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A brief GP intervention for weight loss: The BWeL-B feasibility trial

Submission date
27/03/2018

Recruitment status
No longer recruiting

Registration date
06/06/2018

Overall study status
Completed

Last Edited
15/01/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and aims

Obesity is an increasing problem in the UK, affecting around a quarter of the adult population and the proportion of obese adults is predicted to double in the next 50 years. Obesity is a major cause of illness and chronic illness, particularly increasing the risk of type 2 diabetes, heart and circulatory disease and some cancers. In addition, the direct economic cost in England is estimated at £4.2 billion per year. There is good evidence that moderate weight loss (5-10% of initial body weight) among adults who are obese leads to a reduction in illness, particularly reducing the risk of diabetes. Future obesity should be prevented, but there is also a pressing need to identify effective ways to treat established obesity.

In a recent randomised trial ('BWeL') we showed that 30-second discussions when people have consulted doctors about something other than weight to motivate action on weight are well received by patients, lead to action in many patients, and lead to long-term weight loss. Specifically, 83% of consecutive patients attending 137 GPs agreed to enrol in the trial and 1882 were chosen at random for one of two interventions. In the control group ('advice'), doctors advised patients to lose weight to improve their health. In the intervention group ('support'), doctors advised patients that the best way to lose weight was to attend a commercial weight management group that was available on the NHS and referred patients to it if they agreed. 77% of all patients agreed to attend the group, 40% actually joined the group, and the mean weight loss across the whole population of people in the intervention group was 2.4 kg compared with 1 kg in the control, with a difference of 1.4 kg (95% confidence interval) (0.9, 2.0). 1 in 500 people thought the GP intervention was inappropriate and unhelpful, while over 80% thought it appropriate and acceptable. The intervention is acceptable, practicable, and scalable.

The support intervention offered the best health result and was predicted to reduce NHS costs. However, there is a problem that may limit wider use. The intervention strategies do not reduce overall NHS costs until year 7 of the implementation programme. In the meantime, overall NHS and public health costs must rise if we are to implement this plan. To deliver the support intervention, the NHS and public health must spend an additional £200 million annually, with almost no offset of costs saved in the first year or two. One solution to the problem is for the brief intervention to be modified slightly. Instead of informing patients that the intervention is the best way to lose weight and is free on the NHS, GPs could instead say that it is the best way but has to be paid for by the patient themselves.

We therefore propose a trial testing an intervention where GPs endorse, offer, and facilitate a

referral to a commercial weight loss programme that requires patients to pay for the service. The aim of this trial is to test the feasibility of an opportunitistic intervention whereby GPs endorse, offer, and facilitate a referral to a commercial weight loss programme that requires patients to pay for the service. The primary objective is to determine whether participants will attend a weight management programme within 3 weeks of a GP recommendation, to help inform the development of a larger trial. A secondary objective is to compare two GP 'scripts' used to deliver the intervention, by randomising participants to one of two intervention groups.

Who can participate?
Adults who are obese and are attending their GP for reasons other than weight management.

What does the study involve?
All patients attending GP practices taking part in the study will be invited to be screened to take part before their consultation, by a researcher. Eligible patients will be invited to take part in a study about people's responses to GP's discussion of their weight. When informed consent has been obtained, participants will be given an opaque envelope containing a piece of paper stating which group they have been randomised to. Participants will go and see their GP as normal. At the end of the consultation, if the GP deems it appropriate, they will open the envelope and deliver a 30-second opportunistic intervention whereby they endorse the use of a community weight management service for weight loss. In one intervention group, the GP will state the price: ""Did you know that the best way to lose weight is to go to Slimming World or Weight Watchers? It costs about £5/6 per week but can really boost your weight loss. We can book an appointment today if you would be willing to give it a go." Participants in the second intervention group will receive the same script from GPs, only the GP will compare the cost of the weight loss service to an everyday discretionary item: "It costs the same as [two cups of coffee] a week and can really boost your weight loss…" Immediately after the consultation, participants will record the appropriateness and helpfulness of the brief intervention and will be provided with dates and times of their local community weight management programme. A researcher will contact participants 3 weeks after they receive the intervention to record whether they attended the programme and will also conduct interview them to explore their thoughts and feelings about the brief intervention.

Where is the study run from?
University of Oxford, Nuffield Department of Primary Care Health Sciences (UK)

When is the study starting and how long is it expected to run for?
November 2017 to April 2020

Who is the main contact?
Dr Kate Tudor, kate.tudor@phc.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Kate Tudor

ORCID ID
http://orcid.org/0000-0001-8244-9650

Contact details
Nuffield Department of Primary Care Health Sciences, University of Oxford
Radcliffe Primary Care Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG
Oxford
United Kingdom
OX26GG
01865617131
kate.tudor@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
255410

ClinicalTrials.gov number

Secondary identifying numbers
13325, IRAS 255410

Study information

Scientific Title
A feasibility study testing the acceptance and recruitment methods of weight loss intervention referrals to help inform the development of a larger trial.

Acronym
BWeL-B

Study objectives
Participants' self-reported acceptance and attendance to a weight management programme referral at 3-week follow up will increase following a brief intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford B Research Ethics Committee, 20/03/2018.

