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Brief intervention for weight loss

Submission date	Recruitment status	[X] Prospectively registered
14/11/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/01/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/12/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Obesity, a major cause of chronic disease, affects 1 in 4 adults. Even a small loss of weight is likely to reduce the risk of chronic diseases occurring, such as diabetes that are the consequence of being overweight. However no NHS treatment service exists and general practitioners (GPs) rarely discuss weight management with patients or support behaviour change. Recent evidence shows that attending a commercial weight management service (e.g. Weight Watchers) is more effective than any other widely available alternative weight loss intervention in primary care. Evidence demonstrates the effectiveness of brief, opportunistic interventions by GPs for tobacco control and problem drinking, yet no trial (study) has examined whether screening to identify overweight or obesity in adults and brief intervention are effective.

Who can participate?
Patients, male and female aged 18 and over with a body mass index [BMI] of 30+ kg/m2 (25+ kg /m2 for South Asian population groups) and excess body fat.

What does the study involve?
In the current study GPs will bring up the issue of weight with patients presenting to their GP for reasons other than weight management. Patients will be randomly assigned to receive one of two interventions. In the control group, the GP will encourage weight loss because this will benefit health. In the intervention group, GPs will advocate referral to a weight management service and make that referral immediately. They will also offer a review about a month later to check progress. The main outcome will be weight loss at one year, but we will also record participants' and GPs' reactions to both types of interventions.

What are the possible benefits and risks of participating?
Participating in the study may help patients to lose weight and improve their health, as well as possibly influence the treatment of obesity within primary care. We will compensate participants who attend their 12 month follow up appointment a small honorarium of £10.00 to cover the cost and inconvenience of attending. There is no reason to believe that this study will pose serious risks to participants; advice from the GP and an offer of referral to a weight management service is unlikely to create harm. However it is possible that some participants may find talking about their weight a sensitive issue. GPs and research staff will be trained in ways to approach the topic to avoid offending or upsetting participants.

Where is the study run from?
The Primary Care Clinical Trials Unit (PCCTU) at the University of Oxford is hosting the study. Research will take place in 60 sites (i.e. GP practices) in England, throughout Oxfordshire, Swindon, Gloucestershire, Buckinghamshire and Warwickshire.

When is the study starting and how long is it expected to run for?
The total duration of the study will be 36 months, the study started in September 2012. Each patient will be enrolled on the day of recruitment and followed up for 12 months. Patient recruitment is expected to start in January 2013 and take 12 months.

Who is funding the study?
Medical Research Council (National Prevention Research Initiative - Phase 4)

Who are the main contact(s)?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PA/BWeL/0007

Study information

Scientific Title
A randomised controlled trial to test the effectiveness of a brief intervention for weight management in primary care

Acronym
BWeL

Study objectives
Principal questions addressed by the project:

1. What is the effect of an assistance-orientated (brief referral to a commercial weight management service and review) versus advice-orientated (enhanced usual care) intervention on mean weight change at 12 months?

The analysis of the primary outcome will include the following test of hypothesis:
Null hypothesis: there is no difference in the mean of weight change from baseline to 12 months between the intervention and the control group having adjusted for the baseline weight
Alternative hypothesis: there is a difference in the mean of weight change from baseline to 12 months between the intervention and the control group having adjusted for the baseline weight

2. What is the effect of an assistance-orientated versus advice-orientated intervention on mean weight change at three months (using self-reported weight measure)?
3. What is the difference in the proportion of participants in each intervention group who achieved 5% and 10% weight loss at 12 months?
4. How do obese patients feel about discussing their weight with their general practitioners (GPs) when they have visited for reasons other than their weight and does this vary by intervention type?
5. What actions do people take to manage their weight, at three and 12 months, in response to the two types of GP intervention?
6. How do GPs feel about raising the issue of weight management opportunistically (that is when the patient has visited for reasons other than weight management) and giving the two types of brief intervention both before and after giving opportunistic interventions?
7.1. What is the cost per kg/m2 of the weight lost to the NHS for the two types of interventions?

Added as of 19/02/2013:
7.2. What is the cost per kg of the weight lost to the NHS for the two types of interventions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford C, 14/02/2013, ref: 13/SC/0028

Study design
Pragmatic single-centre randomised controlled trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Obesity in primary care

Interventions
After GPs have dealt with the patient's original presenting complaint(s), they will briefly deliver one of two randomly allocated treatments:

1. An 'assistance-orientated' treatment (intervention)
The GP will advocate referral to a commercial weight management service and make that referral immediately; this is designed not to last longer than a few seconds. They will also offer a review about a month later to check progress. The commercial weight management referral scheme typically consists of 12 vouchers enabling patients to attend classes for free (or use the online equivalent for anyone who does not want to or cannot attend groups). These services encourage weight loss via a healthy lifestyle such as increased physical activity, a reduced fat diet and offer group counselling for motivation and behaviour change, with target setting for weight, activity, and energy intake.

