MRC | Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

Participant Information Sheet

Weight Loss Referrals for Adults in Primary Care **(WRAP) Up**

WRAP

Summary

In the original WRAP Study, we wanted to find out which of three weight management programmes led to the most weight loss and made the best use of NHS resources. We found that both behavioural programmes helped people to lose weight, but the longer programme was more effective over 2 years of follow up. We estimated that in the long term these programmes would reduce the frequency of disease and reduce health care costs. However these estimates were based on assumptions about what happens in the longer term. We would like to follow up participants who took part in the original study to see if these assumptions were correct. This will allow us to evaluate the impact on participants' weight and risk of developing associated illnesses after 5 and 10 years.

This leaflet tells you about the purpose of the WRAP Up study and what will happen if you continue to take part.

- Please take the time to read the following information carefully.
- Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- If you would no longer like to take part you can tell us by email or telephone.
- If you would like to ask some questions about the research, you can contact the Study Coordinator.
- Thank you for your support with our research so far.

Contents

How to contact us

If you have any questions about this study please talk to:
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Tel: 0800 783 4611
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1 Why we are doing this study

What are we studying?

Behavioural weight management programmes can help people to lose weight, which reduces their risk of weight-related illnesses like type 2 diabetes, heart disease and some cancers. Unfortunately many people regain weight when these programmes end and policy makers need to know more about the longer term impacts on health and healthcare costs. There is some evidence to suggest that even a short time at a lower weight can have a positive impact on longer term health, but we need to properly test whether this is true.

The WRAP trial, which you took part in, is the largest UK study of weight management programmes that has measured 2-year outcomes. We would like to be the first study to measure 5 and 10-year outcomes and provide clinicians and decision-makers with this important information about longer term impact.

To do this, we are asking WRAP participants to go to their local GP practice for a study visit, 5 and 10 years after their baseline visit.

2 Why am I being asked to take part?

You are one of 1267 people from across England who took part in the original WRAP Study. We are inviting all WRAP participants who joined the trial between October 2012 and February 2014 and who have agreed to be contacted about follow up studies.

3 What will happen to me if I take part?

To take part, you do not need to follow a diet or take part in another weight loss programme.

Nurse measurement appointment

There will be the opportunity to attend 2 clinic visits – one at 5 years after you first entered the study and another at 10 years. We will invite you to go to your local GP practice and will meet with a trained nurse or healthcare assistant, who will explain the study and answer any questions you may have. If you agree to take part, you will be asked to sign a consent form.

We will then measure your height, weight and blood pressure. If you are willing, we will also take a small blood sample from you of approximately 8ml (about 1 teaspoon full). You can still continue to take part in the study if you do not want to give blood.

The whole visit shouldn't take more than 20 minutes. You will also be asked to complete a short questionnaire. You can complete this questionnaire with pen and paper or online.

Other information we collect

The research team will also use other sources to follow up on your health.

With the help of your GP, we will collect information from your medical notes about your most recent weight and diabetes status. If you are unable to attend the visit (and with your consent) we will collect details on your most recent weight, blood pressure and blood results. We will also look at your health resource use (detailed below).

We will also look at national data sources held by NHS digital, the national provider of information and data for health and social care. This records all hospital admission data for the NHS in England and Wales. We will use this to look at your health status, see what NHS resources you have used and associated costs.

If you would prefer that we didn't look at your medical notes, please let the Study Team know.

Interviews

A small group of participants will also be asked to take part in a discussion with one of the study teams' researchers about their experiences after the weight loss programme ended. We will approach you separately if you will be invited to take part in this.

4 Possible benefits and disadvantages of taking part

What are the possible disadvantages and risks of taking part?

Other than the time it takes you to attend the visit and complete the questionnaire, there should be very little risk or disadvantage to taking part. When taking a blood sample there is a risk of bruising, inflammation and fainting. Our nurses are trained and experienced at taking samples to minimise any discomfort.

What are the possible benefits of taking part?

The information you provide in this study will help our research into the prevention and treatment of obesity and type 2 diabetes. You will be part of a unique long term weight loss study that has followed up participants at 5 and 10 years.

5 More information about taking part

Do I have to take part?

