

	.				

## 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?

--	--

**DEWL Trial**  
**Baseline Questionnaire**

Study number:  
Participant initials:

	.				

**Medical Review:**

Do you have any allergies?  
If yes, list:

Yes  No

.....  
.....

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) Yes  No

If yes, explain:.....  
.....

Review past medical history and current medications recorded on Pre- Baseline questionnaire.

(update as necessary)

**DEWL Trial**  
**Baseline Questionnaire**

Study number:  
Participant initials:

	.				

**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: .....

**DEWL Trial**  
**Baseline Questionnaire**

Study number:  
 Participant initials:


**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   .

**DEWL Trial  
Baseline Questionnaire**

Study number:  
Participant initials:

	.				

*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 ( $\mu\text{mol/l}$ )

		/			/		

NB: If Creatinine  $>160\mu\text{mol/L}$  or has increased by more than  $30\mu\text{mol/L}$  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 ( $\mu\text{mol/l}$ )

		/			/		

Action taken (if any required):

.....

.....

.....

.....

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

		/			/		

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

		/			/		

## 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

Yes  No

### 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**  
**6 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 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 disorders~~ medical conditions since your last visit? Yes  No

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

~~(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? 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:

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

**DEWL Trial**  
**6 Month Questionnaire**

Study number:  .   
 Participant initials:

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.

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

**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):



**DEWL Trial**  
**6 Month Questionnaire**

Study number:  .   
 Participant initials:

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 ( $\mu$ mol/l)   
 Est GFR

*Urine sample:*

Urine albumin concentration  .   
 Urine creatinine concentration  .   
 Urine albumin: creatinine ratio  .

*24 Hour urine:*

24 hour urine protein  .

**DEWL Trial**  
**6 Month Questionnaire**

Study number:  .

Participant initials:

---

24 hour urine creatinine

 . 

24 hour urine sodium

 . 

24 hour urine nitrogen

 . 

hsCRP

 .

**DEWL Trial**  
**6 Month Questionnaire**

Study number:  .   
 Participant initials:

*LFT's:*

ALT (mmol/L)

AST (mmol/L)

GGT (mmol/L)

Albumin (mmol/L)

Bilirubin (mmol/L)

<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>

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

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

NB: If Creatinine  $>160\mu\text{mol/L}$  or has increased by more than  $30\mu\text{mol/L}$  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 ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

Action taken (if any required):

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

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

**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 Yes  No

**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:.....  
.....

**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:  
 .....

**DEWL Trial**  
**12 Month Questionnaire**

Study number:  .   
 Participant initials:

**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  .

**DEWL Trial**  
**12 Month Questionnaire**

Study number:  .   
 Participant initials:

*LFT's:*

ALT (mmol/L)

AST (mmol/L)

GGT (mmol/L)

Albumin (mmol/L)

Bilirubin (mmol/L)

<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>

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

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

NB: If Creatinine  $>160\mu\text{mol/L}$  or has increased by more than  $30\mu\text{mol/L}$  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 ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

Action taken (if any required):

.....

.....

.....

.....

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>

*Repeat test if required:*

Date of blood test

Serum creatinine ( $\mu\text{mol/l}$ )

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>
			<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>



**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

Yes  No

**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 (eg: a cold, any infection, trauma) Yes  No

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. Hyponosis, 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: .....

**DEWL Trial**  
**24 Month Questionnaire**

Study number: [ ] . [ ] [ ] [ ] [ ] [ ]  
Participant initials: [ ] [ ] [ ] [ ]

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: [ ] [ ] / [ ] [ ] / [ ] [ ]  
(Today's 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?  
.....  
.....  
.....  
.....

**DEWL Trial**  
**24 Month Questionnaire**

Study number:  .   
 Participant initials:

**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: .....

**DEWL Trial**  
**24 Month Questionnaire**

Study number:  .

Participant initials:

---

**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)

**DEWL Trial**  
**24 Month Questionnaire**

Study number: 

	.				
--	---	--	--	--	--

  
Participant initials: 

--	--	--

---

**Table 2.2 Loss of body and fat mass with high protein and high carbohydrate diets**

First Author, sample size and intervention description	Study Duration (wks)	BMI Range	Population Group	Carbohydrate: Protein (%TE)	Energy Intake (kJ)	Body Mass Change (kg)	P Value	Fat Mass Change (kg)	P Value
[58] Brinkworth n = 58 (4 + 16 Mths) Individual counselling	68	27-43	M + W, HI	40:30 HP 55:15 HC	6400/8200* 6700/8500*	-8.7 -4.1 -9.1 -2.9	0.44	-7.7 -4.2 -6.9 -2.6	0.2
[59] Brinkworth n = 66 (3 + 15 Mths) Individual counselling and provision of key foods	64	27-40	T2DM	40:30 HP 55:15 HC	6700/8700* 6700/8700*	-5.3 -3.8 -5.4 -2.1	0.17	-4.4 -1.4 -3.9 -0.1	0.29
[49] Claessens n = 48 Individual counselling and casein supplements	18	>27	M + W	45:25 HP 55:15 HC	2000*/7653** 2000*/7820**	-1.09† +1.19	0.01	-1.96 +0.24	Not stated
[50] Due n = 50 (6 + 12 mths) All food provided for 6 months, individual and group counselling	52	26-34	M + W	45:25 HP 58:12 HC	8400* 8200*	-9.4† -6.2 -5.9 -4.3	0.01	-7.6† -4.6 -4.3 -3.1	<0.01
[51] Evangelista n = 14 Individual counselling and written advice	12	>27	M + W, T2DM & heart failure	40:30 HP 55:15 HC Normal diet	5040/6300* 5040/6300*	-9.9† -5.6 -1.1	<0.01	NA	NA
[60] Farnsworth n = 56 Fixed menu plans, key foods provided, dietitians assessments fortnightly	12	27-43	M + W, HI	44:27 HP 57:16 HC	6300* 6500*	-9.0 -8.5	Not stated	-7.8 -7.3	Not stated
[61] Gardner n = 155 ‡ Group sessions and book	52	27-40	W	40:30 HP 52:18 HC	6694** 6321**	-1.6 -2.6	Not stated	NA	NA
[62] Johnston n = 20 All meals prepared in metabolic kitchen	6	Average: 28.7, 29.1	M + W	40:32 HP 65:15 HC	7080* 7080*	-4.7 -4.6	0.83	-2.8 -3.1	0.53
[68] Larsen n = 99 (3 and 12 mths) 9 individual counselling sessions and written advice	52	27-40	M + W, T2DM	40:30 HP 55:15 HC	6400* 6400*	-2.79 -2.23 -3.08 -2.17	0.78	NA	NA
[52] Layman n = 24 Group sessions and written advice	10	>26 Average: 30-35	W	41:30 HP 57:15 HC	6987* (7140) 6941* (7140)	-8.7† -7.8	<0.05	-5.9 -5	<0.05
[65] Lean n = 110 Written advice and some individual counselling	26	> 25	W	35:30 HP 58:20 HC	5040* 5040*	-6.8 -5.6	0.28	NA	NA
[64] Luscombe n = 26 Fixed menu plans, key	12	Average: 32.6	T2DM	42:28 HP 55:16 HC	6657* 6649*	-4.9 -4.3	0.6	NA	NA



foods supplied, fortnightly dietitian assessment		33.9							
[63] Luscombe n = 36 Fixed menu plans, key foods supplied, fortnightly dietitian assessment	16	27-43	M + W, HI	44:27 HP 57:16 HC	6358* 6663*	-7.9 -8.0	Not stated	NA	NA
[48] McAuley N = 62 ‡ (6 + 12 Mths) Written advice, some dietary counselling	52	>27	W, HI	40:30 HP 55:15 HC	6156** 6114**	-8.0† -6.6 -5.9 -4.4	<0.05	-4.5 -3.8 -4.1 -3.5	Not stated
[53] Meckling‡ n = 30 Written material and some counselling	12	25-30	W	35:35 HP 54:18 HC	5787** 5822**	-4.6† -2.1	<0.05	-5.2 -3.7	Not stated
[66] Noakes n = 100 Individual counselling and provision of key foods	12	27-40	W	44:31 HP 61:17 HC	5310* 5219*	-7.6 -6.9	0.04	-5.7 -4.5	Not stated
[67] Sargrad n = 12 Individual dietary counselling and written advice	8	Average: 33-36	T2DM	40:30 HP 55:15 HC	5351* 5758*	-2.5 -2.2	0.9	-2.2 -2.6	Not stated
[54] Skov n = 50 All food provided, individual counselling	26	25-34	M + W	46:25 HP 59:12 HC	8950** 10900**	-8.7† -5.0	<0.01	-7.6† -4.3	<0.01
[55] Te Morenga n = 83 Individual counselling, provision of key foods, written advice	8	>27	W	40:30 HP 50: 20 HC	6509* 5976*	-4.5† -3.3	0.04	-4.0† -2.5	0.03
[47]Te Morenga n= 89 Individual counselling, provision of key foods and written advice	10	Average: 32.5	W	50:30 HP 50:20 LP	7155** 7418**	-1.5† -0.2	<0.01	-1† -0.1	0.01

