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Food related computerised attention training for obesity

Submission date	Recruitment status	[X] Prospectively registered
15/05/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2023	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Many people with eating and weight disorders find it difficult to make changes to their eating habits. Two new computer trainings have had promising effects on reducing symptoms when attention processes are trained. This study is designed to compare the effects on treatment outcomes of two different attention trainings for overweight/obesity, to determine the impact of such training on people in the short and longer term and gain insights on how this might work.

Who can participate?

Males or females who are 18 years old or older and are currently overweight or obese

What does the study involve?

Participants answer questions about their eating behaviour and emotions, complete some computer and behavioural tasks, and have their height and weight measured. They are then asked to participate in the training sessions. They are randomly allocated to either an Attention Bias Modification Training, a Mindfulness Based Intervention, or a waiting list. The trainings consists of eight weekly sessions in the lab, and daily short trainings at home. The lab sessions last for about 30 minutes and the home trainings are 10 minutes long. For the home sessions, participants are provided with an electronic tablet at the beginning of the study to complete the trainings and return it at the end of the 8 weeks. At the end of the training sessions (on week eight), participants undergo a similar assessment to the one at the beginning of the trainings. Lastly, four weeks after having completed the training, participants are contacted by email with a brief questionnaire to be filled in online. They have the option to stop the study at any time.

What are the possible risks and benefits of participating?

There may be some slight discomfort associated with completing questionnaires evaluating eating behaviour and emotions, although all the questionnaires are very widely used and usually do not cause distress. This is an experimental study, the outcomes of which can inform on future treatment options that contribute to eating and weight disorders. The trainings have been shown to be effective in other studies, and are designed to help with eating habits and anxiety around food and eating.

Where is the study running from?
King’s College London (UK)

When is the study starting and how long is it expected to run for?
June 2017 to May 2020

Who is funding the study?
National Council of Science and Technology (Mexico)

Who is the main contact?
Ms Daniela Mercado
Daniela.mercado_beivide@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Daniela Mercado Beivide

ORCID ID
https://orcid.org/0000-0003-1319-8362

Contact details
De Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)2078485608
daniela.mercado_beivide@kcl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2014-00185-40

Integrated Research Application System (IRAS)
241656

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 241656

Study information

Scientific Title

A randomised controlled feasibility study of food related computerised attention training for obesity versus active (mindfulness-based intervention [MBI] and waiting list control [FOCUS])

Acronym
FOCUS

Study objectives
1. This study design will be feasible and acceptable for participants with overweight/obesity
2. MBI will improve general attention control and will reduce food-related AB (in comparison to ABMT). Moreover, it will have higher effect sizes in reducing anxiety symptoms, and will lead to a reduction in overeating and to weight loss

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2018, London- City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; +44(0) 2071048033; nrescommittee.london-cityandeast@nhs.net), ref: 18/LO/1683.

Study design
Single-centred randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
After baseline assessment, participants will be randomly allocated to either Attention Bias Modification Training (ABMT), Mindfulness, Based Intervention (MBI) or a waiting list condition. To balance groups for body weight, randomisation will be stratified by BMI (above or below 30 kg /m2) and by gender. Participants assigned to either condition will be asked to attend the Institute of Psychiatry, Psychology and Neuroscience eight times during an 8-week period (i.e. once a week).

The ABMT condition will last approximately 30 min. per visit and will implicitly train participants to “look towards” low calorie food using a modified version of the anti-saccade task while eye movements are recorded to assess participants' accuracy.

The MBI (provided by a company called Headspace) will last approximately 20 min. per training and will guide participants through a series of breathing exercises focusing on the present moment. In addition, participants allocated to the MBI condition will be asked to bring their favourite food (snack) increasing in calorie content as the training progresses (i.e. low, medium and high calorie), and will be guided to mindfully analyse it, focusing on its characteristics before eating it.

Participants from both training conditions will be asked to complete a Visual Analogue Scale (VAS) measuring hunger and craving.

For home sessions, participants will be given a tablet (Asus ZenPad 10) with the allocated training for a daily 10 min session using an app based ABMT or Headspace.

Participants allocated to the waiting list condition will be asked to wait for 8 weeks after baseline assessment and then they will be asked if they wish to receive either ABMT or MBI for 8 weeks.

Intervention Type
Behavioural

Primary outcome(s)
1. The feasibility of conducting a large scale RCT of attention trainings in overweight/obese patients by assessing recruitment, attendance, and retention rates. An acceptability and credibility questionnaire will be administered at post-assessment (i.e., week 8)
2. The quality, completeness, and variability of the outcome measures, determined using descriptive statistical analyses and graphical methods

Key secondary outcome(s))
Weight, eating behaviour and cognition before and after trainings. Assessment of these outcome measures will include different self-report questionnaires:
1. Hunger, craving, mood, stress and anxiety levels, measured using the Visual Analogue Scale (VAS)
2. Eating behaviour and awareness, assessed using the Food Craving Questionnaire – Trait version (FCQ-T), the Eating Disorders Examination Questionnaire (EDEQ), the Power of Food scale, the Mindful Eating Questionnaire (MEQ) and Mindful Awareness and Attention Scale (MAAS)
3. General psychopathology measured using the Depression, Anxiety and Stress Scale (DASS-21) and the State and Trait Anxiety Inventory (STAI)
4. Quality of diet and calorie intake assessed using 24h dietary recall questionnaire
5. BMI and body composition calculated by taking height and weight on the day of the assessment using a bioelectrical impedance scale
6. Different components of attention (i.e. alerting, orienting and executive attention) assessed by the food-Attention Network Task (Food-ANT)
7. Attention bias for food, measured by a dot-probe task while recording eye movements
8. Preference of low vs high-calorie food items, assessed using the food-choice task
9. State levels of cue-elicited food cravings, assessed using the Food Challenge Task
10. Food intake measured by the Bogus Taste Test, where participants will be asked to rate different kinds of highly palatable food in terms of their visual attractiveness, smell and taste and will be told that they should try as much of the offered items as they like. Food consumption will be determined by weighing remaining food.

All of these measures will be taken both at baseline assessment and post-assessment (8 weeks) with the exception of the EDEQ and the Power of Food Scale, which will also be completed by participants at follow-up (week 12). The size of the treatment effect on each outcome measure will be the difference in outcome data between conditions at post treatment (8 weeks) and follow-up (12 weeks). Group differences will be estimated using linear mixed effects regression models, controlling for the baseline level of the outcome and the strata variable used in the randomisation.

The aim is not to determine significant group differences but to establish a suitably precise effect size for the primary outcome at the post treatment assessment. This estimate will be used to guide the sample size of a future efficacy trial.

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Male or female participants
2. 18 years old or older (women of childbearing age will be included)
3. BMI of >25kg/m2
4. Fluent in English
5. Informed consent (written and witnessed)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Having a current other major psychiatric disorder (e.g., major depression, major suicidality, substance dependence, psychosis) needing treatment in its own right
2. Having a diagnose of Anorexia Nervosa, Bulimia Nervosa or Eating disorder not otherwise specified (EDNOS)
3. Diagnosis of Diabetes Mellitus
4. Having recently started psychotropic medication or increased the dose (i.e. within the previous 2 weeks)
5. Taking medication for weight loss
6. Pregnancy (either current or during the past 6 months)
7. Regular current or past mindfulness meditation or yoga practice (defined as > 20 minutes, twice or more times per week during the past 2 months).
8. Visual impairments that cannot be corrected with contact lenses or glasses

Date of first enrolment
01/10/2018

Date of final enrolment
01/02/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London and Maudsley Hospital
Denmark Hill
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología

Alternative Name(s)
Consejo Nacional de Humanidades, Ciencias y Tecnologías, Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan
Once the study has finished and data has been published, anonymised data could be shared upon direct request to the PI (Ulrike.schmidt@kcl.ac.uk). Participants will agree to this by signing the consent form which state the possibility of anonymised data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/04/2023	13/04/2023	Yes	No
Protocol article	protocol	10/01/2020	13/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes