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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

Registration date
01/02/2018

Overall study status
Completed

Last Edited
03/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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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2. Dr Amy Ahern
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Study website
http://www.mrc-epid.cam.ac.uk/research/studies/wrap/

Contact information

Type(s)
Public

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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≥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

Secondary study design
Longitudinal study

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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 used 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)

Overall study start date
01/09/2017

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

Age group
Adult

Sex
Both

Target number of participants
1040

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
England

United Kingdom

Study participating centre
MRC Epidemiology Unit
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Sponsor information

Organisation
University of Cambridge

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Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

Sponsor details
Lockton House,
Clarendon Road
Cambridge
United Kingdom
CB2 8FH
+44 (0)1223 725400
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Sponsor type
Hospital/treatment centre

Website
http://www.cpft.nhs.uk/

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

Publication and dissemination plan
Protocol and statistical analysis plan will be made available online. Planned publication of the study results in a high-impact peer reviewed journal. Publishing date: within 1 year of the completion of 5 year visits (31/03/2020) and 10 year visits (31/03/2025).

Intention to publish date
31/03/2025

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?
Statistical Analysis Plan	version v9	09/09/2019	18/09/2019	No	No
Results article	secondary analysis	07/11/2021	10/11/2021	Yes	No
Statistical Analysis Plan	version v9 and addendum	11/10/2021	03/02/2022	No	No
Results article		01/10/2022	03/10/2022	Yes	No
HRA research summary			28/06/2023	No	No