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A comparison of short- and medium-term weight loss following a commercial intervention vs an online NHS intervention and free gym membership

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
31/12/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims

Two-thirds of all men and women In the UK are overweight, with a quarter also qualified as obese. Diseases associated with obesity are straining healthcare resources and have created an urgent need to identify effective weight loss strategies. Unfortunately, research has shown that although achieving weight loss in the short term (about 8-12 weeks) is achievable for many people, maintaining weight loss is more difficult, with the majority of people regaining lost weight in the medium term (e.g. about a year). Several factors have been identified which are thought to contribute to weight regain after weight loss, including for example altered appetite, food cravings and activity habits. What is notable is that adaptations to weight loss may persist during weight maintenance, providing an ongoing and unrelenting drive for people to regain lost weight. However, it is unclear to what extent these processes are activated and sustained in response to different interventions that have been shown to be effective in the short term. Commercial organisations have exploited the large marketplace of consumers who seek formal support with their weight loss, and programmes from the leading commercial weight loss service providers in the UK (e.g. Weight Watchers, Slimming World, Rosemary Connelly) are supported by scientific evidence demonstrating their short (8-12 weeks) and medium term (12 months) effectiveness. For example, in 2011 a large study compared weight outcomes from commercial and NHS-based weight loss programmes. It was shown that the commercial programmes induced about 4.5 kg weight loss at 12 weeks, the majority of which was maintained at 12 months. Notably, a clinically significant weight loss of >5% was seen in one-third to almost one-half of all cases in the commercial programmes at 12 weeks. These commercial programmes, however, are costly as they involve a substantial amount of contact time with health advisors. To date there are no studies comparing commercial weight loss studies with effective exercise interventions that can be done with a lower amount of supervision time.

The main aim of the present study is to compare the short and medium term effectiveness of 12-week interventions involving a commercial intervention, standard NHS care provision, or a control condition involving free gym membership only.

Who can participate?
People aged 18-50 who are obese (BMI between 30 kg/m2 and 40 kg/m2), physically inactive and have not engaged on a programme of dieting/weight loss within the last 6 months.

What does the study involve?
Participants are randomly allocated to one of three groups: Healthy Weight Programme (HWP), NHS programme (NHS) or a gym only programme (GYM).

Those allocated to the HWP group initially spend about 90 minutes in total with a nutritional therapist and a personal trainer. The nutritional therapist reviews their diet diary and provides guidance on healthy eating, portion control and cooking methods. The personal trainer advises on exercise suited to healthy weight management. Nutritional support is provided via one-to-one sessions with a nutritional therapist at the start and end of the intervention period and five bi-weekly group sessions in weeks 2, 4, 6, 8 and 10. These educational sessions cover information on controlling hunger and portion sizes, emotional eating, how sleep and stress affect weight, weight loss myths, menu planning and making healthy choices when travelling, and what to do after completing the 12-week programme. Furthermore, exercise guidance is provided by a qualified exercise professional, with group sessions provided at least once a week between weeks 2 and 10. These sessions include a taster class ('getting started'), a circuits class, body weight training, kettlebells, core conditioning, and optional specialist classes (e.g. spinning, body pump, body combat, Pilates, yoga, body balance).
Those in the NHS group are provided with a 45-minute orientation of the 12-week online NHS programme and basic information on healthy living. For participants who do not have access to this resource online, the guide is printed in full.
The GYM group is asked to use the gym at will. Activities are recorded via online booking and entry scanning. Personnel are available to collect additional activity data where required. Participants are familiarised with the guidelines for weight loss which they will use as a guide.

What are the possible benefits and risks of participating?
Participants stand to learn about their state of current health and wellbeing and are provided with advice and guidance on healthy weight practices. Participants also have access to a Nuffield Health Wellbeing Centre. As is the case with all interventions there are risks in participating. We may identify results of clinical significance requiring further medical investigation. Although the risk is very small there is the risk that participants respond adversely to exercise which in the worst case scenario could result in death. A full screening process, physical monitoring and expert personnel will ensure that this remains a minimal risk.

