



**Prediabetes Intervention Package (PIP) in  
Primary Care Study - What predicts regression  
from prediabetes to normal glucose  
regulation?**

**INTERVENTION MANUAL**

## **Prediabetes Intervention Package (PIP) in Primary Care Study - what predicts regression from prediabetes to normoglycaemia?**

### **Contents**

1. Key Facts	3
2. Study Overview	4
3. Protocols	
a. Potential eligible study participants	10
b. Identifying and inviting eligible study participants	11
c. Practice environment	13
d. Welcome to the baseline study appointment – PIP0-B	14
e. Baseline study appointment – PIP0-B	15
f. Study appointment two @ 1-2 weeks – PIP2W	22
g. Study appointment three @ 5-6 weeks – PIP6W	25
h. Study appointment four @ 3 months – PIP3M	28
i. Study appointment five @ 4 months – PIP4M	32
j. Study appointment six @ 6 months – PIP6M	35
k. Study appointment seven @ 9 months – PIP9M	42
l. Study appointment eight @ 12 months – PIP12M	43
m. Study appointment nine @ 15 months – PIP15M	50
n. Study appointment twelve @ 18 months – PIP18M	51
o. Study appointment twelve @ 21 months – PIP21M	52
p. Study appointment twelve @ 24 months – PIP24M	53
4. Appendices	
1. Study invitation letter	60
2. Decline to participate in study form	61
3. Participant information sheet and consent form	62
4. Clinical measurements protocol	68
5. Starting The Conversation (STC): Diet	72
6. PIP in primary care study detailed dietary assessment (DDA) guide	73
7. Stanford programme group education information	75
8. Additional information to be collected by the Research Nurse	76
9. Research specific questionnaires	77
10. Fasting blood sample collection and transport	95
11. Key contacts and study investigators	97

## 1. Key Facts

- Prediabetes (also known as intermediate glycaemia) is a metabolic condition that substantially increases the risk of developing type 2 diabetes (T2DM).
- Prediabetes is typically defined as blood glucose levels higher than normal, but lower than the threshold for diabetes. In New Zealand the definition of prediabetes is HbA1c 41-49mmol/mol or fasting plasma glucose 6.1-6.9 mmol/L.<sup>1</sup>
- In New Zealand screening for diabetes and prediabetes is recommended as part of a cardiovascular risk assessment.<sup>1</sup>
- Prevalence data for prediabetes and diabetes from the 2008/09 Adult Nutrition Survey for different groups aged 15 years and over are shown in the table below.<sup>2</sup>

	Diabetes*	Prediabetes**
Men	8.3%	26.4%
Women	5.8%	24.8%
Maori	9.8%	30.4%
Pacific	15.4%	29.8%
NZ European and Other	6.1%	24.6%
Normal weight	2.5%	19.5%
Overweight	5.9%	26.9%
Obese	14.2%	32.2%
TOTAL POPULATION	7.0%	25.5%

\* Diabetes includes self-reported diagnosed diabetes and undiagnosed diabetes

\*\* Prediabetes defined using the American Diabetes Association diagnostic criteria for HbA1c

- **Implementation of intensive lifestyle advice has the potential to approximately halve the risk of progression from prediabetes to T2DM.<sup>3</sup>**
- **Among those with prediabetes, there is the potential for every 1kg weight loss, the risk of progressing to diabetes is reduced by 16%.<sup>4</sup>**

1. New Zealand Guidelines Group. New Zealand Primary Care Handbook 2012. 3rd ed. Wellington: New Zealand Guidelines Group; 2012.

2. Coppell K, Mann J, Williams S, Jo E, Drury P, Miller J, Parnell W. Prevalence of diagnosed and undiagnosed diabetes and pre-diabetes in New Zealand: findings from the 2008/09 Adult Nutrition Survey New Zealand Medical Journal. 2013;126(1370):1-20.

3. Gillies CL, Abrams KR, Lambert PC, Cooper NJ, Sutton AJ, Hsu RT, Khunti K. Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. BMJ. 2007;334(7588):19.

4. Hamman RF, Wing RR, Edelstein SL, Lachin JM, Bray GA, Delahanty L, Hoskin M, Kriska AM, Mayer-Davis EJ, Pi-Sunyer X, Regensteiner J, Venditti B, Wylie-Rosett J. Effect of weight loss with lifestyle intervention on risk of diabetes. Diabetes Care. 2006;29(9):2102-7.

PIP in Primary Care Study – Key Facts. 18 Jan 2017.

## 2. Study Overview

The aim of the next part of the Prediabetes Intervention Package (PIP) in Primary Care Study:

***To determine if there are clinically relevant differences between those who regress to normoglycaemia, those with persistent prediabetes and those who progress to type 2 diabetes***

The following is a schematic overview of the study:

Identify eligible patients at participating practices using DrInfo PMS audits.



Invite potential participant patients via letter



**INTERVENTION** = 12 individual sessions + 6 community group education.

GPs and PNs opportunistically encourage goal achievement

<u>VISIT</u>	<u>Practice Nurse Consultation</u>
PIP0-B	assessment, goals & advice; baseline measures <b>(45 min)</b>
PIP2W	review & questions; refer Stanford programme (15 min)
PIP6W	reassess & advice (15 min)
PIP3M	reassess & advice (15 min)
PIP4M	reassess & advice (15 min)
PIP6M	reassess & advice; 6 month measures <b>(30 min)</b>
PIP9M	reassess & advice (15 min)
PIP12M	reassess & advice; 12 month measures <b>(30 min)</b>
PIP15M	reassess & advice (15 min)
PIP18M	reassess & advice (15 min)
PIP21M	reassess & advice (15 min)
PIP24M	review & questions; end of study measures <b>(30 min)</b>

**Additional Research Data** at baseline, 6 months, 12 months and 24 months to be collected by a research nurse separate from the clinical visit



Data analysis & interpretation



Feedback to study participants (organisations, practices and patients) & report writing, etc

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### **The following provides a brief explanation for the schematic overview:**

Recruitment of patients through identifying eligible patients at participating practices using DrInfo PMS audits.

#### **Visit PIP0-B @ baseline (45 minutes)**

- information sheet and study consent
- clinical measures (BP, height, weight, waist circumference)
- check blood test results. *If no results within last 4 weeks*, repeat HbA1c, lipids, LFTs (AST, ALT, GGT) and urate, and urine albumin creatinine ratio.
- dietary assessment and goal setting using STC: Diet tool + give dietary advice and appropriate nutrition pamphlet(s)
- give 'Be Active Every Day' pamphlet
- ADDITIONAL questionnaire to be completed with Research Nurse + fasting bloods organised

#### **Visit PIP2W @ 1-2 weeks (15 minutes)**

- record weight, review nutrition goals, reinforce dietary advice and answer questions
- refer to Stanford Programme

#### **Visit or Phone PIP6W @ 5-6 weeks (15 minutes)**

- record weight, review nutrition goals, reinforce dietary advice and answer questions

#### **Visit PIP3M @ 3 months (15 minutes)**

- routine clinical measures (BP, weight, waist circumference) + HbA1c
- review nutrition goals, reinforce dietary advice and answer questions

#### **Visit or Phone PIP4M @ 4 months (15 minutes)**

- record weight, review nutrition goals, reinforce dietary advice and answer questions

## NOT FOR CIRCULATION

### **Visit PIP6M @ 6 months (30 minutes)**

- repeat clinical measures (BP, weight, height, waist circumference)
- repeat blood tests - HbA1c, lipids, LFTs (AST, ALT, GGT) and urate, and urine albumin creatinine ratio.
- reassess diet and review nutrition goals using STC: Diet + give dietary advice and appropriate nutrition pamphlet(s)
- ADDITIONAL questionnaire to be completed with Research Nurse + fasting bloods organised

### **Visit PIP9M @ 9 months (15 minutes)**

- routine clinical measures (BP, weight, waist circumference)
- review goals, reinforce dietary advice and answer questions

### **Visit PIP12M @ 12 months (30 minutes)**

- routine clinical measures (BP, weight, waist circumference)
- repeat blood tests - HbA1c, lipids, LFTs (AST, ALT, GGT) and urate, and urine albumin creatinine ratio.
- reassess diet and review nutrition goals using STC: Diet + give dietary advice and appropriate nutrition pamphlet(s)
- ADDITIONAL questionnaire to be completed with Research Nurse + fasting bloods organised

### **Visit PIP15M @ 15 months (15 minutes)**

- routine clinical measures (BP, weight, waist circumference)
- review nutrition goals, reinforce dietary advice and answer questions

### **Visit PIP18M @ 18 months (15 minutes)**

- routine clinical measures (BP, weight, waist circumference) + recommended HbA1c

PIP in Primary Care Study – Study Overview. 18 Jan 2017.

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- review nutrition goals, reinforce dietary advice and answer questions

### **Visit PIP21M @ 21 months (15 minutes)**

- routine clinical measures (BP, weight, waist circumference)
- review nutrition goals, reinforce dietary advice and answer questions

### **Visit PIP24M @ 24 months (30 minutes)**

- repeat clinical measures (BP, weight, height, waist circumference)
- repeat blood tests - HbA1c, lipids, LFTs (AST, ALT, GGT) and urate, and urine albumin creatinine ratio.
- reassess diet and review nutrition goals using STC: Diet + give dietary advice and appropriate nutrition pamphlet(s)
- ADDITIONAL questionnaire to be completed with Research Nurse + fasting bloods organised

**PLUS for the duration of the 24-month intervention** the following for intervention patients

#### ***Throughout study -***

- GPs will opportunistically encourage goal achievement (will refer to alert with nutritional goals on PMS) and participation in the Stanford programme
- Dietitian will provide dietetic support to practice nurses – monthly practice visits (case reviews) for 6-12 months, and answer phone or email queries as required

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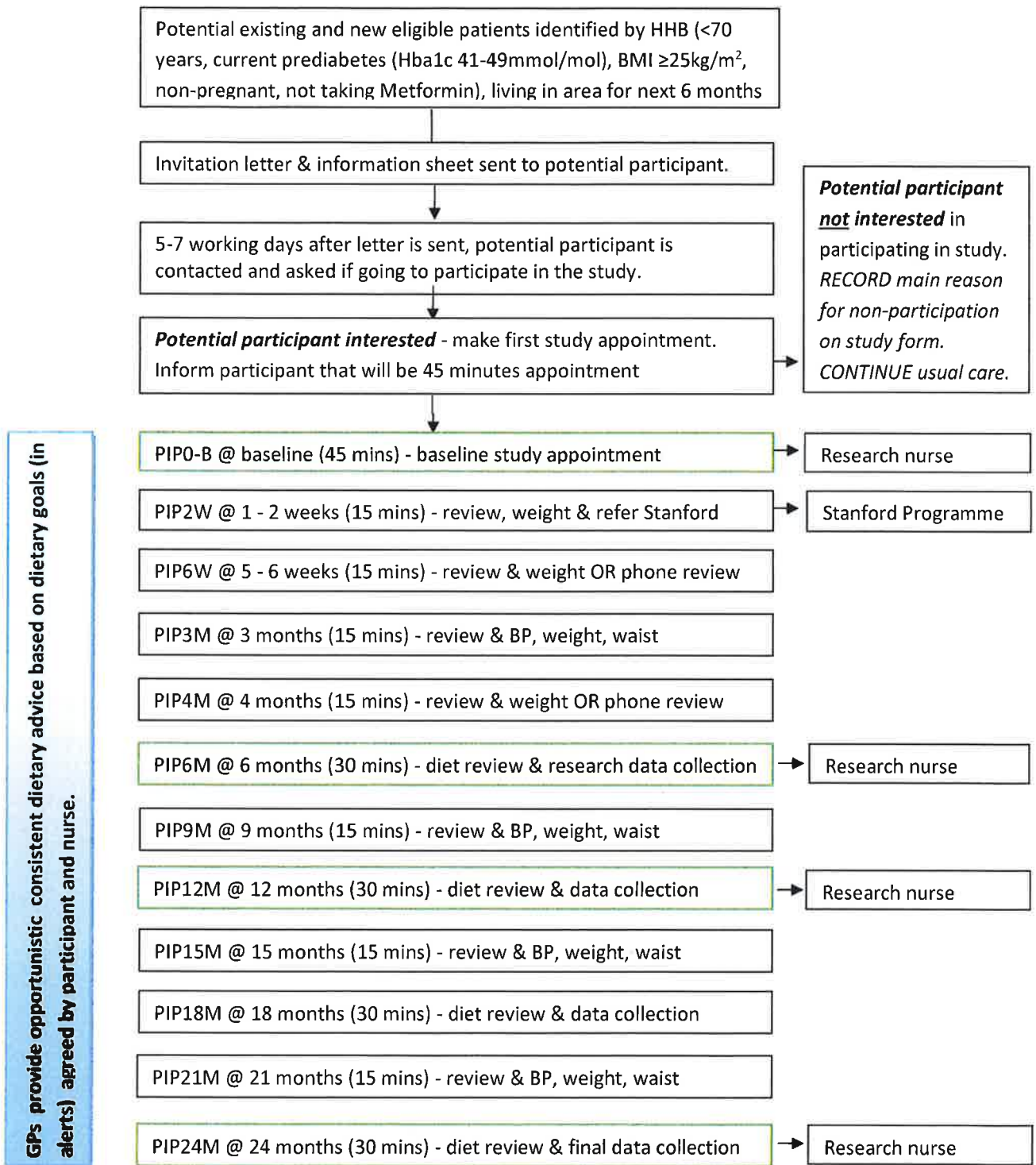
**STANFORD PROGRAMME**

This group programme will be run by trained Stanford programme personnel at weekly intervals over 6 weeks at a different times and places. Each session will last 1-1 ½ hours and will include:

<b>Workshop Overview</b>						
	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>
Overview of self-management and chronic health conditions	•					
Using your mind to manage symptoms	•		•		•	•
Getting a good night's sleep	•					
Making an action plan	•	•	•	•	•	•
Feedback and problem-solving		•	•	•	•	•
Dealing with difficult emotions		•				
Physical activity and exercise		•	•			
Preventing falls		•				
Making decisions			•			
Pain and fatigue management			•			
Better breathing				•		
Healthy eating				•	•	
Communication skills				•		
Medication usage					•	
Making Informed treatment decisions					•	
Dealing with depression					•	
Working with your health care professional and system						•
Weight management						•
Future plans						•



**Flow of intervention participants through the PIP in Primary Care Study**



### **3a. Potential eligible study participants**

The following study inclusion and exclusion criteria will be used:

#### **Inclusion**

- Prediabetes defined as HbA1c = 41-49 mmol/mol
- Confirmation HbA1c = 41-49 mmol/mol within 1 month prior to study entry
- Aged < 70 years
- BMI  $\geq$  25kg/m<sup>2</sup>
- Able to communicate in English

#### **Exclusion**

- Taking Metformin at the time of study enrolment
- Pregnant at the time of study enrolment
- Not willing to participate
- Planning to move from the area during the first 6 months of the study
- Terminal illness

### 3b. Identifying and inviting eligible study participants

- **Existing** eligible participants will be identified using DrInfo Audits by Health Hawke's Bay. A list of existing eligible participants will be sent to the participating practices.
- **New** eligible participants will be identified on an ongoing basis following Cardiovascular Risk Assessments or opportunistic testing.

