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Study to investigate weight loss using virtual gastric band hypnotherapy compared to relaxation hypnotherapy and following a self directed diet.

Submission date
23/01/2012

Recruitment status
No longer recruiting

Registration date
16/03/2012

Overall study status
Completed

Last Edited
26/08/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK it has been reported that 1 in 4 UK adults are obese and a further about 4 in 10 of men and 3 in 10 women are overweight. Excess weight is an increasing problem both to the health of the nation and individuals who are struggling to lose weight. Scientists agree that to lose weight it is necessary to eat fewer calories than their body uses in everyday living. Unfortunately, for many people, this is difficult.Hypnotherapy is a commonly used process of hypnosis, making suggestions to a person for therapeutic (health benefits) purposes. Virtual gastric band hypnotherapy involves mind management techniques designed to form a new set of eating habits and although reported to have a 95% success rate in helping individuals to lose weight, the treatment is not very well known and the results yet to be confirmed. This study aims to show whether the virtual gastric band hypnotherapy technique is an effective method in helping people to lose weight. The study will be carried out by a qualified hypnotherapist and dietitian who are both experienced in supporting weight management.

Who can participate?
Participants in this study will have expressed an interest in wanting to lose weight and will have not lost more than 5% of body weight in the last 6 months. Body Mass Index (BMI) is a measurement calculated using height and weight and is good way of checking if a person is of a healthy weight. In this study participants will need to have a BMI of over 27 which indicates that they are in the overweight category. They will not have been taking any medication for any chronic condition or any medications that may cause an increase or decrease in weight [e.g. steroids, beta blockers and diuretics (water tablets)]. They will also not have any history of eating disorders and have not experienced hypnotherapy for any other condition.

What does the study involve?
Once an individual has expressed an interest in taking part in the study, a patient information sheet will be sent. At least 7 days will be allowed between receiving the patient information sheet and attending the first visit. The first visit for all participants will be at 11 Salmon Grove,

University of Hull, HU6 7SX. The nature of the study will be explained in depth and a health questionnaire will be completed where any past medical history and medication will be disclosed. Height and weight will be measured. Following this, participants will be asked to give informed consent and sign the consent form. Participants will then be allocated to either the group that will receive the virtual gastric band hypnotherapy or the group that will receive the relaxation hypnotherapy. This allocation will be decided by a specialised computer programme. The dates for both of the group sessions will be provided at this first visit. Participants must be able to attend all sessions.
The virtual gastric band hypnotherapy group sessions will involve a number of mind management techniques. The aim is not to get the individual to think that they have had a gastric band operation, but to help them manage portion sizes and form a new set of habits, that they can live with that enables weight loss. Guidelines are also given to the participants to follow. These guidelines are mainly around goal setting, eating three meals a day, exercise and mindful eating.
During the relaxation hypnotherapy sessions, relaxation techniques will be taught. At the first session participants will receive a booklet to aid self directed weight loss.
For both groups there will be 4 sessions (Weeks 1 to 4) that will last approximately 1 hour held at weekly intervals. There will be one further refresher session at week 8. Weight will then be taken at each session and then at weeks 16 and week 24. These two final measurements of weight will be taken at 11 Salmon Grove.

What are the possible benefits and risks of participating?
The possible benefit of taking part in this study is that an individual may lose weight. The only possible risk is that an individual may be upset if weight loss does not occur.

Where is the study run from?
All of the hypnotherapy group sessions will be held in the seminar room at the Sports Centre, University of Hull.

When is study starting and how long is it expected to run for?
The study started in March 2012 and will last for 6 months.

Who is funding the study?
The funding is provided by the Humber Obesity Nutrition Education and Innovation (HONEI) project, University of Hull.

Who is the main contact?
Claire Whitham
Claire.Whitham@hey.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
Head of Academic Diabetes
Endocrinology & Metabolism

Michael White Diabetes Centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2RW
+44 (0)1482 675312
stephen.atkin@hyms.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot study to investigate weight loss using virtual gastric band hypnotherapy compared to relaxation hypnotherapy and following a self directed diet.

Study objectives
This pilot study aims to show whether the virtual gastric band technique is a useful therapy in weight management compared to relaxation hypnotherapy and a self directed diet.

Please note that as of 14/08/2012, patient recruitment for this study is complete.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull York Medical School Ethics Committee, 16/01/2012

Study design
Randomised open labelled parallel trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Virtual gastric band hypnotherapy technique

Once an individual has expressed an interest in taking part in the trial, a patient information sheet will be sent. At least 7 days will be allowed between receiving the patient information sheet and attending the first visit.

The first visit for all participants will be at the University of Hull, 11 Salmon Grove, Hull, HU6 7SX. The nature of the study will be explained in depth and a health questionnaire will be completed where any past medical history and medication will be disclosed. Height and weight will be measured. If fulfilling all of the inclusion and exclusion criteria participants will be asked to give informed consent and sign the consent form.

Participants will then be allocated to either the group that will receive the virtual gastric band hypnotherapy or the group that will receive the relaxation hypnotherapy. This allocation will be decided by a specialised computer programme.

The dates for both of the group sessions will be provided at this first visit. Participants must be able to attend all sessions.

The virtual gastric band hypnotherapy group sessions will involve a number of mind management techniques. The aim is not to get the individual to think that they have had a gastric band operation, but to help them manage portion sizes and form a new set of habits, that they can live with that enables weight loss. Guidelines are also given for the client to follow. These guidelines are mainly around goal setting, eating three meals a day, exercise and mindful eating.

During the relaxation hypnotherapy sessions, relaxation techniques will be taught. At the first session participants will receive a booklet to aid self directed weight loss.
For both groups there will be 4 sessions (Weeks 1 to 4) that will last approximately 1 hour held at weekly intervals. There will be one further refresher session at week 8. Weight will then be taken at each session and then at weeks 16 and week 24.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Investigate the effect of the virtual gastric band hypnotherapy technique on weight loss in healthy overweight adults, compared to weight loss from relaxation hypnotherapy and a self directed diet

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/03/2012

Completion date
13/10/2012

Eligibility

Key inclusion criteria
1. BMI over 27
2. Over the age of 18
3. Having obtained his/her informed assent
4. Having obtained his/her consent
5. Willing to allow their GP to be informed about their participation in the trial
6. Willing to try and lose weight

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. On any weight loss programme
2. Under medical management for being overweight or any other condition
3. Prescribed any medication for a chronic condition
4. Excessive alcohol or recreational drug use
5. Pregnancy
6. Acute illness
7. Any history of eating disorders
8. Previous experience of hypnotherapy for any purpose

Date of first enrolment

13/03/2012

Date of final enrolment
13/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Head of Academic Diabetes
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
University of Hull (UK)

Sponsor details
Cottingham Road
Hull
England
United Kingdom
HU6 7RX
+44 (0)1482 305200
honei@hull.ac.uk

Sponsor type
University/education

Website
http://www2.hull.ac.uk/

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
University/education

Funder Name
University of Hull (UK) - HONEI Project

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