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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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Open individually randomised two-arm parallel group study

Study type(s)
Treatment

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(s)
Change in mean body weight from baseline to 12 months.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Cambridge Weight Plan Ltd (UK)

Results and Publications

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?

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
Results article	Secondary analysis	03/04/2023	22/09/2023	Yes	No
Protocol article	protocol	04/08/2017		Yes	No
HRA research summary			28/06/2023	No	No