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The effect of self-weighing as a weight loss intervention

Submission date
24/07/2012

Recruitment status
No longer recruiting

Registration date
09/08/2012

Overall study status
Completed

Last Edited
05/12/2014

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
There is a public health need to find interventions that can be used by health professionals to help patients lose weight and limit weight regain. One simple and sustainable way could be to suggest to obese patients that they weigh themselves regularly and record their weight. Patients can then use this information to set themselves appropriate weight loss targets. There has been no published study of self-weighing as a standalone intervention in obese patients so it is important to investigate this question further. The primary aim of this study is to investigate the effectiveness of regular (daily) self-weighing on weight loss in obese primary care patients after three months compared to a comparator group. If the intervention proves successful at 3 months, a secondary aim is to assess the effectiveness of the regular weighing intervention at 12 months.

Who can participate?
People aged over 18 years with a BMI greater than 30 kg/m2 can participate.

What does the study involve?
Participants will be randomly allocated to either the intervention group or the comparator group. Both groups will receive two consultations about weight management strategies and asked to complete a food diary at the first consultation. This food diary will then be reviewed at the second consultation. In addition, the intervention group will receive a set of weighing scales and asked to weigh themselves daily and record it on a card provided. They will also get weekly text reminders encouraging them to weigh themselves every day. Participants will complete three questionnaires at the start of the study, after 3 months and after 12 months. Height and weight will be measured at these time points.

What are the possible benefits and risks of participating?
The possible benefits for participants are weight loss and improvements in health and well-being. There are no foreseeable risks from participating in the trial.

Where is the study run from?
Patients will be recruited through GP practices in South Birmingham primary care trust and Birmingham East and North primary care trust via letter sent to their home address inviting

them to contact the research team. The study is run from the University of Birmingham but the interventions will take place at participating general practices.

When is the study starting and how long is it expected to run for?
The study is starting in August 2012 and is expected to finish by December 2013.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
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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
12/WM/0137

Study information

Scientific Title
The efficacy of self-weighing as a weight loss intervention: randomised controlled trial

Study objectives
To investigate the efficacy of regular (daily) self-weighing on weight loss in obese primary care patients at three months (end of intervention), relative to a comparator group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, Birmingham, 31 May 2012, ref: 12/WM/0137

Study design
Two arm pragmatic randomised controlled trial (individual randomisation) with participants allocated to daily self-weighing or comparator group.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Weight management

Interventions
At baseline (visit 1), participants will receive a brief consultation to discuss weight management tips; which would be similar to a consultation that a GP or practice nurse might offer. Participants will also receive a booklet detailing weight management tips adapted from the Department of Health publication, Your Weight, Your Health. We will ask participants to complete a four day food diary and this will be discussed with the researcher one week later (i.e. at visit 2). There are two reasons for doing this. We want to make sure participants are weighing themselves daily and that they can identify potential changes that could be made to their diet.

Participants will also receive a leaflet, and have a discussion about the potential benefits of daily self-weighing within the consultation. Participants will be given a set of weighing scales and instructed to weigh themselves daily and record their weight on the report card provided. As this is an efficacy trial it is important to ensure participants weigh themselves daily and therefore brief weekly text message reminders will be sent to participants. At visit 2 the frequency of participants self-weighing over the previous week will be discussed. Those not weighing themselves daily will be further encouraged to do so and given ideas/strategies of how they might implement (frequent) self weighing into their everyday lives (e.g. using social support and cues to action). The benefits of self-weighing will be reiterated. Participants will be advised they should aim to lose 0.5 kg of body weight per week.

The comparator group will receive the same consultations as the intervention group as described above but there will be no mention or encouragement of daily self-weighing.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Weight change between baseline and three months

Secondary outcome measures
1. The difference in weight change from baseline to 12 months between the groups (subject to the results at 3 months)
2. The difference in physical activity, quality of life, and weight management strategies between the groups

Overall study start date
01/08/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients must be aged >18 years
2. Have a raised BMI of >30 kg/m2
3. Considered suitable to participate by their GP

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
216 participants

Key exclusion criteria
1. Pregnant or intending to fall pregnant within the study time period
2. Cannot understand or speak English sufficiently to undertake the tasks of the study

3. Currently attending a weight management programme (including pharmacotherapy or bariatric surgery) or has taken part in a formal weight management programme in the previous three months
4. Currently weigh them self at least once per week

Date of first enrolment
01/08/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.rcs.bham.ac.uk/governance/app/index.shtml

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2014		Yes	No