Where is the study run from?
Central Glasgow Nuffield Health Wellbeing Centre (UK)

When is the study starting and how long is it expected to run for?
July 2016 to January 2017

Who is funding the study?
Nuffield Health Research Group (UK)

Who is the main contact?
Dr Ben Kelly
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
HWP-01

Study information

Scientific Title
A comparison of short- and medium-term weight loss following a commercial intervention vs an online NHS intervention and free gym membership: a randomised controlled trial

Study objectives
Participants engaged in the commercial weight loss programme stand to demonstrate greater weight loss after 12 weeks in comparison to an NHS or gym only group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Bath 'REACH' ethics committee, 22/07/2016, ref: EP 15/16 259/283

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Participants are randomised into three groups.

Those randomised to the HWP group will initially spend approximately 90 minutes in total with a nutritional therapist and a personal trainer. The nutritional therapist will review their diet diary and provide guidance on healthy eating, portion control and cooking methods. The personal trainer will assess the baseline data and will advise on exercise suited to healthy weight management which will include a multi-modal approach. For the HWP Group, nutritional support will be provided via one-to-one sessions with a nutritional therapist at the start and end of the intervention period and five bi-weekly group sessions in weeks 2, 4, 6, 8 and 10. These educational sessions will cover information on controlling hunger and portion sizes, emotional eating, how sleep and stress affect weight, weight loss myths, menu planning and making healthy choices when travelling, and what to do after completing the 12-week programme. Furthermore, exercise guidance will be provided by a qualified exercise professional, with group sessions provided at least once a week between weeks 2 and 10. These sessions will include a taster class ('getting started'), a circuits class, body weight training, kettlebells, core conditioning, and optional specialist classes (e.g. spinning, body pump, body combat, Pilates, yoga, body balance).

Those in the NHS group will be provided with a 45-minute orientation of the 12-week online NHS programme and basic information on healthy living. This will not be altered in any way for the trial. For individuals who do not have access to this resource online, the guide will be printed in full.

The GYM group will be asked to use the gym at will. Activities are recorded via online booking and entry scanning. Personnel are available to collect additional activity data where required. The participant will be familiarised with the ACSM guidelines for weight loss which they will use as a guide.

Intervention Type
Behavioural

Primary outcome(s)
Body mass measured via Seca clinical grade weighing scale at the following timepoints: week -2 (pre screening), week 0 (baseline data collection), week 12 (post-intervention data collection), month 6 (6 months post-intervention), month 12 (12 months post-intervention)

Updated 07/01/2019:
Measured at week -2 (pre screening), week 0 (baseline data collection), week 12 (post-intervention data collection) only.

Key secondary outcome(s))
1. Blood glucose
2. Insulin
3. HbA1C
4. Lipids

These analytes will measured from whole blood sample and will be processed within a Nuffield Health Clinical Pathology Laboratory. Time points for whole blood analysis will be: week 0 (baseline data collection), week 12 (post-intervention data collection)

Completion date
31/03/2018

Eligibility

Key inclusion criteria
1. Apparently healthy males and females
2. Aged 18-50 years
3. BMI>30 kg·m-2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Having been on a diet during the past 6 months
2. Classification as highly physically active on the International Physical Activity Questionnaire (IPAQ)
3. Uncontrolled blood pressure >140/90 mm Hg
4. Total blood cholesterol >6.21 mM
5. Fasted blood glucose >6.1 mM

Date of first enrolment
28/07/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Nuffield Health Research Group - Glasgow Central Team
Nuffield Health
141 Finnieston Street
Glasgow
United Kingdom
G3 8HB

Sponsor information

Organisation
University of Bath (UK)

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Research organisation

Funder Name
Nuffield Health Research Group (UK)

Results and Publications

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?
Results article	results	23/12/2019	31/12/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes