ISRCTN13262256 https://doi.org/10.1186/ISRCTN13262256

Causes, mechanisms and consequences of binge eating: understanding maladaptive reward memory processes in young people who binge eat

Submission date
23/01/2019

Recruitment status
No longer recruiting

Registration date
28/02/2019

Overall study status
Completed

Last Edited
01/12/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Some people occasionally binge on large amounts of food and feel that they lose control over their eating, which can induce negative thoughts and emotions, have various negative health consequences such as weight gain, and lead to more serious eating problems, like Binge Eating Disorder. We aim to understand why some people binge eat, and determine whether this understanding can help us develop better ways to help people reduce or manage bingeing. Some people, for instance, find that certain 'trigger foods' tend to cause bingeing. We wish to test whether it is possible to change these unhelpful responses to foods and hence, reduce bingeing.

Who can participate?
Women and men aged between 18 and 25, who binge on food on one or more occasions per month but are otherwise healthy, are invited to participate in this research.

What does the study involve?
The study involves attending three sessions at University College London and keeping an online 'food diary'. The first two sessions are conducted within 24-48 hours of one another, and the final session takes place after a further 10-14 days. Participants will be randomised into one of three experimental treatment groups: memory reactivation with cognitive bias modification, cognitive bias modification alone, or memory reactivation alone. Participants are also asked to complete some brief follow-up questionnaires at 1, 3, 6 and 9 months.

What are the possible benefits and risks of participating?
Possible benefits from participating include a potentially natural improvement in bingeing behaviour through study participation and consistent food-intake monitoring. The research is considered to be low risk with no anticipated side effects.

Where is the study run from?
The study is run from the research department of the Clinical Psychopharmacology Unit, University College London, which is located at 1-19 Torrington Place, London.

When is the study starting and how long is it expected to run for?
The approximate start date for the study is March 2018. Including all follow-up measures, the approximate duration of the trial will be 21 months, from March 2018 to November 2019.

Who is funding the study?
The study is funded by the Medical Research Council and Medical Research Foundation.

Who is the main contact?
Dr Sunjeev Kamboj
sunjeev.kamboj@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Ravi Das

ORCID ID
http://orcid.org/0000-0003-0104-1544

Contact details
Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street
UK
London
United Kingdom
WC1E6BT

Type(s)
Scientific

Contact name
Dr Sunjeev Kamboj

ORCID ID
http://orcid.org/0000-0003-2197-0826

Contact details
Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street
UK

London
United Kingdom
WC1E 6BT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3901/004

Study information

Scientific Title
The effects of cognitive bias modification alone vs. during the reconsolidation of binge-eating memories in binge-eating young adults: study I - cognitive bias modification

Acronym
UPBEAT

Study objectives
1. 'True' ('standard') cognitive bias modification (CBM), (where 'no-go' responses are consistently paired with binge food images) will be more effective than 'sham' CBM (where equal numbers of go/no-go responses are made to binge food cues) at reducing subsequent motor and oculomotor approach biases to binge food images.
2. CBM will be more effective in reducing these approach biases when conducted following retrieval and destabilisation of binge food memories, than 'standard' CBM.
3. If CBM is sufficient to produce behavioural changes in actual binge eating, 'standard' CBM will produce greater reductions in self-reported binge episodes, associated calorie intake and disordered eating vs. 'sham' CBM. It is hypothesised that these reductions will be significantly greater when CBM is conducted shortly after reactivation of binge eating-relevant memories, consistent with reconsolidation-updating mechanisms.
4. Response to manipulations of CBM and memory reactivation will be positively associated with the level of 'prediction error' or 'surprise' engendered during the memory reactivation procedure.

NB: Full study details were pre-registered on the Open Science Framework (https://osf.io/82c4r/)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 28/09/2017, ref. 3901/004.

Study design
Single centre mechanistic study, mixed within/between subjects

Primary study design
Other

Secondary study design

Study setting(s)
Other

Study type(s)
Other

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
Binge eating behaviour

Interventions
This is a mechanistic study using a mixed within/between subjects design conducted in a single (academic) centre. There is one between-subjects factor (Group) with three levels, and a within-subjects factor (Time) with two levels for computerised assessments and three levels for measures of binge-eating responses. Participants are randomly allocated to one of the three groups using block randomisation.

We use a Go/No-Go task to train inhibitory responses to highly palatable food cues, aiming to produce acute reductions in food consumption. This training is part of an intervention modality generically known as cognitive bias modification (CBM). We conduct CBM procedures during the 'reconsolidation window' of binge-food memory associations, which refers to a time-limited period of memory instability that can be triggered via specific kinds of memory retrieval that destabilise or ‘reactivate’ long-term memory traces.

Participants are evenly and randomly allocated to one of three experimental groups: 1) Binge memory reactivation (BMR) + CBM (N = 30), 2) Non-binge memory reactivation + CBM (NR+CBM; N = 30); 3) Binge memory reactivation+ sham CBM (BMR + sham; N= 30). The total duration of treatment and follow-up for all study arms was 9 months.

Full details on Open Science Framework website https://osf.io/82c4r/.

Intervention Type
Behavioural

Primary outcome measure
1. Motor approach bias to highly palatable foods as assessed by changes in performance on a food Go/No-Go task from pre-manipulation on Day 1 (baseline) to post-intervention on Day ~14 (test). Approach bias is demonstrated by faster ‘go’ responses and more commission errors to binge food images than low-palatability and control images in a Go/No-Go CBM task.
2. Changes in oculomotor approach to highly palatable foods as assessed by eyetracking in dot-probe/ attentional bias task, performed pre-intervention on Day 1 (baseline) and post-intervention on Day ~14 (test).
3. Binge frequency and daily food consumption. This is logged via an online app (MyFitnessPal).

Experimenters will extract frequency of subjective binges and objective consumption information (caloric volume of binge foods and non-binge foods consumed). Outcomes from this measure will thus be 1) frequency of subjective binge episodes in the pre-intervention on Day 1 (baseline) period, post-intervention Day ~14 (test) period and at follow-up periods of ~28 days, 3 months, 6 months and 9 months post-intervention 2) average (mean, or median if high skew is present) corresponding macronutrient intake over these same periods.
4. Binge Eating Scale (BES), a questionnaire-based measure of specific binge eating symptomatology severity is used at pre-intervention on Day 1 (baseline), post-intervention Day ~14 (test) and at follow-up periods of ~28 days, 3 months, 6 months and 9months post-intervention.
5. Eating Disorders Examination-Questionnaire (EDE-Q) is used to assess disordered eating at pre-intervention on Day 1 (baseline), post-intervention Day ~14 (test) and at follow-up periods of ~28 days, 3 months, 6 months and 9 months post-intervention.
6. Food Craving Questionnaire State/Trait (FCQ-T/FCQ-S) will be used to assess momentary craving evoked by exposure to binge food images and in-vivo high-palatability food at pre-intervention on Day 1 (baseline), post-intervention Day ~14 (test) and at follow-up periods of ~28 days, 3 months, 6 months and 9 months post-intervention.
7. A subjective, self-rated 'surprise' rating is collected to assess the efficacy of the prediction-error generation procedure during memory reactivation. This is a single-item 11-point scale utilised on the second (intervention) day of the study following the binge food memory reactivation or non-binge food memory reactivation procedure.
8. Adherence to task requirements is assessed by measuring performance accuracy during the CBM and sham CBM procedures on the intervention day. Accuracy will be formalised as d' (d-prime), a normalised measure that takes into account the hit and false alarm rate for binary responses.

Secondary outcome measures

1. Height/weight and BMI, resting heart rate, blood pressure, and blood glucose are assessed in-lab at Day 1 (baseline), Day 2 (intervention day) and at Day ~14 post-intervention (test) using high-accuracy scales, an Omron heart rate/blood pressure cuff, and through finger-prick glucose oxidase with an SDCheck monitor, respectively.
2. Basic information, Family History of Eating Disorders and Typical Binge Foods List are recorded pre-intervention on Day 1 (baseline).
3. Depression via the Beck Depression Inventory (BDI), Trait Anxiety via the Spielberger Trait Anxiety Index, Trait Impulsivity via the Barratt Impulsiveness Scale (BIS), Trait Behavioural Inhibition and Activation via the BIS/BAS scale, temporal discounting via the Kirby Delay-Discounting Task (DDT), tolerance for distress via the Distress Tolerance Scale, and disgust via the Disgust Propensity and Sensitivity Scale-Revised, are assessed pre-intervention on Day 1 (baseline) and post-intervention on Day ~14 (test).
4. Food Addiction Symptomatology are assessed using the Yale Food Addiction Scale (Y-FAS), Three Factor Eating Questionnaire-revised (TFEQ-r), and the Power of Food Scale (PFS), at pre-intervention on Day 1 (baseline) period, post-intervention Day ~14 (test) period.
5. Calorie consumption and satiety are assessed via a Timeline Follow-Back (TLFB) and Hunger Scale, respectively, at pre-intervention on Day 1 (baseline) and post-intervention on Day ~14 (test).
6. Anxiety via a Visual Analogue scale, and affect via the Positive and Negative Affect Scale are assessed on Day 2 (intervention), pre and post intervention.
7. The YFAS, BES, FCQT, PFS, TFEQ-r, EDE-Q, and TLFB are used again at follow-up periods of ~28 days, 3 months, 6 months and 9 months post-intervention.
8. Electroencephalography (EEG) in response to binge food images. We will assess neural correlates of successful and unsuccessful response inhibition to binge food images at baseline

and test (Day 1 vs. Day ~14). We will also record neural oscillatory activity during the binge memory reactivation/non-reactivation and CBM/sham CBM manipulations on the second study day (intervention day). EEG data is recorded using an EEGo Sports 64 channel amplifier with WaveGuard electrode caps (ANT Neuro).

Overall study start date
01/03/2018

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Aged 18-24
2. Binge on food 2 or more times per month
3. Experience a sense of loss-of-control when bingeing

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Are pregnant or breastfeeding, or are likely to become pregnant during the study
2. Are currently seeking treatment for binge eating or any other psychiatric condition
3. Suffer from any major psychiatric or physical health disorder
4. Have a family history of any major psychiatric disorder
5. Engage in 'purging' e.g. vomiting, use of laxatives or other medications to compensate for bingeing
6. Drink over the daily governmental alcohol allowance more than 4 times per week
7. Use recreational drugs more than once a week
8. Have an unresolved diagnosis of any eating, drug or alcohol use disorder(s)
9. Are diabetic or currently using blood-sugar-control medication
10. Have a BMI of less than 18.5
11. Have high blood pressure
12. Are unable to abstain from drugs and alcohol for 24 hours prior to each session

13. Eat a vegan diet
14. Are not motivated to change the bingeing behaviour
15. Have a permanent hairstyle such as dreadlocks, braids, cornrows that means we will not be able to fit an EEG cap

Date of first enrolment
01/04/2018

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Psychopharmacology Unit
University College London
Gower St
London
United Kingdom
WC1E6BT

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
https://www.ucl.ac.uk/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Foundation

Results and Publications

Publication and dissemination plan
Results will be published/disseminated through conferences, conference abstracts and peer reviewed scientific journals. Where possible, the team will present the findings at forums intended to improve public understanding of psychological science and mental health.

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ravi Das (ravi.das@ucl.ac.uk), co-investigator. The data is expected be available to researchers once all data collection and initial analysis has been completed (approximately Jan 2021). Data will include relevant group allocations and outcome variables and will be anonymised.

IPD sharing plan summary

Available on request