* 6400*</td>
<td>-0.52 -0.23 -0.49 -0.28</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sargrad n = 12</td>
<td>8</td>
<td>40:30 HP 55:15 HC</td>
<td>5351* 5758*</td>
<td>-1.0 -1.3†</td>
<td>No change</td>
<td>-1.6†</td>
<td>-19 -11</td>
</tr>
</tbody>
</table>

† p < 0.05 for difference between the diets
* Fixed energy intake
** Measured urinary albumin excretion with no change throughout the study
‡ Actual final result – no comparison given
Figure 3.1 Process of recruitment and intervention

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)

Group Sessions
Attend first group session and receive dietary advice – start diet. Attend next 11 group sessions.

6 Month Assessments & Investigations
Attend next 6 group sessions

12 Month Assessments & Investigations
Optional monthly weigh in clinics

24 Month Assessments & Investigations
Figure 3.2 Process of determining eligibility from blood results

No Serum Creatinine (sCr), Liver function tests (LFT’s), HbA1c &/or Albumin Creatinine Ratio (A/C Ratio) result available from ≤ 3 months

Send lab form for Serum Creatinine, LFT’s, HbA1c &/or A/C Ratio

Results

Serum Creatinine, LFT’s, HbA1c & Albumin Creatinine Ratio (A/C Ratio) result available from ≤ 3 months

<table>
<thead>
<tr>
<th>SCr &gt;160 μmol/L</th>
<th>SCr ≤160 &amp; &gt;140 μmol/L</th>
<th>SCr ≤140 μmol/L</th>
<th>A/C Ratio ≤ 30</th>
<th>A/C Ratio &gt; 30 - ≤ 70</th>
<th>A/C Ratio &gt; 70</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat test</td>
<td></td>
<td></td>
<td>LFT’s ≤ 3 x ULN*</td>
<td></td>
<td>LFT’s &gt; 3 x ULN</td>
</tr>
<tr>
<td>SCr &gt; 160 μmol/L</td>
<td>SCr ≤ 160 μmol/L</td>
<td></td>
<td>HbA1c ≤ 9.5%</td>
<td></td>
<td>HbA1c &gt; 9.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exclusion from study</td>
<td>Continue in study</td>
<td></td>
<td>Discus with local investigator</td>
<td></td>
<td>Exclusion from study</td>
</tr>
</tbody>
</table>

* Upper limit of normal
Figure 4.1: Consort diagram of participant recruitment and retention

Assessed for eligibility (n= 884)

Excluded (n= 465)
- Not meeting inclusion criteria (n= 289)
- Declined to participate (n=176)

Randomized n = 419
- Auckland (133)
- Wellington (186)
- Christchurch (100)

Allocated to high protein (n=207)
- Received initial intervention advice (n=207)

6 months – n = 173 (83.6%)
12 months - n = 152 (73.4%)
24 months - n = 144 (69.6%)

Allocated to high carbohydrate (n=212)
- Received initial intervention advice (n=211)
  (1 withdrew between randomization and intervention start)

6 months n = 174 (82.5%)
12 months n = 158 (74.9%)
24 months n = 150 (71.1%)

Analysis – all available data used for analysis, no data excluded as per intention to treat

Participants withdrawn and reasons:
- 7 disliked diet
- 2 died
- 13 health problems
- 41 other

Participants withdrawn and reasons:
- 6 disliked diet
- 1 died
- 10 health problems
- 44 other
**Figure 4.2** Attendance at group sessions by diet (n = 18)

Attendance at Group Sessions by Diet

Where 0 = high carbohydrate and 1 = high protein. No significant effect of diet was found for attendance, \( p = 0.926 \)

**Figure 4.3** Attendance at group sessions by centre (n = 18)

Attendance by Centre

Where 1 = Auckland, 2 = Wellington and 3 = Christchurch. No significant effect of centre was found for attendance, \( p = 0.358 \)
### Table 4.5

Anthropometric measurements of participants on HP and HC diets at all time points (n = 419 total sample at baseline)

<table>
<thead>
<tr>
<th>Variable</th>
<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)&lt;sup&gt;1&lt;/sup&gt;</th>
<th>P&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>HC</td>
<td>101.94 (20.10)</td>
<td>98.69 (19.25)</td>
<td>99.48 (19.12)</td>
<td>95.94 (17.06)</td>
<td>-0.24 (-1.33, 0.86)</td>
<td>0.67</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>103.42 (19.73)</td>
<td>100.17 (18.76)</td>
<td>100.24 (17.83)</td>
<td>99.45 (17.18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>HC</td>
<td>36.67 (6.42)</td>
<td>35.47 (6.61)</td>
<td>35.80 (6.12)</td>
<td>35.04 (5.59)</td>
<td>-0.25 (-0.62, 0.13)</td>
<td>0.19</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>36.55 (6.70)</td>
<td>35.54 (6.36)</td>
<td>35.35 (6.17)</td>
<td>34.88 (6.10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>HC</td>
<td>115.10 (13.49)</td>
<td>112.10 (13.15)</td>
<td>112.03 (13.86)</td>
<td>108.73 (12.07)</td>
<td>0.49 (-0.73, 1.71)</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>114.37 (13.67)</td>
<td>111.54 (12.95)</td>
<td>111.44 (12.78)</td>
<td>110.06 (14.05)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Body Fat (kg)</td>
<td>HC</td>
<td>45.18 (14.34)</td>
<td>42.94 (14.26)</td>
<td>43.53 (14.20)</td>
<td>41.38 (12.80)</td>
<td>-0.51 (-1.61, 0.60)</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>43.89 (13.90)</td>
<td>41.64 (12.85)</td>
<td>41.10 (12.57)</td>
<td>40.88 (11.89)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fat Free Mass (kg)</td>
<td>HC</td>
<td>56.64 (11.32)</td>
<td>55.63 (10.51)</td>
<td>55.74 (10.42)</td>
<td>54.50 (9.44)</td>
<td>0.20 (-0.65, 1.05)</td>
<td>0.65</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>59.54 (12.14)</td>
<td>58.42 (11.80)</td>
<td>58.91 (11.61)</td>
<td>57.88 (10.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>HC</td>
<td>131.20 (17.01)</td>
<td>129.26 (16.25)</td>
<td>129.75 (17.13)</td>
<td>131.53 (20.02)</td>
<td>1.64 (-0.67, 3.94)</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>133.03 (26.65)</td>
<td>130.78 (17.13)</td>
<td>130.97 (16.99)</td>
<td>132.91 (20.82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>HC</td>
<td>76.93 (10.90)</td>
<td>76.07 (10.31)</td>
<td>76.25 (10.50)</td>
<td>76.24 (11.70)</td>
<td>0.50 (-0.86, 1.85)</td>
<td>0.47</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>77.03 (10.22)</td>
<td>76.47 (10.53)</td>
<td>76.8 (10.99)</td>
<td>76.77 (11.19)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup> difference between HC relative to HP diets estimated by mixed model analysis with adjustment for baseline value and centre;  
<sup>2</sup> p-value for the difference between the HC and HP diets
Table 4.6 Mean nutrient intake of participants on HP and HC diets at all time points

<table>
<thead>
<tr>
<th>Nutrient</th>
<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>P²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy KJ</td>
<td>HC</td>
<td>7850.2 (2298.1)</td>
<td>6815.4 (1841.1)</td>
<td>6784.4 (1792)</td>
<td>7093.2 (1851.2)</td>
<td>508.2 (110.3, 906.1)</td>
<td>0.012</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>7860.2 (2335.3)</td>
<td>7399.9 (3057)</td>
<td>7258 (2098)</td>
<td>7170.1 (1973.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein (g)</td>
<td>HC</td>
<td>88.1 (26.5)</td>
<td>80.9 (24.6)</td>
<td>82 (22.3)</td>
<td>84.4 (22.4)</td>
<td>11.8 (6.0, 17.6)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>87.8 (26)</td>
<td>95.3 (44.4)</td>
<td>91.2 (28.8)</td>
<td>87 (23.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein (%TE)</td>
<td>HC</td>
<td>19.2 (4)</td>
<td>20.2 (4.5)</td>
<td>20.6 (4.4)</td>
<td>20.3 (4.4)</td>
<td>1.1 (0.5, 1.8)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>19.1 (3.6)</td>
<td>21.9 (5.1)</td>
<td>21.2 (4.5)</td>
<td>20.6 (3.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHO (g)</td>
<td>HC</td>
<td>213.8 (66.7)</td>
<td>196.6 (60.7)</td>
<td>194.1 (55.6)</td>
<td>203.4 (56.6)</td>
<td>-3.2 (-14.9, 8.6)</td>
<td>0.599</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>219.8 (68.1)</td>
<td>198 (88.0)</td>
<td>190.6 (53.9)</td>
<td>194.1 (56.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHO (%TE)</td>
<td>HC</td>
<td>46.0 (7.9)</td>
<td>48.5 (8.7)</td>
<td>48.1 (7.4)</td>
<td>48.1 (6.6)</td>
<td>-3.7 (-5, -2.4)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>47.1 (7.6)</td>
<td>45.0 (8.3)</td>
<td>44.7 (8.2)</td>
<td>45.5 (6.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total fat (g)</td>
<td>HC</td>
<td>70.7 (28.4)</td>
<td>55.9 (22.6)</td>
<td>55.7 (21.2)</td>
<td>58.9 (23.1)</td>
<td>8.5 (4.1, 12.9)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>68.5 (27.9)</td>
<td>63.9 (31.9)</td>
<td>64.4 (28.6)</td>
<td>63.7 (24.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total fat (%TE)</td>
<td>HC</td>
<td>33.0 (6.9)</td>
<td>30.1 (6.9)</td>
<td>30.1 (6.0)</td>
<td>30.4 (6.8)</td>
<td>2.3 (1.2, 3.4)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>32.0 (6.6)</td>
<td>31.9 (7.9)</td>
<td>32.4 (7.3)</td>
<td>32.8 (6.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saturated fat</td>
<td>HC</td>
<td>27.1 (12.9)</td>
<td>20.3 (10)</td>
<td>21.1 (9.5)</td>
<td>22.4 (10.5)</td>
<td>3.1 (1.2, 5.0)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>26.7 (12.4)</td>
<td>24 (14.1)</td>
<td>23.8 (11.3)</td>
<td>24.4 (10.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saturated fat (% TE)</td>
<td>HC</td>
<td>12.6 (3.6)</td>
<td>10.9 (3.5)</td>
<td>11.3 (3.1)</td>
<td>11.5 (3.6)</td>
<td>0.9 (0.3, 1.4)</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>12.4 (3.5)</td>
<td>11.9 (3.8)</td>
<td>11.9 (3.2)</td>
<td>12.5 (3.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibre (g)</td>
<td>HC</td>
<td>22.9 (7.3)</td>
<td>23.9 (7.3)</td>
<td>23.8 (7.1)</td>
<td>23.7 (7.8)</td>
<td>0.4 (-1.06, 1.93)</td>
<td>0.568</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>23.4 (8.2)</td>
<td>25 (9.9)</td>
<td>25 (12.3)</td>
<td>23.2 (7.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol (g)</td>
<td>HC</td>
<td>5.5 (13.0)</td>
<td>3.7 (7.3)</td>
<td>3.1 (6.7)</td>
<td>3.4 (7.2)</td>
<td>1.2 (-0.47, 2.81)</td>
<td>0.161</td>
</tr>
<tr>
<td></td>
<td>HP</td>
<td>5.6 (14.8)</td>
<td>4.1 (13.4)</td>
<td>4.9 (16.4)</td>
<td>3.6 (10.6)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ difference between HC and HP diets estimated by ANCOVA with adjustment for baseline value and centre; ² p-value for the difference between the HC and HP diets
Numbers completing diet records at each timepoint: baseline – 417, 6 months – 311, 12 months – 285, 24 months - 274
Table 4.9 Blood and urine test results of participants on HP and HC diets at all time points (n = 419 total sample at baseline)

<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 (^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Cholesterol (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>4.61 (1.02)</td>
<td>4.49 (0.95)</td>
<td>4.57 (1.01)</td>
<td>4.43 (1.07)</td>
<td>0.01 (-0.12, 0.13)</td>
<td>0.91</td>
</tr>
<tr>
<td>HP</td>
<td>4.77 (0.98)</td>
<td>4.75 (1.01)</td>
<td>4.67 (0.96)</td>
<td>4.53 (0.98)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HDL (mmol/l)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>1.11 (0.28)</td>
<td>1.10 (0.31)</td>
<td>1.13 (0.29)</td>
<td>1.13 (0.32)</td>
<td>-0.01 (-0.05, 0.03)</td>
<td>0.64</td>
</tr>
<tr>
<td>HP</td>
<td>1.09 (0.32)</td>
<td>1.11 (0.29)</td>
<td>1.12 (0.31)</td>
<td>1.08 (0.30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LDL (mmol/l)</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>HC</td>
<td>2.67 (0.92)</td>
<td>2.59 (0.88)</td>
<td>2.59 (0.88)</td>
<td>2.47 (0.93)</td>
<td>0.06 (-0.07, 0.18)</td>
<td>0.39</td>
</tr>
<tr>
<td>HP</td>
<td>2.74 (0.91)</td>
<td>2.77 (1.01)</td>
<td>2.68 (0.94)</td>
<td>2.57 (0.92)</td>
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<td></td>
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<tr>
<td><strong>TAG (mmol/l)</strong></td>
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</tr>
<tr>
<td>HC</td>
<td>1.82 (0.84)</td>
<td>1.75 (0.84)</td>
<td>1.86 (0.92)</td>
<td>1.83 (0.96)</td>
<td>-0.03 (-0.15, 0.09)</td>
<td>0.64</td>
</tr>
<tr>
<td>HP</td>
<td>2.07 (1.34)</td>
<td>1.90 (1.08)</td>
<td>1.90 (1.12)</td>
<td>1.94 (1.08)</td>
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<td></td>
</tr>
<tr>
<td><strong>Fasting Glucose (mmol/l)</strong></td>
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<tr>
<td>HC</td>
<td>8.54 (2.54)</td>
<td>7.93 (2.14)</td>
<td>8.12 (2.19)</td>
<td>8.39 (2.62)</td>
<td>0.12 (-0.22, 0.45)</td>
<td>0.49</td>
</tr>
<tr>
<td>HP</td>
<td>8.45 (2.33)</td>
<td>7.99 (2.40)</td>
<td>8.38 (2.40)</td>
<td>8.56 (2.98)</td>
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<td></td>
</tr>
<tr>
<td><strong>HbA1c (%)</strong></td>
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</tr>
<tr>
<td>HC</td>
<td>7.99 (1.17)</td>
<td>7.69 (1.13)</td>
<td>7.81 (1.26)</td>
<td>8.09 (1.35)</td>
<td>0.01 (-0.17, 0.18)</td>
<td>0.96</td>
</tr>
<tr>
<td>HP</td>
<td>8.14 (1.20)</td>
<td>7.92 (1.32)</td>
<td>7.98 (1.29)</td>
<td>8.16 (1.49)</td>
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<td></td>
</tr>
<tr>
<td><strong>Serum Creatinine (µmol/l)</strong></td>
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</tr>
<tr>
<td>HC</td>
<td>74.64 (18.63)</td>
<td>76.12 (20.38)</td>
<td>76.25 (19.78)</td>
<td>78.51 (22.03)</td>
<td>0.69 (-1.84, 3.22)</td>
<td>0.59</td>
</tr>
<tr>
<td>HP</td>
<td>78.68 (25.47)</td>
<td>79.89 (19.48)</td>
<td>81.34 (20.57)</td>
<td>83.10 (23.57)</td>
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<tr>
<td><strong>Albumin/Creatinine ratio</strong></td>
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<tr>
<td>HC</td>
<td>3.21 (9.12)</td>
<td>3.32 (11.31)</td>
<td>3.28 (10.31)</td>
<td>3.89 (11.55)</td>
<td>1.42 (-2.85, 5.69)</td>
<td>0.52</td>
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<tr>
<td>HP</td>
<td>4.02 (14.97)</td>
<td>4.37 (16.27)</td>
<td>4.81 (23.35)</td>
<td>10.17 (58.68)</td>
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<td></td>
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</tbody>
</table>

