The effect of monetary deposits on weight loss, specifically the effect of monetary deposits that are refunded contingent on weight loss of an individual and a 'weight loss partner'

| Submission date 17/11/2016 | Recruitment status No longer recruiting | Prospectively registered Protocol |
|-------------------------------------|--|--|
| Registration date 29/11/2016 | Overall study status Completed | Statistical analysis plan [X] Results |
| Last Edited 30/01/2020 | Condition category Nutritional, Metabolic, Endocrine | [] Individual participant data |

Plain English summary of protocol

Background and study aims:

Over half of the adults in the UK are overweight or obese and these numbers are expected to increase even further. As obesity often leads to serious health problems such as heart disease and certain types of cancer, this puts a huge strain on NHS resources. Therefore, there is a need to research new ways of helping these individuals reduce their weight. The aim of this study is to test the effect of a new type of weight loss treatment (a Monetary Contingency Contract or MCC). The MCC treatment involves a person who is motivated to lose weight being set a safe goal for how much weight they will lose over a given period of time (8 weeks in the present study). The individual then deposits a certain amount of money chosen by themselves within a certain range, which is then returned to them based on the amount of weight they lose. This study also tests whether this treatment might be improved by pairing people who both want to lose weight.

Who can participate: People between the ages of 18-65 with a body mass index above 25 who want to lose weight

What does the study involve:

All participants are given a weight loss goal to lose 4.56% of their body weight over an 8-week period and are provided with basic printed weight loss information. Participants are randomly allocated to one of four groups:

1. Participants are put in contact with one of the other participants they have not met before to become 'weight loss partners'. Each participant is asked to pay a sum of money (an amount of their choice) at the start of the 8-week period, a proportion of which was returned to them at the end of treatment according to the proportion of their weight loss goals that the two partners had achieved on average.

2. Participants are put in contact with a weight loss partner and are asked to pay a sum of money, but return of the money relies only on each participant's own weight loss.

3. Participants are not provided with a weight loss partner. Participants are asked to pay a sum

of money, a proportion of which is returned to them at the end of treatment according to the proportion of the weight loss goal that they had achieved.

4. Participants are asked to pay a sum of money at the start of the study, this money is given immediately back to them and they are told that the researchers are just making sure that they are motivated to pay in money and so are motivated to lose weight. These participants are not provided with a weight loss partner.

Weight and body fat are measured in all four groups at the start of the study and at the end of the 8-week period.

What are the possible benefits and risks of participating?

Participants may lose weight and improve their health. The weight loss information provides them with hints and tips regarding weight loss, which could be used even after the study has ended. As the refund of their deposit was contingent on actual weight loss, there is a risk that if participants are struggling to lose weight, they may use unsafe weight loss methods to try and achieve the weight loss quickly before their weigh-in (e.g. use of laxatives, fasting, purging). To prevent this, participants are discouraged from using such methods at the first meeting.

Where is the study run from? University of Leeds (UK)

When is the study starting and how long is it expected to run for? March 2013 to August 2014

Who is funding the study? University of Leeds (UK)

Who is the main contact? Dr Bianca Sykes-Muskett

Contact information

Type(s) Scientific

Contact name Dr Bianca Sykes-Muskett

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The effect of pair-based monetary contingency contracts for weight loss: a randomized controlled pilot study

Study objectives

 Do monetary contingency contracts for weight loss result in significantly more weight /adiposity reduction?
 Do pair-based monetary contingency contracts result in significantly more weight/adiposity reduction than individual monetary contingency contracts?

Ethics approval required

Old ethics approval format

Ethics approval(s) University of Leeds Faculty of Medicine and Health Ethics Committee, 26/09/2013, ref: 14-0092

Study design Randomized controlled pilot study with a mixed design

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

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

Overweight and obesity

Interventions

Participants were randomized into one of four conditions via a computer generated randomization sequence. All participants were set a weight loss goal to lose 4.56% of their

baseline weight to lose over an 8-week period. They were provided with basic printed weight loss materials at baseline.

1. Partner with pair-based refund

Participants were put into contact with another participant in the same condition as them whom they had not met before to form 'weight loss partners'. Each partner deposited a monetary amount of their choice. They were informed that at the end of the 8 week intervention period, they would be refunded a percentage of their own deposit according to the percentage of the weight loss goal that they and their partner had achieved on average.

2. Partner with individual refund

Participants were also put into pairs to form'weight loss partners'. Each partner deposited a monetary amount of their choice. They were informed that at the end of the 8 week intervention period, they would be refunded a percentage of their own deposit according to the percentage of the weight loss goal that they themselves only had achieved.