No, it is entirely up to you to decide whether or not you continue to take part in the study. If you do decide to take part, you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. This will not affect the standard or type of care you receive. If the information/data you have provided has been included in any analyses prior to your withdrawal then we will be unable to remove these from the results. You can still be part of future studies even if you choose not to continue to take part in the WRAP Up 5 year Study.

You don't have to take part in all aspects of the study mentioned in section 3. You can withdraw from taking part in the measurement appointment or the medical notes review for both the 5 and 10 year follow up.

Will I receive any payment for taking part?

As a thank you for your continued participation in the WRAP study, you will receive a £30 high street voucher for attending each follow up visit. We will also reimburse the cost of your travel to and from your GP practice.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the study team who will do their best to answer your questions on (Freephone) 0800 783 4611 or email Wrap.Study@mrc-epid.cam.ac.uk

If you remain unhappy and wish to complain formally, the normal University of Cambridge complaints process is available to you through the University of Cambridge Clinical School Secretary: telephone: 01223 333543 or email: SchoolSec@medschl.cam.ac.uk

Independent Advice

If you would like some independent information and advice about taking part in this study, please have a look at the clinical trials page on the NHS Choices website:

https://www.nhs.uk/conditions/clinical-trials/

Or contact your local Patient and Advice Liaison Service (PALS)

https://www.nhs.uk/chq/pages/1082.aspx?CategoryID=68

What will happen to information about me that is collected during the study?

Information we collect during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be identified from it and it will not be used or made available for any purpose other than for research.

With your permission, information will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge. Codes connecting your individual identity to the stored data records will be kept separately. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge.

Occasionally our studies may be monitored by our Sponsors. This is to ensure our research is conducted soundly. This procedure is routine and carried out by fully qualified personnel and data confidentiality will be adhered to at all times. At the end of the study the confidential records will be kept for 20 years and then destroyed.

What will happen to any samples I give?

Any samples that are collected during the course of the project will be processed and kept in accordance with the MRC Epidemiology Unit's standard operating procedures. You were assigned a unique code when you first took part in WRAP. This code will be used to label all samples collected during the study. It is used in place of personal information. With your agreement, we may store samples for up to 10 years and then they will be destroyed. With your consent, and with the appropriate research ethics approval, retained samples may be used for future studies.

Involvement of your GP

With your consent, we will inform you and your GP of the results of your weight, blood pressure and blood tests. It may be the results of these tests will result in the GP reviewing your care needs.

Keeping our records up to date

We know that since the WRAP Study started in 2012 many of you will have moved away and our contact details for you are no longer up to date. To ensure everyone who took part in the study has an opportunity to take part in the follow up, we will be requesting up to date address and GP information from NHS Digital. Information transferred between us and the NHS Digital will be subject to the same high standard of data security and confidentiality as all our research data.

What will happen to the results of the study?

When the study is completed, the results will be presented at scientific meetings and published in scientific journals. If published, your identity and personal details will be kept confidential. No information that could identify you, like your name, will be published in any report about this study. We will also continue to provide you with a summary of our findings from the study through our newsletters.

Who is organising and funding the study?

This trial is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder of the follow up study is the National Institute for Health Research (NIHR).

The study is co-sponsored by the University of Cambridge and NHS Cambridgeshire and Peterborough CCG.

Who has reviewed the study?

This trial has been reviewed by an independent group of people, called the Research Ethics

Committee, to protect your safety, rights, wellbeing, and dignity. The study has been given a favourable opinion by Coventry and Warwickshire Ethics Committee. It has also been reviewed by the NHS National Institute of Health Research, who awarded the funding for this study.

6 Contact for further information

If you would like to continue to take part in the WRAP Up study, please call or email the study team to arrange an appointment.
Contact information:

Study Coordinator

Jenny Woolston
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University of Cambridge
Level 3 Institute of Metabolic Science
Addenbrooke's
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Email: Wrap.Study@mrc-epid.cam.ac.uk

Chief Investigator

Dr Amy Ahern
Senior Investigator Scientist
Prevention of Diabetes and Related Metabolic Disorders Group

Thank you for taking the time to consider taking part in this follow-up study.