Study design
Pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
After GPs have dealt with the participating patient's original presenting complaint(s), and have confirmed the appropriateness of proceeding, they will briefly deliver one of two treatments, which the participant is randomly allocated to. The treatments include: A referral to a commercial weight management service (CWMS) stating the cost (basic cost), and referral to a CWMS stating the cost compared to the weekly cost of an item that people commonly buy but could choose not to (cost-comparison).
Consistent with the assistance orientated treatment arm of the BWeL trial, the GPs brief intervention is aimed to last no more than a few seconds. For example, in the 'basic cost' arm: "Did you know that the best way to lose weight is to go to Slimming World or Weight Watchers? It costs about £5/6 per week but can really boost your weight loss. We can book an appointment today if you would be willing to give it a go." The cost-comparison arm will have a relatively minor difference: "Did you know that the best way to lose weight is to go to Slimming World or Weight Watchers? It costs about the same as two cups of coffee a week but can really boost your weight loss. We can book an appointment today if you would be willing to give it a go" The choice of weight management service will mainly be determined by availability in the local area. If the person agrees to referral to the CWMS, the GP will ask the participant to make an appointment at reception and to return in a month: "I know it can be difficult to lose weight, so I' d like you to return in a month to see how you are getting on". If the participant wants to try weight loss without assistance, the GP might say: "It's fine for you to try to lose weight on your own but I know it's hard. Would you like to make an appointment to return in a month to see how you are getting on?" This provides an opportunity to re-refer those who accepted referral but did not attend, refer those who tried to lose weight on their own but did not do well, prescribe orlistat to those who have followed the treatment programme but not succeeded (in line with NICE guidance), and it lets the patient participant know their doctor is taking this seriously. If the participant wants to discuss this with their GP, the GP will encourage the participant to make another appointment to do so. (English GPs have 10 minutes per consultation).

Participants will be randomised to a treatment arm at the baseline visit, which will be conducted at their GP practice. After informed consent is obtained, the researcher will give eligible patients who are willing to participate in the trial an opaque A4 sealed envelope, which will contain a colour coded randomisation card. The envelopes will be numbered in sequence. We will use block randomisation of randomly sequenced blocks of 2 and 4 stratified by GPs, which will balance individual consulting styles. The trial statistician will be responsible for the production of randomisation schedule, prior to recruitment.

The researcher will ask patient participants to give the sealed envelope to their GP upon entering their consultation. The card inside the sealed envelope will reveal to the GP, but not

the patient, which intervention to deliver. We will ask GPs not to open the randomisation envelope until they are satisfied that it is suitable for the patient participant to be included in the trial, i.e. after they have addressed the patient's primary reason for visiting them and feel that it would be clinically appropriate to offer a brief intervention at this time to this patient; once the randomisation envelope is opened then the patient has been enrolled in the trial. It would undermine the ability of the study to detect differences between the arms if we enrolled participants who did not receive an intervention. Attached to the outside of each randomisation card envelope will be a detachable 'patient withdrawal card'. The researcher will discreetly write the patient participant's weight and BMI on the back of the withdrawal card before handing the sealed envelope to them so that the GP will be aware of their up-to-date measurement, if required, during the consultation. Furthermore, there will be a tick box option on the card for GPs to select, if they did not randomise the patient to the trial, indicating that the person has not been randomised and therefore not enrolled. The tick box will indicate the reason for non-enrolment, i.e. clinically inappropriate, not appropriate in the consultation, or special reasons. If 'special reasons' is selected, the GPs will be asked to state why, if they can without breaking patient confidentiality, in the space provided. The sealed envelope and withdrawal card would be returned to the patient participant after their consultation who will return to the researcher and the envelope will then be replaced at the top of the randomisation envelope pile for use by the next appropriate potential participant.

Intervention Type
Behavioural

Primary outcome measure
Attendance at weight management programme assessed using participant report via telephone at 3 weeks after the consultation.

Secondary outcome measures
1. Acceptance of GP referral immediately after the appointment, specifically whether they planned to attend the weight management programme in the immediate future (recorded immediately after the referral by the investigator).
2. Participants also rate the helpfulness and the appropriateness of the GP's very brief intervention on five-item Likert-type scales.
3. Participants' thoughts about the opportunistic intervention, (and the script specifically) that was delivered when they visited for reasons other than their weight. Also whether other styles may have resulted in a different reaction than the one experienced. This is assessed using a 3-week follow-up phone call via a semi-structured interview by the investigator.
4. GPs' thoughts and attitudes about the two brief intervention scripts. This will include exploring: why GPs felt as they did; whether other brief interventions might be more or less acceptable than the one they gave; and whether these interventions might be suitable for all people who are obese, or only those with relevant medical conditions. This is measured via a questionnaire pre- and post-intervention and a semi-structured interview up to 1 week post-intervention.
5. Comparison of the proportion of participants who attend a weight management programme in each treatment arm (basic cost vs cost comparison) at 3-week post-intervention follow-up.

Overall study start date
01/11/2017

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Body mass index (BMI) >30 kg/m2 (or >25 kg/m2 for South Asian population groups) and excess body fat
2. Aged 18 years or over
3. Participant is willing and able to give informed consent for participation in the study and comply with study procedures.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
65

Total final enrolment
93

Key exclusion criteria
1. Pregnant or imminently intending to become pregnant
2. Persons with pacemakers or other electronic medical implants
3. Currently or within the past three months participated in a weight management programme (including pharmacotherapy or bariatric surgery)
4. Visiting the GP for weight management
5. 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 (see section 7.5 Randomisation, blinding, and code breaking).
6. Unable to understand and speak English sufficiently to give informed consent and complete the research assessments

Date of first enrolment
16/10/2018

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Department of Primary Care Health Sciences,
Radcliffe Observatory Quarter
Woodstock Road
Oxford
Oxford
United Kingdom
OX26GG

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services, Clinical Trials and Research Governance, Joint Research Office, Block 60, Churchill Hospital, Headington
Oxford
England
United Kingdom
OX37LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
Oxford Biomedical Research Centre

Results and Publications

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

Intention to publish date
01/07/2020

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?
Participant information sheet			01/04/2019	No	Yes
Participant information sheet			01/04/2019	No	Yes
Results article	results	30/04/2020	15/01/2021	Yes	No