

The impact of adding compassion-focused modules to a commercial weight management program on control of self-evaluation, emotion, eating, weight and wellbeing

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Registration date 27/01/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/07/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Shame and self-criticism may cause people to overeat to feel better. Compassion-focused therapy (CFT) is a talking therapy that helps people to be compassionate to themselves, with the aim of reducing shame and self-criticism. The University of Derby is examining whether adding compassion-focused online video exercises into a commercial weight-loss programme (the intervention) helps people to feel better about themselves, improves their well-being, and also helps them take control of their eating habits and therefore body weight compared to the regular programme.

Who can participate?

Participants over the age of 18, attending a Slimming World group and have a BMI of between 20-70.

What does the study involve?

Slimming World groups are assigned to either a intervention or control group depending upon the number of participants per group leader, number of paying participants and how many people in the group keep attending (retention percentage). Those participants in the control groups have their sessions as usual. Those in the intervention groups are given eight specific video-based exercises that focus on conscious awareness, breathing, mindfulness, compassionate imagery, compassionate self, and working with compassionate self, showing compassion to the inner critic and compassionate letter writing. The study will measure the impact of the intervention through psychological questionnaires, body weight and programme attendance before the study starts and then after 3, 6 and 12 months.

What are the possible benefits and risks of participating?

The researchers do not expect that taking part will pose any additional risk and may not provide a detectable benefit to the participants.

Where is the study run from?

The study will take part at Slimming World groups and run from the University of Derby.

When is the study starting and how long is it expected to run for?

March 2014 to October 2015

Who is funding the study?

Slimming World (UK)

Who is the main contact?

Professor R James Stubbs

Contact information

Type(s)

Scientific

Contact name

Prof R James Stubbs

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

105-13-PG

Study information

Scientific Title

The impact of adding compassion-focused modules to a commercial weight management programme on weight-related self-evaluation, emotion, wellbeing, control of eating and body weight outcomes: an interventional study

Study objectives

1. The addition of online compassion-focused modules into a commercial weight management programme will improve self-evaluation (shame, self criticism, self reassurance and weight focused affect), compared to usual practice at 3 months.
2. The addition of online compassion-focused modules into a commercial weight management programme will improve psychological adjustment (symptoms of depression, stress, anxiety and wellbeing), compared to usual practice at 3 months.
3. The addition of online compassion-focused modules into a commercial weight management programme will improve psychometric measures of control (restraint, disinhibition and perceived hunger) and loss of control of eating (binge eating symptoms, compared to usual practice at 3 months.
4. The addition of online compassion-focused modules into a commercial weight management programme will improve weight outcomes (weight loss, adherence and retention) at 3 months in a commercial weight management programme.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Derby Ethics committee, 25/02/2014, ref: 105-13-PG.

Study design

Single-centre two-arm parallel design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Weight management

Interventions

Slimming World groups were assigned to the intervention or control arm based on balanced performance criteria of group leaders (termed Consultants in the Slimming World programme). These criteria were total number of participants per group leader, number of paying participants per group leader in the last week of the month prior to the study (some attend without fees), retention percentage.

1. Control arm: Multicomponent commercial weight management programme.
2. Intervention arm: The same multicomponent commercial weight management programme with the addition of 3 days training for weight management group leaders and online video exercises available to participants throughout the trial. Both training for group leaders and exercises available to participants centred around:
 1. An overview introductory video about compassion-based approaches in the context of weight management
 2. 8 specific video based exercises focused on conscious awareness, breathing, mindfulness, compassionate imagery, compassionate self, and working with compassionate self, showing compassion to our inner critic and compassionate letter writing

Intervention Type

Behavioural

Primary outcome measure

1. Change between baseline and 3 months, compared to control, in self-evaluation (shame, self criticism, self reassurance and weight focused affect)
2. Change between baseline and 3 months, compared to control, in psychological adjustment (symptoms of depression, stress, anxiety and wellbeing)
3. Change between baseline and 3 months, compared to control, in psychometric measures of control (restraint, disinhibition and perceived hunger) and loss of control of eating (binge eating symptoms) compared to usual practice at 3 months
4. Change between baseline and 3 months, compared to control, in weight outcomes (weight loss, adherence and retention at 3 months in a commercial weight management programme)

Secondary outcome measures

1. Participants experience and perception of participating in the programme after exposure to components of compassionate-based online modules (measured by focus groups and questionnaires)
2. Change between baseline and 6 months in the primary outcome measures
3. Change between baseline and 12 months in the primary outcome measures

All outcome measures were made by questionnaire using standard psychometric scales, delivered by an online questionnaire platform (CheckBox TM) except for qualitative interviews (n=34), which were conducted by telephone and weight and attendance data were collected using Slimming World's digital data collection system, in which weekly body weights and attendance data are collected at Slimming World groups and streamed into a live database using a specifically designed data capture architecture and stored on a Microsoft Structured Query Language servers, 2008 r2. Weight and attendance data were collected and stored in line with the UK Data Protection Act and information Governance level 2.

Overall study start date

24/03/2014

Completion date

30/10/2015

Eligibility

Key inclusion criteria

1. Members of the public who are attending the commercial weight management support sessions
2. Aged over 18 years
3. A BMI range between 20-70

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

To detect differences of 2 kg in weight at 3 months, assuming participant variability is 4 kg (SD) requires 65-85 participants to achieve 80-90% power. We have therefore chosen a figure that would leave ~70-100 participants assuming 30% drop out. We therefore conservatively estimate that a minimum of 200 participants will be required per arm of the study. We will therefore consider a minimum of 200 members per arm of study (total N=400).

Key exclusion criteria

1. Participants in the commercial weight management programme who cannot read and write English (since this would prevent the use of standardised psychometric measures)
2. Participants in the commercial weight management programme with a BMI below 20 and above 70
3. Participants in the commercial weight management programme below the age of 18
4. Participants who were pregnant or lactating
5. Participants disclosing diagnosis of an eating disorder

Date of first enrolment

24/03/2014

Date of final enrolment

14/10/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Derby

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Sponsor information

Organisation

University of Derby

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Sponsor type

University/education

ROR

<https://ror.org/02yhrrk59>

Funder(s)

Funder type

Industry

Funder Name

Slimming World

Results and Publications

Publication and dissemination plan

Intention to publish date

31/08/2016

Individual participant data (IPD) sharing plan

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	05/12/2019	01/07/2020	Yes	No