#### Existing Eligible Participants

*These are patients who have been previously diagnosed with prediabetes and have persistent prediabetes*

1. Check potential participant meets study criteria (see 3a)
2. Practice sends study invitation letter (see Appendix 1), and information sheet (see Appendix 3), to existing eligible participants. *This is best staggered over weeks to allow planned management of workload.*
3. 5-7 working days after sending the invitation letter, the practice nurse contacts eligible participants to determine if they want to participate in the study or not.
4. For those who want to participate, make an initial appointment (PIPO-B) at the practice, and arrange blood and urine tests if study blood tests (HbA1c, lipids, LFTs (AST, ALT, GGT) and urate) and urine albumin creatinine ratio have not been completed in the previous 4 weeks.  
Encourage patient to bring family/whanau to the appointment.
5. If required, send a confirmation letter with the date and time of the appointment.
6. Practice contacts participant (phone/txt/email) the day before first study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
7. **For those who decline to participate**, please record the date and the reason for declining to participate on the Decline to Participate form (see Appendix 2).

#### Newly Identified Eligible Participants

*These are patients diagnosed with prediabetes either as the result of a cardiovascular risk assessment or opportunistic testing after study start*

1. Check newly identified prediabetes patient meets the study criteria (see 3a)
2. Check that the patient has been informed that they have prediabetes

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3. Practice sends study invitation letter (see Appendix 1), and information sheet if appropriate (see Appendix 3), to newly identified eligible participant.
4. 5-7 working days after sending the invitation letter, the practice nurse contacts eligible participant to determine if they want to participate in the study or not.
5. For those who want to participate, make an initial appointment (PIPO-B) at the practice, and arrange blood and urine tests if study blood tests (HbA1c, lipids, LFTs (AST, ALT, GGT) and urate) and urine albumin creatinine ratio have not been completed in the previous 4 weeks.
6. If required, send a confirmation letter with the date and time of the appointment.
7. Practice contacts participant (phone/txt/email) the day before first study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
8. **For those who decline to participate**, please record the date and the reason for declining to participate on the Decline to Participate form (see Appendix 2).

### Invitation Letter

A sample letter (see Appendix 1). This letter will be on MedTech.

Alter the letter as appropriate to include instructions about getting a blood test.

***If, repeat pre-study HbA1c is within the normal range,  
that is,  $\leq 40\text{mmol/mol}$***

***These patients do NOT meet the study inclusion criteria, and  
will NOT be eligible to participate in the study.***

### 3c. Practice environment

***A nutritionally friendly practice environment will help to reinforce the healthy nutrition messages given to patients during a consultation. Consistent messages are important.***

***It is also important to create an environment which does not further stigmatise overweight and obesity.***

The following are suggestions to aid with establishing a healthy nutrition environment, and to minimise stigmatising overweight and obesity.

#### Waiting rooms

- Posters promoting sensible healthy messages. Check out [www.vegetables.co.nz/resources](http://www.vegetables.co.nz/resources)
- Avoid women's magazines which often promote conflicting nutrition advice and unsustainable weight loss plans.
- Better magazines which promote healthy lifestyle messages include the Healthy Food Guide, Good Health, Hunting & Fishing, Fishing NZ
- The practice will be sent back issues of the Healthy Food Guide (one month outdated) complimentary of the Healthy Life Media Limited
- Offer chairs *without restrictive arms*

#### Staff practises

- Provide a nutritionally friendly work environment – good for both staff and patients
- Consistent health messages across staff and patients
- Healthy tea rooms - fruit bowls, soup days
- Avoid rewarding with food. Flowers whether homegrown or bought is a good alternative, or fruit and vegetable swaps when excess homegrown produce

#### Equipment

- Appropriate sized blood pressure cuffs
- Weighing scales that reach 200kg
- Waist circumference tape measures that extend to 2 metres
- Stadiometer that measures to 2 metres
- Ideally nurse/weight loss consultations to be conducted in a dedicated private consulting room

### 3d. Welcome to the baseline study appointment (PIP0-B)

#### Receptionist

1. Greet the patient.
2. Check the patient has arrived at the right time for the right appointment.
3. Check contact details.
4. Thank him/her for participating in the study.

Depending on organisation within each practice, the receptionist may or may not ask the patient to complete the Starting The Conversation: Diet questionnaire while waiting to see the nurse. **If the receptionist is to ask the patient to complete the questionnaire then:**

5. Get a Starting The Conversation: Diet questionnaire (see Appendix 5).<sup>†</sup> Write the patient's name and the date on the questionnaire.
6. Give the patient the Starting The Conversation: Diet questionnaire (see Appendix 5) and a pen. Ask him/her to complete the eight questions before the nurse appointment. Specify that the questions are on one side only and that it should only take a couple of minutes to fill out.
7. Ask the patient to take a seat.
8. If a patient has an acknowledged learning deficit the receptionist is to communicate this to the practice nurse.

<sup>†</sup> Practice nurses are to work out with the receptionist where best to keep a folder with the STC: Diet questionnaires.

### 3e. Baseline study appointment - PIP0-B

*The purpose of the first appointment is:*

1. *to explain the study to the patient*
2. *to obtain written study consent*
3. *to complete questionnaire*
4. *to complete clinical measures (anthropometry and blood pressure)*
5. *to check blood and urine tests completed within last 4 weeks (HbA1c, lipids, AST, ALT, GGT and urate)*
6. *to undertake a dietary assessment using Starting The Conversation: Diet tool, establish nutrition and weight goals and provide dietary advice and appropriate written dietary resources*
7. *to provide Be Active Every Day pamphlet*

#### BEFORE APPOINTMENT

1. Check recent blood and urine test results. Arrange ***if no results within the last 4 weeks***, HbA1c, lipids, liver function tests (LFTs: AST, ALT, GGT) and urate, and urine albumin creatinine ratio. Contact the patient and arrange a blood and urine test, if required.
2. Practice contacts participant (phone/txt/email) the day before study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.

#### DURING NURSE APPOINTMENT

**Length of appointment: 45 minutes**

1. Welcome patient and his/her family/whanau.
2. Take patient and his/her family/whanau through to nurse consultation room.
3. Go through the study information sheet (see Appendix 3) and answer any questions. Go through the written consent form (see Appendix 3), and ***if the patient wants to participate in the study, he/she signs the consent form.***
4. The ***nurse also signs the consent form*** indicating they have explained the study and answered any of the patient's questions.

#### For those choosing to participate in the PIP in Primary Care study

5. Briefly explain to the participant what will be covered in the first study appointment (additional questions about their health, blood pressure and anthropometric measures, lifestyle factors, goal setting (for nutrition and weight loss) and lifestyle advice.

6. Complete the first section of the questionnaire with the participant using the PIP Advanced Form on MedTech. Some information such as date of birth, ethnicity will be pre-populated. *Update information* such as smoking history, alcohol intake, as necessary. *Acquire new information* such as type 2 diabetes family history, supplements taken, sociocultural questions. See page 18-20 for a copy of the questions.
7. Measure the participant's **blood pressure** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
8. Measure the participant's **height** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on the PIP Advanced Form.
9. Measure the participant's **weight** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
10. Measure the participant's **waist circumference** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
11. Complete the STC: Diet questionnaire, if not already completed by patient, entering answers into the Med Tech PIP Advanced Form. Review responses.
12. Use the laminated Detailed Dietary Assessment guide (see Appendix 6) to investigate his/her diet further by asking additional questions. Begin by choosing the food groups with ticks in the **red** column. Then use food groups in the **yellow** column. *It is important to ask all the additional questions within a food group before setting nutritional goals.* The additional questions are in the middle column of the Detailed Dietary Assessment guide.  
***If there are more than 3 red column ticks***, ask participant to choose which three food groups he/she would prefer to begin with.
13. Insert brief notes as appropriate into clinical notes section of MedTech.
14. ***Establish three nutritional goals*** relating to positive behaviour change moving the patient closer to the desired behaviour in the blue boxes with the participant. Goal prompts are listed in the right hand column of Detailed Dietary Assessment guide (see Appendix 6).
15. Check that each nutritional goal is simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic and Time-bound). Each goal is to be realistically achievable within the time before the 6 week appointment.
16. Insert the three agreed nutritional goals into MedTech.
17. ***Repeat blood pressure and the three anthropometry measurements***, and record each measure on PIP Advanced Form.
18. ***Establish weight goal. The aim is a 5-10% weight loss over 6 months, preferably 10%.*** To calculate the 6 month weight goal, multiply current body weight by 0.9 to calculate the 10% weight loss goal, then multiply current body weight by 0.95 to calculate the 5% weight loss goal.  
For example, if a participant's body weight is 105.5kg, the 10% weight loss goal is  $0.9 \times 105.5\text{kg} = 95\text{kg}$ , and the 5% weight loss goal is  $0.95 \times 105.5\text{kg} =$



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100.2kg. Then, agree a 6-month weight loss goal in the range 95kg to 100.2kg with the participant, ***but preferably a 10% weight loss, in this case weight goal = 95kg as achieving this goal in 6 months is more likely to lead to normoglycaemia.***

19. Insert the weight goal into PIP Advanced Form.
20. Print the participant's three nutritional goals and weight goal, and give to him/her.
21. Give the Diabetes NZ pamphlet titled "Diabetes and healthy food choices" to the participant. *Emphasise that the nutritional information applies to everybody not just people living with diabetes.* Give other appropriate resources that support goal achievement to the participant.
22. Give Ministry of Health 'Be Active Every Day' pamphlet.
23. *Inform* the patient that the dietary intervention includes 6 group education group sessions run through the Health Hawke's Bay Stanford Programme, that these will be run at different times and at different places, and a referral will be made at the next appointment. ***Emphasise the importance of attending these group sessions.***
24. Ask the participant if he/she has any questions. For questions where the answer is not known or there is uncertainty, state they will be contacted later after discussing the issue with the study dietitian with an answer.
25. Make a follow-up appointment (PIP2W) in 1-2 weeks. **Insert a recall alert into Medtech.**
26. **Consider** and discuss need for follow-up support phone calls/txts or emails.
27. Copy the signed consent form, and give to the participant, along with the study information sheet.
28. Scan the signed consent form into Medtech patient medical records.
29. ***Advise the patient that a Research Nurse will contact him/her to arrange completion of a questionnaire and fasting blood test (see Appendices 8-10)***

### SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT

1. Study information sheet and a copy of the signed consent form
2. Printed copy of Nutritional Goals and 6-month Weight Goal
3. Diabetes NZ pamphlet titled "Diabetes and healthy food choices"
4. Supplementary written nutrition information, as appropriate to support goal achievement
5. Ministry of Health 'Be Active Every Day' pamphlet
6. Date and time of next appointment

### POST APPOINTMENT

1. Check all required data are entered into PIP Advanced Form.
2. **OPTIONAL** – Contact (phone/txt/email) participant for brief follow-up support, as appropriate.

## Baseline study data (PIP0-B) to be collected and recorded using the MedTech PIP Advanced Form

### 1. Demographic Details

Birthdate: \_\_\_\_\_ NHI Number: \_\_\_\_\_  
Sex:  Male  Female Ethnicity: \_\_\_\_\_  
Smoking Status (update):  Never  Past  Current  
Alcohol (update): AUDIT tool (see PMS)  
Date of prediabetes diagnosis: \_\_\_\_/\_\_\_\_/20\_\_\_\_\_  
HbA1c at diagnosis (mmol/mol): \_\_\_\_\_

### 2. Family History

A) Do you have a family history of Type 2 Diabetes?  Yes  No

B) Please indicate if the following have Type 2 Diabetes:

- Father
- Mother
- Sister(s) – How many? \_\_\_\_\_
- Brother(s) – How many? \_\_\_\_\_
- Child(ren) – How many? \_\_\_\_\_

### 3. Health Status

A) Past medical history (tick if applicable):

- Hypertension
- Dyslipidaemia
- Ischaemic Heart Disease
- Stroke
- Gout
- Non-Alcoholic Fatty Liver Disease (NAFLD)
- Depression
- Women - Polycystic Ovary Syndrome (PCOS)
- Women - Gestational Diabetes Mellitus (GDM)

B) Current prescribed medications:

- Antihypertensive medication
- Lipid modifying medication
- Allopurinol
- Antiplatelet therapy
- Metformin
- Other diabetes medication
- Antidepressant medication

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C) Current Supplements:

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

**4. Bloods (within 1 month prior to baseline appointment) + Urine**

Blood Test		Result	Date Taken	Target Ranges:
Lipids	Total Cholesterol			<4.0 mmol/L
	LDL Cholesterol			<2.0 mmol/L
	HDL Cholesterol			>1.0 mmol/L
	Triglycerides			<1.7 mmol/L
	HDL/LDL Ratio			<4.0
HbA1c				≤40 mmol/mol
Liver Function Tests	ALT			
	AST			
	GGT			
Urate				
Urine albumin creatinine ratio				

**5. Clinical Measures**

	Clothing worn	Measure 1	Measure 2	Average
Weight (kg) (1 layer light clothing)				
Height (mm) (No shoes)				
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)				
Systolic Blood Pressure (mmHg)	N/A			
Diastolic Blood Pressure (mmHg)	N/A			
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech			
6 Month Weight Loss Goal 5-10% body weight, ideally 10%	10% weight loss goal = Wgt (kg) x 0.9			

**6. Lifestyle**

A) Special Diet or food allergies (tick if applicable):

- Vegetarian
- Vegan
- Pescatarian (vegetarian + fish)
- Nut free
- Dairy free
- Fish free
- Egg free
- Gluten free
- Soy free

B) What physical activities do you do (including household chores and exercise programmes)? \_\_\_\_\_

C) On average how many hours of physical activity per week? \_\_\_\_\_ hours

D) Please indicate who you live with?

- Spouse/partner
- Children aged <18 years – How many: \_\_\_\_\_
- Father
- Mother
- Other adults aged 18 years and over – How many: \_\_\_\_\_

E) Who mostly buys food in your house?

- Myself
- Spouse/partner
- Parent
- Other

F) Who mostly cooks food in your house?

- Myself
- Spouse/partner
- Parent
- Other

G) Is your budget for food limited?  Yes  No

H) On a scale of 1 – 10, how ready are you to make food changes (1 – not ready at all; 10 – really motivated)? \_\_\_\_\_

**7. Weight History**

- A) Has your weight tended to go up and down?  Yes  No
- B) How long have you been your current weight? \_\_\_\_\_ months
- C) What was a weight that you felt comfortable at? \_\_\_\_\_ kgs

**8. Diet Assessment**

- A) Starting The Conversation (STC): Diet – See Appendix 5 or Laminated Card
- B) Detailed Dietary Assessment (DDA) Guide – See Appendix 6 or Laminated Card

**9. Nutritional Goals**

- 1. \_\_\_\_\_  
\_\_\_\_\_
- 2. \_\_\_\_\_  
\_\_\_\_\_
- 3. \_\_\_\_\_  
\_\_\_\_\_

**10. Further study participation**

Do you consent to being contacted by a member of the PIP study research team to participate in further research related to this study?

