

# LIMIT

## Participant Contact Details (home visit)

*(Please complete for all participants)*

1. Participant ID

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Number:

2. Forename(s):

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3. Surname:

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4. Address:

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5. Postcode:

--	--	--	--	--	--	--	--

6. Home Telephone:

--	--	--	--	--	--	--	--	--	--	--

7. Mobile  
Telephone:

--	--	--	--	--	--	--	--	--	--	--

8. Email: 

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# LIMIT

## Case Report Form

- Participant ID Number:  
(Gateway ID)

--	--	--	--	--	--

- Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

- Randomisation  
(Tick relevant box)

**CON**

**INT**

group:

### Section 1: Summary record (Researcher to complete)

Session	Date	Object weight	SR weight	Height	Scales given/collected*	Study Q's completed/returned
	dd-mm-yy	kg	kg	cm	Yes	Yes
Baseline home visit			n/a			
3 month follow up				n/a	n/a	
6 month data collection		n/a	n/a	n/a	n/a	
12 month follow up				n/a		
Participant withdraws		n/a		n/a	n/a	n/a

**NOTES:**

## Section 2: Baseline patient data collection (home visit)

(Please complete for all participants)

1. Weight at the start of the weight loss program: \_\_\_\_\_ kg
2. Maximum weight participant could be to be eligible (i.e. weight loss  $\geq 4\%$ )  
\_\_\_\_\_ kg

3. Height: \_\_\_\_\_ cm

4. Weight: \_\_\_\_\_ kg

Note for researcher: Please ask participants to remove their shoes and any excess clothing (e.g. heavy jumpers) before measuring them. Place the scales and height measure on a solid floor surface.

### 5. PROVIDE BASELINE QUESTIONNAIRE

The following questions should be asked in a general chat relaxed conversation style. They are simply listed here as prompts to remind you to ask the questions and give you a feel for how they might be asked. **Please try and avoid a question and answer style conversation.** One of the best ways of doing this is to express an interest in how the participant is getting on, but you should avoid getting into a lengthy detailed conversation about their diet and eating habits etc. Try to encourage the participant to elaborate on their answers; usually open ended questions are the best approach to achieving this.

**Praise participants about their weight loss.** (As part of the Lighten Up programme they would have lost at least 5% of initial body weight.)

I would like to talk to you about your weight history, and the sorts of things you have been doing recently to control your weight, it won't take long. Is that ok?

6. Before this weight loss attempt, have you ever tried to deliberately lose weight?

Yes

☐

No

☐

.....

.....

.....

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.....

.....

.....

7. The last time you lost weight, how much did you lose, did you regain it, how much did you regain and how long did it take to regain weight?

Weight  
loss

Did you  
regain it

How  
much

How  
long

Please continue to complete section 2 on the next page

8. How many times have you lost 1 stone or more?

9. How much weight did you lose on your most successful attempt and when was this?

Weight loss	<input type="text"/>	When	<input type="text"/>
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10. As an adult what is the most you have ever weighed and how old were you?

Weight	<input type="text"/>	How old	<input type="text"/>
--------	----------------------	---------	----------------------

11. What has been your lowest body weight as an adult and how old were you?

Weight	<input type="text"/>	How old	<input type="text"/>
--------	----------------------	---------	----------------------

12. You have just finished your Lighten Up weight management programme and I would like to ask you if you did anything particular or used any skills/ strategies to help you lose weight during the programme?

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.....

Do you plan to keep using these strategies now? Do you plan to use any different strategies/approaches now?”. If participants says “no” ask why this is the case?

.....

.....

.....

### Randomisation

Does the participant intend to carry on attending the weight loss programme?

Yes

☐

No

☐

Researcher: Use randomisation envelope

**Brown**

Use randomisation

envelope **White**

Number

Date

**Control**  
(Information  
support)

☐

**Intervention**  
(telephone  
support)

☐

Questions 13 to 14 apply only for participants in the **INTERVENTION** group.

**13. I have provided the participant with scales, demonstrated how they work and checked that they are working. (Complete scale type & serial number)**

Scale type:

Serial number:

  
Last 7 digits

**14. Have you issued the weighing card and ask participants to keep it in a safe place as they will receive a call from Gateway to explain it ?**

Yes

☐

**15. Have you collected the Baseline questionnaire? Please check that all sections are completed correctly**

(tick relevant box)

Completed and collected at visit

☐

Not completed nor willing to complete at visit. Asked to return – SAE provided.

☐

**16. ADVISE THE PARTICIPANT THAT A RESEARCHER WILL CONTACT THEM AROUND 3 MONTHS TO ARRANGE A FOLLOW-UP HOME VISIT. A QUESTIONNAIRE WILL BE POSTED PRIOR TO THE APPOINTMENT FOR THEM TO COMPLETE IN ADVANCE.**

**Section 3: RA's checklist – baseline home visit** *(Complete accordingly)*  
*If you are unable to tick 'Yes' for any question please detail in notes section at foot of page.*

**BEFORE END OF HOME VISIT:**

Measured and recorded participant's height and weight? Yes ☐

Provided participant with weighing scales, and completed relevant information in CRF (Section 2, page 4)? (INTERVENTION GROUP ONLY. N/A for control group) N/A ☐ Yes ☐

Reminded the participant they will receive a £20 gift voucher for each follow up appointment they attend? Inform them that follow up is important even if they decide not to continue with the study at a later date. Yes ☐

**AFTER HOME VISIT:**

Forwarded the completed clinic list and CRFs to the trial coordinator for logging? Yes ☐

- **Name of Researcher** (who completed sections 1-3): \_\_\_\_\_
- **Signature:** \_\_\_\_\_ **Date of completion** (sections 1-3): \_\_\_\_\_

**Section 4: Trial management/co-ordinator checklist**  
**(following baseline home visit)** *(Complete accordingly)*

Completed CRFs logged?

Yes

☐

Date:

Double checked that all possible sections of the  
CRF are complete at this stage?

Yes

☐

Date:

Automated text messaging set up

Yes

☐

Date:

- **Name of trial management team/assessor:** \_\_\_\_\_
- **Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**NOTES:**

## Section 5: 3-month follow up appointment

**INTERVENTION GROUP ONLY** Have you checked that the participant's scales are working?\* Yes ☐

*\* Please report any faults to the trial manager and note below.  
Ensure scales are replaced ASAP.*

**INTERVENTION GROUP ONLY** Have you taken a photograph of the participant's self-weighing record cards? Yes ☐

**INTERVENTION GROUP WITH USB-TYPE SCALES ONLY:** Yes ☐  
have you downloaded the USB scale data, saved it and reset the scales?

**Visit conducted by** (insert RA name): \_\_\_\_\_

**Date:** \_\_\_\_\_

**Participant's Weight** (objective):  kg  
(Indicate clearly below if this is self-reported weight)

**Location of Visit** (tick box): ☐ Home ☐ Self-reported weight

☐ Other

**3-month questionnaire(s) collected?:** Please check that all sections are completed correctly

Completed and collected at visit

(tick relevant box)

Not completed nor willing to complete at visit. Asked to return – SAE provided.

**NOTES:**



*The following questions should be asked in a general chat relaxed conversation style. They are simply listed here as prompts to remind you to ask the questions and give you a feel for how they might be asked. Please try and avoid a question and answer style conversation. One of the best ways of doing this is to express an interest in how the participant is getting on, but you should avoid getting into a lengthy detailed conversation about their diet and eating habits etc. Try to encourage the participant to elaborate on their answers; usually open ended questions are the best approach to achieving this.*

**I would just like to ask you a few questions about the sorts of things you might have been doing recently to control your weight, they won't take very long, is that ok?**

For **INTERVENTION PARTICIPANTS** only - *Ask how regular self weighing is going*

**You are in the intervention group so you have been asked to weigh yourself regularly? How has that been for you? How's it been going?**

.....

.....

.....

.....

For **ALL PARTICIPANTS**

**Since finishing your lighten up programme, have you continued to attend sessions?**

☐

**If yes, how many have you paid for?**

☐

**Have you been using any of the skills that you learnt when you were attending your Lighten Up weight loss programme to help you maintain/lose weight?**

*If answers 'yes' – could you tell me what specific things or strategies you have used (e.g. reduced portion size, more exercise, avoid fatty food, count calories etc).*

.....

.....

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.....

.....

**Do you plan to keep using these strategies now? Do you plan to use any different strategies/approaches now? If participants says “no” ask why this is the case?**

.....

.....

.....

*Some participants may have given up trying to lose or maintain their weight. If you sense this from any of the responses or the tone of the conversation please ask the following question.*

**From what you have said it seems like you might not be aiming to control your weight at the moment, is that right? Or have I misunderstood that? If the response is ‘yes’ they are not controlling their weight then ask the question below:**

**It would be really useful to know why that might be? Can you tell me a bit about why?**

.....

.....

.....

.....

**Payment:** A £20 gift voucher is only given upon completion of each objective weight follow up (i.e. not for self-reported weights). They **MUST** sign this receipt. If the voucher is not given, please record why in the note section below.

**Payment made:**

Yes

☐

No

☐

*Ask the participant to print their name and sign below to confirm they have received a £20 voucher.*

“I confirm that I have received a £20 gift voucher for participating in LIMIT”.