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**

First Author	Study Duration (wks)	Carbohydrate: Protein (%TE)	Total Chol (mmol/L)	HDL (mmol/L)	LDL (mmol/L)	TAG (mmol/L)
Brinkworth n = 66 (3 + 15 Mths)	64	40:30 HP 55:15 HC	-0.37 +0.08 -0.1 +0.35	-0.02 +0.16 +0.03 +0.15	-0.18 -0.19 -0.03 +0.27	-0.42 +0.06 -0.18 -0.13
Brinkworth n = 58 (4 + 16 Mths)	68	40:30 HP 55:15 HC	-0.4 0.0 -0.2 +0.6	0.0 +0.15 +0.04 +0.14	-0.2 0.0 -0.3 +0.4	-0.5 -0.3 -0.1 0.0
Claessons n = 48	18	45:25 HP 55:15 HC	+0.58 +0.73	+0.2 +0.1	+0.36 +0.43	-0.06 +0.56
Due n = 50 (6 + 12 mths)	52	45:25 HP 58:12 HC	-0.31 +0.1 +0.03 +0.68	-0.03 +0.12 -0.21 +0.09	Not reported	-0.15 -0.05 +0.11 +0.33
Evangelista N = 14	12	40:30 HP 55:15 HC Normal diet	-0.9 -0.5 +0.43	+0.39† No change No change	-0.12† No change +0.8	-1.7† -0.46 +0.05
Farnsworth n = 56	12	44:27 HP 57:16 HC	-0.6 -0.3	+0.08 +0.06	-0.28 +0.10	-0.52 † -0.21
Gannon n = 12	5 x-over With WO	40:30 HP 55:15HC	4.4‡ 4.7‡	1.0‡ 1.0‡	2.6‡ 2.6‡	1.8‡ † 2.2‡
Gardner n = 155 (6 + 12 months)	52	40:30 HP 52:18 HC	Not Reported	+0.09 +0.06 +0.05 +0.07	+0.01 0.0 -0.06 +0.02	-0.24 -0.04 -0.18 -0.16
Larsen n = 99 (3 and 12 mths)	52	40:30 HP 55:15 HC	-0.23 -0.15 -0.31 +0.01	0.00 +0.08 0.00 +0.08	-0.04 -0.05 -0.11 +0.04	-0.50 -0.47 -0.45 -0.30
Layman n = 24	10	41:30 HP 57:15 HC	-0.24 -0.55	-0.03† -0.10	-0.07 -0.45†	-0.3† -0.02
Johnston n = 16	6	40:32 HP 65:15 HC	-9.5 %* -12.2 %*	-13.5 %* -19.1 %*	-8.2 %* -12.4 %*	-18.6 %* -11.9 %*
Lean n = 110	26	35:30 HP 58:20 HC	-0.12 -0.34	+0.05 -0.02	-0.03 -0.17	-0.25 -0.27
McAuley N = 62 ‡ (6 + 12 Mths)	52	40:30 HP 55:15 HC	-0.5 -0.4 -0.6 -0.4	+0.01 +0.05 -0.05 -0.2	-0.03 -0.2 0.0 -0.1	-0.55 † -0.66† -0.34 -0.31
Noakes N = 100	12	44:31 HP 61:17 HC	-0.48 -0.33	-0.09 -0.09	-0.26 -0.19	-0.30 † -0.11
Sargrad n = 12	8	40:30 HP 55:15 HC	-0.81 -0.81	-0.08§ -0.05	-0.32 -0.36§	-2.00 -1.97
Te Morenga n= 89	10	50:30 HP 50:20 LP	-0.21† +0.16	-0.02 -0.01	-0.14† +0.06	-0.11 0.00

‡ 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**

First Author	Duration (wks)	Carbohydrate: Protein (%TE)	Energy intake (kJ)	HbA1c (%)	Fasting glucose (mmol/L)	Fasting serum Insulin (pmol/L)	Serum Creatinine (µmmol/L)
Brinkworth n = 66 (3 + 12 Mths)	64	40:30 HP 55:15 HC	6700/8700* 6700/8700*	-0.5 +0.1 -0.5 +0.4	-0.6 0.0 -0.6 +1.1	-15.6 +1.2 -13.2 +11.4	NA**
Evangelista n = 14	12	40:30 HP 55:15 HC Normal diet	5040/6300* 5040/6300*	-0.7 -0.8 -0.5	NA	NA	NA
Gannon n = 12	5 (x-over With washout)	40:30 HP 55:15 HC	9387* 9517*	-0.8† -0.3	No change No change	110‡ 104‡	No change No change
Larsen n = 99 (3 and 12 mths)	52	40:30 HP 55:15 HC	6400* 6400*	-0.52 -0.23 -0.49 -0.28	NA	NA	NA
Sargrad n = 12	8	40:30 HP 55:15 HC	5351* 5758*	-1.0 -1.3 †	No change -1.6 †	-19 -11	No change No change

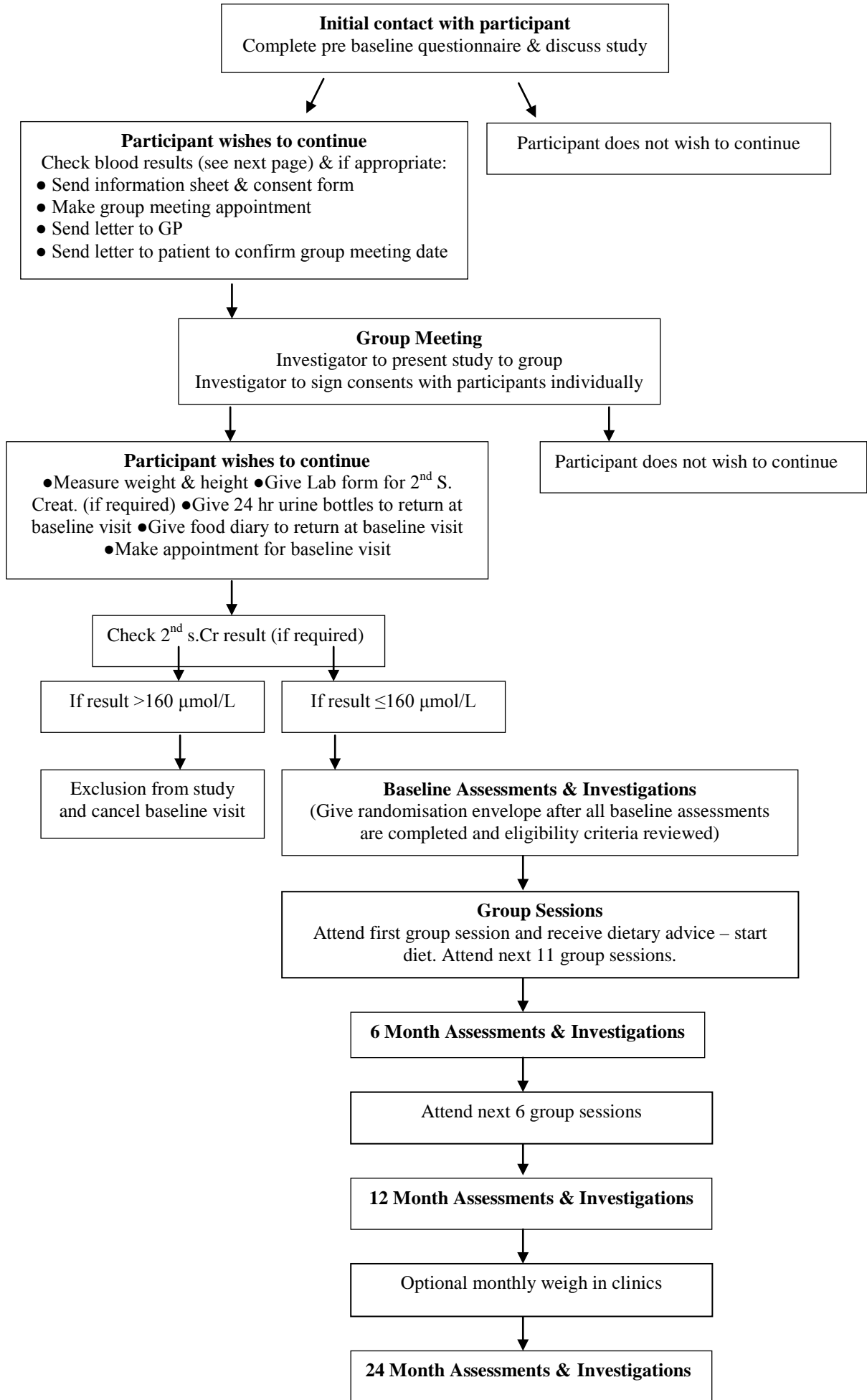
† p < 0.05 for difference between the diets

\* Fixed energy intake

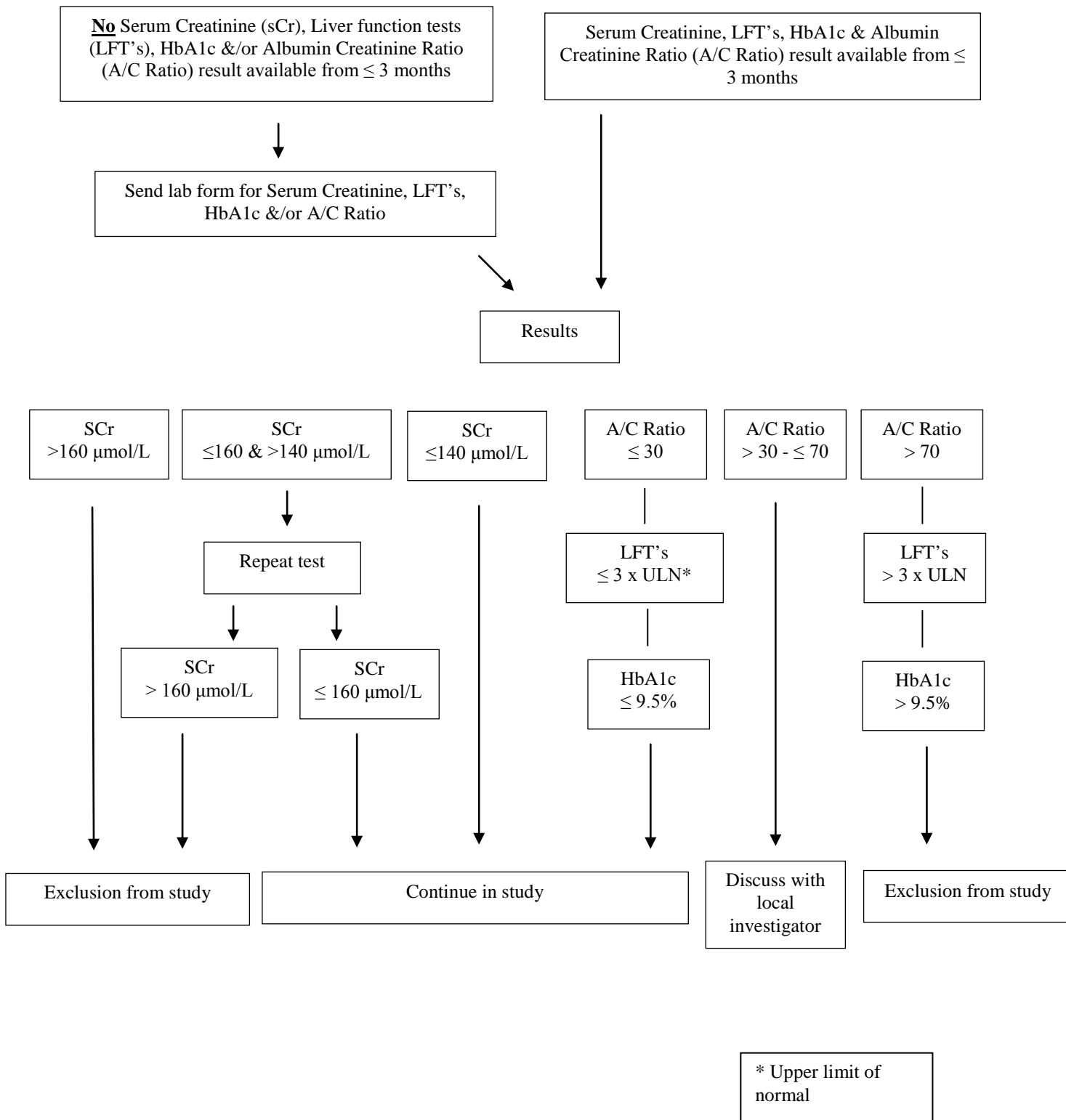
\*\* Measured urinary albumin excretion with no change throughout the study