\(^1\) difference between HC and HP diets estimated by mixed model analysis with adjustment for baseline value and centre; \(^2\) p-value for the difference between the HC and HP diets
<table>
<thead>
<tr>
<th>Variable</th>
<th>Category</th>
<th>6 Months</th>
<th>Univariate Estimate (95%CI)</th>
<th>p</th>
<th>Multivariate Estimate (95%CI)</th>
<th>p</th>
<th>24 Months</th>
<th>Univariate Estimate (95%CI)</th>
<th>p</th>
<th>Multivariate Estimate (95%CI)</th>
<th>p</th>
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<td>Univariate Estimate</td>
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<td>Multivariate Estimate</td>
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<td>p</td>
<td></td>
<td>p</td>
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<td></td>
<td>p</td>
<td></td>
<td>p</td>
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<tr>
<td>Lean Body Mass (kg)</td>
<td>15-25</td>
<td>N = 240</td>
<td>1.22 (-0.56, 3.01)</td>
<td>0.18</td>
<td>1.29 (-0.53, 3.10)</td>
<td>0.16</td>
<td>0.84</td>
<td>0.37 (-1.52, 2.26)</td>
<td>0.70</td>
<td>0.70</td>
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<tr>
<td></td>
<td>&gt;25</td>
<td>N = 62</td>
<td>0.48 (-1.56, 2.52)</td>
<td>0.64</td>
<td>0.78 (-1.30, 2.86)</td>
<td>0.46</td>
<td>1.71</td>
<td>0.16 (-0.65, 4.07)</td>
<td>0.10</td>
<td>0.02</td>
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<tr>
<td></td>
<td>Continuous variable</td>
<td>0.02 (-0.08, 0.12)</td>
<td>0.70</td>
<td>0.02 (-0.08, 0.12)</td>
<td>0.70</td>
<td>0.15</td>
<td>0.02 (-0.03, 0.28)</td>
<td></td>
<td>0.17</td>
<td>0.01 (-0.04, 0.30)</td>
<td></td>
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<tr>
<td>Triglycerides (mmol/l)</td>
<td>15-25</td>
<td>N = 240</td>
<td>-0.00 (-0.26, 0.26)</td>
<td>0.99</td>
<td>-0.01 (-0.28, 0.25)</td>
<td>0.93</td>
<td>-0.35</td>
<td>0.02 (-0.65, -0.05)</td>
<td>0.02</td>
<td>0.02</td>
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<tr>
<td></td>
<td>&gt;25</td>
<td>N = 62</td>
<td>-0.13 (-0.43, 0.17)</td>
<td>0.40</td>
<td>-0.18 (-0.48, 0.13)</td>
<td>0.26</td>
<td>-0.33</td>
<td>0.09 (-0.71, 0.05)</td>
<td>0.07</td>
<td>0.13</td>
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<tr>
<td></td>
<td>Continuous variable</td>
<td>-0.01 (-0.02, 0.01)</td>
<td>0.28</td>
<td>-0.01 (-0.02, 0.01)</td>
<td>0.23</td>
<td>0.01</td>
<td>-0.03 (-0.03, 0.01)</td>
<td></td>
<td>0.20</td>
<td>-0.02 (-0.04, 0.00)</td>
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<tr>
<td>Systolic BP (mmHg)</td>
<td>15-25</td>
<td>N = 240</td>
<td>6.48 (0.88, 12.08)</td>
<td>0.02</td>
<td>6.41 (0.75, 12.07)</td>
<td>0.03</td>
<td>0.95</td>
<td>0.77 (-5.39, 7.29)</td>
<td>0.81</td>
<td>0.81</td>
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<tr>
<td></td>
<td>&gt;25</td>
<td>N = 62</td>
<td>7.31 (0.92, 13.69)</td>
<td>0.03</td>
<td>6.53 (0.00, 13.05)</td>
<td>0.05</td>
<td>1.61</td>
<td>0.69 (-6.36, 9.58)</td>
<td>0.56</td>
<td>0.56</td>
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<tr>
<td></td>
<td>Continuous variable</td>
<td>0.21 (-0.09, 0.52)</td>
<td>0.17</td>
<td>0.17 (-0.14, 0.47)</td>
<td>0.29</td>
<td>-0.09</td>
<td>-0.09 (-0.52, 0.34)</td>
<td></td>
<td>0.68</td>
<td>-0.04 (-0.48, 0.40)</td>
<td></td>
</tr>
<tr>
<td>Serum creatinine (µmol/l)</td>
<td>15-25</td>
<td>N = 240</td>
<td>1.78 (-3.87, 7.43)</td>
<td>0.54</td>
<td>2.39 (-3.30, 8.08)</td>
<td>0.41</td>
<td>-7.68</td>
<td>&lt;0.01 (-13.31, -2.05)</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
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<tr>
<td></td>
<td>&gt;25</td>
<td>N = 62</td>
<td>2.24 (-4.21, 8.69)</td>
<td>0.50</td>
<td>3.45 (-3.12, 10.02)</td>
<td>0.30</td>
<td>-7.55</td>
<td>0.04 (-14.62, -0.47)</td>
<td>0.02</td>
<td>0.02</td>
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<tr>
<td></td>
<td>Continuous variable</td>
<td>0.10 (-0.21, 0.40)</td>
<td>0.55</td>
<td>0.08 (-0.23, 0.40)</td>
<td>0.60</td>
<td>-0.29</td>
<td>0.15 (-0.67, 0.10)</td>
<td></td>
<td>0.38</td>
<td>0.06 (-0.77, 0.02)</td>
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</tr>
</tbody>
</table>