---

**Participant’s Printed Name**

**Participant’s Signature**

**Date**

## Section 6: 12-month follow up appointment *(Please complete as required)*

**Type of scales previously provided (INTERVENTION GROUP. ONLY):** *(enter scale details)*

*(If you are unable to tick 'Yes' for any of the following please detail in notes section below)*

**INTERVENTION GROUP ONLY:** Have you checked that the participant's scales are working?\*

Yes ☐

*\* Please report any faults to the trial manager and note below.*

**For participants in the intervention group with USB-type scales (only):** have you downloaded the USB scale data, saved it and collected the scales?

Yes ☐

**For participants in the intervention groups provided with a set of Bodytrace scales:** Have you collected the scales for return to the University?

Yes ☐

**Visit conducted by** *(insert RA name):* \_\_\_\_\_

**Date:**

\_\_\_\_\_

**Participant's Weight** (objective):

*(Indicate clearly below if this is self-reported weight)*

kg

**Location of Visit** *(tick box):*

☐

Home

☐

Self-reported weight

☐

Other

**12-month questionnaire(s) collected?:** *Please check that all sections are completed correctly*

*(tick relevant box)*

Completed and collected at visit

☐

Not completed nor willing to complete at visit. Asked to return – SAE provided.

☐

**NOTES:**

*The following questions should be asked in a general chat relaxed conversation style. They are simply listed here as prompts to remind you to ask the questions and give you a feel for how they might be asked. Please try and avoid a question and answer style conversation. One of the best ways of doing this is to express an interest in how the participant is getting on, but you should avoid getting into a lengthy detailed conversation about their diet and eating habits etc. Try to encourage the participant to elaborate on their answers; usually open ended questions are the best approach to achieving this.*

**I would just like to ask you a few questions about the sorts of things you might have been doing recently to control your weight, they won't take very long, is that ok?**

For **INTERVENTION PARTICIPANTS** only - *Ask how regular self weighing is going*

**You are in the intervention group so you have been asked to weigh yourself regularly? How has that been for you? How's it been going?**

.....

.....

.....

.....

For **ALL PARTICIPANTS**

**Since we last saw you (6 months ago) how many sessions of your programme have you attended?**

**Have you been using any of the skills that you learnt when you were attending your Lighten Up weight loss programme to help you maintain/lose weight?**

*If answers 'yes' – could you tell me what specific things or strategies you have used (e.g. reduced portion size, more exercise, avoid fatty food, count calories etc).*

.....

.....

.....

.....

.....

**Do you plan to keep using these strategies now? Do you plan to use any different strategies/approaches now? If participants says "no" ask why this is the case?**

.....

.....

.....

.....

*Some participants may have given up trying to lose or maintain their weight. If you sense this from any of the responses or the tone of the conversation please ask the following question.*

**From what you have said it seems like you might not be aiming to control your weight at the moment, is that right? Or have I misunderstood that? If the response is 'yes' they are not controlling their weight then ask the question below:**

**I would be really useful to know why that might be? Can you tell me a bit about why?**

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

**Have you been hospitalized in the last 12 months?** Yes ☐ No ☐

**Would you mind telling us why?** Yes ☐ No ☐

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

**Payment:** A £20 gift voucher is only given upon completion of each objective weight follow up (i.e. not for self-reported weights). They **MUST** sign this receipt. If the voucher is not given, please record why in the note section below.

**Payment made:** Yes

No	<input type="checkbox"/>
	<input type="checkbox"/>

*Ask the participant to print their name and sign below to confirm they have received a £20 voucher.*

"I confirm that I have received a £20 gift voucher for participating in LIMIT".

---

**Participant's Printed Name**  
**Date**

---

**Participant's Signature**

## Section 7: Participant withdrawal form from the intervention *(Please complete as required)*

1. Since enrolling in the study, I confirm that this participant has withdrawn from the LIMIT trial INTERVENTION. *(please tick appropriate box and complete ID number if necessary).*

Yes ☐ No ☐ ID Number:

2. The patient withdrew on:  
(e.g. 01-Jan-2014)

-    - **2** **0**

3. Reason(s) for withdrawal *(please tick all boxes that apply):*

Ineligible	<input type="checkbox"/>	Moved from the area	<input type="checkbox"/>
Withdrawn consent	<input type="checkbox"/>	Study tasks an inconvenience	<input type="checkbox"/>
Cannot complete necessary study procedures	<input type="checkbox"/>	No reason given	<input type="checkbox"/>
Healthcare professional recommended withdrawal	<input type="checkbox"/>	Other... <i>(please state below)</i>	

4. Method of INTERVENTION (only) withdrawal? *(tick appropriate box)*

Verbal, face-to-face	<input type="checkbox"/>	Verbal, via telephone	<input type="checkbox"/>
In writing	<input type="checkbox"/>	Healthcare professional	<input type="checkbox"/>

5. Patient happy to continue being followed up? Yes ☐ No ☐

- Person recording participant trial withdrawal: \_\_\_\_\_
- Research role: \_\_\_\_\_
- Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Section 8: Participant withdrawal form from the trial *(Please complete as required)*

1. Since enrolling in the study, I confirm that this participant has withdrawn from the LIMIT trial. *(please tick appropriate box and complete ID number if necessary).*

Yes ☐ No ☐ ID Number: 

--	--	--	--	--	--

2. The patient withdrew on:  
(e.g. 01-Jan-2014)

		-				-	<b>2</b>	<b>0</b>		
--	--	---	--	--	--	---	----------	----------	--	--

3. Reason(s) for withdrawal *(please tick all boxes that apply):*

Ineligible	<input type="checkbox"/>	Moved from the area	<input type="checkbox"/>
Withdrawn consent	<input type="checkbox"/>	Study tasks an inconvenience	<input type="checkbox"/>
Cannot complete necessary study procedures	<input type="checkbox"/>	No reason given	<input type="checkbox"/>
Healthcare professional recommended withdrawal	<input type="checkbox"/>	Other... <i>(please state below)</i>	<input type="checkbox"/>

4. Method of trial withdrawal? *(tick appropriate box)*

Verbal, face-to-face	<input type="checkbox"/>	Verbal, via telephone	<input type="checkbox"/>
In writing	<input type="checkbox"/>	Healthcare professional	<input type="checkbox"/>

- **Person recording participant trial withdrawal:** \_\_\_\_\_
- **Research role:** \_\_\_\_\_
- **Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## **Section 9: Events that might affect follow up** *(if applicable)*

*Please only write here if there are/were any events that might affect follow-up. We will assume that there were no events if this space is left empty.*



**Section 10: 6-month data collection** *(Please complete as required)***INTERVENTION-GROUP PARTICIPANTS WITH USB-TYPE SCALES****ONLY:** arrange a home visit to download USB data from scales. Collect set of questionnaires.

1. Was this participant in the INTERVENTION group provided with USB-type scales?

*(please tick the relevant box)***YES**☐**NO**☐

- If **YES to Q1**: please complete Qs 2-6 below.

2. Have you checked that the participant's scales are working?\*

*\* Please report any faults to the trial manager and note below. Ensure scales are replaced ASAP.*

**YES**☐**NO**☐

3. Have you downloaded the data from the scales USB stick, saved it and reset the scales?

**YES**☐**NO**☐

4. Date of visit and data download: e.g. 01 - J A N - 2014

		-				-	2	0		
--	--	---	--	--	--	---	---	---	--	--

5. Participant's Weight (objective):

*(Indicate clearly if this is self-reported)***kg**

6. 6-month questionnaire(s) collected?: *Please check that all sections are completed correctly*

Completed and collected at visit

*(tick relevant box)*Not completed nor willing to complete at visit.  
Asked to return – SAE provided.


- **Name of researcher:** \_\_\_\_\_
- **Signature:** \_\_\_\_\_

**NOTES:**



Weighing record card for intervention participants

Weighing Record Card

Week 1kg/stone/lbs		Week 2kg/stone/lbs	
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week (add every day and divide by 7)			
Week 3kg/stone/lbs		Week 4kg/stone/lbs	
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week			

My goal weight is: \_\_\_\_\_



Week 5kg/stone/lbs		Week 6kg/stone/lbs	
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week			
Week 7kg/stone/lbs		Week 8kg/stone/lbs	
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week			

My goal weight is: \_\_\_\_\_

Week 9	kg/stone/lbs	Week 10	kg/stone/lbs
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week		Average weight for the week	
Week 11	kg/stone/lbs	Week 12	kg/stone/lbs
Monday		Monday	
Tuesday		Tuesday	
Wednesday		Wednesday	
Thursday		Thursday	
Friday		Friday	
Saturday		Saturday	
Sunday		Sunday	
Average weight for the week		Average weight for the week	

“You will be able to evaluate your progress against set goals and see improvements, or realise you have to make

“People who weigh themselves regularly are more likely to manage their weight”

“By weighing yourself daily it will gradually become a habit, a bit like brushing your teeth, and you will notice how your

## Text message schedule for intervention participants

### Text messages content and schedule

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Day												
Tuesday	1	4	7	10								
Thursday	2	5	8	11	1	3	5	7	9	11	2	9
Sunday	3	6	9	12	2	4	6	8	10	12	4	11

	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Day									
Week 2 Fri	1	5	4	7	11	2	1	5	6
Week 4 Fri	12	3	9	8	6	10	4	12	7

### Content

1. Have you remembered to weigh yourself today?
2. Here's a reminder- keep your weight booklet by your scales, write down your weight every day, and check it against the target
3. Evidence shows that those who weigh themselves regularly keep their weight off over time
4. I hope the daily weighing is going well. Do try and keep it up!
5. Here's a reminder to think. Has your weight gone up since yesterday? Have a think about why and what you could do differently today.
6. Clinical trials show that those who weigh themselves regularly keep their weight off
7. Remember to keep weighing yourself daily
8. Those who weigh themselves regularly keep their weight off; remember to hop on those scales daily!
9. Remember how beneficial daily weighing is for maintaining your weight. Keep it up!
10. Keep tracking your weight - it will pay off over time
11. Here's a reminder- have you gone over your target weight? If so, go back on your diet until you are 1kg under your target.
12. If your weight has gone up think about what you have eaten, what changes can you make

# LIMIT STUDY MANUAL

**Universities of Birmingham and Oxford**

**In collaboration with Gateway Family Services and  
Birmingham Public Health**

**Funded by NIHR Public Health Programme**



**Prepared by:  
The LIMIT study investigators**

**No part of this manual should be used or copied without the permission of  
the principal investigator, Dr Amanda Daley, University of Birmingham**

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# OVERVIEW OF THE LIMIT STUDY

## 1.0 Summary of the LIMIT Study

### 1.1 Why is this study needed?

Although studies have shown that many weight loss programmes, work in the short term i.e. over a few months, the large majority of people put weight on again. Typically people who have lost weight regain about 0.5 kg per year, though this varies a lot from person to person.

### 1.2 How can we help to avoid putting weight back on?

Although some complicated programmes have been successful, we have no practical tips for people, which is why we are testing this approach. We are testing the idea that it will be helpful to ask people to set a target and to check themselves against the target by weighing themselves every day to see whether they have exceeded the target or not. If they have we will ask people to go back on their weight loss diet that has led to them losing weight. It is up to them whether or not they go back to the weight loss programme but they will have to pay.

### 1.3 What does the study involve?

This study will test whether a 12 week programme that encourages people who have recently lost weight to set themselves a weight target, weigh themselves daily and record their weight is effective in preventing them regaining weight at one year after they start the study. 560 adults who have lost at least 5% of their initial body weight after completing a commercial (Weight Watchers, Slimming World & Rosemary Conley), an NHS led support, or an online weight loss programme within the Lighten Up Service will be randomly allocated (like tossing a coin) to one of two options. In one option, people receive three brief telephone support calls (telephone support group) to help explain about target setting and regular weighing and to encourage people to keep on with this. The other is meant to be no intervention at all to help them maintain their lost weight, which is what most people who join a weight loss programme get when they finish. In this case, we will give them a short booklet full of tips, a copy of the eatwell plate and a list of useful websites to make people less aware that they are in the no intervention group. **Please do not explain this rationale to the participants in the study and do not appear to express a preference or belief that one treatment or the other will be more successful. This is very important to the proper conduct of the study.**

**The telephone support group:** With this group you will focus on setting a target and then on getting the person to plan where, when and how they will weigh themselves and then how they will record their weight. The vast majority (90%) of people *do not* recover from even small (1-2 kg) amounts of weight regain. Regular weighing can be used as an early warning sign that weight is going up and allow people to start using strategies (physical activity, reduced portion size etc) to keep them on track and to stop their weight going up. The goal is for participants to avoid putting back on more

than 1 kg of their weight from when they started the study. The telephone support group will also receive regular text messages to remind them to weigh themselves every day.

**The booklet support group:** This group will be given written information about how to best manage their weight and stop themselves putting weight back on again. They will not receive the telephone calls or the text messages.

#### **1.4 What is the study looking at?**

We want to know if the weight of people who set a target and weigh themselves is lower than those given the booklet. To find this out we will weigh participants at the start of the study and one year later. We will also look at whether the study has any negative effects on participants' psychological health and wellbeing, by asking them to complete a few questionnaires throughout the study.

#### **1.5 How long will the study take?**

The study will run over three years. Participants will be approached to take part for one year and they will be followed for one year.

## **IDENTIFYING POTENTIAL PARTICIPANTS (GATEWAY)**

### **2.0 Study Procedures**

#### **2.1 Recruitment and identifying potential participants**

Every week you will send the participant information leaflet to everyone who has reached week nine of their weight loss programme. The leaflet explains about the study so that people who read it can decide whether they want to take part or not (Appendix 1). This means that you can ask them to agree to take part on the phone when you ring them for the maintenance programme screening call at week 11. This process is an ethical requirement of the study because it gives potential participants time to think about whether they would want to take part *before* they agree/consent to do so at the maintenance programme screening call.

Packs containing an invitation letter for the study and an information leaflet explaining the study will be provided by the UoB team. All you need to do is print the cover letter on University of Birmingham headed paper and insert it into the envelope pack using the automated mail merge on the database for participant details. The envelopes will already have stamps on them ready for you to post.

#### **2.2 Maintenance screening call (week 11 of the weight loss programme)**

You should telephone all participants in the Lighten Up service when their maintenance screening call is due. We know that you normally make three attempts for this call if there is no response but for the purposes of this study we ask that you make five attempts. The database will take you through a sequence of questions that will determine whether a participant is eligible for LIMIT. The main entry criteria at this stage is that participants must have lost at least 5% of their weight compared to when they started their Lighten Up weight loss programme. The database will

calculate this for you. The database will know participants' weight when they started the programme and it will ask you to ask the participant for their weight today and enter this into the database. If participants have not lost more than 5% of their initial body weight, do not mention the trial and continue with the process for the standard weight maintenance protocol.

## 2.3 Explaining the LIMIT study at the maintenance screening call

After all the routine issues in the maintenance screening call have been discussed the following kinds of things should be said to participants to explain the LIMIT study.

*"As you have finished your Lighten Up weight loss programme [insert name of programme] I wanted to ask you whether you are interested in taking part in a study which helps people to avoid putting the weight back on again... so to try and help you keep off your weight over the longer term which is obviously very important for your health."*

*"The study is called LIMIT and it's been developed by a research team at the University of Birmingham. You should have received a letter and a green leaflet in the post a couple of weeks ago about it?. [assuming 'yes' then continue] [if 'no' see below for comment on this]."*

*"So the study is evaluating two different ways of helping people to avoid putting their weight back on again after they have lost it; some people will get three quick (5 min) phone calls from me over a month and some text messages to help them manage their weight for three months and some people instead will get written information about weight management and some useful hints and tips about how to watch your weight."*

*"Does this study seem like something you would like to take part in? [No]: ok no problem thanks for considering it anyway best of luck with everything. [Yes]: great that's brilliant. Thanks very much. One thing I wanted to say is that you will be allocated to one of these groups randomly (like tossing a coin) so you can't choose which group you get. Is that ok with you? Great."*

*"Ok so now I just need to ask you a couple of questions before we carry on and we can go from there..ok? Great. [ask and follow screening questions on database]."*

**Participant not eligible (see section 2.4 for list of who can and cant take part below):** *"Unfortunately we can only take people who [insert whatever criteria they do not meet] so unfortunately you won't be eligible for this particular study today but thanks anyway for considering it. You will receive a call from one of my colleagues in about week and we will send you some information in the post to help you with maintaining you weight."*

**Participant eligible:** *"Great news... so far it seems you have lost more than 5% of your weight so it looks like you are eligible for the study. The next thing we need to do is get your agreement to take part in the study and then weigh you in the next few days and get you to fill in a short questionnaire.....we can come to your house to do this to make it really easy for you. is that ok?" or we could arrange to meet you somewhere else if you prefer [ONLY offer this to those who do not seem keen on a home visit]. It will only take about 10-15 minutes for us to visit you and we can come at a time that suits you". Is that ok? That's great". Just to let you know as well we will need to do this again in 3 months and 12 months time because this will let us see how you have been getting on over time".*

*"Ok, so let's get your agreement first and then we can work out when is a good time to pop by and weigh you"*

## 2.4 Who is eligible to take part in LIMIT?

The database will take you through a sequence of questions that will determine whether a participant is eligible for LIMIT. You will have already established if they have lost more than 5% of their initial body weight and this is the main criteria. If they meet the criteria below the database will allow you to invite people to take part in the study.

- Lost 5% of their weight since starting Lighten Up
- Not currently pregnant or intending to become pregnant in next 12 months
- Can speak sufficient English to complete the study

## **2.5 What to do if participants have not received the participant information leaflet?**

You need to ask participants if they have received the green participant information leaflet. If they have not, remind them that it should have arrived a couple of weeks ago with a cover letter from the University of Birmingham. If they say they definitely have not received the leaflet then explain that you will send another one today and you will call again in few days because you cannot enrol people in the study who have not received it. Try to schedule a time during this current call to call them back.

## **2.6 Taking consent to participate in LIMIT**

We will train you to take consent. All research is governed by ethics committees. Besides that, we want to make sure that people only join the study if they really know what they are agreeing to. It harms the study if people pull out before the end. You have already explained the study so now you need to double check that people know what they are agreeing to. It is going to feel a bit contrived, but it is important that you do it this way.

- Read out the four statements on the consent form (Appendix 2) and ask the participant to say 'yes' or 'ok' or similar after each.
- Then you need to put your initials (not a tick) in each box next to the statement. You must use a black pen to do this. Your initials on the paper copy confirm that the participant has said 'yes' and consents to the statement.
- The participant has to agree to all four statements before they can take part in the trial. There are NO exceptions to this. It is important to ask whether the participant has understood everything that has been explained to them during the phone call.
- Send the pink carbon paper copy of the consent form to the participant after the weight maintenance screening call. Store the white carbon consent form in the study file at Gateway and these will be collected by the UoB team.
- Once a participant provides consent they will be automatically added on to the database. You must ensure the database has the correct information for each participant as the UoB team will need this information to do the home visit (see below).

## **2.7 Booking the baseline home visit for the UoB team**

Explain to the participant that a member of the team will come and chat to the participant in their home, weigh them, measure their height and complete a brief questionnaire. This is a vital part of the research.

Use the online calendar to book home visits.

<https://accounts.google.com/ServiceLogin?service=cl&passive=1209600&continue=https://www.google.com/calendar/render&followup=https://www.google.com/calendar/render&sc=1>

This will show the availability of the people who are responsible for making the home visits. Book the visit within a few days of the call and in any case as soon as possible. Make sure you make allowance for people to get to different parts of the city – work on the basis they need 30 minutes to get from A to B unless you know the locations are close by in which case allow about 15 minutes between appointments. There will usually be two or maybe three people available to do these home visits. Book the baseline visit as a task in the google calendar.

## **2.8 Summary checklist for call**

1. Explain the study
2. Check the participant information leaflet has been received and understood
3. Check participant's details are correct
4. Take consent
5. Book a home visit
6. Send a copy of the consent form to the participant

# TELEPHONE SUPPORT INTERVENTION BY GATEWAY

## 3.0 Telephone support intervention

### 3.1 Overview

This is a self-help intervention so something people will mainly do for themselves at home and your role is to advise them what to do. We do not want you to act like a counsellor so do not get drawn into lengthy debate about weight, physical activity and diet as this is not the purpose of the calls. There are three parts to the intervention that you are responsible for:

1. Helping people to set a target so that people gain no more than 1 kg more than they did at the end of the weight loss programme
2. Helping people get into the habit of weighing themselves
3. Helping people notice how what they eat and how much activity they do affects their weight and encouragement to take action

To help people do these tasks we are asking you to make three brief telephone calls; these are at weeks one, two and four of the intervention. The calls should last about 5 mins so they are designed to be quick. We have organised the calls so they cover and emphasise different elements of the intervention as outlined below:

#### **Week 1: Call 1: Introducing the intervention and what it is about**

This first call is about:

- Explaining to participants the importance of maintaining weight loss
- Getting participants to set an overall target for their weight
- Getting participants to agree to daily self-weighing and outlining the benefits of doing this
- Encouraging participants to write down their weight on the weight record card and explaining why it is important to do this

#### **Week 2: Call 2: Understanding how and when to take action**

The second call is about

- Encouraging participant to write down their target weight on the record card and explaining we are asking them to do this
- Reviewing participants' current weight against their target weight
- Understanding what constitutes a breach of the target weight and agreeing to take action if the target is exceeded
- Giving information on what participants might do if they breach the target
- A check that Call 1 behaviours are being done

#### **Week 4: Call 3: Review of progress**

The second call is about

- Reviewing how participants are progressing generally and reviewing any barriers they raise
- Reviewing that participants are doing the things they were asked to do in the previous calls and if not, why not

- Discussing if participants have exceeded their target weight and did this prompt them to take action, if so what do they do

The sections below outline some of the key points or 'rules' that you should cover for each component of the intervention.

## 4.0 Detailed information about the intervention components

### 4.1 Week 1 (call 1): Introducing the intervention and explaining what is involved

#### 4.1.1 Explaining the importance of maintaining weight maintenance

Explain that lots of people often regain weight after they have lost it. Explain that lots of people don't realise they have gained weight initially so it's important to keep a track of weight regularly before it creeps back on again. This study aims to stop people putting back on the weight they have lost.

**Gateway:** *I know you did well and lost weight on Lighten Up didn't you?*

**Participant:** *Yes, I have and I'm really chuffed because usually I find it really hard to get rid of the weight*

**Gateway:** *Yes its great when you lose weight isn't it but sometimes it can be hard to keep it off and that's important as well isn't it?*

**Participant:** *Oh yes definitely I have struggled with my weight for years its really hard to keep it down. I'm up and down all the time*

**Gateway:** *I know lots of people find it hard but there are ways we might be able to help you to keep it off*

**Participant:** *Oh tell me please!! You got a magic pill for me!!?*

**Gateway:** *I wish I had!! Its often hard to know you are gaining back the weight and it can just creep back on without you noticing but if you can keep a track of your weight it can help you to keep on top of it before it goes up and you feel that getting it down again is going to take a mammoth effort.*

#### 4.1.2 Getting participants to set an overall target

Encourage participants to think about what they might want to achieve in terms of their weight and get them to set a weight goal with you today that would help to stop them regaining their weight, for example, '*In a year I aim to weigh no more than I do now*', or "*I want to be about the same weight in six months time*". These are the kind of goals we want people to set for themselves. It's important that people choose it but your job is to guide that choice.

Make it clear that it is ok to keep losing weight but remind them that the purpose of the study is to stop them putting on more than 1 kg from today. Ask participants to agree that '*at the worst*' or '*very least*' they will try to avoid regaining more than 1 kg (2 pounds) of their weight loss so far.

Encourage participants to set a goal that is realistic which they feel they can achieve. Encourage them to share that goal with someone they care about who can remind them of their goal and give them support when their motivation is flagging.



**Gateway:** People tend to stick to their promises more closely if they tell their promise to someone they care about.

**Gateway:** And you've decided that you don't want to gain more than 2 pounds. Right?

**Participant:** Right' I don't want to no

**Gateway:** 'Ok, well a really good thing to do is to tell someone about that... about the fact you have promised yourself that you are going to try not to gain more than 2 pounds..... Is there someone you could tell about your promise?'

**Participant:** Well I could tell my friend, Sharon

**Gateway:** Ok, so when will you tell Sharon?'

**Participant:** Tomorrow, I see her at work.'

**Gateway:** Great. Remember to tell Sharon about your promise and ask her to remind you every week/month. Perhaps you could ask her to set a reminder on her phone to remind you?'

**Participant:** That's a good idea'

#### 4.1.3 Agreeing to daily self weighing and outlining the benefits

Strange as it may seem, we want people to weigh themselves every day. This is going to seem a bit obsessional for people so you are going to need to let them tell you this and then reassure them. Explain that frequent monitoring of weight is important to detect early signs of weight gain so that they can keep on track to achieve their goal.

**Participant:** Wow, you're saying weigh myself every day?'

**Gateway:** 'Yep. I know that they told you not to do this at Slimming World, but it's a good idea'.

**Participant:** Really?

**Gateway:** Yes. The thing is it's easy to put on weight without noticing it

**Participant:** Ain't that the truth!

**Gateway:** Right. So it's much better to catch it before you've put on too much. That's why we think it's best to do it every day.

**Participant:** 'Ok'

**Gateway:** And another thing. We want this to become a habit. It's hard to remember something you do once a week. It's easy to remember to brush your teeth, right? typically because you do it the same time every day...

**Participant:** Yes

**Gateway:** Ok so we want weighing yourself to become like brushing your teeth.. so part of your every day routine

Some of the potential benefits of self weighing for preventing weight regain are outlined in the table below and you should express these to participants. We don't expect you to use all of these examples.

Weighing can give you immediate feedback on how you are getting on in case you need to watch what you are eating	If you are doing well it can give you a real pat on the back and keep you going
Weighing yourself everyday can tell you how you are getting on with meeting your	When you weigh yourself every day and meet you goal it can let you

target	know its time to give yourself a healthy treat for all you hard work
If you find your weight creeping up weighing can let you know its time to take action	Weighing helps you to decide not to eat fatty foods
Weighing can give you will power to resist tempting foods and drinks	Weighing can remind you to be make sure you do some exercise
By weighing yourself daily it can make you more aware about what you eat. For example if you go for a coffee you may decide not to have that cake with it as you know you will step on the scales the next day.	Weighing gives you much quicker and more accurate feedback than waiting for your clothes too get tight.
Weighing can be a reminder that you need to watch what you are eating and keep your physical activity levels up.	Weighing lets you see how much your weight goes up and down

#### 4.1.4 *Using the weight record card and writing down weight*

Explain that every day the participant should weigh themselves and write down their weight. Ask the participant if they can do this and ask them to commit to doing it if so.

## 4.2 **Week 2 (call 2): Understanding how and when to take action**

#### 4.2.1 *Encouraging participant to write down their target*

Ask participants to write down their target weight which they set and discussed with you in Call 1 in the box on their weight record card. Explain they should aim to weigh no more than this target weight at any point.

#### 4.2.2 *Reviewing participants' current weight against their target weight*

Explain that after weighing themselves every day they should write down their weight and check it against their target weight to help them see how they are progressing.