- YES
- NO

### 3f. Study appointment two @ 1-2 weeks – PIP2W

*The purpose of study appointment 2 is:*

1. *to review the nutrition goals, reinforce dietary advice and answer questions*
2. *refer to the Stanford Programme for seven group education sessions*

#### BEFORE APPOINTMENT

1. Practice contacts participant (phone, txt or email) the day before study appointment two, to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
2. Check participant's current health status and medications on Medtech.
3. Review the participant's nutritional goals and weight loss goal set at the last appointment.

#### DURING NURSE APPOINTMENT

**Length of appointment: 15 minutes**

1. Greet the participant and his/her family/whanau
2. Review and update any change in health and medications.
3. Enquire about and review the nutritional goals set at the first appointment.  
Make and record clinical notes as appropriate for each goal.
  - a. How are you going with achieving your goal(s)?
  - b. Have you achieved any goals? Why or why not?
  - c. What were some difficulties/ challenges?
  - d. What made it easier?
  - e. What are some benefits you have found?
  - f. Was the goal too easy or too hard or just right for you?
4. **OPTIONAL** - Weigh the patient according to the protocols under "CLINICAL MEASURES".
5. **IF any of, or all the goals have been achieved** →
  - a. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant.
  - b. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the **red** column hand column first. Then use food groups in the **yellow** column.
  - c. When all the prompt questions have been investigated, set a new nutritional goal(s) relating to positive behaviour change if appropriate. Goal prompts are listed in the right hand column to help you, if

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needed. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

6. **For each goal, if the goal has not been achieved or only partially achieved:**
  - a. Keep the goal, if partially achieved  
The goal may still be appropriate – provide encouragement, **OR**
  - b. Keep the goal, if still appropriate, but not achieved  
The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success, **OR**
  - c. Change goal, if it was inappropriate  
If the goal was inappropriate, change or partially change the goal to something more suitable.
7. Check that any new nutritional goal(s) is/are simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic, and Time-bound (achievable before their 6-week appointment)).
8. Enter the Nutritional Goals into MedTech.
9. Remind the participant of their 6-month Weight Goal.
10. Print the participant's Nutritional and 6-month Weight Goals, and give to him/her, *if the nutritional goals have changed*.
11. Give participant further resources, as required, to support the achievement of their goals.
12. Give participant Stanford Programme Education Information Sheet (Appendix 7).
13. Ask the participant if he/she has any questions and answer these.
14. Inform the participant the next appointment will be in 4 weeks.
15. **Consider** and discuss need for follow-up support contacts (phone/txt/email).

### SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT

1. Printed copy of Nutritional Goals and 6-month Weight Goal, *if the nutritional goals have changed*.
2. Supplementary written nutrition information, as appropriate to support goal achievement.
3. Stanford Programme Community Group Education Information Sheet.

### POST APPOINTMENT

1. Send participant referral to the Stanford Programme using the referral form linked on Medtech.
2. **Add to own personal task list to make the PIP6W study appointment for the participant.** This appointment is to take place 6 weeks after study start.
3. **OPTIONAL** – Contact (phone/txt/email) participant for brief follow-up support, as appropriate.

**Study appointment two (PIP2W) data to be collected and recorded using the MedTech PIP Advanced Form**

**1. Clinical Notes**

**A) Any change in health or medications, in particular any diabetes medicines?:**

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**B) Progress towards achieving nutritional goals:**

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**C) Weight measurement (1 layer of light clothing):**

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**2. Diet Review - OPTIONAL, if any nutritional goals achieved**

**A) Starting The Conversation: Diet**

**B) Nutritional Goals - Revised**

1. \_\_\_\_\_

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2. \_\_\_\_\_

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3. \_\_\_\_\_

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### 3g. Study appointment three @ 5-6 weeks – PIP6W

*The purpose of study appointment 3 (practice visit or phone consultation) is:*

1. *to review the nutrition goals, reinforce dietary advice and answer questions*
2. *to provide support for dietary change*
3. *to check that participant is booked or is attending Stanford programme*

#### BEFORE APPOINTMENT

1. Practice contacts participant (phone/txt/email) the day before study appointment three to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
2. Check participant's current health status and medications on Medtech.
3. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

**Length of appointment: 15 minutes**

1. Greet the participant and his/her family/whanau.
2. Review and update any change in health and medications.
3. Enquire as to whether booked in or attending the Stanford programme.
4. Enquire about the achievement of nutritional goals using the following prompt questions. Make and record clinical notes as appropriate for each goal.
  - a. How are you going with achieving your goal(s)?
  - b. Have you achieved any goals? Why or why not?
  - c. What were some difficulties/ challenges?
  - d. What made it easier?
  - e. What are some benefits you have found?
  - f. Was the goal too easy or too hard or just right for you?
5. **OPTIONAL** - Weigh the patient according to the protocols under "CLINICAL MEASURES".
6. **If any of, or all the goals have been achieved →**
  - a. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant.
  - b. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the **red** column hand column first. Then use food groups in the **yellow** column.
  - c. When all the prompt questions have been investigated, set a new nutritional goal(s) relating to positive behaviour change if appropriate. Goal prompts are listed in the right hand column to help you, if

## NOT FOR CIRCULATION

needed. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

7. **For each goal, if the goal has not been achieved or only partially achieved:**
  - a. Keep the goal, if partially achieved  
The goal may still be appropriate – provide encouragement,  
**OR**
  - b. Keep the goal, if still appropriate, but not achieved  
The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success,  
**OR**
  - c. Change goal, if it was inappropriate  
If the goal was inappropriate, change or partially change the goal to something more suitable.
8. Check that any new nutritional goal(s) is/are simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic, and Time-bound (achievable before their follow up 3-month appointment)).
9. Enter the Nutritional Goals into the PIP Advanced Form.
10. Remind the participant of their 6-month Weight Goal.
11. Print the participant's Nutritional and 6-month Weight Goals, and give to him/her, *if the nutritional goals have changed*.
12. Give participant further resources, as required, to support the achievement of their goals.
13. Ask the participant if he/she has any questions and answer these.
14. Inform the participant the next appointment will be in 1 month.
15. **Consider** and discuss need for follow-up support contacts (phone/txt/email).

### **SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT**

1. Printed copy of Nutritional Goals and 6-month Weight Goal, *if the nutritional goals have changed*.
2. Supplementary written nutrition information, as appropriate to support goal achievement.

### **POST APPOINTMENT**

1. Send participant referral to Stanford Programme Group Education sessions using the referral form linked on Medtech.
2. **Add to own personal task list to make the PIP3M study appointment for the participant.** This appointment is to take place 3 months after study start.
3. **OPTIONAL** – Contact (phone/txt/email) participant for brief follow-up support, as appropriate.

**Study appointment three (PIP6W) data to be collected and recorded using the MedTech PIP Advanced Form**

**1. Clinical Notes**

**A) Any change in health or medications, in particular any diabetes medicines?:**

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**B) Progress towards achieving nutritional goals:**

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**C) Weight measurement (1 layer of light clothing):**

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**2. Diet Review - OPTIONAL, if any nutritional goals achieved**

**A) Starting The Conversation: Diet**

**B) Nutritional Goals - Revised**

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2. \_\_\_\_\_

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3. \_\_\_\_\_

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### 3h. Study appointment four @ 3 months – PIP3M

*The purpose of study appointment 4 is:*

1. *to repeat clinical measures (BP, weight, waist circumference) and HbA1c*
2. *to reassess diet, review goals and dietary advice using STC:Diet*

#### BEFORE APPOINTMENT

1. Practice contacts participant (phone/txt/email) the day before study appointment four to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
2. Check participant's current health status and medications on Medtech.
3. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

Length of appointment: 15 minutes

1. Greet the participant and his/her family/whanau.
2. Review and update any change in health and medications.
3. Enquire about attendance at the Stanford programme.
4. Measure the participant's **blood pressure** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
5. Measure the participant's **height** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on the PIP Advanced Form.
6. Measure the participant's **weight** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.  
Measure the participant's **waist circumference** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
7. Enquire about the achievement of nutritional goals using the following prompt questions. Make and record clinical notes as appropriate for each goal.
  - a. How are you going with achieving your goal(s)?
  - b. Have you achieved any goals? Why or why not?
  - c. What were some difficulties/ challenges?
  - d. What made it easier?
  - e. What are some benefits you have found?
  - f. Was the goal too easy or too hard or just right for you?
8. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant, and enter answers into the PIP Advanced Form.

9. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the **red** column hand column first. Then use food groups in the **yellow** column.
10. Review and set new nutritional goal(s) as appropriate. Goal prompts are listed in the right hand column of the Detailed Dietary Assessment Guide. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

**For each goal, if the goal has not been achieved or only partially achieved ->**

- a. Keep the goal, if partially achieved

The goal may still be appropriate – provide encouragement.

**OR**

- b. Keep the goal, if still appropriate but not achieved

The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success.

**OR**

- c. Change or partially change the goal, if it was inappropriate

If the goal was inappropriate, change or partially change the goal to something more suitable.

**AND, use this optional tool if goals not achieved or partially achieved**

- d. Explore barriers and enablers – Looking at the nutritional goals, identify enablers that will help the participant reach their goal(s). Identify barriers that are keeping them from reaching their nutritional goal(s). Use this information to suggest actions to help enable progress and overcome barriers.

11. Check that any new nutritional goal(s) is simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic, and Time-bound (achievable before their 4 month appointment).
12. Enter the three Nutritional Goals into PIP Advanced Form.
10. Remind the participant of their 6-month Weight Goal. Positively enforce progress. Encourage the participant if there hasn't been progress.
11. Print and give the participant their nutritional goals.
12. If appropriate give participant further resources to support the achievement of their goals.
13. Ask the participant if he/she has any questions and answer these.
14. Inform the participant the next intervention appointment will be in 1 month.
15. **Consider** and discuss need for follow-up support phone calls or txts or emails.

### **SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT**

1. Printed copy of Nutritional Goals and 6-month Weight Goal, *if the nutritional goals have changed.*

NOT FOR CIRCULATION

2. Supplementary written nutrition information, as appropriate to support goal achievement.

**POST APPOINTMENT**

1. Check all required data are entered into PIP Advanced Form.
2. Add to own personal task list to make the PIP4M study appointment for the participant. This appointment is to take place 4 months after study start.
3. **OPTIONAL** – Contact (phone/txt/email) participant for brief follow-up support, as appropriate.

## Study appointment four (PIP3M) data to be collected and recorded using the MedTech PIP Advanced Form

### 1. Clinical Notes

A) Any change in health or medications, in particular any diabetes medicines?:

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B) Progress towards achieving nutritional goals:

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### 2. HbA1c – arrange to be taken prior to this 3 month study appointment

Blood Test	Result	Date Taken	Target Ranges:
HbA1c			≤40 mmol/mol

### 3. Clinical Measures

	Clothing worn	One Measure Only
Weight (kg) (1 layer light clothing)		
Height (mm) (No shoes)		
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)		
Systolic Blood Pressure (mmHg)	N/A	
Diastolic Blood Pressure (mmHg)	N/A	
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech	

### 4. Diet Review - Starting The Conversation (STC): Diet

#### 5. Revised Nutritional Goals

1. \_\_\_\_\_

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2. \_\_\_\_\_

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3. \_\_\_\_\_

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### 3i. Study appointment five @ 4 months – PIP4M

*The purpose of study appointment 5 (practice visit or phone consultation) is:*

1. *to review the nutrition goals, reinforce dietary advice and answer questions*
2. *to provide support for dietary change*

#### BEFORE APPOINTMENT

1. Practice contacts participant (phone/txt/email) the day before study appointment three to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
2. Check participant's current health status and medications on Medtech.
3. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

Length of appointment: 15 minutes

1. Greet the participant and his/her family/whanau
2. Review and update any change in health and medications.
3. Enquire about attendance at the Stanford programme.
4. Enquire about the achievement of nutritional goals using the following prompt questions. Make and record clinical notes as appropriate for each goal.
  - a. How are you going with achieving your goal(s)?
  - b. Have you achieved any goals? Why or why not?
  - c. What were some difficulties/ challenges?
  - d. What made it easier?
  - e. What are some benefits you have found?
  - f. Was the goal too easy or too hard or just right for you?
5. **OPTIONAL** - Weigh the patient according to the protocols under "CLINICAL MEASURES".
6. **If any of, or all the goals have been achieved** →
  - a. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant.
  - b. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the **red** column hand column first. Then use food groups in the **yellow** column.
  - c. When all the prompt questions have been investigated, set a new nutritional goal(s) relating to positive behaviour change if appropriate. Goal prompts are listed in the right hand column to help you, if



needed. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

7. **For each goal, if the goal has not been achieved or only partially achieved:**
  - a. Keep the goal, if partially achieved  
The goal may still be appropriate – provide encouragement,  
**OR**
  - b. Keep the goal, if still appropriate, but not achieved  
The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success,  
**OR**
  - c. Change goal, if it was inappropriate  
If the goal was inappropriate, change or partially change the goal to something more suitable.
8. Check that any new nutritional goal(s) is/are simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic, and Time-bound (achievable before their follow up 6-month appointment)).
9. Enter the Nutritional Goals into the Advanced Form on MedTech.
10. Remind the participant of their 6-month Weight Goal.
11. Print the participant's Nutritional and 6-month Weight Goals, and give to him/her, *if the nutritional goals have changed*.
12. Give participant further resources, as required, to support the achievement of their goals.
13. Ask the participant if he/she has any questions and answer these.
14. Inform the participant the next appointment will be in 2 months.
15. **Consider** and discuss need for follow-up support contacts (phone/txt/email).

#### **SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT**

1. Printed copy of Nutritional Goals and 6-month Weight Goal, *if the nutritional goals have changed*.
2. Supplementary written nutrition information, as appropriate to support goal achievement.

#### **POST APPOINTMENT**

1. **Add to own personal task list to make the PIP6M study appointment for the participant.** This appointment is to take place 6 months after study start.
2. **OPTIONAL** – Contact (phone/txt/email) participant for brief follow-up support, as appropriate.

**Study appointment five (PIP4M) data to be collected and recorded using the MedTech PIP Advanced Form**

**3. Clinical Notes**

**A) Any change in health or medications, in particular any diabetes medicines?:**

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**B) Progress towards achieving nutritional goals:**

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**C) Weight measurement (1 layer of light clothing):**

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**4. Diet Review - OPTIONAL, if any nutritional goals achieved**

**A) Starting The Conversation: Diet**

**B) Nutritional Goals - Revised**

1. 

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2. 

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3. 

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### 3j. Study appointment six @ 6 months – PIP6M

*The purpose of study appointment 6 is:*

- 1. to repeat the baseline measures – questionnaire, clinical measures (BP, height, weight, waist circumference) and blood tests*
- 2. to reassess diet, review goals and reinforce dietary advice and answer questions*
- 3. to plan ongoing 3-monthly follow up and support for next 18 months. For those who achieved normoglycaemia and a BMI within the healthy range, the aim of follow up appointments will be maintenance of normoglycaemia and a healthy weight. For those who continue to have an elevated HbA1c and/or BMI  $\geq 25\text{kg/m}^2$ , the aim of follow-up appointments will ongoing weight loss advice and support.*

#### BEFORE APPOINTMENT

1. Arrange for participant to have repeat HbA1c, lipids, liver function tests (LFTs: AST, ALT, GGT) and urate **before** the study appointment.
2. Practice contacts participant (phone/txt/email) the day before study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
3. Check participant's current health status and medications on Medtech.
4. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

Length of appointment: **30 minutes**

1. Welcome patient and his/her family/whanau
2. Enquire about attendance at the Stanford programme.
3. Complete the questionnaire with the participant. Some information will be prepopulated eg date of birth, ethnicity. Update information such as smoking history, alcohol intake, family history, as necessary. Insert answers into Med Tech PIP Advanced Form.
4. Measure the participant's **blood pressure** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
5. Measure the participant's **height** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on the PIP Advanced Form.
6. Measure the participant's **weight** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
7. Measure the participant's **waist circumference** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.

8. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant, and **enter answers into the PIP Advanced Form**.
9. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the **red** column hand column first. Then use food groups in the **yellow** column.
10. Review and set new nutritional goal(s) as appropriate. Goal prompts are listed in the right hand column of the Detailed Dietary Assessment Guide. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

**For each goal, if the goal has not been achieved or only partially achieved ->**

a. Keep the goal, if partially achieved

- i. The goal may still be appropriate – provide encouragement

**OR**

b. Keep the goal, if still appropriate but not achieved

- i. The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success.

**OR**

c. Change or partially change the goal, if it was inappropriate

- i. If the goal was inappropriate, change or partially change the goal to something more suitable.

11. Check that each nutritional goal is simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic and Time-bound). Each goal is to be realistically achievable before the follow up appointment.
12. Enter the nutritional goals into MedTech.
13. **Repeat** blood pressure and anthropometry (height, weight and waist circumference) measurements.
14. **Set new 6-month weight goal.**  
**If BMI < 25kg/m<sup>2</sup>**, the goal will be to maintain a healthy body weight  
**If BMI still ≥ 25kg/m<sup>2</sup>**, the goal will be a 5-10% weight loss over 6 months. To calculate the 6-month weight goal, multiply current body weight by 0.9 to calculate the 10% weight loss goal, then multiply current body weight by 0.95 to calculate the 5% weight loss goal. For example, if a participant's body weight is now 101kg,
  - a. the 10% weight loss goal is 0.9 x 101kg = 91kg, and
  - b. the 5% weight loss goal is 0.95 x 101kg = 96kg.
  - c. Agree on a 6-month weight loss goal in the range 91 to 96kg with the participant, **but preferably a 10% weight loss, in this case weight goal = 91kg as achieving this goal in 6 months is more likely to lead to and maintain normoglycaemia.**
15. Insert the weight goal into MedTech

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16. Print the participant's three nutritional goals and weight goal, and give to him/her.
17. If appropriate, *give* participant further resources to support the achievement of their goals.
18. Discuss and plan ongoing weight loss and or weight maintenance support eg follow-up appointment in 3 months, monthly weigh-ins.
19. ***Advise the patient that the Research Nurse will contact him/her to arrange completion of a questionnaire and fasting blood test (see Appendices 8-10).***

### **SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT**

1. Printed copy of Nutritional Goals and **new 6-month Weight Goal**.
2. Supplementary written nutrition information, as appropriate to support goal achievement

### **POST APPOINTMENT**

1. Check all required data are entered into PIP Advanced Form.

## 6 Month (PIP6M) Study Data to be collected and recorded in MedTech using the PIP Study Advanced Form

### 1. Demographic Details (check that correct and update accordingly)

Birthdate: \_\_\_\_\_ NHI Number: \_\_\_\_\_  
Sex:  Male  Female Ethnicity: \_\_\_\_\_  
Smoking Status (update):  Never  Past  Current  
Alcohol (update): AUDIT tool (see PMS)

### 2. Family History (update)

A) Has any family member developed Type 2 Diabetes over the last 6 months?  
 Yes  No

B) Please indicate if the following have Type 2 Diabetes:

- Father
- Mother
- Sister(s) – How many? \_\_\_\_\_
- Brother(s) – How many? \_\_\_\_\_
- Child(ren) – How many? \_\_\_\_\_

### 3. Health Status (update)

A) Past medical history (tick if applicable):

- Hypertension
- Dyslipidaemia
- Ischaemic Heart Disease
- Stroke
- Gout
- Non-alcoholic Fatty Liver Disease
- Women - Polycystic Ovary Syndrome (PCOS)
- Women - Gestational Diabetes Mellitus (GDM)
- Depression

B) Current prescribed medications:

- Antihypertensive medication
- Lipid modifying medication
- Allopurinol
- Antiplatelet therapy
- Metformin
- Other diabetes medication
- Antidepressant medication

NOT FOR CIRCULATION

C) Current Supplements:

Name \_\_\_\_\_

Name \_\_\_\_\_

Name \_\_\_\_\_

**4. Bloods (preferably taken before 6-month appointment) + Urine**

Blood Test		Result	Date Taken	Target Ranges:
Lipids	Total Cholesterol			<4.0 mmol/L
	LDL Cholesterol			<2.0 mmol/L
	HDL Cholesterol			>1.0 mmol/L
	Triglycerides			<1.7 mmol/L
	HDL/LDL Ratio			<4.0
HbA1c				≤40 mmol/mol
Liver Function Tests	ALT			
	AST			
	GGT			
Urate				
Urine albumin creatinine ratio				

**5. Clinical Measures**

	Clothing worn	Measure 1	Measure 2	Average
Weight (kg) (1 layer light clothing)				
Height (mm) (No shoes)				
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)				
Systolic Blood Pressure (mmHg)	N/A			
Diastolic Blood Pressure (mmHg)	N/A			
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech			
<b>If BMI ≥ 25 kg/m<sup>2</sup>:</b>	Calculate <b>new</b> 6 Month Weight Loss Goal (5-10% body weight) =Wgt (kg) x 0.95 to Wgt (kg) x 0.9			

**6. Lifestyle (review and update accordingly)**

A) Special Diet or food allergies (tick if applicable):

- Vegetarian
- Vegan
- Pescatarian (vegetarian + fish)
- Nut free
- Dairy free
- Fish free
- Egg free
- Gluten free
- Soy free

B) What physical activities do you do (including household chores and exercise programmes)? \_\_\_\_\_

C) On average how many hours of physical activity per week? \_\_\_\_\_ hours

D) Please indicate who you live with?

- Spouse/partner
- Child – How many: \_\_\_\_\_
- Father
- Mother
- Other adults – How many: \_\_\_\_\_
- Other children – How many: \_\_\_\_\_

E) Who mostly buys food in your house?

- Myself
- Spouse/partner
- Parent
- Other

F) Who mostly cooks food in your house?

- Myself
- Spouse/partner
- Parent
- Other

G) Is your budget for food limited?  Yes  No

H) On a scale of 1 – 10, how ready are you to make/maintain food changes (1 – not ready at all; 10 – really motivated)? \_\_\_\_\_



**7. Diet Assessment**

A) Starting The Conversation (STC): Diet – See Appendix 5 or Laminated Card

B) Detailed Dietary Assessment Guide – See Appendix 6 or Laminated Card

**8. Nutritional Goals**

1. \_\_\_\_\_  
\_\_\_\_\_

2. \_\_\_\_\_  
\_\_\_\_\_

3. \_\_\_\_\_  
\_\_\_\_\_

### 3k. Study appointment seven @ 9 months (PIP9M)

*The purpose of study appointment 7 is the same as study appointment 4:*

1. to repeat clinical measures (BP, weight, waist circumference)
2. to reassess diet, review goals and dietary advice using STC:Diet

**The data to be collected are:**

**1. Clinical Notes**

A) Any change in health or medications, in particular any diabetes medicines?:

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B) Progress towards achieving nutritional goals:

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**2. HbA1c – if clinically indicated arrange to be taken, ideally prior to the 9 month study appointment**

Blood Test	Result	Date Taken	Target Ranges:
HbA1c			≤40 mmol/mol

**3. Clinical Measures**

	Clothing worn	One Measure Only
Weight (kg) (1 layer light clothing)		
Height (mm) (No shoes)		
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)		
Systolic Blood Pressure (mmHg)	N/A	
Diastolic Blood Pressure (mmHg)	N/A	
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech	

**4. Diet Review - Starting The Conversation (STC): Diet**

**5. Revised Nutritional Goals**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

### 31. Study appointment eight @ 12 months – PIP12M

*The purpose of study appointment 8 is:*

- A. to repeat the baseline measures – questionnaire, clinical measures (BP, height, weight, waist circumference) and blood tests)*
- B. to reassess diet, review goals and reinforce dietary advice and answer questions*
- C. to plan ongoing 3-monthly follow up and support for next 12 months. For those who achieved normoglycaemia and a BMI within the healthy range, the aim of follow up appointments will be maintenance of normoglycaemia and a healthy weight. For those who continue to have an elevated HbA1c and/or BMI  $\geq 25\text{kg/m}^2$ , the aim of follow-up appointments will be ongoing weight loss advice and support.*

#### BEFORE APPOINTMENT

1. Arrange for participant to have repeat HbA1c, lipids, liver function tests (LFTs: AST, ALT, GGT) and urate **before** the study appointment.
2. Practice contacts participant (phone/txt/email) the day before study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
3. Check participant's current health status and medications on Medtech.
4. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

Length of appointment: 30 minutes

20. Welcome patient and his/her family/whanau
21. Enquire about attendance at the Stanford programme.
22. Complete the questionnaire with the participant. Some information will be prepopulated eg date of birth, ethnicity. Update information such as smoking history, alcohol intake, family history, as necessary. Insert answers into Med Tech PIP Advanced Form.
23. Measure the participant's **blood pressure** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
24. Measure the participant's **height** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on the PIP Advanced Form.
25. Measure the participant's **weight** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
26. Measure the participant's **waist circumference** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.

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27. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant, and **enter answers into the PIP Advanced Form**.
28. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the red column hand column first. Then use food groups in the yellow column.
29. Review and set new nutritional goal(s) as appropriate. Goal prompts are listed in the right hand column of the Detailed Dietary Assessment Guide. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

**For each goal, if the goal has not been achieved or only partially achieved ->**

- a. Keep the goal, if partially achieved
  - i. The goal may still be appropriate – provide encouragement

**OR**

- b. Keep the goal, if still appropriate but not achieved
  - i. The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success.

**OR**

- c. Change or partially change the goal, if it was inappropriate
  - i. If the goal was inappropriate, change or partially change the goal to something more suitable.

**AND, use this optional tool if goals not achieved or partially achieved**

- d. Explore barriers and enablers – Looking at the nutritional goals, identify enablers that will help the participant reach their goal(s). Identify barriers that are keeping them from reaching their nutritional goal(s). Use this information to suggest actions to help enable progress and overcome barriers.

30. Check that each nutritional goal is simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic and Time-bound). Each goal is to be realistically achievable before the follow up appointment.
31. Enter the nutritional goals into MedTech.
32. Repeat blood pressure and anthropometry (height, weight and waist circumference) measurements.
33. **Set new 6-month weight goal.**  
**If BMI < 25kg/m<sup>2</sup>, the goal will be to maintain a healthy body weight**  
**If BMI still ≥ 25kg/m<sup>2</sup>, the goal will be a 5-10% weight loss over 6 months. To calculate the 6-month weight goal, multiply current body weight by 0.9 to calculate the 10% weight loss goal, then multiply current body weight by 0.95 to calculate the 5% weight loss goal. For example, if a participant's body weight is now 101kg,**

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- a. the 10% weight loss goal is  $0.9 \times 101\text{kg} = 91\text{kg}$ , and
  - b. the 5% weight loss goal is  $0.95 \times 101\text{kg} = 96\text{kg}$ .
  - c. Agree on a 6-month weight loss goal in the range 91 to 96kg with the participant, ***but preferably a 10% weight loss, in this case weight goal = 91kg as achieving this goal in 6 months is more likely to lead to and maintain normoglycaemia.***
34. Insert the weight goal into MedTech
  35. Print the participant's three nutritional goals and weight goal, and give to him/her.
  36. If appropriate, *give* participant further resources to support the achievement of their goals.
  37. Discuss and plan ongoing weight loss and or weight maintenance support eg follow-up appointment in 3 months, monthly weigh-ins.
  38. ***Advise the patient that the Research Nurse will contact him/her to arrange completion of a questionnaire and fasting blood test (see Appendices 8-10).***

### SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT

1. Printed copy of Nutritional Goals and 6-month Weight Goal.
2. Supplementary written nutrition information, as appropriate to support goal achievement

### POST APPOINTMENT

1. Check all required data are entered into PIP Advanced Form.

## 12 Month (PIP12M) Study Data to be collected and recorded in MedTech using the PIP Study Advanced Form

### 1. Demographic Details (check that correct and update accordingly)

Birthdate: \_\_\_\_\_ NHI Number: \_\_\_\_\_  
Sex:  Male  Female Ethnicity: \_\_\_\_\_  
Smoking Status (update):  Never  Past  Current  
Alcohol (update): AUDIT tool (see PMS)

### 2. Family History (update)

A) Has any family member developed Type 2 Diabetes over the last 6 months?  
 Yes  No

B) Please indicate if the following have Type 2 Diabetes:

- Father
- Mother
- Sister – How many: \_\_\_\_\_
- Brother – How many: \_\_\_\_\_
- Child – How many: \_\_\_\_\_

### 3. Health Status (update)

A) Past medical history (tick if applicable):

- Hypertension
- Dyslipidaemia
- Ischaemic Heart Disease
- Stroke
- Gout
- Non-alcoholic Fatty Liver Disease
- Women - Polycystic Ovary Syndrome (PCOS)
- Women - Gestational Diabetes Mellitus (GDM)
- Depression

B) Current prescribed medications:

- Antihypertensive medication
- Lipid modifying medication
- Allopurinol
- Antiplatelet therapy
- Metformin
- Other diabetes medication
- Antidepressant medication

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C) Current Supplements:

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

**4. Bloods (preferably taken before 6-month appointment)**

Blood Test		Result	Date Taken	Target Ranges:
Lipids	Total Cholesterol			<4.0 mmol/L
	LDL Cholesterol			<2.0 mmol/L
	HDL Cholesterol			>1.0 mmol/L
	Triglycerides			<1.7 mmol/L
	HDL/LDL Ratio			<4.0
HbA1c				≤40 mmol/mol
Liver Function Tests	ALT			
	AST			
	GGT*			
Urate				
Urine albumin creatinine ratio				

**5. Clinical Measures**

	Clothing worn	Measure 1	Measure 2	Average
Weight (kg) (1 layer light clothing)				
Height (mm) (No shoes)				
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)				
Systolic Blood Pressure (mmHg)	N/A			
Diastolic Blood Pressure (mmHg)	N/A			
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech			
<b>If BMI ≥ 25 kg/m<sup>2</sup>:</b>	Calculate <b>new</b> 6 Month Weight Loss Goal (5-10% body weight) =Wgt (kg) x 0.95 to Wgt (kg) x 0.9			

**6. Lifestyle (review and update accordingly)**

A) Special Diet or food allergies (tick if applicable):

- Vegetarian
- Vegan
- Pescatarian (vegetarian + fish)
- Nut free
- Dairy free
- Fish free
- Egg free
- Gluten free
- Soy free

B) What physical activities do you do (including household chores and exercise programmes)? \_\_\_\_\_

C) On average how many hours of physical activity per week? \_\_\_\_\_ hours

D) Please indicate who you live with?

