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Extended follow-up of participants in the DROPLET randomised controlled trial

Submission date
13/03/2019

Recruitment status
No longer recruiting

Registration date
18/04/2019

Overall study status
Completed

Last Edited
01/10/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Around 1 in 4 people in the UK are seriously overweight (obese). Being obese makes it more likely that a person will develop diabetes, heart disease and some types of cancer. Extra body weight also puts a strain on muscles and joints, making it difficult and sometimes painful to move around. The aim of the DROPLET study, conducted in 2015-2017 was to investigate whether a GP referral of patients who are obese to a commercial low-energy total diet replacement (TDR) programme, could help these people to lose more weight than a weight loss programme provided by the practice nurse. 278 participants were recruited from GP practices across Oxfordshire CCG. The participants who were assigned to the TDR programme lost on average 10.7 kg after one year, compared with those assigned to the nurse advice who lost on average 3.1 kg, which resulted in an average difference between the groups of 7.2 kg in favour of the TDR group. These results clearly demonstrate that TDR is clinically effective at 1 year, and the health benefits are largely commensurate with the weight losses observed. However, there are concerns that a rapid weight may be followed with rapid regain, which could negate some of the health benefits. A better understanding of the longer-term effects on weight and health outcomes will help to determine whether the treatment is a cost-effective option in the longer term. The aim of this study is to contact the original participants in the DROPLET trial to invite them to
enrol in this study and to attend a new appointment about 3 years from their original randomisation visit to measure body weight and collect other information on their health and weight control efforts.

Who can participate?
Adults who participated in the original DROPLET study

What does the study involve?
Participants are seen by a nurse or a member of the research team to collect measures of weight, body fat, waist circumference and a fasting blood sample to assess change in blood markers, such as cholesterol and insulin. This is to assess participants' risk of developing heart disease or diabetes. Participants are also asked to complete questionnaires about weight control strategies. These measures collected at 3 years are compared with the same measures that were collected at the beginning of and during the main trial.

What are the possible benefits and risks of participating?
The risks of taking part are minimal, some people feel faint and have a small bruise where the blood sample has been collected.

Where is the study run from?
Oxfordshire Clinical Commissioning Group (UK)

When is the study starting and how long is it expected to run for?
March 2019 to September 2019

Who is funding the study?
1. Cambridge Weight Plan Ltd (UK)
2. National Institutes of Health Research Collaboration for Leadership in Health Research and Care (UK)

Who is the main contact?
Dr N Astbury
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
13987

Study information

Scientific Title
Participants enrolled in the DROPLET randomised controlled trial which compared referral to a commercial total diet replacement (TDR) weight loss programme with usual care weight management on weight at 3 years

Study objectives
The aim of the Extended follow up of the Doctor Referral of Overweight People to a Low-Energy Treatment (DROPLET) trial (https://www.isrctn.com/ISRCTN75092026) is to determine the clinical effectiveness, of referral to a low-energy total diet replacement programme compared with usual weight management interventions for long term weight management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford B Research Ethics Committee, Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NTTel: +44 (0)207 1048058, Email: nrescommittee.southcentral-oxfordb@nhs.net, ref: 19/SC/0012

Study design
Observational follow-up study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
This is an extended follow-up of the participants who were enrolled in the DROPLET randomised controlled trial (https://www.isrctn.com/ISRCTN75092026). Eligible participants have already taken part in the Doctor Referral of Overweight People to Low-Energy treatment (DROPLET) study whereby they were randomly assigned to either a TDR programme or usual care for weight loss, and were followed up at 1 year after randomisation. This study will invite those

participants to attend an extended follow-up at 3 years after randomisation. There will be no further randomisation or additional intervention; this is an observational follow-up only. The participants attend a new appointment approximately 3 years from their original randomisation visit to measure body weight and collect other information on their health and weight control efforts.

Intervention Type
Behavioural

Primary outcome measure
Weight change from baseline to 3 years

Secondary outcome measures
Proportion of participants in each group achieving 5% weight loss at 3 years
Proportion of participants in each group achieving 10% weight loss at 3 years
Change in fat mass between baseline and 3 years
Change in LDL cholesterol between baseline and 3 years
Change in HbA1c between baseline and 3 years
Change in systolic and diastolic blood pressure between baseline and 3 years
Change in QRISK2 between baseline and 3 years

Overall study start date
01/03/2019

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Participant in the original DROPLET randomised controlled trial and consented to re-contact

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
272

Total final enrolment
179

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/03/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
The Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trial and Research Governance
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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Cambridge Weight Plan UK Ltd

Funder Name
NIHR CLAHRC Oxford

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal sometime in 2020.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan
The current IPD 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	results	23/07/2021	01/10/2021	Yes	No
HRA research summary			28/06/2023	No	No