#### 4.2.3 *Understanding what constitutes a breach of the target and agreeing to take action if the target is breached*

You should tell participants that weight can often naturally fluctuate around about 1 kg or 2 pounds or so per day anyway, and this variation is normal and does not immediately mean that they have gained fat.

#### 4.2.4 *Giving information on what participants might do if they breach the target.*

If participants find that they have exceeded their target weight on one day they should be advised to “*be careful with what they eat*” and “*try to do some more activity*”. If they find they have exceeded the target three days in a row then they should start to use the strategies they learnt when they were doing their weight loss programme.

#### 4.2.5 *A check that Call 1 behaviours are being done*

Check with participants that they are weighing themselves regularly and if not why not. You should explain that it is easier to keep doing something if it becomes a habit, part of the daily routine ‘*like brushing your teeth*’ and encourage them to keep doing this.

Suggest to participants that when you start to do something new you have to think about it and remember to do it every day - this is much easier to do if you have a visual cue. Encourage participants to think about where the best place is to leave the weight record card and weighing scales – explain that the best place is put them right where they expect to weigh themselves as this will prompt and remind them to do it each day (e.g. in the bathroom or in the bedroom).

**Gateway:** *I would like you to take few seconds now to think about when and where you're going to weigh yourself*

**Participant:** *Ok, well sometimes I go into work a bit later and come home later so I could do it in the morning sometimes and after work other times. '*

**Gateway:** *Ok, well it is hard to get into a habit if you do it at different times. I guess you brush your teeth every morning even when you go in early. It's best to get into a habit of weighing yourself just like that. Some people find that it works well to weigh themselves after a shower. Would that work?*

**Participant:** *Yes, but I put the scales are in the other bathroom so I would have to walk through the house to get to them after my shower.*

**Gateway:** *Ok, could you move the scales? That way they would act as a reminder to you to do it after your shower*

**Participant:** *Yeah, that would work*

**Gateway:** *Ok, good. So when we've finished talking will you go and do that?*

**Participant:** *Sure*

**Gateway:** *Good. And do you remember the weight record chart the person from the University gave you when they came to your house the order day? Its in the folder they left you?*

**Participant:** *Yeah*

**Gateway:** *Well you need to put that by the scales so you can write down your weight. Again, could you go and do that now/after we've finished talking?*

In the box below are some practical examples of what to say to people in response to the question “can you think about where the best place is for you to put you record card and weighing scales to help them implement this.

Participant response	Gateway cue to do it
After I have cleaned my teeth in the morning	Make sure the scales are in the bathroom so you can weigh yourself as soon as you've finished your teeth
When I go into the kitchen and put the kettle on is good for me	Why don't you keep the scales in the kitchen or utility room? You could stick a note on the tea or coffee jar to remind you or set a reminder on your mobile phone
Before I go to work	How about moving your scales to wherever you keep your work shoes

	so you can hop on them just before you put them on
'As soon as I get home from work' (shift work)	How about moving your scales to wherever you keep your work shoes and/or bag so you can hop on them just after you take them off" and/or "You could place your scales near your wardrobe so that you remember to weigh yourself when you come home and change out of your work clothes
Before I have dinner/breakfast each day	You could always place your scales in your kitchen/utility room, so that before you have [breakfast/dinner] you remember to quickly weigh yourself"
After I have taken the kids to school	Good idea – the children are at school and you can take just a minute to yourself to hop on the scales. You could place them near the door, or where you put your shoes/handbag/keys to remind you."

### 4.3 Week 4: call 3: reviewing progress

#### 4.3.1 Reviewing how participants are progressing generally and reviewing any barriers they raise

Explain that this is the last call and you would like to spend the next couple of minutes seeing how they have been getting on. For participants who seem to be struggling you need to ask them to think about what's the best way for them to do the regular weighing and checking their weight against their target. Some barriers and solutions you might suggest are listed below.

#### 4.3.2 Reviewing that participants' are doing the things they were asked to do in previous calls

*Check that participants have found a way or strategy to remember to do their daily weighing to help them make it a healthy habit. Check the know and understand what to do if they find they are putting on weight*

#### 4.3.3 Discussing if any breaches to the target weight occurred and did this prompt them to take action, if so what do they do

*Encourage participants to tell you if they have exceeded their target weight and ask them to tell you what they did, if anything, to take get back on track. Encourage them to keep taking action if this occurs again – so things like do some extra physical activity or cut down on their portion sizes etc.*

### 4.4 Helping participants overcome barriers

The table below list some examples of the types of things participants might say are getting in the way of them weighing themselves regularly and some suggestions of how you might help them solve these.

<b>Barrier</b>	<b>Possible Solution</b>
<b>I haven't got time to do it</b>	<p>Most people say <i>it takes about 30 seconds to weigh themselves each day and record this in their record chart</i>. So I'm wondering if it would be possible to find this very small amount of time in your day to do this... I know you must be very busy but if you could find 30 seconds or so to do this it will help you keep on track with your weight... could you try this and see how you get on?</p>
<b>I keep forgetting to do it</b>	<p>Try to put the scales in a place that will help to remind you. You could always set an alarm on your phone to help you remember. Or, ask a family member to remind you daily.</p> <p>Try to link it with some other activity, such as cleaning your teeth in the morning.</p>
<b>It is a bit excessive and over the top doing it everyday</b>	<p>It will allow you to keep on track and identify patterns, for example some people tend to eat more at weekends and put weight on then. You can identify what has caused the weight gain quicker.</p> <p>It's easier to set up a daily routine than trying to remember which day it is and whether it is your weighing day (especially when you are only half awake!)</p> <p>It may seem like this at first, but over time it will hopefully become a habit and you'll do it without even thinking about it – like when you brush your teeth each day.</p>
<b>Its was making me a bit obsessive about my weight</b>	<p>Use it to keep on track and look at the overall pattern over the week.</p> <p>The aim of self weighing is to you see how your behaviours, e.g. eating and exercise, affect your weight. We really don't want you to become obsessive about it and we are sorry we made you feel like this</p>
<b>My weight is going up so I don't want to do it anymore</b>	<p>Remember you have been successful at losing weight and ideally you wouldn't want to put this weight back on.</p> <p>If you start using the suggested weight loss strategies the weight will go down as before.</p> <p>It's better to quickly spot that your weight is going up, before you have regained too much weight. You can use the strategies that you learned on your weight loss programme.</p> <p>We strongly encourage you not to give up if you have gained some weight. This can happen sometimes.. The aim of daily self weighing is to help you monitor the consequences of your behaviours and help you realise that you need to adjust your dietary intake, for example, if you have gained weight. Use the strategies that you have been taught to help.</p>
<b>I'm feeling low at the moment so I don't want to do it (anymore)</b>	<p>I am sorry to hear that. Perhaps by taking control of this part of your life it will help other parts. Focus on one thing at a time. Simply hopping on the scales once a day to keep track may be helpful.</p>

<b>I'm going on holiday and I don't want to be worrying about my weight until I get back</b>	<p><i>Obviously you cannot take the scales with you. However we tend to put weight on holiday and it might be a good idea for you to weigh yourself now and try and lose a bit of weight before you go. So even if you put a bit of weight on whilst away, when you get back you will be a similar weight.</i></p> <p><i>There is always something ahead which means we can put off starting our daily weighing. Start now and pick it up again as soon as you get back.</i></p>
<b>I don't have any motivation to control my weight anymore</b>	<p><i>You have done so well and just remember how you felt when you lost the weight before. Just try and keep the weight off. Self-weighing will help you to do this.</i></p>
<b>I don't like doing it</b>	<p><i>Why don't you like it, how does it make you feel?</i></p> <p><i>It may be hard at the beginning, especially if you're not losing as much weight as you'd like, but weight loss is gradual and will take some time. Don't give up yet, stick with the strategies you've been taught and if you do, you will see results.</i></p>
<b>I can monitor my weight without weighing myself every day</b>	<p><i>It's very hard to monitor our weight without seeing it on the scales. Those people who are very successful at maintaining weight loss report weighing themselves regularly.</i></p> <p><i>By the time your waistband feels tight you will have gained more weight than you would like. Weighing yourself means you can take action early and make changes to your diet and activity.</i></p>
<b>I am Jewish and therefore cannot use technology on a Saturday</b>	<p><i>That is fine, as long as you can remember to weigh yourself the other days to keep track.</i></p>
<b>I work shifts and it will be really difficult to weigh myself at the same time every day.</b>	<p><i>That is understandable but perhaps you could do it just before you went to work be it in the day or before a night shift.</i></p>
<b>My weight goes up and down all of the time</b>	<p><i>Hopefully by writing your weights down on the record card you will be able to find patterns and work out what is causing the changes. Also try not to worry unless there is more than a kg difference in weight.</i></p>

## 5.0 General points to consider

### 5.1 When should participants weigh themselves?

Encourage participants to weigh themselves at the same time every day wearing similar amounts of clothing or no clothing. It doesn't matter what time of day, but it's best if it is the same time every day. If participants are not able to commit to daily weighing then ask them to try it for a week and you will review it next time you call. If at the next call they are still not managing daily weighing or recording their weight then ask them to go for as many times as they can and at least 3-4 times per week.

### 5.2 Providing encouragement and motivation

You should encourage participants to review their weight target, weigh themselves and record this in their booklet at every opportunity *"remember every time you record your weight you are one step nearer to this becoming a healthy habit"*.