- Spouse/partner
- Child – How many: \_\_\_\_\_
- Father
- Mother
- Other adults – How many: \_\_\_\_\_
- Other children – How many: \_\_\_\_\_

E) Who mostly buys food in your house?

- Myself
- Spouse/partner
- Parent
- Other

F) Who mostly cooks food in your house?

- Myself
- Spouse/partner
- Parent
- Other

G) Is your budget for food limited?  Yes  No

H) On a scale of 1 – 10, how ready are you to make/maintain food changes (1 – not ready at all; 10 – really motivated)? \_\_\_\_\_



**7. Diet Assessment**

C) Starting The Conversation (STC): Diet – See Appendix 5 or Laminated Card

D) Detailed Dietary Assessment Guide – See Appendix 6 or Laminated Card

**8. Nutritional Goals**

1. \_\_\_\_\_  
\_\_\_\_\_
2. \_\_\_\_\_  
\_\_\_\_\_
3. \_\_\_\_\_  
\_\_\_\_\_

### 3m. Study appointment nine @ 15 months - PIP15M

**The purpose of study appointment 9 is:**

1. to repeat clinical measures (BP, weight, waist circumference)
2. to reassess diet, review goals and dietary advice using STC:Diet

**The data to be collected are:**

**1. Clinical Notes**

Any change in health or medications, in particular any diabetes medicines?:

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A) Progress towards achieving nutritional goals:

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**2. HbA1c – if clinically indicated arrange to be taken, ideally prior to the 15 month study appointment**

Blood Test	Result	Date Taken	Target Ranges:
HbA1c			≤40 mmol/mol

**3. Clinical Measures**

	Clothing worn	One Measure Only
Weight (kg) (1 layer light clothing)		
Height (mm) (No shoes)		
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)		
Systolic Blood Pressure (mmHg)	N/A	
Diastolic Blood Pressure (mmHg)	N/A	
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech	

**4. Diet Review - Starting The Conversation (STC): Diet**

**5. Revised Nutritional Goals**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

### 3n. Study appointment ten @ 18 months – PIP18M

**The purpose of study appointment 10 is:**

1. to repeat clinical measures (BP, weight, waist circumference)
2. to reassess diet, review goals and dietary advice using STC:Diet

**The data to be collected are:**

**1. Clinical Notes**

A) Any change in health or medications, in particular any diabetes medicines?:

---



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B) Progress towards achieving nutritional goals:

---



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**2. HbA1c – if clinically indicated arrange to be taken, ideally prior to the 18 month study appointment**

Blood Test	Result	Date Taken	Target Ranges:
HbA1c			≤40 mmol/mol

**3. Clinical Measures**

	Clothing worn	One Measure Only
Weight (kg) (1 layer light clothing)		
Height (mm) (No shoes)		
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)		
Systolic Blood Pressure (mmHg)	N/A	
Diastolic Blood Pressure (mmHg)	N/A	
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech	

**4. Diet Review - Starting The Conversation (STC): Diet**

**5. Revised Nutritional Goals**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

### 3o. Study appointment eleven @ 21 months – PIP21M

**The purpose of study appointment 11:**

1. to repeat clinical measures (BP, weight, waist circumference)
2. to reassess diet, review goals and dietary advice using STC:Diet

**The data to be collected are:**

**1. Clinical Notes**

A) Any change in health or medications, in particular any diabetes medicines?:

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B) Progress towards achieving nutritional goals:

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**2. HbA1c – if clinically indicated arrange to be taken, ideally prior to the 21 month study appointment**

Blood Test	Result	Date Taken	Target Ranges:
HbA1c			≤40 mmol/mol

**3. Clinical Measures**

	Clothing worn	One Measure Only
Weight (kg) (1 layer light clothing)		
Height (mm) (No shoes)		
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)		
Systolic Blood Pressure (mmHg)	N/A	
Diastolic Blood Pressure (mmHg)	N/A	
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech	

**4. Diet Review - Starting The Conversation (STC): Diet**

**5. Revised Nutritional Goals**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

### 3p. Study appointment twelve @ 24 months – PIP24M

*The purpose of study appointment 12 is:*

1. *to repeat the baseline measures – questionnaire, clinical measures (BP, height, weight, waist circumference) and blood tests*
2. *to reassess diet, review goals and reinforce dietary advice and answer questions*
3. *to plan ongoing 3-monthly follow up and support. For some, it will be weight maintenance, if BMI is within the healthy range. For others, it will ongoing weight loss advice and support*

#### BEFORE APPOINTMENT

1. Arrange for participant to have repeat HbA1c, lipids, liver function tests (LFTs: AST, ALT, GGT) and urate **before** the study appointment.  
**Please note** – GGT will need to be added to the laboratory request form.
2. Practice contacts participant (phone/txt/email) the day before study appointment to remind him/her of their appointment. Where there is no answer to phone calls leave a message on the answering machine. If there is no answer to phone calls and no answering machine, try contacting the participant once more later in the day.
3. Check participant's current health status and medications on Medtech.
4. Review the participant's nutritional goals and weight loss goal.

#### DURING NURSE APPOINTMENT

**Length of appointment: 30 minutes**

1. Welcome patient and his/her family/whanau
2. Update the questionnaire with the participant. Some information will be prepopulated eg date of birth, ethnicity. Update information such as smoking history, alcohol intake, family history, as necessary. Insert answers into Med Tech PIP Advanced Form.
3. Measure the participant's **blood pressure** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
4. Measure the participant's **height** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on the PIP Advanced Form.
5. Measure the participant's **weight** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.
6. Measure the participant's **waist circumference** according to the "CLINICAL MEASURES" protocol (see Appendix 4). Record on PIP Advanced Form.

**As part of ongoing post study weight management/maintenance, complete the following as appropriate:**

7. **Re-do** the Starting the Conversation (STC): Diet questionnaire with the participant, and **enter answers into the PIP Advanced Form.**

8. Investigate two to three food groups further by asking the prompt questions. Choose the food groups with ticks in the red column hand column first. Then use food groups in the yellow column.
9. Review and set new nutritional goal(s) as appropriate. Goal prompts are listed in the right hand column of the Detailed Dietary Assessment Guide. The goals should move the participant closer to the ideal behaviour specified in the blue-shaded box in the left hand column.

**For each goal, if the goal has not been achieved or only partially achieved ->**

e. Keep the goal, if partially achieved

- i. The goal may still be appropriate – provide encouragement

**OR**

f. Keep the goal, if still appropriate but not achieved

- i. The goal may be appropriate but the participant has not been able to achieve it. If so, discuss possible different strategies that could be tried to increase the likelihood of success.

**OR**

g. Change or partially change the goal, if it was inappropriate

- i. If the goal was inappropriate, change or partially change the goal to something more suitable.

10. Check that each nutritional goal is simple and S.M.A.R.T (Specific, Measurable, Achievable, Realistic and Time-bound). Each goal is to be realistically achievable before the follow up appointment.
11. Enter the nutritional goals into MedTech.
12. **Set new 6-month weight goal, if BMI still  $\geq 25\text{kg}/\text{m}^2$ . The aim is 5-10% weight loss over 6 months.** To calculate the 6 month weight goal, multiply current body weight by 0.9 to give lower range, then multiply current body weight by 0.95 to give upper range.
  - a. For example, if a participant's body weight is now 101kg, the lower weight goal is  $0.9 \times 101\text{kg} = 91\text{kg}$ , and the upper weight goal is  $0.95 \times 101\text{kg} = 96\text{kg}$ .
  - b. Agree a weight goal in the range 91 to 96kg with the participant.
13. Insert the weight goal into MedTech
14. Print the participant's three nutritional goals and weight goal, and give to him/her.
15. If appropriate, *give* participant further resources to support the achievement of their goals.
16. Discuss and plan ongoing weight loss and or weight maintenance support following the end of the study, for example, a follow-up appointment in 3 months, monthly weigh-ins.
17. **Advise the patient that the Research Nurse will contact him/her to arrange completion of a questionnaire and a fasting blood test (see Appendices 8-10).**

18. Thank the participant for participating in and completing the study.
19. Inform him/her that the results of the whole study are expected in the latter half of 2019. A presentation will be given to study participants, and a written copy of the study results will be sent.
20. Check participant contact details so that study information can be sent to the correct address.

#### **SUMMARY OF INFORMATION TO BE GIVEN TO PARTICIPANT**

1. Printed copy of Nutritional Goals and 6-month Weight Goal.
2. Supplementary written nutrition information, as appropriate to support goal achievement

#### **POST APPOINTMENT**

1. Check all required data are entered into PIP Advanced Form.

## **24 Month (PIP24M) Study Data to be collected and recorded in MedTech using the PIP Advanced Form**

### **1. Demographic Details (check that correct and update accordingly)**

Birthdate: \_\_\_\_\_ NHI Number: \_\_\_\_\_  
Sex:  Male  Female Ethnicity: \_\_\_\_\_  
Smoking Status (update):  Never  Past  Current  
Alcohol (update): AUDIT tool (see PMS)

### **2. Family History (update)**

A) Has any family member developed Type 2 Diabetes over the last 12 months?  
 Yes  No

B) Please indicate if the following have Type 2 Diabetes:

- Father
- Mother
- Sister(s) – How many? \_\_\_\_\_
- Brother(s) – How many? \_\_\_\_\_
- Child(ren) – How many? \_\_\_\_\_

### **3. Health Status (update)**

A) Past medical history (tick if applicable):

- Hypertension
- Dyslipidaemia
- Ischaemic Heart Disease
- Stroke
- Gout
- Non-Alcoholic Fatty Liver Disease (NAFLD)
- Depression
- Women - Polycystic Ovary Syndrome (PCOS)
- Women - Gestational Diabetes Mellitus (GDM)

B) Current prescribed medications:

- Antihypertensive medication
- Lipid modifying medication
- Allopurinol
- Antiplatelet therapy
- Metformin
- Other diabetes medication
- Antidepressant medication



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C) Current Supplements:

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

**4. Bloods (preferably taken before 24-month appointment)**

Blood Test		Result	Date Taken	Target Ranges:
Lipids	Total Cholesterol			<4.0 mmol/L
	LDL Cholesterol			<2.0 mmol/L
	HDL Cholesterol			>1.0 mmol/L
	Triglycerides			<1.7 mmol/L
	HDL/LDL Ratio			<4.0
HbA1c				≤40 mmol/mol
Liver Function Tests	ALT			
	AST			
	GGT*			
Urate				
Urine albumin creatinine ratio				

**5. Clinical Measures**

	Clothing worn	Measure 1	Measure 2	Average
Weight (kg) (1 layer light clothing)				
Height (mm) (No shoes)				
Waist Circumference (cm) (Preferably no layers or 1 layer light clothing)				
Systolic Blood Pressure (mmHg)	N/A			
Diastolic Blood Pressure (mmHg)	N/A			
BMI (kg/m <sup>2</sup> ) = Weight (kg)/Height (m) x Height (m)	Calculated automatically on MedTech			

**6. Lifestyle (review and update accordingly)**

A) Special Diet or food allergies (tick if applicable):

- Vegetarian
- Vegan
- Pescatarian (vegetarian + fish)
- Nut free
- Dairy free
- Fish free
- Egg free
- Gluten free
- Soy free

B) What physical activities do you do (including household chores and exercise programmes)? \_\_\_\_\_

C) On average how many hours of physical activity per week? \_\_\_\_\_ hours

D) Please indicate who you live with?

- Spouse/partner
- Child – How many: \_\_\_\_\_
- Father
- Mother
- Other adults – How many: \_\_\_\_\_
- Other children – How many: \_\_\_\_\_

E) Who mostly buys food in your house?

- Myself
- Spouse/partner
- Parent
- Other

F) Who mostly cooks food in your house?

- Myself
- Spouse/partner
- Parent
- Other

G) Is your budget for food limited?  Yes  No

H) On a scale of 1 – 10, how ready are you to make/maintain food changes (1 – not ready at all; 10 – really motivated)? \_\_\_\_\_

**7. Clinical Notes – management post study**

Discuss ongoing weight loss or weight maintenance post study

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**8. Diet Assessment**

E) Starting The Conversation (STC): Diet – See Appendix 5 or Laminated Card

F) Detailed Dietary Assessment Guide – See Appendix 6 or Laminated Card

**9. Nutritional Goals**

1. \_\_\_\_\_

\_\_\_\_\_

2. \_\_\_\_\_

\_\_\_\_\_

3. \_\_\_\_\_

\_\_\_\_\_

## **Appendix 1: Study invitation letter**

### **Sample Invite Letter to Patient**

Date

Address

Dear

#### **Invitation to participate in the Hawke's Bay Pre-diabetes Intervention Package in (PIP) Primary Care study**

Hawke's Bay is the first region in New Zealand to run a Pre-diabetes Lifestyle Support Programme which lasts for two years. The programme will support people who have pre-diabetes and/or who are thought to be at risk of developing diabetes.

The programme involves 12 FREE appointments over the next two years. During these appointments you will be offered nutrition and lifestyle support from your practice nurse to help you reduce your weight and improve your HbA1c (a blood test that measures average blood glucose levels over the last 8-12 weeks). Your blood test and weight will be monitored. In addition, seven FREE community-based group education sessions are offered, as well as written resources.

The programme has approval from the Ethics Committee and is a collaboration with Edgar Diabetes and Obesity Research, University of Otago, and Health Hawkes Bay general practices.

We hope that with easy access to your nurse and/or doctor, along with an increased focus on your health, you will see an improvement in your health.

Our practice is participating in this programme and we would like to invite you to take part.

If you would like to be a part of this programme, please phone the practice to make an appointment. Family/whanau members are very welcome to come along to the programme to support you.

Further information about this programme is available from Ms Terrie Spedding at Health Hawke's Bay – telephone: 871 5834.

Yours sincerely

For Practice Manager

**Appendix 2: Decline to participate in study form**

	<b>Date (dd/mm/yyyy)</b>	<b>Main Reason</b>
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		

## Appendix 3: Participant information sheet and Consent form

### Participant Information Sheet



Study title: *Prediabetes Intervention Package (PIP) in Primary Care Study – what predicts regression from prediabetes to normoglycaemia?*

Locality: **Hawke's Bay** Ethics committee ref.: **17/NTA/24**

Lead investigator: **Dr Kirsten Coppel** Contact phone number: **03 470 9074**

You are invited to take part in a study on prediabetes lifestyle management. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

#### WHAT IS THE PURPOSE OF THE STUDY?

Both prediabetes and diabetes are common in New Zealand, and testing for these conditions is recommended as part of a heart disease risk assessment in New Zealand. Good research has shown that progressing from prediabetes to diabetes can be stopped or reversed through lifestyle changes. We have developed a 6 month prediabetes nutrition programme which is provided by practice nurses. It has been successful for some people. In this study we will continue the programme for a longer time (2 years) and we will ask the question why the programme is more effective for some people than others.

The aim of this study is to find out if there are any reasons as to why blood glucose levels return to normal after taking part in the prediabetes nutrition programme for some people with prediabetes,

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but not others. We will look at changes in weight and measures of blood glucose control. We will also look at how many people get diabetes during the 2 year study.

This study is funded by the Health Research Council, and is being carried out by the University of Otago and Health Hawke's Bay with support from the Hawke's Bay District Health Board. The research team is Kirsten Coppell, Joanna Norton, Andrew Gray, Jeremy Krebs, Trudy Sullivan and Tony Merriman from the University of Otago, Trish Freer, Terrie Spedding and Lillian Ward from Health Hawke's Bay, Sally Abel from Kaupapa Consulting Ltd, David Tipene-Leach from Eastern Institute of Technology Hawke's Bay, Lisa Whitehead from Edith Cowan University, Australia and Leigh Perreault from University of Colorado Denver School of Medicine.

If you have any questions about the study, please do not hesitate to contact us.

Mrs Trish Freer  
Health Programmes Manager  
Health Hawke's Bay

Dr Kirsten Coppell  
Senior Research Fellow  
Edgar Diabetes and Obesity Research  
University of Otago

Ph: (06) 871 5646

Email: [Trish@healthhb.co.nz](mailto:Trish@healthhb.co.nz)

Ph: (03) 470 9074

Email: [kirsten.coppell@otago.ac.nz](mailto:kirsten.coppell@otago.ac.nz)

This study has been approved by the Health and Disability Ethics Committee.

### WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to participate in this study because your blood tests show that you have prediabetes, you are not taking medicine for prediabetes and are aged less than 70 years.

All people found to have prediabetes should be given lifestyle advice to prevent diabetes.

In this study we will be looking at why the prediabetes nutrition programme provided by trained practice nurses works well for some people and not others. There could be many possible reasons, and we will be asking questions and doing blood tests to try to find any important reasons. The prediabetes nutrition programme will involve seeing your practice nurse for a brief dietary assessment, followed by good dietary advice and support for weight loss. You will be asked to see your practice nurse six times during the first six months, then every three months until the end of the study at two years. You will also be invited to attend a group education programme for extra advice and support. During the study you will continue to see your GP as you normally do for medical advice and treatment.

As part of monitoring your progress with the lifestyle programme, the main measures we will look at are blood glucose control and body weight. Usual clinical blood and urine tests will be done at the beginning of the study, and at 6 months, 1 year and 2 years.

A research nurse will also contact you to ask some extra questions about any support you may have to help make lifestyle changes, your sleep patterns, your physical activity and your quality of life. These questions will be asked at the beginning of the study, and again at 6 months, 1 year and 2

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years. At the same time, the research nurse will also arrange for a fasting blood test to get more information about your prediabetes, such as your insulin levels.

Only health information relating to your prediabetes will be looked at. The researchers will not see any other health information and will not be able to identify who you are.

### WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

This new prediabetes nutrition programme provided by practice nurses aims to lower the chance of getting diabetes, and if so, this programme will benefit the many people with prediabetes.

There are no unforeseen risks associated with participating in this study.

Throughout the study you will continue to receive your usual medical care.

### WHO PAYS FOR THE STUDY?

There will be no extra costs for taking part in this prediabetes lifestyle study, if you chose to participate. There will be no consultation cost for seeing your practice nurse and no cost for attending the group education sessions.

### WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

### WHAT ARE MY RIGHTS?

Taking part in this study is voluntary (your choice). You do not have to take part, or you can leave the study at any time without any disadvantage.

All participants have the right to access information about them collected as part of this study.

All participants will be told of any new information about harmful or beneficial effects related to this study that becomes available during the study that may have an impact on their health.

The privacy and confidentiality of all participants will be respected and maintained throughout the study.

We will not be able to provide interpreters as part of this study.

### WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

After the study you will continue to receive medical care from your general practitioner and practice nurse as you normally do. If you change your mind about taking part in the study you will continue to receive medical care from your general practitioner and practice nurse as you normally do.

PIP in Primary Care Study – Patient Information Sheet. Version 2. 24 Feb 2017.



## NOT FOR CIRCULATION

All study data sent to the Edgar Diabetes and Obesity Research at the University of Otago will not be identifiable. Dr Kirsten Coppell will be responsible for the secure storage of the data. The data will be stored in a locked room on a password protected computer for 10 years until the end of the study. At the end of the study, all study data held at the University of Otago will be deleted.

Any remaining blood samples taken as part of the research will be disposed of at the end of the study. This can be done using standard disposal methods or with an appropriate karakia. You will be asked on the consent form if you would like any of your remaining samples to be disposed with appropriate karakia at the end of the study.

When the main part of the study is finished (end of 2019), all study participants will be invited to a presentation to hear the results of the study. Refreshments will be provided at this meeting.

### WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr Kirsten Coppell, Senior Research Fellow, Edgar Diabetes and Research,  
University of Otago  
Telephone: 03 470 9074  
Email: [kirsten.coppell@otago.ac.nz](mailto:kirsten.coppell@otago.ac.nz)

OR

Name: Mrs Trish Freer, Health Programmes Manager,  
Health Hawke's Bay  
Telephone: (06) 871 5655  
Email: [Trish@healthhb.co.nz](mailto:Trish@healthhb.co.nz)

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

For Maori health support please contact :

Name: Ms Lillian Ward, Team Mauri Ora Coordinator,  
Health Hawke's Bay  
Telephone: (06) 871 5661  
Email: [lillian@healthhb.co.nz](mailto:lillian@healthhb.co.nz)

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS  
Email: [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)

## Consent Form



**Please tick to indicate you consent to the following**

---

I have read and I understand the Participant Information Sheet.

---

I have been given sufficient time to consider whether or not to participate in this study.

---

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

---

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

---

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

---

I consent to the research staff collecting and processing my information, including information about my health.

---

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes  No

---

I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. Yes  No

---

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

---

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

---

I understand the compensation provisions in case of injury during the study.

---

NOT FOR CIRCULATION

---

I know who to contact if I have any questions about the study in general.

---

I understand my responsibilities as a study participant.

---

I choose to have my research blood samples disposed with an appropriate karakia. Yes  No

---

I wish to receive a summary of the results from the study. Yes  No

---

I consent to being contacted by a member of the PIP study research team to participate in further research related to this study. Yes  No

---

**Declaration by participant:**

I hereby consent to take part in this study.

Participant's name:

---

Signature:

Date:

---

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's/Practice Nurse's name:

---

Signature:

Date:

---

## Appendix 4. Clinical measurements protocol

The clinical measures to be taken as part of the PIP in Primary Care study are blood pressure, height, weight and waist circumference.

### A. BLOOD PRESSURE

***Two separate blood pressure measurements are to be taken and recorded.***

#### Equipment

- Calibrated sphygmomanometer.

#### Participant preparation

- Participants are to be rested for five minutes in a seated position.
- Ask the participant to remove any clothing from the dominant arm to improve accuracy of the reading.

#### Measurement method

- Blood pressure is to be measured using a calibrated sphygmomanometer.
- Apply blood pressure cuff firmly to dominant arm with artery indicator in the correct position.
- *Make sure that the appropriate cuff size is used. (Large Adult 11 25-34 cm OR Adult 12 32-43cm).*

#### ***For automated sphygmomanometer***

- Push 'ON' button, and wait for screen to appear.
- Press inflate button.
- The systolic and diastolic measurements will be shown on the screen.
- Record systolic and diastolic pressures on the PIP Advanced Form.
- Repeat measurement 5-10 minutes later and record on the PIP Advanced Form.

#### ***For manual sphygmomanometer***

- Tighten cuff knob.
- Place stethoscope over the brachial artery in the antecubital space.
- Pump cuff up until pressure reaches 220-230mmHg. (For those with high blood pressure you may have to pump higher).
- Release pressure slowly by loosening the knob.
- Listen for systolic and diastolic sounds.
- The systolic and diastolic measurements are taken to the nearest 2mmHg.
- Fully release knob.
- Record systolic and diastolic pressures on the PIP Advanced Form.
- Repeat measurement 5-10 minutes later and record on the PIP Advanced Form.

## B. HEIGHT

***Duplicate height measurements are to be taken and recorded.***

### Equipment

- Stadiometer positioned so that participant is standing on firm flooring.

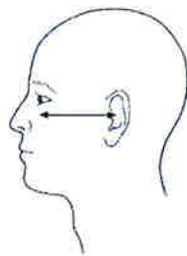
### Participant preparation:

- Ask the participant to remove his/her footwear.
- If the hair is done up on top of the head ask the person to undo it.

### Measurement method:

- Position the participant, without footwear, with his/her heels, buttocks and upper part of the back touching the stadiometer pole with body weight evenly distributed and both feet flat on the platform.
- Gently position the head so that it is aligned in the **Frankfort horizontal plane**. The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard.
- Ask the participant to stand tall and take a deep breath and hold this position.
- Lower the measuring block firmly on the head, crushing hair if necessary.
- Measurement is taken at the end of the deep inward breath.
- The measurement is taken to the nearest whole millimetre (0.1cm).
- Ask the participant to step away from the stadiometer.
- Record the height measurement on the PIP Advanced Form.
- Repeat measurement 5-10 minutes later and record on the PIP Advanced Form.

### The Frankfort Plane



## C. WEIGHT

**Duplicate weight measurements are to be taken and recorded.**

### Equipment

- Calibrated weighting scales.
- Scales must be on firm flooring.
- ***Use the same set of scales each time that an individual patient is weighed.***

### Participant preparation

- Ask the participant to remove his/her footwear, any bulky jackets or jerseys and any heavy items from pockets eg key chains, cell-phones, wallets, etc.
- It is preferable that participant wears only one layer of light clothing.
- Make a note of the type of clothing the participant is wearing and instruct them to try to wear similar clothing for future weight measurements.

### Measurement method

- Weight is to be measured using a set of calibrated scales.
- Use the same set of scales for all weight measurements.
- Turn scales on by tapping the front bar and wait for them to zero.
- Ask the participant to step onto the scales and ensure they are evenly balanced.
- The measurement is to be taken to the nearest 0.1 kilogram.
- Ask the participant to stand off the scale.
- Record the weight measurement on the PIP Advanced Form.
- Repeat measurement 5-10 minutes later and record on the PIP Advanced Form.

## D. WAIST CIRCUMFERENCE

***Duplicate waist circumference measurements are to be taken and recorded.***

### Equipment

- Lufkin Executive thinline (2m) tape measure (provide by the study)

### Participant preparation

- Inform participant you are going to take a measurement around their waist and that it needs to be against their skin.
- Ask participant to lift clothing so the umbilicus region is visible.

### Measurement:

- On the right-hand side of the body palpate the hip bone to locate the anterior superior iliac spine, or ask the participant to find this landmark.
- Directly above the anterior superior iliac spine palpate the rib region to find the bottom of the rib cage, or ask the participant to find this landmark.
- Ask the participant if it is OK to make two small marks with a pen on their skin (one on the right and one on the left).
- With a tape measure make a small mark at the mid-point between the anterior superior iliac and the bottom of the rib cage.
- Repeat marking on the left side of the body.
- Ask the participant to breathe quietly and apply the Lufkin Executive thinline tape measure against the skin around the body at the level of the two marked points.
- Ensure the tape measure is flat and taut – the pressure of the tape measure should not cause the flesh to bulge, nor should the tape measure bag.
- ***Ensure the measurement reading is taken from '0cm' on the tape measure, which is about 10cm from the end of the tape measure.***
- The measurement is to be taken to the nearest 0.5 centimetre.
- Remove tape measure.
- Record the waist circumference measurement on the PIP Advanced Form.
- Repeat measurement 5-10 minutes later and record on the PIP Advanced Form.

***NB. In situations where an abdominal flesh fold exists, take the measurement with the tape placed over the fold.***



## Appendix 5. Starting The Conversation: Diet

### Starting The Conversation: Diet

Edited and used with permission from the University of North Carolina

#### Over the past few months:

1. How many times a week did you eat takeaways or eat out?	Less than 1 Time <input type="checkbox"/>	1-3 Times <input type="checkbox"/>	4 or More Times <input type="checkbox"/>
2. How many servings of fruit did you eat each day?	5 or More <input type="checkbox"/>	3-4 <input type="checkbox"/>	2 or Less <input type="checkbox"/>
3. How many servings of vegetables did you eat each day?	5 or More <input type="checkbox"/>	3-4 <input type="checkbox"/>	2 or Less <input type="checkbox"/>
4. How many soft drinks or glasses of sweetened beverages did you drink each day?	Less than 1 <input type="checkbox"/>	1-2 <input type="checkbox"/>	3 or More <input type="checkbox"/>
5. How many times a week did you eat beans (like kidney beans or chick peas), chicken, or fish?	3 or More Times <input type="checkbox"/>	1-2 Times <input type="checkbox"/>	Less than 1 Time <input type="checkbox"/>
6. How many times a week did you eat regular snack chips or crackers?	1 Time or Less <input type="checkbox"/>	2-3 Times <input type="checkbox"/>	4 or More Times <input type="checkbox"/>
7. How many times a week did you eat desserts and other sweet foods (not the low-fat kind)?	1 Time or Less <input type="checkbox"/>	2-3 Times <input type="checkbox"/>	4 or More Times <input type="checkbox"/>
8. How much margarine, butter, or meat fat do you use to season vegetables or put on potatoes, bread, or corn?	Very Little <input type="checkbox"/>	Some <input type="checkbox"/>	A Lot <input type="checkbox"/>



## Appendix 6. PIP in primary care study detailed dietary assessment (DDA) guide

FOOD GROUP	ADDITIONAL QUESTIONS	GOAL PROMPTS
<p><b>1. Takeaways; Eating out</b></p> <p>Choose healthy takeaway options that include some vegetables</p> <p>Appropriate portion sizes</p> <p>Accompany with healthy sides and drinks</p>	<p>What type of takeaway meals do you eat?</p> <p>What type of meals do you choose when you eat out?</p> <p>What size do you order?</p> <p>Do you have drinks when you eat out? What type? How much? Do you add sugar to hot drinks?</p>	<ul style="list-style-type: none"> <li>Decrease the amount of times you eat takeaway food, that is, eat more home prepared (homemade) food</li> <li>Choose healthier takeaway options: salad containing sandwiches (Subway, Turkish, Pita Pit)</li> <li>Downsize your combo</li> <li>Swap soft drinks for diet soft drinks, water, milk (<u>not</u> milkshakes or flavoured milk)</li> <li>Limit extras: cookies, muffins, fries, etc</li> </ul>
<p><b>2. Fruit</b></p> <p>Eat at least 2 pieces of fruit per day</p> <p>Choose fresh fruit. Frozen fruit or tinned fruit in unsweetened juice are good choices</p>	<p>What type of fruits do you eat?</p> <p>What is your serving size?</p> <p>NOTE: A serving of banana is half a large banana or one small 'bobby' banana. A green banana is considered to be a serving of carbohydrate</p>	<ul style="list-style-type: none"> <li>Increase servings of fruit e.g. add 1 serving per day</li> <li>Aim to include a piece of fruit with breakfast</li> <li>Swap to healthier versions e.g. tinned fruit in syrup to tinned fruit in juice</li> </ul>
<p><b>3. Vegetables</b></p> <p>Eat at least 4 portions of vegetables each day</p> <p>Eat lots of non-starchy vegetables (Unlimited)</p> <p>Eat a rainbow of colours</p> <p>Choose fresh vegetables. Frozen or tinned are good choices too</p>	<p>What type of vegetables do you eat?</p> <p>What is your serving size?</p>	<ul style="list-style-type: none"> <li>Increase servings of vegetables e.g. add 1 serving per day</li> <li>Aim to include vegetables with lunch and dinner meals, making up 50% of the meal (plate model)</li> <li>Keep starchy vegetables (potato, kumara, green bananas, taro) to ¼ of the plate (plate model)</li> <li>Swap to healthier versions e.g. potato chips for baked potatoes</li> </ul>
<p><b>4. Fluids</b></p> <p>Drink 6-8 glasses of fluid each day</p> <p>Water is the best choice, but can also include low fat milk, vegetable juice, tea, coffee, cocoa and diet soft drinks</p> <p>Limit intake of alcohol, soft drinks, fruit juice, energy drinks and sports drinks</p>	<p>What soft drink or sweetened beverages do you drink? How much?</p> <p>What other fluids do you drink over the day? How much?</p> <p>Do you drink water? How much?</p> <p>Do you drink hot drinks? Do you add sugar? How much?</p> <p>What type of milk do you buy/use?</p> <p>How often do you drink alcohol? How many standard drinks per occasion?</p>	<ul style="list-style-type: none"> <li>6-8 glasses water per day (or healthy fluids)</li> <li>Decrease the number of unhealthy drinks or eliminate</li> <li>Swap unhealthy drinks for healthier drinks (water, trim milk, flavoured water, tea, coffee)</li> <li>Limit alcohol to &lt;3 standard drinks per day for men and &lt;2 for women</li> <li>Swap blue milk for green or light blue</li> </ul> <p>NOTE: One standard drink is: 330ml can beer, 100ml wine, 30ml spirits)</p>