‡ Actual final result – no comparison given

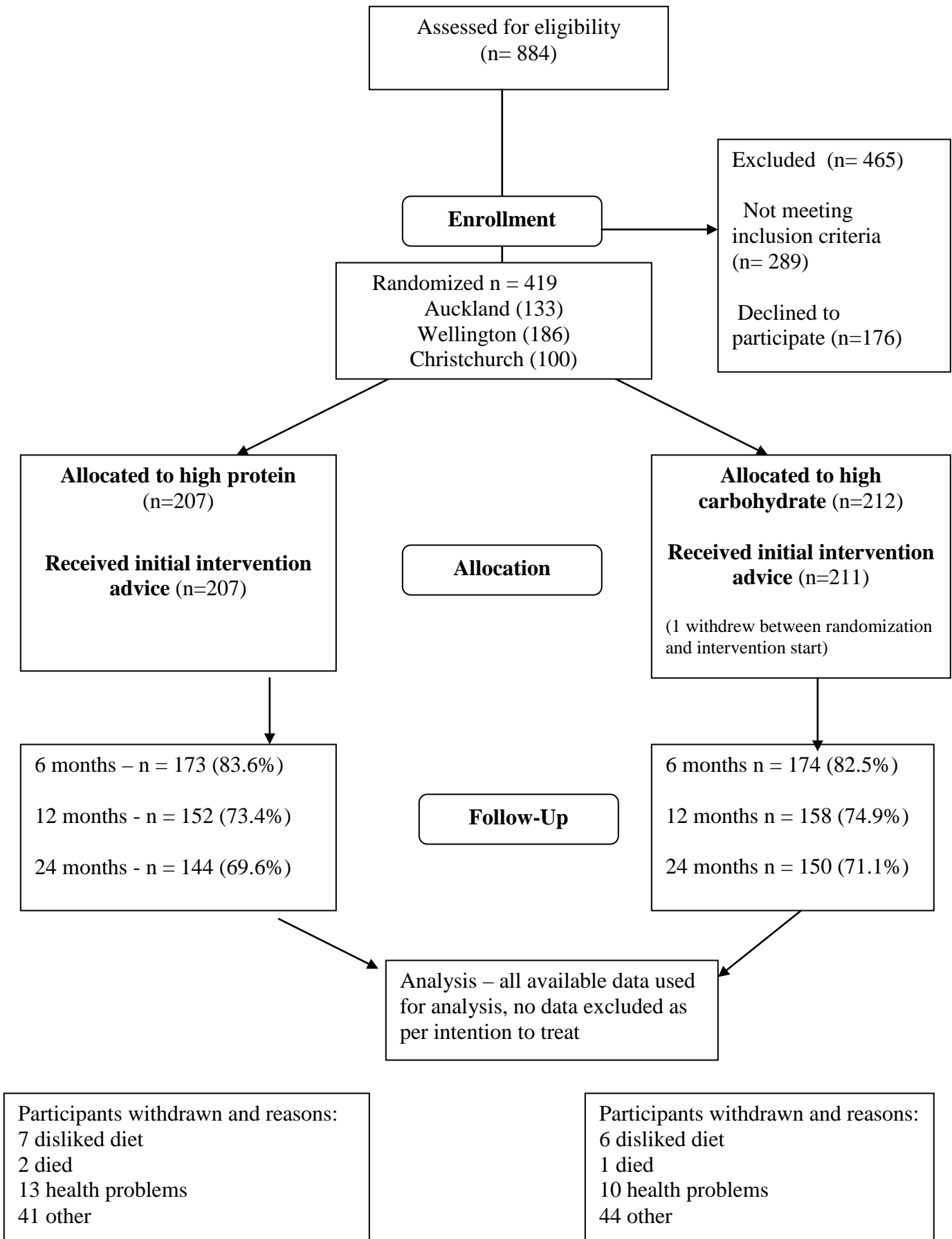
**Figure 3.1 Process of recruitment and intervention**



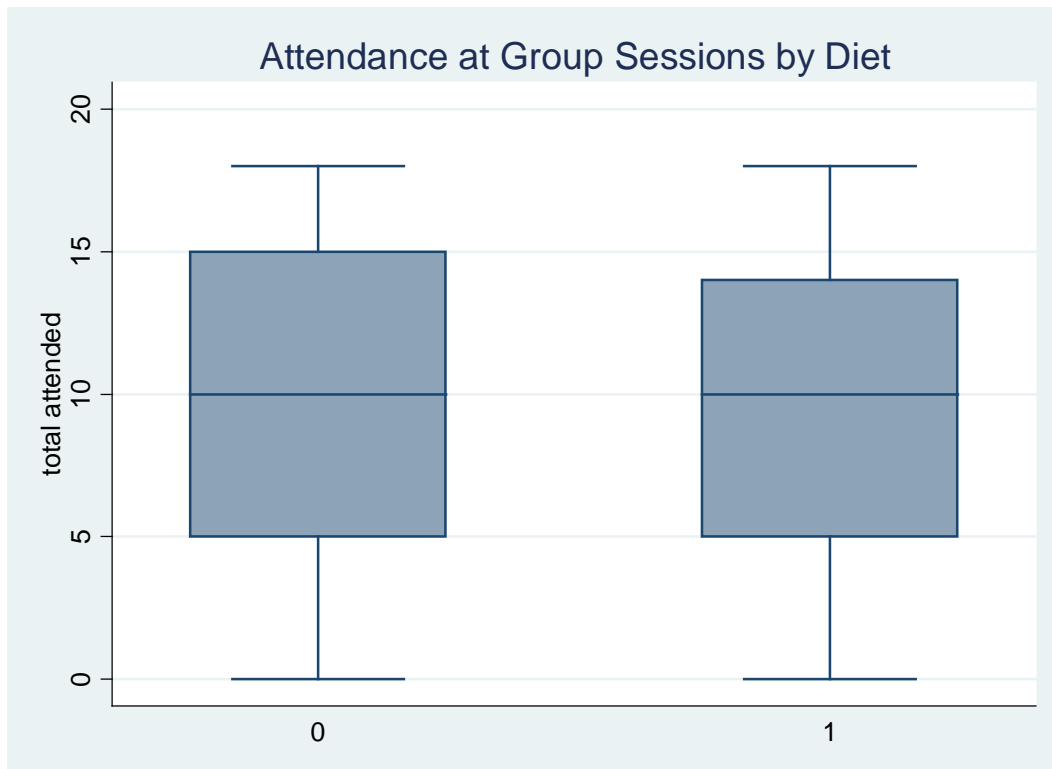
**Figure 3.2 Process of determining eligibility from blood results**



**Figure 4.1: Consort diagram of participant recruitment and retention**

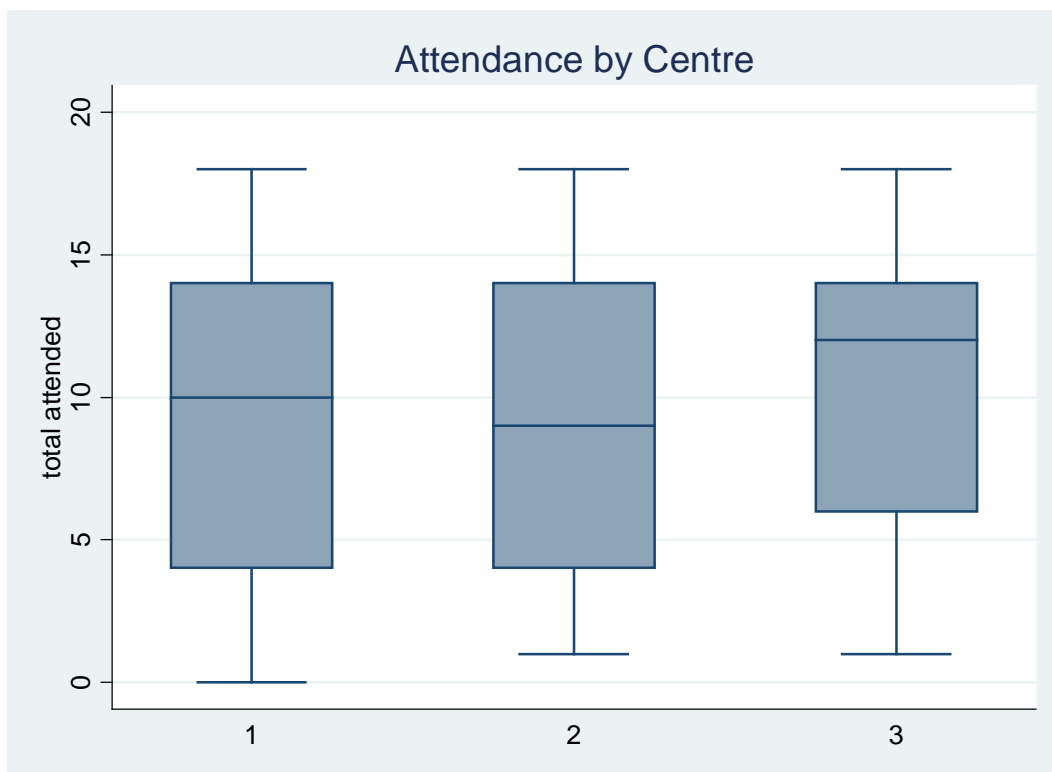


**Figure 4.2** Attendance at group sessions by diet (n = 18)



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)



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)

Variable	Group	Baseline (SD)	6 months (SD)	12 months (SD)	24 months (SD)	Difference (95% CI) <sup>1</sup>	P <sup>2</sup>
Weight (kg)	HC	101.94 (20.10)	98.69 (19.25)	99.48 (19.12)	95.94 (17.06)	-0.24 (-1.33, 0.86)	0.67
	HP	103.42 (19.73)	100.17 (18.76)	100.24 (17.83)	99.45 (17.18)		
BMI (kg/m <sup>2</sup> )	HC	36.67 (6.42)	35.47 (6.61)	35.80 (6.12)	35.04 (5.59)	-0.25 (-0.62, 0.13)	0.19
	HP	36.55 (6.70)	35.54 (6.36)	35.35 (6.17)	34.88 (6.10)		
Waist Circumference (cm)	HC	115.10 (13.49)	112.10 (13.15)	112.03 (13.86)	108.73 (12.07)	0.49 (-0.73, 1.71)	0.43
	HP	114.37 (13.67)	111.54 (12.95)	111.44 (12.78)	110.06 (14.05)		
Total Body Fat (kg)	HC	45.18 (14.34)	42.94 (14.26)	43.53 (14.20)	41.38 (12.80)	-0.51 (-1.61, 0.60)	0.37
	HP	43.89 (13.90)	41.64 (12.85)	41.10 (12.57)	40.88 (11.89)		
Fat Free Mass (kg)	HC	56.64 (11.32)	55.63 (10.51)	55.74 (10.42)	54.50 (9.44)	0.20 (-0.65, 1.05)	0.65
	HP	59.54 (12.14)	58.42 (11.80)	58.91 (11.61)	57.88 (10.64)		
Systolic BP (mmHg)	HC	131.20 (17.01)	129.26 (16.25)	129.75 (17.13)	131.53 (20.02)	1.64 (-0.67, 3.94)	0.16
	HP	133.03 (26.65)	130.78 (17.13)	130.97 (16.99)	132.91 (20.82)		
Diastolic BP (mmHg)	HC	76.93 (10.90)	76.07 (10.31)	76.25 (10.50)	76.24 (11.70)	0.50 (-0.86, 1.85)	0.47
	HP	77.03 (10.22)	76.47 (10.53)	76.8 (10.99)	76.77 (11.19)		

<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

Nutrient	Group	Baseline (SD)	6 months (SD)	12 months (SD)	24 months (SD)	Difference (95% CI) <sup>1</sup>	P <sup>2</sup>
Energy KJ	HC	7850.2 (2298.1)	6815.4 (1841.1)	6784.4 (1792)	7093.2 (1851.2)	508.2 (110.3, 906.1)	0.012
	HP	7860.2 (2335.3)	7399.9 (3057)	7258 (2098)	7170.1 (1973.6)		
Protein (g)	HC	88.1 (26.5)	80.9 (24.6)	82 (22.3)	84.4 (22.4)	11.8 (6.0, 17.6)	0.000
	HP	87.8 (26)	95.3 (44.4)	91.2 (28.8)	87 (23.5)		
Protein (% TE)	HC	19.2 (4)	20.2 (4.5)	20.6 (4.4)	20.3 (4.4)	1.1 (0.5, 1.8)	0.001
	HP	19.1 (3.6)	21.9 (5.1)	21.2 (4.5)	20.6 (3.9)		
CHO (g)	HC	213.8 (66.7)	196.6 (60.7)	194.1 (55.6)	203.4 (56.6)	-3.2 (-14.9, 8.6)	0.599
	HP	219.8 (68.1)	198 (88.0)	190.6 (53.9)	194.1 (56.6)		
CHO (% TE)	HC	46.0 (7.9)	48.5 (8.7)	48.1 (7.4)	48.1 (6.6)	-3.7 (-5, -2.4)	0.000
	HP	47.1 (7.6)	45.0 (8.3)	44.7 (8.2)	45.5 (6.9)		
Total fat (g)	HC	70.7 (28.4)	55.9 (22.6)	55.7 (21.2)	58.9 (23.1)	8.5 (4.1, 12.9)	0.000
	HP	68.5 (27.9)	63.9 (31.9)	64.4 (28.6)	63.7 (24.3)		
Total fat (% TE)	HC	33.0 (6.9)	30.1 (6.9)	30.1 (6.0)	30.4 (6.8)	2.3 (1.2, 3.4)	0.000
	HP	32.0 (6.6)	31.9 (7.9)	32.4 (7.3)	32.8 (6.3)		
Saturated fat	HC	27.1 (12.9)	20.3 (10)	21.1 (9.5)	22.4 (10.5)	3.1 (1.2, 5.0)	0.001
	HP	26.7 (12.4)	24 (14.1)	23.8 (11.3)	24.4 (10.4)		
Saturated fat (% TE)	HC	12.6 (3.6)	10.9 (3.5)	11.3 (3.1)	11.5 (3.6)	0.9 (0.3, 1.4)	0.002
	HP	12.4 (3.5)	11.9 (3.8)	11.9 (3.2)	12.5 (3.2)		
Fibre (g)	HC	22.9 (7.3)	23.9 (7.3)	23.8 (7.1)	23.7 (7.8)	0.4 (-1.06, 1.93)	0.568
	HP	23.4 (8.2)	25 (9.9)	25 (12.3)	23.2 (7.4)		
Alcohol (g)	HC	5.5 (13.0)	3.7 (7.3)	3.1 (6.7)	3.4 (7.2)	1.2 (-0.47, 2.81)	0.161
	HP	5.6 (14.8)	4.1 (13.4)	4.9 (16.4)	3.6 (10.6)		

<sup>1</sup> difference between HC and HP diets estimated by ANCOVA with adjustment for baseline value and centre; <sup>2</sup> 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)

	Group	Baseline (SD)	6 months (SD)	12 months (SD)	24 months (SD)	Difference (95% CI) <sup>1</sup>	P <sup>2</sup>
Total Cholesterol (mmol/l)	HC	4.61 (1.02)	4.49 (0.95)	4.57 (1.01)	4.43 (1.07)	0.01 (-0.12, 0.13)	0.91
	HP	4.77 (0.98)	4.75 (1.01)	4.67 (0.96)	4.53 (0.98)		
HDL (mmol/l)	HC	1.11 (0.28)	1.10 (0.31)	1.13 (0.29)	1.13 (0.32)	-0.01 (-0.05, 0.03)	0.64
	HP	1.09 (0.32)	1.11 (0.29)	1.12 (0.31)	1.08 (0.30)		
LDL (mmol/l)	HC	2.67 (0.92)	2.59 (0.88)	2.59 (0.88)	2.47 (0.93)	0.06 (-0.07, 0.18)	0.39
	HP	2.74 (0.91)	2.77 (1.01)	2.68 (0.94)	2.57 (0.92)		
TAG (mmol/l)	HC	1.82 (0.84)	1.75 (0.84)	1.86 (0.92)	1.83 (0.96)	-0.03 (-0.15, 0.09)	0.64
	HP	2.07 (1.34)	1.90 (1.08)	1.90 (1.12)	1.94 (1.08)		
Fasting Glucose (mmol/l)	HC	8.54 (2.54)	7.93 (2.14)	8.12 (2.19)	8.39 (2.62)	0.12 (-0.22, 0.45)	0.49
	HP	8.45 (2.33)	7.99 (2.40)	8.38 (2.40)	8.56 (2.98)		
HbA1c (%)	HC	7.99 (1.17)	7.69 (1.13)	7.81 (1.26)	8.09 (1.35)	0.01 (-0.17, 0.18)	0.96
	HP	8.14 (1.20)	7.92 (1.32)	7.98 (1.29)	8.16 (1.49)		
Serum Creatinine (µmol/l)	HC	74.64 (18.63)	76.12 (20.38)	76.25 (19.78)	78.51 (22.03)	0.69 (-1.84, 3.22)	0.59
	HP	78.68 (25.47)	79.89 (19.48)	81.34 (20.57)	83.10 (23.57)		
Albumin/Creatinine ratio	HC	3.21 (9.12)	3.32 (11.31)	3.28 (10.31)	3.89 (11.55)	1.42 (-2.85, 5.69)	0.52
	HP	4.02 (14.97)	4.37 (16.27)	4.81 (23.35)	10.17 (58.68)		

<sup>1</sup> difference between HC and 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 4.12:** Exploratory subgroup analysis of relationship between protein, lean body mass, triglycerides, systolic blood pressure and serum creatinine

Variable	Category	6 Months			24 Months				
		Univariate Estimate (95% CI)	p	Multivariate Estimate (95% CI)	p	Univariate Estimate (95% CI)	p	Multivariate Estimate (95% CI)	p
Lean Body Mass (kg)	15-25 N = 240	1.22 (-0.56, 3.01)	0.18	1.29 (-0.53, 3.10)	0.16	0.19 (-1.68, 2.07)	0.84	0.37 (-1.52, 2.26)	0.70
	>25 N = 62	0.48 (-1.56, 2.52)	0.64	0.78 (-1.30, 2.86)	0.46	1.71 (-0.65, 4.07)	0.16	2.00 (-0.39, 4.39)	0.10
	Continuous variable	0.02 (-0.08, 0.12)	0.70	0.02 (-0.08, 0.12)	0.70	0.15 (0.03, 0.28)	<b>0.02</b>	0.17 (0.04, 0.30)	<b>0.01</b>
Triglycerides (mmol/l)	15-25 N = 240	-0.00 (-0.26, 0.26)	0.99	-0.01 (-0.28, 0.25)	0.93	-0.35 (-0.65, -0.05)	<b>0.02</b>	-0.37 (-0.67, -0.06)	<b>0.02</b>
	>25 N = 62	-0.13 (-0.43, 0.17)	0.40	-0.18 (-0.48, 0.13)	0.26	-0.33 (-0.71, 0.05)	0.09	-0.36 (-0.75, 0.02)	0.07
	Continuous variable	-0.01 (-0.02, 0.01)	0.28	-0.01 (-0.02, 0.01)	0.23	-0.01 (-0.03, 0.01)	0.20	-0.02 (-0.04, 0.00)	0.13
Systolic BP (mmHg)	15-25 N = 240	6.48 (0.88, 12.08)	<b>0.02</b>	6.41 (0.75, 12.07)	<b>0.03</b>	0.95 (-5.39, 7.29)	0.77	0.80 (-5.59, 7.18)	0.81
	>25 N = 62	7.31 (0.92, 13.69)	<b>0.03</b>	6.53 (0.00, 13.05)	<b>0.05</b>	1.61 (-6.36, 9.58)	0.69	2.39 (-5.66, 10.44)	0.56
	Continuous variable	0.21 (-0.09, 0.52)	0.17	0.17 (-0.14, 0.47)	0.29	-0.09 (-0.52, 0.34)	0.68	-0.04 (-0.48, 0.40)	0.86
Serum creatinine (µmol/l)	15-25 N = 240	1.78 (-3.87, 7.43)	0.54	2.39 (-3.30, 8.08)	0.41	-7.68 (-13.31, -2.05)	<b>&lt;0.01</b>	-7.97 (-13.64, -2.30)	<b>&lt;0.01</b>
	>25 N = 62	2.24 (-4.21, 8.69)	0.50	3.45 (-3.12, 10.02)	0.30	-7.55 (-14.62, -0.47)	<b>0.04</b>	-8.89 (-16.03, -1.75)	<b>0.02</b>
	Continuous variable	0.10 (-0.21, 0.40)	0.55	0.08 (-0.23, 0.40)	0.60	-0.29 (-0.67, 0.10)	0.15	-0.38 (-0.77, 0.02)	0.06

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

	HC	HP	P value
Total Cost (\$)	8.69	11.38	0.001
Cost/1000kJ (\$)	1.44	1.68	0.06
Cost of protein (\$)	3.92	6.54	0.003

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

	Time point	HC	HP
Total Cost (\$)	Baseline	10.99	10.68
	6 Months	10.83	12.74
Cost/1000kJ (\$)	Baseline	1.54	1.41
	6 Months	1.65	1.38
Cost of protein (\$)	Baseline	4.35	3.52
	6 Months	4.13	6.42*

\*p = 0.01 for change from baseline