3. Individual with individual refund

Participants were not put into contact with a 'weight loss partner'. Each participant paid a monetary deposit and were informed that at the end of the 8 week intervention period, they would be refunded a percentage of the deposit according to the percentage of the weight loss goal they had achieved.

4. Comparison condition

Participants were not provided with a weight loss partner and although they were asked to pay a monetary deposit at baseline, they were refunded this deposit immediately, and were told that the deposit was just to make sure that they were motivated to lose weight.

Measures were taken at baseline and at the end of the 8 week intervention.

Intervention Type

Behavioural

Primary outcome measure

1. Weight (kg) 2. Fat mass (kg)

Both measured using Bio-Impedance Analysis (Tanita model BC-420MA) at baseline (0 weeks), 4 weeks post baseline and at the end of the intervention (8 weeks)

Secondary outcome measures

All secondary outcome measures (except intervention acceptability measures) were taken at baseline (0 weeks), 4 weeks post baseline and at the end of the intervention (8 weeks):

- 1. Percentage body fat, measured using Bio-Impedance Analysis (Tanita model BC-420MA)
- 2. Visceral fat rating, measured using Bio-Impedance Analysis (Tanita model BC-420MA)
- 3. Muscle mass (kg), measured using Bio-Impedance Analysis (Tanita model BC-420MA)
- 4. Degree of obesity, measured using Bio-Impedance Analysis (Tanita model BC-420MA)

5. Body Mass Index, measured using Bio-Impedance Analysis (Tanita model BC-420MA) and a stadiometer (Seca Model 213)

6. Weight loss intention, assessed by a measure adapted from Schifter and Ajzen (1985) which averaged responses to four items on 7-point scales

7. Autonomous and controlled motivation, measured using the Treatment Self-Regulation Questionnaire (TSRQ)

8. Weight-loss self-efficacy, measured using the Weight Self Efficacy Lifestyle Questionnaire (WEL)

9. Intervention acceptability measures, assessed using a series of feedback questions distributed approximately 3 weeks after the final participant had their final measures taken. The time interval between baseline and the intervention acceptability measure therefore varied between participants, according to the time that the participant was recruited into the study. This time interval varied ranged from 11 weeks and 12 months.

Overall study start date

01/03/2013

Completion date

26/08/2014

Eligibility

Key inclusion criteria

1. Identify themselves as motivated to lose weight

2. Have a BMI above 25

3. Age 18-65 years

Participant type(s) Healthy volunteer

Age group Adult

Lower age limit 18 Years

Upper age limit 65 Years

Sex Both

Target number of participants 48

Total final enrolment 77

Key exclusion criteria

- 1. Have lost weight at an unsafe rate during the last year
- 2. Had experienced unexplained weight loss during the last year
- 3. Were taking (had taken during the last month) any medication that could influence the accumulation of expenditure of energy
- 4. Have any cardiac problems
- 5. Have uncontrolled hypertension
- 6. Have a genetic syndrome associated with obesity

7. Have untreated hyperthyroidism
8. Are on a specific food diet (e.g., Atkins diet)
9. Have a significant health problem (e.g., diabetes)
10. Have a history of anaphylaxis to food
11. Have undergone bariatric surgery
12. Have any planned future surgery of any kind
13. Have an eating disorder
14. Are pregnant or breastfeeding

Date of first enrolment

01/10/2013

Date of final enrolment 04/07/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Leeds School of Psychology Faculty of Medicine and Health Leeds United Kingdom LS2 9JT

Sponsor information

Organisation University of Leeds

Sponsor details

School of Psychology Leeds England United Kingdom LS2 9JT

Sponsor type University/education

ROR

Funder(s)

Funder type University/education

Funder Name University of Leeds

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Results and Publications

Publication and dissemination plan

The report of the anthropometric outcomes for this study has been accepted for publication as a brief report.

Intention to publish date

01/12/2016

Individual participant data (IPD) sharing plan

The data will be quantitative data stored as an SPSS file. The repository name is 'Research Data Leeds Repository', the web link is http://archive.researchdata.leeds.ac.uk/. The data will be available to anyone. The data will be deposited within the next couple of months. Participants provided their informed consent for data to be published after anonymization. Data will be fully anonymised and participants will only be identified by participant number.

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------|---------|--------------|------------|----------------|-----------------|
| <u>Results article</u> | results | 01/03/2017 | 30/01/2020 | Yes | No |