ISRCTN75092026 https://doi.org/10.1186/ISRCTN75092026

# Doctor referral of overweight people to low energy treatment: the DROPLET trial

**Submission date**
28/04/2015

**Recruitment status**
No longer recruiting

**Registration date**
19/05/2015

**Overall study status**
Completed

**Last Edited**
22/09/2023

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] 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. Together, these factors increase the likelihood that people who are overweight will experience poor health and a reduced quality of life. At the moment, doctors and nurses in primary care support people to lose weight by referring patients to a commercial weight loss provider offering support in a group setting, such as Weight Watchers. But weight loss in a group setting does not suit everybody. Another alternative available is low-energy total diet replacement. Low-energy diets have been used to help people lose weight for many years and there are a number of companies who provide diet products together with individual advice and support. Low-energy total diet replacement programmes usually consist of a period where regular foods are replaced entirely by meal replacement products, providing around 800 kcal a day,. The diet has all the vitamins and minerals that are essential for good health, but contains a lot less energy than most people eat on a regular weight loss diet. This means that these type of programmes usually lead to more rapid weight loss, especially in the early weeks. However, it is not known whether low-energy total diet replacement programmes are effective at helping people maintain weight loss a year or more later. The aim of this study, the DROPLET study, is to test whether GPs referring patients who are obese to a low-energy total diet replacement programme, can help people to lose more weight than a weight loss programme provided by the practice nurse.
Who can participate?
Adults diagnosed as obese.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are put on a low energy total diet replacement diet plan by their GP. Those in group 2 (control group) are given standard care for weight management by their GP. Participants visit their GP practice at the start of the study, and then again 4, 12, 26 and 52 weeks later to see a GP, nurse or a member of the research team for follow up. Participants also speak to the study team over the phone at 4, 8 and 12 weeks into the study. Blood samples are taken at the start of the study, and again after 1 year, to see if there is any change in blood markers, such as

cholesterol and insulin. This is to assess participants' risk of developing heart disease or diabetes. Participants also complete questionnaires at the end of the trial.

What are the possible benefits and risks of participating?
Everyone who takes part in the trial should benefit as both groups will receive support to help them to lose weight.

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?
January 2015 to January 2018

Who is funding the study?
Cambridge Weight Plan Ltd (UK)

Who is the main contact?
Dr N Astbury
nerys.astbury@phc.ox.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Nerys Astbury

### Contact details
Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care
Woodstock Road
Oxford
Oxford
United Kingdom
OX2 6GG
+44 (0)18656 17871
nerys.astbury@phc.ox.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
SJ/DROPLET/0012

# Study information

## Scientific Title
A randomised controlled trial of a low energy diet treatment compared with usual care for weight management in primary care

## Acronym
DROPLET

## Study objectives
Hypothesis as of 15/12/2016:
A GP referral of obese adults to a low energy diet treatment results in greater weight loss after 12 months than usual care for weight management in primary care.

Original hypothesis:
Does a GP referral of obese adults to a low energy liquid diet treatment result in a larger reduced weight change after 52 weeks than usual care for weight management in primary care?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South Central –Oxford B Research Ethics Committee, 16/06/2015, ref: 15/SC/0337

## Study design
Open individually randomised two-arm parallel group study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied
Obesity in adults

## Interventions
Participants are allocated to one of two groups:
1. GP referral to a low energy total diet replacement programme
2. Standard care for weight management offered by primary care providers

### Intervention Type
Behavioural

### Primary outcome measure
Change in mean body weight from baseline to 12 months.

### Secondary outcome measures
Secondary outcome measures as of 15/12/2016:
1. Change in mean weight between baseline, 3 and 6 months
2. Proportion of participants achieveing 5 and 10% weight loss at 12 months
2. Change in mean fat mass between baseline and 12 months
3. Change in mean low-density lipoprotein (LDL) cholesterol between baseline and 12 months
4. Change in mean HbA1c between baseline and 12 months
5. Change in mean systolic and diastolic blood pressure between baseline and 12 months

Original secondary outcome measures:
1. Change in mean weight between baseline, 12 and 26 weeks.
2. Change in mean fat mass between baseline and 12, 26 and 52 weeks.
3. Change in mean low-density lipoprotein (LDL) cholesterol between baseline and 52 weeks
4. Change in mean HOMA IR (insulin resistance) between baseline and 52 weeks
5. Change in mean systolic and diastolic blood pressure between baseline and 12 weeks, 26 weeks and 52 weeks.
6. Change in the SF-12 physical functioning scale between baseline and 52 weeks