Reference Category for % of Total Energy from Protein < 15 N = 27. 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.
Table 4.13 Mean daily food costs for sample menu plans

<table>
<thead>
<tr>
<th></th>
<th>HC</th>
<th>HP</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cost ($)</td>
<td>8.69</td>
<td>11.38</td>
<td>0.001</td>
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<tr>
<td>Cost/1000kJ ($)</td>
<td>1.44</td>
<td>1.68</td>
<td>0.06</td>
</tr>
<tr>
<td>Cost of protein ($)</td>
<td>3.92</td>
<td>6.54</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Table 4.14 Mean daily food costs for three day diet records at baseline and six months

<table>
<thead>
<tr>
<th></th>
<th>Time point</th>
<th>HC</th>
<th>HP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cost ($)</td>
<td>Baseline</td>
<td>10.99</td>
<td>10.68</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>10.83</td>
<td>12.74</td>
</tr>
<tr>
<td>Cost/1000kJ ($)</td>
<td>Baseline</td>
<td>1.54</td>
<td>1.41</td>
</tr>
<tr>
<td></td>
<td>6 Months</td>
<td>1.65</td>
<td>1.38</td>
</tr>
<tr>
<td>Cost of protein ($)</td>
<td>Baseline</td>
<td>4.35</td>
<td>3.52</td>
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<tr>
<td></td>
<td>6 Months</td>
<td>4.13</td>
<td>6.42*</td>
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</table>

*p = 0.01 for change from baseline