### 5.3 Why are you asking me to weigh myself every day instead of every week?

Many of the weight loss programmes in Lighten Up discourage people from weighing themselves at home every day so participants might be concerned about going against what they have been told to do. If participants raise this it should be explained that daily weighing has been chosen over weekly weighing for several reasons.

- They will soon stop going to their weight loss programme every week [unless they decide to continue to pay themselves] and then they are on their own. We are trying to get you into new healthy habits for when you are on your own.
- Daily weighing is more likely to become a habit if performed daily *"like brushing your teeth"*.
- Daily weighing is better than less frequent weighing because it can give immediate feedback about how eating and physical activity is affecting weight.
- If you monitor your weight frequently you can take action more quickly if you need to and before weight gain gets too much.
- Highlight that medical studies have shown that more frequent weighing is associated with less weight regain than infrequent weighing.
- People who weigh themselves frequently tend to eat less fatty food and take more physical activity.

## 6.0 Reminder text messages

The sending of the text messages are the responsibility of the University research team. Inform participants that they will receive text messages to help remind and encourage them to weigh themselves. Some participants may not like the high frequency of the texts but let them know they will contain words of support and encouragement because we really want to help them avoid putting weight back on. Remind them to let us know if they want us to change this or if they want to stop the text messages at anytime, although where possible we want to avoid this happening. See Appendix 4 for a list of the messages.

Months	Frequency of texts messages
--------	-----------------------------

Month 1	Three times per week
Months 2-3	Twice per week
Months 4-12	Twice per month

## 7.0 Example Scripts

### 7.1 Example week 1 telephone support call script

# WEEK 1 EXAMPLE TELEPHONE SUPPORT CALL SCRIPT

Introducing the intervention and what it is about

## Week 1

### Explaining the importance of maintaining weight loss

*"As you have been allocated to the intervention group you will have additional support from me over the next few weeks to help you avoid regaining the weight you have lost. I just wanted to say that its not always easy to lose weight so you have done really well... and it is important now to try and keep it off... would you agree? So, I will talk to you about this today, and then I will call you again next week and again once more in a few weeks time to see how you have been getting on. Is that ok? Great."*

### Setting an overall target for weight

*"Can I just ask if you have any goals at the moment in terms of you weight? Are you hoping to maintain your current weight or would you like to lose some more weight? Ok.. great. . "I would like to ask you to set yourself a goal for your weight.. it needs to be realistic though so something you have a chance of achieving by say six months time. Goals are important because they help to keep you on track and give you something to aim for."*

*Well whether you want to lose more weight or just maintain your weight its my job to try and help you avoid gaining no more than 1 kg of the weight you have lost already. If you lose more weight then that's great... it a bonus, but we really want to try and help you as a worst case to avoid putting back on the weight you have already lost... does that make sense? that sound ok to you?"*

*A really good way of keeping yourself on track is to tell someone you care about what your goal is and they can remind you and encourage you every week or whatever...they might even want to watch their own weight so you can do it together and then see how you go with reaching your goal."*



### **Getting participants to agree to daily self weighing and outlining the benefits**

*“One of the important things I would like you to do is weigh yourself regularly, ideally every day. I know at first this might sound like a lot but the reason we are asking you to do this is because weighing yourself regularly is a really easy and simple way of monitoring your weight and it lets you know straight away how you are getting on in terms of keeping on track with your weight. It can tell you straightaway whether you need to adjust what you are eating or whether you need to do a bit more physical activity. Does that make sense?”*

*Medical studies have also shown that people who weigh themselves regularly gain less weight than those who don't. probably because they are monitoring their weight and are able to make sure it doesn't keep creeping up before the weight gain gets too high. We are asking you to do it every day because the best way of remembering to do it is to get into a regular habit of do it... a bit like it is when we brush our teeth,, we don't really think about it we just do it out of habit.*

### **Encouraging participants to write down their weight**

*You received your new scales yesterday [Insert appropriate day] and your record card didn't you? The reason you were given the record card is because it can be really useful to write down your weight to see how you are getting on from one day or one week to the next. If things are going well it can feel really good to look at it and give you self a pat on the back. And if things aren't going so well it can help to let you know or remind you to think a bit more about what you are eating perhaps.*

*One thing I really wanted to stress to you is that even if your weight is creeping up don't stop weighing yourself or writing it down... keep with it because it will help you in the long run to keep on track.*

## **7.2. Example week 2 telephone support call script**

# **WEEK 2 EXAMPLE TELEPHONE SUPPORT CALL SCRIPT Understanding when and how to take action**

## **Week 2**

### **Opening lines for the calls at week two**

**Gateway:** *Hi its XXX from Gateway Family Services, we spoke recently about the LIMIT study to help people with their weight... do you remember?*

**Participant:** *oh hi yes i do remember*

**Gateway:** Great. I'm just calling to see how you are getting on....?  
Are you getting on ok with it...?

**Participant:** Not bad

**Gateway:** Are you remembering to do it every day?

### **Encouraging participants to write down their target weight**

*Last time we spoke you set a weight target didn't you... do you remember? What was the goal you set yourself? Ok so we agreed you would try not to weigh more than you weigh now in 6 months time? What I would like you to do now is right down your target weight on your weight record card to remind you every day what you are hoping to achieve. Can you do that please?*

### **Reviewing current weight against target**

*The reason we are asking you to write down your weight in the record card every day is because it's a really good way of keeping you on track because each day you can check your weight against the target you set yourself... do you see what i mean?*

### **Understanding what is considered a breach of target and agreeing to take action**

*If you find any time that you have gained a bit more say 1 pound or so than your target weight then don't worry about that too much just try to adjust your eating and do some more physical activity. But if you find your weight has crept up over say three days then it is important to try and stop it going up any more and try to keep on track with keeping to your target.... would you agree?*

### **What participants might do if they breach the target?**

*If you find you weight creeping up then the we would normally recommend you don't worry too much if it's just a little bit on one day, but if you find yourself gaining weight each day over a week then best thing you can do is to think about using some of the skills and strategies you learnt when you were doing your Lighten Up weight loss programme.. Can you think about doing this if this happens to you? I'm not suggesting you enrol back in the programme...I was thinking more about you using the strategies you learnt – so doing more physical activity, thinking about your portion size, reducing your snacks... all those sorts of things that were covered in your weight loss programmes.*

*If you are finding the recording of your weight and the weighing difficult at anytime a really good thing to do is to think about how, where and when you might do your regular self weighing and record your weight... shall we just talk about that now quickly? so when might be the best time for you? Lots of people say after a shower is a good time for them so to help you do that it might be best to move your scales next to the shower to remind you to do it each morning. Some people also find it useful to set themselves reminders on their phone to do it so they don't forget. You lost quite a bit of weight when you did that programme didn't you..? So you can remind yourself of this if you do find yourself gaining weight at anytime and this can be a really good way to encourage yourself to do it again.*

*The other thing that is important to think about is what your target weight might be now? Ideally we would want you to work towards your weight being about what it was when we first spoke so if you could work towards that then that might be helpful for you..? What do you think? Is that ok with you? And we can review how you are doing at the next call in a couple of weeks time. I really want you to know that I do know it can be difficult sometimes to keep weight off but I really want to encourage you to stick with it and remember you can do it because you have done it before...stick with it and I'm sure you will see the benefits over time... is that ok with you? Great.*

## Checking behaviours from Call 1

*How's the weight record card going...you know the booklet we gave you where you weigh yourself each day and write it down?*

*Not going very well: I know it can be hard to remember and some people have said they forget sometimes. Can you tell me a bit about when you do it and where you have put your weighing record card scales?... You might find it useful to put it in a place where you definitely won't forget... some people have said they find it best to put it next to the bed or next to the scales in the bathroom or something like that. Would that work for you?*

*Not going well: Sometimes when people initially lose weight they can find it difficult to keep the weight off. The most important thing now though is to focus on the fact you can lose weight and you have been very successful in doing this very recently so that's really encouraging isn't it?*

*Going well: If you are managing to do it every day or most days then that's really great.. well done for doing that. I'm really pleased to hear you are getting on great with it... I just want to encourage you to keep going with it as much as you can because it will really help you to keep to your target.*

## 7.3 Telephone week 4 support call script

# WEEK 4 EXAMPLE TELEPHONE SUPPORT CALL SCRIPT Reviewing progress

## Week 4:

### Opening lines for the calls at week 4

**Gateway:** *Hi its XXX from Gateway Family Services again, we spoke a couple of weeks ago about the LIMIT study to help people with their weight... do you remember?*

**Participant:** *hi there*

**Gateway:** *I'm just calling to see how you are getting on with things? Are you getting on ok with it...?*

**Participant:** *Ok i think*

**Gateway:** *This is our last call today so I wanted to spend a couple of minutes doing a review of how you are doing...*

### Reviewing how participants are progressing generally and reviewing any barriers they raise

*This is our last call so I just wanted to see how you're getting on?*

*Getting on well: Ok that's great I'm really pleased to hear that. I know your doing really well and I would just like to really encourage with it all, you know the writing down your weight and thinking about ways you can keep to your target weight over time. Don't forget, if you put on a little bit of weight but if you find at any point that is*

*creeping back on ..say more than 1 kg/2 pounds the best thing you can do is start to use the strategies you learnt when you were on your weight loss programme.. so thinking about your portion size and doing more physical activity etc. Ok so can you agree to do that?*

*Not getting on well: Ok so it sounds like its not going very well for you at the moment. Have you been trying anything to get back to your target weight? I would just like to really encourage you with it all, you know the writing down your weight and thinking about ways you can keep to your target weight over time. You can also set yourself a reminder on your phone or something to remind you to do this each day.*

## **Discussing if any breaches to the target weight occurred and did this prompt them to take action, if so what do they do**

*How you getting on with meeting your target weight? Don't forget it is really important to weigh yourself each day, write it down and compare it with your target weight because this will tell you straight away if your weight is creeping up and prompt you to think about how you can keep on track. So it's really useful that way.*

## **8.0 What to do if a participant does not want to take part anymore?**

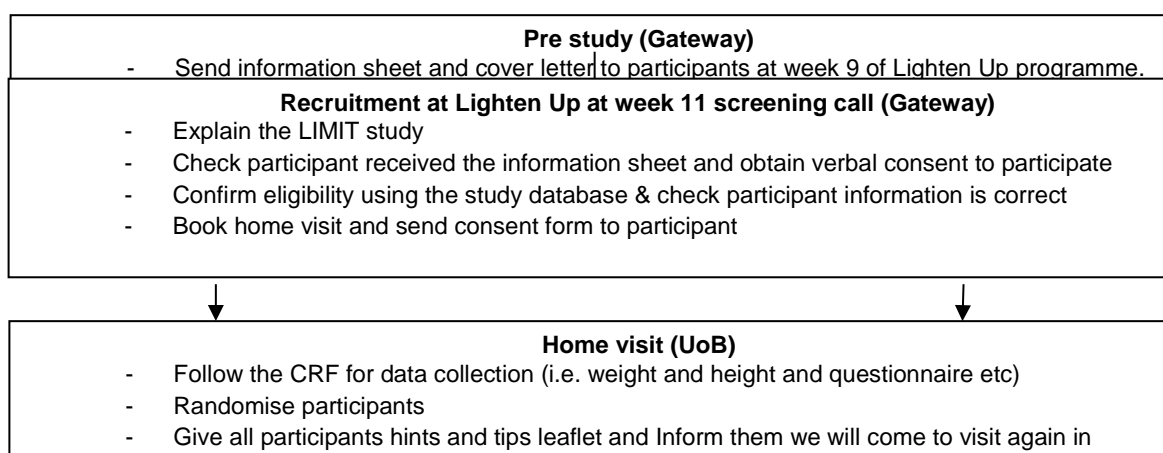
### **8.1 Participant decides to withdraw from having telephone support**

Participant can withdraw from receiving the telephone support by calling in to you or making a request to the University research team. If this happens ask if it would be possible to still contact them at three and 12 months to see if they would be willing to do the follow assessments. Stress that it is really helpful for the research for people to be followed up. Otherwise we can get an overly rosy view of a new programme and its important we don't recommend programmes to people to help with their weight if they don't work.

### **8.2 Participant decides to withdraw from the trial**

Participants can withdraw from the study by contacting the research team at the University so if they call you about this, ask them to call the University research team instead. Ask if it would be possible to still contact them at a later date to see if they would be willing to do the follow assessments. Stress that it is really helpful for the research for people to be followed up. Otherwise we can get an overly rosy view of a new programme and its important we don't recommend programmes to people to help with their weight if they don't work.

## **9.0 Flow diagram of events**



## 10.0 Appendices

### 10.1 Appendix 1: Cover letter and Participant information Leaflet

Participant name  
Sciences

Primary Care Clinical

Address  
Birmingham

University of

Edgbaston  
Birmingham  
B15 2TT

Date  
a.daley@bham.ac.uk

Email:

Dear [insert name]

We would like to invite you to take part in a study that is investigating the benefits of two different approaches to helping people avoid putting weight back on after taking part in a weight loss programme. You have been invited because you are approaching the end of your 12 week weight-loss programme as part of the Lighten Up service.

Please take some time to read the enclosed information leaflet which contains more details about our study, including who is eligible to participate and what it would involve for you. This study is being conducted by a research team at the University of Birmingham and funded by the Department of Health.

After you have reached the end of your 12 week Lighten Up weight loss programme, a facilitator from Lighten Up will telephone you to discuss how you got on in your weight loss programme. During this call they will also ask whether you are interested in joining the research study.

If you have any further questions please do not hesitate to contact Claire Madigan on 0121 414 8067 who will be happy to answer your queries.

Thank you for considering participating in this study.

Yours sincerely

Dr Amanda Daley

Enclosed: *Information leaflet*

## **10.2 Appendix 2 Participant Information Sheet**

### **LIMIT: Lighten-Up Weight Maintenance Study**

#### **Information about the Research**

##### **PART 1**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether you wish to take part.

##### **What is the purpose of the study?**

After people have lost weight many people put the weight back on again. We want to find the best way to help people to maintain their weight loss over the 12 months after completing the Lighten Up programme. This study is going to compare two different ways of helping people to avoid putting weight back on.

##### **Why have I been invited?**

This study is being offered to all people who have joined the Lighten Up programme and have lost 5% of their weight since they started. You joined the Lighten up programme, and if you continued to attend the sessions or continued to use the online programme you are eligible to take part in this study.

##### **Do I have to take part?**

It is up to you to decide. This leaflet describes what the study involves. At the end of your weight management programme you should expect a telephone call from a Lighten Up facilitator. The facilitator at the Lighten Up service will go through any questions you may have and ask you to give your consent to join the study. You are free to withdraw at any time before the study is completed (31<sup>st</sup> December 2016) without giving a reason.

##### **What will happen to me if I take part?**

We don't know the best way of helping people to avoid putting weight back on after they have lost weight. To find out, we need to compare different approaches. We put people into groups and give each group a different programme. To try to make sure the groups are the same to start with, each person is put into a group by chance (randomly, like tossing a coin). The facilitator at the 'Lighten-Up' service will randomly allocate you to one of two weight maintenance programmes.

##### **What will I have to do?**

All participants in the study will receive a hints and tips leaflet in the post about maintaining weight. Some people will also receive two brief phone calls (5 min) over a month and regular (weekly) text messages for three months to encourage them to avoid putting weight back on.

At the start of the study a member of the research team will visit you at home or your GP surgery and record your weight. After three months the research team will visit you again to record your weight and ask you to complete some brief questionnaires about your health. One year after starting the study you will be contacted for the last time so that we can measure your weight and ask you to complete some questionnaires about your health.

##### **What are the possible disadvantages and risks of taking part?**

We do not predict any risks or side-effects from the weight maintenance programmes offered in this study. Should you become pregnant during the study you should call the Lighten Up service and no longer take part in the study.

##### **What are the possible benefits of taking part?**

We cannot promise that you will maintain your weight loss, but similar programmes have helped people in the past.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

**PART 2**

**What will happen if I don't want to carry on with the study?**

If you decide to stop your weight maintenance programme we do hope that you would be willing for the research team to contact you at three and 12 months from when you started the study; this is important as it helps us to find out why a particular programme might not suit someone. However, if you do not want to take part in the research at any time you can withdraw without giving a reason.

**What if there is a problem?**

If you have concerns about any aspect of this study, you should ask to speak to the researchers (Dr Amanda Daley 0121 414 3762). If you remain unhappy and wish to complain formally, you can contact Charlene Mulhern at Birmingham Public Health on *0121 303 4454 or by email at charlene.mulhern@birmingham.gov.uk*.

**Will my taking part in this study be kept confidential?**

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the Lighten-Up service will have your name/address removed so you cannot be identified.

**What will happen to the results of the research study?**

The results of the study will be used by the Birmingham Public Health services to plan weight management services in the future and to improve the Lighten up service. We plan to publish the results. No person would be able to be identified in any published report.

**Who is organising**

This study is being organised jointly by the University of Birmingham, Birmingham Public Health and Gateway Family Services.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the University of Birmingham Research Ethics Committee.

**Contact details for further information**

For further information please contact Claire Madigan 0121 414 8067 at the University of Birmingham.

### 10.3 Appendix 3: Consent form

Patient Identification number for this trial:

**Title of Project: LIMIT study**

Please initial box

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time before the study is completed (31<sup>st</sup> December 2016) without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that data collected by Gateway as part of my involvement in the Lighten Up weight loss programme will be shared with the LIMIT research team. This means information collected about you by Gateway at the start of your weight loss programme will be shared with the research team but this information will not be shared with anyone else not involved in your care. ☐
4. I agree to take part in the above study. ☐

**No signature obtained from the participant as verbal consent taken by telephone.**

_____	_____	_____
Name of Person taking consent	Date	Signature

When completed, 1 for participant; 1 for researcher site file



## **PROCEDURES FOR BASELINE AND FOLLOW UP HOME VISITS (UoB RESEARCH)**

### **1.0 Procedures for baseline home visit**

#### **1.1 Pre visit**

Claire is responsible for ensuring the online home visit booking calendar is well maintained and up to date. Claire will ensure there is adequate cover from the UoB team for the home visits when booked by staff at Gateway. Claire will provide all the information required for the visit (e.g. name, address, ID etc).

The home visits at follow up will be arranged by the study administrator (Tina). When booking the home visits participants must be asked to not tell the person visiting them which group they have been allocated to receive until after they have had their weight measured.

#### **1.2 Equipment and materials required for the home visits**

Please make sure you have all of the following before you leave to conduct a home visit.

##### *1.2.1 Checklist for baseline home visits*

- Name, address, phone numbers and ID of participant from Lighten Up database
- Make sure you have the starting weight of the participant to calculate they have lost 4% or more of their starting weight
- Seca weighing scales
- Seca height meter
- BodyTrace scales (for telephone support group only)
- Randomisation envelopes (brown batch and white batch)
- CRF
- Baseline questionnaire
- Pens
- Mobile phone to call or text in and out of the home you are visiting
- Weight record card
- Weight maintenance packs

##### *1.2.2 Checklist for three and 12 month home visits*

- Name, address, phone numbers, participant ID and group allocation of participant
- Seca weighing scales
- Participants' CRF that was completed at baseline in a sealed envelope
- Spare three month questionnaire. Make sure you have the correct one according participants' group allocation
- Pens
- Mobile phone to call in and out of the home you are visiting
- £20 high street voucher
- Phone or camera for taking a picture of the weight record card (3 month visit only)

### **1.3 Procedure for home visits**

### *1.3.1 Step 1: Introductions*

Call in to the team to let someone know you are entering the home. Show your ID and introduce yourself. Explain the purpose of the visit is to weigh participants, measure their height and then randomise them to one of the study groups; booklet support or telephone support. At 3 and 12 months follow-up ask/remind the participant not to tell you which group they have been allocated to.

### *1.3.2 Step 2: Measure weight and height*

Weight and height should be measured in light clothing with shoes removed. Make sure scales are on a flat surface. Write down the weight exactly as it appears on the screen of the weighing scales. At baseline record this on the CRF. At three and 12 months record this on the sticker on the front of the envelope. Do not open the envelope until weight has been taken. We need to do this to ensure that the primary outcome i.e. weight is blinded. At baseline you need to calculate whether participants have lost at least 4% of their starting weight. Participants not eligible should be told they will receive the standard weight maintenance programme from Gateway. Claire will need to notify Gateway of these people so they can be added to the Gateway system.

### *1.3.3 Step 3: Ask participants to complete the study questionnaire*

*At baseline:* Give participants the questionnaire along with a pen and ask them complete it. At baseline the questionnaire is the same for both groups but at the follow up visits they are different. Check the questionnaire has been completed correctly. If participants don't have time to complete the questionnaire at the home visit give them a prepaid envelope.

### *1.3.4 Three and 12 month follow ups:*

Give participants the questionnaire along with a pen and ask them complete it. Make sure you have the correct version of the questionnaires for the participant you are seeing.

### *1.3.5 Step 4: Randomise participants*

Participants will be randomly allocated to either the telephone support or booklet support group. This means the group the participant receives is a result of chance and not pre-determined in any way. Inform participants that they cannot choose which group they receive and the best way to describe this is by saying its 'like tossing a coin' or "your group will depend on what's in the envelope".

Participants will be allocated to the groups according to the number order of the batch of envelopes you are given. It is **VERY** important that each envelope is opened sequentially in number order – **do not** choose an envelope from your batch unless it is the next in the number sequence.

You will be given two batches envelopes; WHITE and BROWN

- If participants indicate they intend to continue to attend their weight loss intervention then open the next **envelope in the BROWN batch**
- If participants indicate they **DO NOT** intend to continue to attend their weight loss programme then open the next envelope in the **WHITE**
- You should open the envelope and show the slip to the participant and tell them which group they are in (telephone support or booklet support). Participants' name, ID and date of birth, date of visit and name of person opening the envelope should be written on the back of the slip.
- Put the randomisation envelope in the participant's visit envelope and give this back to Claire as soon as you can along with the CRF.

- Claire will then record the group allocation on the database and enter the CRF data on to the database.

#### *1.3.5 Step 5: Call out*

Ring or text the study team to let them know you have left the home.

#### **1.4 What do I do and say to each group of participants after randomisation?**

What you say will depend on which group they are allocated to; this is outlined below. For each group follow the instructions below.

##### *1.4.1 Booklet support group*

1. Explain they are in the booklet support group and that you will now give them the hints and tips leaflet that contains information about how to best maintain weight loss over time. Ask them to read it as they will find lots of stuff to help them keep their weight on track.
2. Thank the participant for taking part in the study, remind them someone will come to visit them in three months time to weigh them again and at this visit they will receive a £20 high street shopping voucher for their time.
3. **At no point should you tell the booklet support group that this is a study about self weighing. Remember you will have the BodyTrace scales with you in case they had been randomised to the telephone support group so you will need to say they are your spare scales if participants ask. Alternatively leave the BodyTrace Scales in your car and only collect them if a participant is randomised to telephone support.**

##### *1.4.2 Telephone Support group*

1. Explain that this is a study to help people keep their weight off. Give them the information booklet which contains information about how to best maintain their weight over time and the weight record chart. Explain they will also get three brief phone calls and some text messages to help motivate and encourage them to avoid gaining weight.
2. Explain that once this visit is over Gateway will call to offer some support to manage their weight, and that they will probably call in the next 1-2 days so watch out for their call.
3. Set up and test the BodyTrace weighing scales and write the serial number in the space provided in the CRF. Explain that these scales are for them to weigh themselves so they can monitor their weight. See below.
4. Thank participants for taking part, remind them someone will come to visit them in three months time to weigh them again
5. Remind participants they will receive a £20 high street shopping voucher for their time at their next visit.

#### **1.5 Explaining the BodyTrace Scales (telephone support group only)**

Explain that you will leave some BodyTrace scales for them to use to weigh themselves. Explain how the BodyTrace scales work and ensure they are working properly.

Explain these scales have a function that allow the research team to monitor how they are getting on but we will NOT personally monitor or give any feedback because we are only interested in how all participants in the study as a group get on and not any individual.

*Say something like:*

**Staff:** *Will you use our scales to weigh yourself, please?*

**Participant:** *Ok why is that? I've already got some scales upstairs?*

**Staff:** *The reason we are using these scales is that we want to know how often people manage to weigh themselves and how much their weight varies day to day. The scales will record that for us. Please don't think we are there watching whether or not you weigh yourself. We're not. We won't come knocking on your door if you not doing it. We're just checking how easy it is for people to follow the programme we are suggesting here. Is that ok with you?*

**Participant:** *Yes*

**Staff:** *Great*

A list of frequently asked question about the BodyTrace scales is in Appendix 1

### **1.6 What happens after the home visit for the telephone support group?**

Explain that someone from Gateway [most likely Jamie, or Bob who they spoke to before] will be in touch within the next two days to talk to them a bit more and offer some support to them generally with maintaining their weight.

### **1.6 Follow up home visits at three and 12 months**

These will be arranged by the UoB research team. The first follow up is at three month after the baseline home visit. There is another home visit at 12 months. There is also a follow up is at six months but this is done by postal questionnaire not home visit.

### **1.7 Completing the CRF**

Before you leave the house check that all the information that is required in the CRF has been recorded.

### **1.8 Generating the calls for the telephone support group**

It is imperative that you let Claire know that you have randomised the participant and return the paperwork to her as soon as possible. This is because she is required to let Gateway know the person has been randomised so that the telephone supports calls can be activated.

Call ID: \_\_\_\_\_

Name of assessor: \_\_\_\_\_

Intervention fidelity

Week 1 Intervention call	Yes	No	Comments
Telephonist explained that weight regain is the norm after weight loss as successful slimmer’s often feel overly confident in the likelihood of keeping weight off			
Got participant to agree that at worst they will avoid regaining more than 1kg of their weight loss			
Both agreed a goal weight that is somewhere near to weight stability			
Telephonist introduced daily weighing, explained importance of it becoming a habit and its benefits for preventing weight regain.			
Telephonist explained that they should check their recorded weight against the target weight everyday			
Participant advised that if their current weight is more than 1kg above target weight then they should restart following the plan they followed for eating and physical activity when they were on their weight loss programme.			
Totals:			
Duration of call:			

Call ID: \_\_\_\_\_

Name of assessor: \_\_\_\_\_

Week 2 Intervention call	Yes	No	Comments
Reviewed frequency of weighing and recording of weight over previous weeks?			
If not weighing telephonist asked participant about barriers and provided help with overcoming these?			
Reminded participant of their goals, commitment to them and value of self-weighing?			
Participants further encouraged to weigh daily			
Participant reminded of the importance of using the record card.			
Importance of engaging in regular physical activity/healthy eating to prevent relapse emphasised			
<b>Totals:</b>			
<b>Duration of call:</b>			

Call ID: \_\_\_\_\_

Name of assessor: \_\_\_\_\_

Week 4 Intervention call	Yes	No	Comments
Reviewed frequency of weighing and recording of weight over previous weeks?			
If not weighing telephonist asked participant about barriers and provided help with overcoming these?			
Reminded participant of their goals, commitment to them and value of self-weighing?			
Participants further encouraged to weigh daily			
Participant reminded of the importance of using the record card.			
Importance of engaging in regular physical activity/healthy eating to prevent relapse emphasised			
Totals:			
Duration of call:			