2. An 'advice-orientated' treatment (control)
The GP will advise the participant to lose weight on health grounds. For example, 'It is important to lose weight because it would reduce your chances of getting heart problems, diabetes, and arthritis'. Other than no intervention, this appears to be the most common brief intervention offered currently and there is evidence that it is associated with attempts to lose weight.

Intervention Type
Behavioural

Primary outcome measure
Participants' weight change, measured by a researcher in the patients' GP practice at baseline and at 12 months

Secondary outcome measures
Efficacy outcomes:
1. The mean change in participants' weight from baseline to 3 months. Weight measured at baseline by a researcher and self-reported at three months by the participant over the telephone.
2. The proportion of participants who lose 5% and 10% of their initial weight at 12 months. Weight measured at baseline and at 12 months.
3. Costs of the two types of intervention to calculate the NHS cost per kg/m2 lost. Costs of the

two types of intervention will be assessed to calculate:
3.1. The NHS cost per kg/m2 lost

Added as of 19/02/2013: 3.2. The NHS cost per kg lost

Non-efficacy outcomes:
1. Participants' reaction to the GP discussing weight management, when they visited for reasons other than their weight. Participants' rating of the helpfulness and the appropriateness of the GP's very brief intervention on a five-item Likert-type scale measured immediately after their GP appointment.
2. The actions participants take to manage their weight, at 3 months, in response to the two types of GP intervention. A researcher will contact all participants, via telephone (or by alternative methods if telephone contact is not possible), 3 months after their initial appointment to assess what actions they have taken, if any, to manage their weight since their first appointment.
3. The actions participants take to manage their weight between 3 and 12 months following a brief opportunistic intervention. A researcher will contact all participants, via telephone (or by alternative methods if telephone contact is not possible), 12 months after enrolment to assess which methods of weight management they have used/continued to use, if any, since the 3 month follow up.
4. Participants' thoughts about the opportunistic intervention that was delivered and whether other styles may have resulted in a different reaction than the one experienced. The research team will interview, via telephone, up to 30 participants (selected based on the range of responses to the post-consultation questionnaire [secondary outcome #4]), to ask them about why they responded as they did and whether another style of opportunistic intervention might engender a different reaction.
5. GPs' attitudes to making opportunistic interventions and treating obese people before and after participating in the trial. The research team will ask all GPs to complete a short questionnaire about their attitudes towards making opportunistic interventions and treating obese people before and after their involvement in the trial. Questionnaires will be the same at both time-points.
6. GPs reactions to, including views on the helpfulness and appropriateness of, raising the issue of weight management opportunistically and giving the two types of brief intervention. The research team will ask all GPs to complete a short questionnaire about their views of the appropriateness and helpfulness of giving brief interventions, after their involvement in the trial.
7. GPs' thoughts about the brief intervention. The research team will interview up to 30 participating GPs, via telephone, to examine their thoughts about the brief intervention. GPs will be purposively selected based on the range of responses to the post-trial questionnaire to represent a range of reactions to delivering the intervention.

Overall study start date
01/01/2013

Completion date
28/02/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/02/2013:
Any patient, during a recruitment session, that is:

1. Identified with a body mass index (BMI) greater or equal to 30 (or greater than or equal to 25 for South Asian population groups)
2. Identified with excess body fat
3. 18 years of age or older, either sex
4. Willing to be randomised, consent and comply with study procedures
5. Willing to possibly have the brief intervention component of their GP consultation recorded for the purpose of fidelity checks

Previous inclusion criteria until 19/02/2013:
Any patient, during a recruitment session, that is:
1. Identified with a body mass index (BMI) greater or equal to 30
2. 18 years of age or older, either sex
3. Willing to be randomised, consent and comply with study procedures
4. Willing to possibly have the brief intervention component of their GP consultation recorded for the purpose of fidelity checks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1824

Total final enrolment
1882

Key exclusion criteria
1. Pregnant or intending to become pregnant during the trial period, i.e. the next 12 months
2. Currently or within the past three months participated in a weight management programme (including pharmacotherapy or bariatric surgery)
3. Unable to understand and speak English sufficiently to give informed consent and complete the research assessments
4. Visiting the GP for weight management
5. The GP deems it inappropriate to make an opportunistic intervention on weight management. This includes personal medical reasons known to the GP, such as an eating disorder, or reasons related to the consultation e.g. the patient has become distressed and it would seem insensitive to make such an intervention at this time. If the GP does not consider it appropriate, then the patient will not be enrolled and randomised into the trial

Date of first enrolment
04/06/2013

Date of final enrolment

23/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) - National Prevention Research Initiative - Phase 4, Ref: Lewis.a-mr/j000515/l

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
Not provided at the time of registration

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	19/11/2013		Yes	No
Results article	results	19/11/2016		Yes	No
Results article	results	19/11/2016		Yes	No
Results article	results	01/03/2019		Yes	No
Results article		07/10/2020	03/12/2021	Yes	No
HRA research summary			28/06/2023	No	No