### Overall study start date
01/01/2015

### Completion date
01/01/2018

## Eligibility

### Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, 18 years and older.
3. Body Mass Index ≥30 kg/m2
4. Likely to benefit from weight loss in the GP's opinion

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

## Target number of participants
270

## Key exclusion criteria
Eclusion criteria as of 15/12/2016:
1. Unable to understand English
2. Currently or recently (within 3 months of study entry) attended a weight management programme, currently participating in another weight loss study
3. Had bariatric surgery, or scheduled to have bariatric surgery
4. Breastfeeding, pregnant or planning to become pregnant during the course of the study.
5. Receiving insulin therapy
6. Heart attack or stroke within the last 3 months,
7. Heart failure of grade II New York Heart Association and more severe,
8. Angina, arrhythmia including atrial fibrillation or prolonged QT syndrome.
9. Taking MAOI medication
10. Taking anticouagulant medication (e.g. warfarin)
11. Taking varenicline (smoking cessation medication)
12. Chronic renal failure of stage 4 or 5
13. Active liver disease except fatty liver or anyone with a past history of hepatoma or within 6 months of onset of acute hepatitis.
14. People having active treatment for cancer other than skin cancer treated with curative intent by local treatment only, or people taking hormonal or other long-term secondary prevention treatment after initial cancer treatment.
15. Active treatment or investigation for possible or confirmed gastric or duodenal ulcer. (Maintenance treatment with acid-suppression is not a contraindication.)
16. Porphyria
17. Scheduled for surgery within 1 year
18. Any member of household is already enrolled in the study
19. Unwilling to provide blood samples
10. Patients that the GP judges not able to meet the demands of either treatment programme or measurement schedule. This may include severe medical problems not listed above or severe psychiatric problems including substance misuse that make following the treatment programme or adhering to the protocol unlikely.

Original exclusion criteria:
1. Unable to understand English
2. Currently or recently (within 3 months of study entry) attended a weight management programme, currently participating in another weight loss study or ever had bariatric surgery.
3. Breastfeeding, pregnant or planning to become pregnant during the course of the study.
4. Receiving insulin therapy
5. Heart attack or stroke within the last 3 months, heart failure of grade II New York Heart Association and more severe, or prolonged QT syndrome.
6. MAOI medication
7. Chronic renal failure of stage 4 or 5
8. Active liver disease except fatty liver or anyone with a past history of hepatoma or within 6 months of onset of acute hepatitis.
9. People having active treatment for cancer other than skin cancer treated with curative intent by local treatment only, or people taking hormonal or other long-term secondary prevention treatment after initial cancer treatment.
10. Active treatment or investigation for possible or confirmed gastric or duodenal ulcer. Maintenance treatment with acid-suppression is not a contraindication.

11. Porphyria
12. Scheduled or on a waiting list for surgery within 1 year
13. Any member of household is already enrolled in the study
14. Unwilling to provide blood samples
15. Patients that the GP judges not able to meet the demands of either treatment programme or measurement schedule. This may include severe medical problems not listed above or severe psychiatric problems including substance misuse that make following the treatment programme or adhering to the protocol unlikely.

### Date of first enrolment
01/01/2016

### Date of final enrolment
28/07/2016

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### Oxfordshire Clinical Commissioning Group
Jubilee House, John Smith Drive
Oxford Business Park South
Oxford
United Kingdom
OX4 2LH

## Sponsor information

### Organisation
University of Oxford

### Sponsor details
Research Services
University of Oxford
Joint Research Office,
Block 60,
Churchill hospital
Oxford
England
United Kingdom
OX3 7LE

**Sponsor type**
University/education

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Industry

**Funder Name**
Cambridge Weight Plan Ltd (UK)

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal in 2018.

**Intention to publish date**
31/12/2018

**Individual participant data (IPD) sharing plan**
The current 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 04/08/2017 | | Yes | No |
| Results article | results | 26/09/2018 | | Yes | No |
| Results article | results | 01/03/2019 | 18/12/2019 | Yes | No |
| Results article | results | 16/04/2020 | 17/04/2020 | Yes | No |
| Results article | exploratory results | 07/04/2021 | 09/04/2021 | Yes | No |
| Results article | descriptive qualitative study | 08/09/2020 | 14/06/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | Secondary analysis | 03/04/2023 | 22/09/2023 | Yes | No |