<p><b>5. Protein</b></p> <p>1-2 servings of protein food per day</p> <p>Choose lean meats</p> <p>Eat a variety of sources of protein including: fish, seafood, legumes, soy products, skinned chicken, lean meats, nuts, eggs and dairy products</p>	<p>What types of meats and fish do you currently eat? How often? How much?</p> <p>Do you eat peas and beans, tofu, nuts, eggs, dairy products or other meat alternatives? How often? How much?</p> <p>Do you trim the fat and skin off meat?</p> <p>What cooking methods do you use to cook meat?</p>	<ul style="list-style-type: none"> <li>• Eat lean meat</li> <li>• Adjust to appropriate portion sizes (size of your palm)</li> <li>• Swap meat for beans, tofu, nuts or eggs one night of the week</li> <li>• Add a portion of fish</li> <li>• Add a portion of oily fish (red flesh fish)</li> <li>• Trim fat and skin from meat</li> <li>• Use low fat cooking methods- steam, microwave, grill, stir fry, boil, bake</li> </ul>
<p><b>6. Snack foods &amp; bread</b></p> <p>Choose healthy snacks foods (see list in resource folder)</p> <p>Choose wholegrain or wholemeal bread</p> <p>Appropriate portion sizes</p>	<p>What type of snack chips or crackers do you eat?</p> <p>What other foods do you snack on?</p> <p>What is your portion size? How much would you eat?</p> <p>Do you eat bread? How often? How much? What type?</p>	<ul style="list-style-type: none"> <li>• Decrease portion size/ amount</li> <li>• Swap for healthy snack alternatives</li> <li>• Switch to low fat varieties (check for sugar)</li> <li>• Switch to wholegrain or wholemeal varieties</li> </ul>
<p><b>7. Sugar</b></p> <p>Limit high sugar foods</p> <p>Choose sweet foods with some nutritional benefits e.g. fruit, low fat yoghurt</p> <p>OR Eat small portions of sweet foods</p>	<p>What types of desserts and sweet foods do you eat? How much?</p> <p>Do you use jam and honey as spreads? How much?</p>	<ul style="list-style-type: none"> <li>• Decrease frequency</li> <li>• Decrease portion size</li> <li>• Swap for healthy alternatives</li> <li>• Save special foods to enjoy on special occasions</li> </ul>
<p><b>8. Fat</b></p> <p>Eat foods low in fat</p> <p>Eat foods low in saturated fat (animal based) and trans-fats</p> <p>Choose polyunsaturated and monounsaturated fats (plant based)</p> <p>Include nuts, seeds and nut butters up to 1 dessert spoon per day</p>	<p>What type of fat do you use in cooking?</p> <p>Demonstrate a portion size</p> <p>What type of fat do you use as a spread? How much?</p> <p>Do you eat nuts or nut butters? How often? How much?</p>	<ul style="list-style-type: none"> <li>• Decrease portion size</li> <li>• Swap for saturated fat (animal fats) for monounsaturated or polyunsaturated fat (plant fats)</li> <li>• Use low fat cooking methods</li> <li>• Use low fat varieties (watch for sugar)</li> <li>• Use other seasonings instead of fat: stock, herbs, spices, lemon</li> <li>• Include small amounts of nuts and seeds regularly, up to 1 dessert spoon per day</li> </ul>

## Appendix 7. Stanford programme group education information

### STANFORD PROGRAMME COMMUNITY GROUP EDUCATION

These will run at weekly intervals over 6 weeks. We encourage you to bring a family member or friend to these sessions.

**Date and time of first session:**

---

**To be held at:**

---

The 6 modules, each lasting 1-1 ½ hours will cover:

<p><b>Week 1:</b></p> <ul style="list-style-type: none"> <li>• Overview of self-management and chronic health conditions</li> <li>• Using your mind to manage symptoms</li> <li>• Getting a good night's sleep</li> <li>• Making an action plan</li> </ul>	<p><b>Week 4:</b></p> <ul style="list-style-type: none"> <li>• Making an action plan</li> <li>• Feedback and problem-solving</li> <li>• Better breathing</li> <li>• Healthy eating</li> <li>• Communication skills</li> </ul>
<p><b>Week 2:</b></p> <ul style="list-style-type: none"> <li>• Making an action plan</li> <li>• Feedback and problem-solving</li> <li>• Dealing with difficult emotions</li> <li>• Physical activity and exercise</li> <li>• [Preventing falls]</li> </ul>	<p><b>Week 5:</b></p> <ul style="list-style-type: none"> <li>• Using your mind to manage symptoms</li> <li>• Making an action plan</li> <li>• Feedback and problem-solving</li> <li>• Healthy eating</li> <li>• [Medication usage]</li> <li>• Making Informed treatment decisions</li> <li>• Dealing with depression</li> </ul>
<p><b>Week 3:</b></p> <ul style="list-style-type: none"> <li>• Using your mind to manage symptoms</li> <li>• Making an action plan</li> <li>• Feedback and problem-solving</li> <li>• Physical activity and exercise</li> <li>• Making decisions</li> <li>• Pain and fatigue management</li> </ul>	<p><b>Week 6:</b></p> <ul style="list-style-type: none"> <li>• Using your mind to manage symptoms</li> <li>• Making an action plan</li> <li>• Feedback and problem-solving</li> <li>• Working with your health care professional and system</li> <li>• Weight management</li> <li>• Future plans</li> </ul>

## **Appendix 8. Additional information to be collected by the Research Nurse**

An additional questionnaire (see Appendix 9) will be completed with the participating patient by the Research Nurse. The specific areas that will be included in the questionnaire are:

- A. Social Support and Eating Habits
- B. Social Support and Exercise
- C. Social Support in general
- D. Sleep Quality
- E. Stages and Processes of Change in Weight Management
- F. Physical Activity
- G. Quality of Life

The Research Nurse will also arrange for a fasting blood test to be taken. The additional non-routine blood tests that will be done are fasting insulin, fasting glucose and creatinine, and lipoproteins and inflammatory markers.

The Research Nurse will make contact with each participating patient following their baseline appointment with their practice nurse. The practice nurse will have informed the study participants about the Research Nurse contacting them (see page 17)

The fasting blood test will be taken either by the Research Nurse or at Southern Community Laboratories (see Appendix 10).

## Appendix 9. Research specific questionnaires

### SOCIAL SUPPORT AND EATING HABITS SURVEY

Below is a list of things people might do or say to someone who is trying to improve their eating habits. We are interested in high fat and high salt (or high sodium) foods. If you are not trying to make any of these dietary changes, then some of the questions may not apply to you, but please read and give an answer to every question.

Please rate each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

**SAMPLE:**

- |  |                 |                 |
|--|-----------------|-----------------|
|  | Family          | Friends         |
| A. If my family <i>rarely</i> makes fun of the foods I eat, and my friends <i>very often</i> do, I would answer like this: |                 |                 |
| A. Made fun of the foods I eat   | A. <u>  2  </u> | A. <u>  5  </u> |

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	8

During the past three months, my family (or members of my household) or friends:

- |  | Family                | Friends               |
|--|-----------------------|-----------------------|
| 1. Encouraged me not to eat "unhealthy foods" (cake, salted chips) when I'm tempted to do so.  | 1. <u>          </u>  | 1. <u>          </u>  |
| 2. Discussed my eating habit. changes with me (asked me how I'm doing with my eating changes). | 2. <u>          </u>  | 2. <u>          </u>  |
| 3. Reminded me not to eat high fat, high salt foods.   | 3. <u>          </u>  | 3. <u>          </u>  |
| 4. Complimented me on changing my eating habits ("Keep it up", "We are proud of you ") .       | 4. <u>          </u>  | 4. <u>          </u>  |
| 5. Commented if I went back to my old eating habits.   | 5. <u>          </u>  | 5. <u>          </u>  |
| 6. Ate high fat or high salt foods in front of me.   | 6. <u>          </u>  | 6. <u>          </u>  |
| 7. Refused to eat the same foods I eat.  | 7. <u>          </u>  | 7. <u>          </u>  |
| 8. Brought home foods I'm trying not to eat.   | 8. <u>          </u>  | 8. <u>          </u>  |
| 9. Got angry when I encouraged them to eat low salt, low fat foods.                            | 9. <u>          </u>  | 9. <u>          </u>  |
| 10. Offered me food I'm trying not to eat.   | 10. <u>          </u> | 10. <u>          </u> |

## SOCIAL SUPPORT AND EXERCISE SURVEY

Below is a list of things people might do or say to someone who is trying to exercise regularly. If you are not trying to exercise, then some of the questions may not apply to you, but please read and give an answer to every question.

Please rate each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

none	rarely	a few times	often	very often	does not apply
1	2	3	4	5	8

During the past three months, my family (or members of my household) or friends:

	Family	Friends
11. Exercised with me.	11. _____	11. _____
12. Offered to exercise with me.	12. _____	12. _____
13. Gave me helpful reminders to exercise ("Are you going to exercise tonight?").	13. _____	13. _____
14. Gave me encouragement to stick with my exercise program.	14. _____	14. _____
15. Changed their schedule so we could exercise together.	15. _____	15. _____
16. Discussed exercise with me.	16. _____	16. _____
17. Complained about the time I spend exercising.	17. _____	17. _____
18. Criticized me or made fun of me for exercising.	18. _____	18. _____
19. Gave me rewards for exercising (bought me something or gave me something I like).	19. _____	19. _____
20. Planned for exercise on recreational outings.	20. _____	20. _____
21. Helped plan activities around my exercise.	21. _____	21. _____
22. Asked me for ideas on how <i>they</i> can get more exercise.	22. _____	22. _____
23. Talked about how much they like to exercise.	23. _____	23. _____

Office Use Only

1. English  2. Spanish Date: Entered   /   /

Coder:

## Social Support Questionnaire (Short Form)

### SSQSR

#### INSTRUCTIONS:

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all the people you know, excluding yourself, whom you can count on for help or support in the manner described. Give the persons' initials, their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have.

If you have had no support for a question, check the words "No one," but still rate your level of satisfaction. Do not list more than nine persons per question.

Please answer all the questions as best you can. All your responses will be kept confidential.

#### EXAMPLE:

Who do you know whom you can trust with information that could get you in trouble?

No one	1) T.N. (brother)	4) T.N. (father)	7)
	2) L.M. (friend)	5) L.M. (employer)	8)
	3) R.S. (friend)	6)	9)

How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
-----------------------	-------------------------	---------------------------	------------------------------	----------------------------	--------------------------

1. Whom can you really count on to be dependable when you need help?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

2. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

3. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

4. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

5. Who accepts you totally, including both your worst and your best points?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

6. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

7. Whom can you really count on to care about you, regardless of what is happening to you?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

8. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

9. Whom can you really count on to help you feel better when you are feeling generally down-in-the dumps?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

10. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

11. Whom can you count on to console you when you are very upset?

No one	1)	4)	7)
	2)	5)	8)
	3)	6)	9)

12. How satisfied?

6 - very satisfied	5 - fairly satisfied	4 - a little satisfied	3 - a little dissatisfied	2 - fairly dissatisfied	1 - very dissatisfied
--------------------	----------------------	------------------------	---------------------------	-------------------------	-----------------------

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**TO SCORE SSQR:**

- Count the total number of people for each of the odd-numbered items. Add the totals together (Max. = 54). Divide by 6 for per item SSQ Number Score, or SSQN.
- Add the total Satisfaction scores for the 6 even-numbered items (Max. = 36). Divide by 6 for per item SSQ Satisfaction score or SSQS.
- You can also compute a Family score and a Non-Family score by using the method in #1 for all people described as family members, or not described as family members respectively.



Name \_\_\_\_\_

Date \_\_\_\_\_

## Sleep Quality Assessment (PSQI)

### What is PSQI, and what is it measuring?

The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.

### INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

#### During the past month,

1. When have you usually gone to bed? \_\_\_\_\_
2. How long (in minutes) has it taken you to fall asleep each night? \_\_\_\_\_
3. What time have you usually gotten up in the morning? \_\_\_\_\_
4. A. How many hours of actual sleep did you get at night? \_\_\_\_\_  
 B. How many hours were you in bed? \_\_\_\_\_

5. During the past month, how often have you had trouble sleeping because you:	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

### Scoring

- |             |  |          |
|-------------|--|----------|
| Component 1 | #9 Score   | C1 _____ |
| Component 2 | #2 Score (<15min (0), 16-30min (1), 31-60 min (2), >60min (3))<br>+ #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3) | C2 _____ |
| Component 3 | #4 Score (>7(0), 6-7 (1), 5-6 (2), <5 (3))   | C3 _____ |
| Component 4 | (total # of hours asleep) / (total # of hours in bed) x 100<br>>85%=0, 75%-84%=1, 65%-74%=2, <65%=3                      | C4 _____ |
| Component 5 | # sum of scores 5b to 5j (0=0; 1-9=1; 10-18=2; 19-27=3)  | C5 _____ |
| Component 6 | #6 Score   | C6 _____ |
| Component 7 | #7 Score + #8 score (0=0; 1-2=1; 3-4=2; 5-6=3)   | C7 _____ |

Add the seven component scores together \_\_\_\_\_ Global PSQI \_\_\_\_\_

**A total score of "5" or greater is indicative of poor sleep quality.  
 If you scored "5" or more it is suggested that you discuss your sleep habits with a healthcare provider**

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## Stages and processes of change questionnaires in weight management (S-Weight and P-Weight)

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Please cite as:

Andrés, A., Saldaña, C., Gómez-Benito, J. (2009).  
Establishing the stages and processes of  
change for weight Loss by consensus of  
experts. *Obesity*, 17(9), 1717-1723.

Andrés, A., Saldaña, C., Gómez-Benito, J. (2011).  
The transtheoretical model in weight  
management: Validation of the processes  
of change questionnaire. *Obesity Facts*, 4,  
433–442.

Andrés, A., Saldaña, C., Beeken, R. (2015).  
Assessment of processes of change for  
weight management in a UK sample.  
*Obesity Facts*, 8, 43-53.

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Updated 7th April 2016

## Stages of change questionnaire in weight management (S-Weight English version)

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*Please answer this questionnaire honestly. Mark with a cross the statement that best describes your current weight situation.*

- At the moment I'm not doing anything to lose weight and I have no intention of doing anything over the next 6 months
- At the moment I'm not doing anything to lose weight but I'm thinking about doing something over the next 6 months
- During the last year I haven't done anything to lose weight but I'm planning to do something over the next 30 days
- I've been making an effort to lose weight (by dieting<sup>1</sup> and/or exercising<sup>2</sup>) for less than 6 months
- I've been making an effort to maintain my weight (by dieting<sup>1</sup> and/or exercising<sup>2</sup>) for more than 6 months

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<sup>1</sup> Being on a diet means having a well-balanced diet in which fat, sugar and salt consumption are restricted and where greater amounts of fruit, vegetables and pulses are eaten.

<sup>2</sup> Remember that in this case we are referring to regular exercise. This means any planned physical activity (e.g. brisk walking, cycling, swimming, etc.) that is done in order to increase physical fitness. This activity should be performed three or more times per week for at least twenty minutes per session, and at a level that increases your breathing rate and causes you to break into a sweat.

## Processes of change questionnaire in weight management (Original P-Weight English version)

Please answer this questionnaire honestly. Mark with a cross the extent to which you agree or disagree with the statements below, using the following scale:

1 <i>Strongly disagree</i>	2 <i>Disagree</i>	3 <i>Neither agree nor disagree</i>	4 <i>Agree</i>	5 <i>Strongly agree</i>
-------------------------------	----------------------	--	-------------------	----------------------------

- |  |   |   |   |   |   |
|--|---|---|---|---|---|
| 1. I think I should eat food with less fat   | 1 | 2 | 3 | 4 | 5 |
| 2. I look for information about the types of food that could help me lose weight   | 1 | 2 | 3 | 4 | 5 |
| 3. I try to put food away to avoid nibbling  | 1 | 2 | 3 | 4 | 5 |
| 4. I now realize I have a weight problem   | 1 | 2 | 3 | 4 | 5 |
| 5. Society's view of obese people affects me emotionally                           | 1 | 2 | 3 | 4 | 5 |
| 6. I tell myself positive things to avoid overeating                               | 1 | 2 | 3 | 4 | 5 |
| 7. I try not to have food in sight   | 1 | 2 | 3 | 4 | 5 |
| 8. My weight restricts my relationships  | 1 | 2 | 3 | 4 | 5 |
| 9. I am worried about gaining more weight  | 1 | 2 | 3 | 4 | 5 |
| 10. When I really want to eat, I do activities to avoid it                         | 1 | 2 | 3 | 4 | 5 |
| 11. There are no snack foods in my fridge or cupboards*                            | 1 | 2 | 3 | 4 | 5 |
| 12. My current weight makes my daily life difficult                                | 1 | 2 | 3 | 4 | 5 |
| 13. Losing weight would help me improve my relationships with others               | 1 | 2 | 3 | 4 | 5 |
| 14. I have learnt to control my appetite*  | 1 | 2 | 3 | 4 | 5 |
| 15. I avoid places where people eat a lot  | 1 | 2 | 3 | 4 | 5 |
| 16. My family and friends are worried about my weight                              | 1 | 2 | 3 | 4 | 5 |
| 17. Being overweight makes me feel bad   | 1 | 2 | 3 | 4 | 5 |
| 18. I have learnt skills that reduce my desire to eat (e.g. distracting myself)    | 1 | 2 | 3 | 4 | 5 |
| 19. When I am on a diet <sup>1</sup> I avoid eating with people who I overeat with | 1 | 2 | 3 | 4 | 5 |
| 20. Most of my health problems are due to my being overweight                      | 1 | 2 | 3 | 4 | 5 |
| 21. I feel guilty when I overeat   | 1 | 2 | 3 | 4 | 5 |
| 22. I avoid buying high-calorie food   | 1 | 2 | 3 | 4 | 5 |

<sup>1</sup> Being on a diet means having a well-balanced diet in which fat, sugar and salt consumption are restricted and where greater amounts of fruit, vegetables and pulses are eaten.

1 <i>Strongly disagree</i>	2 <i>Disagree</i>	3 <i>Neither agree nor disagree</i>	4 <i>Agree</i>	5 <i>Strongly agree</i>
-------------------------------	----------------------	--	-------------------	----------------------------

23. If I lost weight, I would feel better about myself	1	2	3	4	5
24. I am aware that there are more and more people who encourage me to lose weight	1	2	3	4	5
25. I'm not happy with my current weight	1	2	3	4	5
26. To avoid overeating I prefer eating at home or cooking my own food	1	2	3	4	5
27. If I lost weight, I would be happier	1	2	3	4	5
28. My family and friends praise me for not overeating	1	2	3	4	5
29. I feel good when I am able to control my eating habits	1	2	3	4	5
30. My family and friends congratulate me when I manage to lose weight	1	2	3	4	5
31. When I lose weight I feel proud of myself	1	2	3	4	5
32. People around me support me in trying to lose weight	1	2	3	4	5
33. I have someone who listens to me when I need to talk about my being overweight	1	2	3	4	5
34. I am committed to losing weight	1	2	3	4	5

\* Items number 11 and 14 were deleted according to the UK validation (Andrés et al., 2015)

Processes of change in weight management and their corresponding items according to the UK validation (Andrés et al., 2015)

<i>Process of change</i>	<i>Items</i>
Emotional re-evaluation (EmR)	1, 9, 13, 17, 21, 23, 25, 27, 29, 31, and 34.
Weight consequences evaluation (WCE)	4, 5, 8, 12, 16, and 20.
Supporting relationships (SR)	24, 28, 30, 32, and 33.
Weight management actions (WMA)	2, 3, 6, 7, 10, 15, 18, 19, 22, and 26.

**Scoring key.** Scores for each of the four processes of change are calculated by summing the scores obtained on items belonging to the same subscale. None of the items are reverse scored. In order to make scores from the different subscales comparable, these scores are transformed onto a scale from 0 to 100 (0 reflecting no use of a given process of change and 100 being full use of that process).

# INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (October 2002)

## LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

### FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

#### ***Background on IPAQ***

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

#### ***Using IPAQ***

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

#### ***Translation from English and Cultural Adaptation***

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at [www.ipaq.ki.se](http://www.ipaq.ki.se). If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

#### ***Further Developments of IPAQ***

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

#### ***More Information***

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at [www.ipaq.ki.se](http://www.ipaq.ki.se) and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

## INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

### **PART 1: JOB-RELATED PHYSICAL ACTIVITY**

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

Yes

No →

**Skip to PART 2: TRANSPORTATION**

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

\_\_\_ **days per week**

No vigorous job-related physical activity



**Skip to question 4**

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

\_\_\_ **hours per day**

\_\_\_ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

\_\_\_ **days per week**

No moderate job-related physical activity



**Skip to question 6**

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

\_\_\_\_\_ **days per week**

No job-related walking



**Skip to PART 2: TRANSPORTATION**

7. How much time did you usually spend on one of those days **walking** as part of your work?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

#### **PART 2: TRANSPORTATION PHYSICAL ACTIVITY**

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

\_\_\_\_\_ **days per week**

No traveling in a motor vehicle



**Skip to question 10**

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

\_\_\_\_\_ **days per week**

No bicycling from place to place



**Skip to question 12**



11. How much time did you usually spend on one of those days to **bicycle** from place to place?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go from place to place?

\_\_\_\_\_ **days per week**

No walking from place to place



**Skip to PART 3: HOUSEWORK,  
HOUSE MAINTENANCE, AND  
CARING FOR FAMILY**

13. How much time did you usually spend on one of those days **walking** from place to place?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

### **PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY**

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging in the **garden or yard**?

\_\_\_\_\_ **days per week**

No vigorous activity in garden or yard



**Skip to question 16**

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking in the **garden or yard**?

\_\_\_\_\_ **days per week**

No moderate activity in garden or yard



**Skip to question 18**

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

\_\_\_\_\_ **days per week**

No moderate activity inside home



**Skip to PART 4: RECREATION,  
SPORT AND LEISURE-TIME  
PHYSICAL ACTIVITY**

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

#### **PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY**

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time in your **leisure time**?

\_\_\_\_\_ **days per week**

No walking in leisure time



**Skip to question 22**

21. How much time did you usually spend on one of those days **walking** in your leisure time?

\_\_\_\_\_ **hours per day**  
\_\_\_\_\_ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming in your **leisure time**?

\_\_\_\_\_ **days per week**

No vigorous activity in leisure time



**Skip to question 24**

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

\_\_\_\_\_ hours per day  
\_\_\_\_\_ minutes per day

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis in **your leisure time**?

\_\_\_\_\_ days per week

No moderate activity in leisure time



**Skip to PART 5: TIME SPENT SITTING**

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

\_\_\_\_\_ hours per day  
\_\_\_\_\_ minutes per day

#### **PART 5: TIME SPENT SITTING**

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

\_\_\_\_\_ hours per day  
\_\_\_\_\_ minutes per day

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

\_\_\_\_\_ hours per day  
\_\_\_\_\_ minutes per day

**This is the end of the questionnaire, thank you for participating.**



**Health Questionnaire**

**English version for the UK**

Under each heading, please tick the ONE box that best describes your health TODAY.

**MOBILITY**

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

**SELF-CARE**

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

**USUAL ACTIVITIES** (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

**PAIN / DISCOMFORT**

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

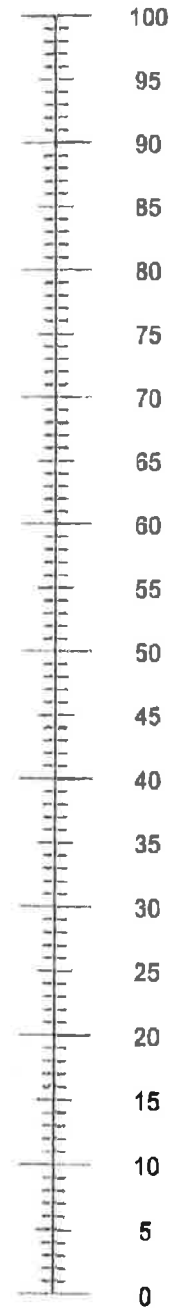
**ANXIETY / DEPRESSION**

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health  
you can imagine



The worst health  
you can imagine

## Appendix 10. Fasting blood sample collection and transport

*The additional non-routine fasting blood tests that will be done are fasting insulin, fasting glucose, creatinine, lipoproteins and inflammatory markers.*

### When the blood tests are to be taken

The fasting blood test will be done at baseline, 6 months, 12 months and 24 months.

*It is imperative that the fasting blood tests are done at baseline and 6 months for each participant.*

### Where blood test is to be taken

A fasting blood sample can be taken either by:

1. the Research Nurse, or
2. at Southern Community Laboratories

The Research Nurse will complete the laboratory request form, at the time of completing the questionnaires at baseline, 6 months, 12 months and 24 months.

### Procedures

#### Equipment

Test tubes - 1x 7ml purple top EDTA (Plasma) Lavender

Needle, holder, alcohol swab, cotton wool, tourniquet, tape.

#### Specimen labelling

The following information needs to be on the specimen container (blood tube) **BEFORE** the sample is taken:

Participant study code (see above)

Date of birth

Date specimen taken

#### Specimen collection - venepuncture

Check with the participant that their date of birth is correct. Check the participant's unique study visit code is recorded accurately on the laboratory request form and test tube.

Explain which blood tests will be performed.

## NOT FOR CIRCULATION

Check that the participant has been fasting from 10pm the night before the test. (12 hours prior)

Collect the blood sample from the antecubital fossa using minimal tourniquet to prevent stasis. A good flow is required to prevent haemolysis.

Invert the tube 8-10 times prior to packaging on wet ice and transporting to Southern Community Laboratories Hastings.

If two unsuccessful venepuncture attempts are made by the Research Nurse, then refer the participant to Southern Community Laboratories.

### Laboratories

Southern Community Laboratories Hastings will be the collection point for all non-clinical research blood samples.

Each blood sample is to be centrifuged at 2000G for 10 minutes. Plasma is then separated from the red cells, aliquoted into two labelled 0.5 ml cryogenic vials and frozen at -20C until transported to the Diabetes and Lipid Laboratory, Department of Human Nutrition, University of Otago. The vials will be labelled with participants' unique visit study code and date of birth.

Samples are sent to Dunedin stored in blue ice in chilly boxes monthly, overnight with courier company (PBT & NZ Couriers) with samples.

### Participant fasting instructions

You are required to fast for your special study blood test.

The duration of your fast must be at least 8 hours and no more than 14 hours.

The evening before your fasting blood test, have your normal evening meal and supper (no later than 10pm).

Do not drink anything EXCEPT water from 10pm until after you have had your test the following morning.

ON the morning of the test DO NOT eat breakfast. *You may drink water only.*

If you are taking any medication you should continue to take this, unless instructed otherwise by your health professional.



## Appendix 11. Key contacts and study investigators

The following is a list of key contacts for the PIP in Primary Care study. Terrie Spedding is the study clinical co-ordinator and Anna Horgan is the clinical dietitian who will provide dietetic support.

**Please note** not everyone is available every day, but we will endeavour to respond promptly.

	Phone	Email
<b>PROJECT LEADERS</b>		
Trish Freer, HHB	(06) 871 5655	Trish@healthhb.co.nz
Kirsten Coppell, University of Otago	(03) 470 9074	kirsten.coppell@otago.ac.nz
<b>PROJECT CO-ORDINATOR</b>		
Faye Milner, HHB	(06) 871 5660	Faye@healthhb.co.nz
<b>STUDY NURSES</b>		
Terrie Spedding, Clinical Coordinator, HHB	(06) 871 5646 ext 730; 027 836 2083	Terrie@healthhb.co.nz
Angeline Tangiora, Research Nurse, HHB	(06) 871 5646 027 767 1599	Angeline@healthhb.co.nz
Jo Norton, Research Nurse (Dunedin)	(03) 470 9102 027 609 9056	joanna.norton@otago.ac.nz
<b>STUDY DIETITIAN</b>		
Anna Horgan, Clinical Dietitian	06 8734806 ext 5893 027 313 8011	Anna.Horgan@hawkesbaydhb.govt.nz
<b>RESEARCH CO-INVESTIGATORS</b>		
Andrew Gray, Biostatistician	University of Otago, Dunedin, NZ	
Jeremy Krebs, Endocrinologist	Capital and Coast DHB & University of Otago, Wellington, NZ	
Leigh Perreault, Endocrinologist	University of Colorado, Denver, US	
Lisa Whitehead, Nurse	Edith Cowan University, Perth, Australia	
Sally Abel, Qualitative Researcher	Kaupapa Consulting, Napier, NZ	
Tony Merriman, Geneticist	University of Otago, Dunedin, NZ	
<b>RESEARCH COLLABORATORS</b>		
Trudy Sullivan, Health Economist	University of Otago, Dunedin, NZ	
David Tipene-Leach, GP & Researcher	Eastern Institute of Technology, Napier, NZ	

