

Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity: 5 & 10 year follow up of the WRAP trial

Submission date 12/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/02/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2022	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Referral to commercial open-group behavioural weight loss programmes (such as Weight Watchers) can help people to lose weight and reduces risk factors for diseases including diabetes, cardiovascular (heart) disease and some cancers. Modelling of the long-term impact of these programmes on illnesses and related treatment costs suggests that these programmes are likely to be cost-effective in the long term for adults who are overweight or obese. However, no studies of this type of intervention have measured outcomes beyond 2 years and uncertainty over the long-term impact of these programmes on body weight, diabetes, and other obesity-related conditions, limits the strength of evidence. It is important to reduce these uncertainties and provide a more precise estimate of longer-term impact. The Weight Loss Referrals for Adults in Primary Care (WRAP) study is one of only two studies of this type of programme that has measured weight at 2-year follow up and has measured diabetes-related outcomes. WRAP is also larger and has a considerably higher retention rate than the other trial at 2 years: 68% vs 26%. The aim of this study is to measure the effect of the weight loss programmes on body weight and diabetes risk after 5 and 10 years.

Who can participate?

Adults who are overweight or obese and who took part in the original WRAP study

What does the study involve?

Participants are contacted and invited to attend their 5-year and 10-year follow up visit at their GP surgery. Changes in weight, fat mass, blood HbA1C and lipid levels, blood pressure, diabetes status and modelled 10-year cardiovascular risk are all measured.

What are the possible benefits and risks of participating?

Participants receive a free weight management intervention as part of the original study. The

knowledge gained in this study will help research into the prevention and treatment of obesity and type 2 diabetes. Participants will be part of a unique long-term weight loss study that has followed participants up for 5 years to date. The results from the visit will be reported back to the participant and their GP (if the participant has given consent). The results will be clearly explained and any results that are outside of the healthy range will be highlighted to both the GP and participant. Taking part in the study will not affect the participant's usual standard of care. This is a low-risk study. The two follow-up assessment visits and the small number of blood samples have deliberately been chosen to reduce the burden on participants. Participants will have blood taken by venepuncture at both follow-up visits. Venepuncture can cause minor discomfort and bruising, but the effects are likely to be short lived. Fully trained and experienced practice/CRN nurses will carry out the sampling to minimise any potential risk. By analysing samples for lipids and blood glucose in house using standard scientific equipment, a smaller amount of blood will be required than would be needed in a hospital setting.

Where is the study run from?
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
September 2017 to March 2024

Who is funding the study?
NIHR Programme Grants for Applied Research (UK)

Who is the main contact?
1. Jenny Woolston (public)
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Contact information

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Public

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Additional identifiers

Protocol serial number

RG85078

Study information

Scientific Title

Evaluation of the medium to long term impact of commercial open-group behavioural weight loss programmes on body weight and diabetes risk in adults with overweight and obesity: 5 & 10 year follow up of the WRAP trial

Acronym

WRAP Up

Study objectives

To evaluate the effect of open-group behavioural weight loss programmes of different lengths (12 weeks or 52 weeks) on 5 year (and 10 year) changes in body weight and diabetes risk, in adults with overweight or obesity (Body Mass Index; BMI \geq 28kg/m²).

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands - Coventry & Warwickshire Research Ethics Committee, 08/12/2017, ref: 17/WM/0432

Study design

5-year and 10-year follow up of participants from an existing parallel-group non-blinded multicentre randomised controlled trial

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Obesity, diabetes

Interventions

The interventions used in the original WRAP trial (ISRCTN82857232) included: brief intervention (brief advice and self-help materials; BI), referral to a commercial open-group behavioural programme (Weight Watchers) for 12 weeks (CP12), and referral to the same programme for 52 weeks (CP52). Participant details were entered into the trial database, which randomly assigned participants to one of three interventions (BI, CP12, CP52), based on a block randomisation sequence generated by the Trial Statistician with a 2:5:5 allocation stratified by centre and gender, with the sequence unknown to researchers and participants.

Participants who took part in the original WRAP study and consented for further follow up will be contacted and invited to attend their 5-year and 10-year follow up visit at their GP surgery, with all measurements carried out according to the protocol.

Intervention Type

Behavioural

Primary outcome(s)

5 year (and 10 year) changes in weight, adjusted for baseline. Participants will be weighed at their local GP surgery using calibrated scales. Where participants are unable/unwilling to attend a visit the trialists will obtain a weight measurement from NHS records and/or self-report.

Key secondary outcome(s)

5 year changes (and 10 year changes) in:

1. Fat mass, measured by Tanita body composition analyser
2. HbA1C and lipid profile, measured by blood sample and analysed using standardised methods
3. Blood pressure, measured using OMRON meter in a resting state
4. Diabetes status (normoglycaemia, non-diabetic hyperglycaemia and diabetes)
5. Modelled 10-year cardiovascular risk (Q-Risk)

Completion date

31/03/2024

Eligibility

Key inclusion criteria

Participants who took part in the original WRAP study and consented for further follow up

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

22/01/2018

Date of final enrolment

31/08/2019

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**MRC Epidemiology Unit**

University of Cambridge

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Sponsor information**Organisation**

University of Cambridge

ROR

<https://ror.org/013meh722>

Organisation

Cambridgeshire and Peterborough NHS Foundation Trust

ROR

<https://ror.org/040ch0e11>

Funder(s)**Funder type**

Government

Funder Name

Programme Grants for Applied Research (NIHR RP-PG-0216-20010)

Alternative Name(s)

NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	secondary analysis	07/11/2021	10/11/2021	Yes	No
Results article		01/10/2022	03/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version v9	09/09/2019	18/09/2019	No	No
Statistical Analysis Plan	version v9 and addendum	11/10/2021	03/02/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes