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Causes, mechanisms and consequences of binge eating: Understanding maladaptive reward memory processes in young people who binge eat: Study II - Counterconditioning

Submission date
31/01/2019

Recruitment status
No longer recruiting

Registration date
28/02/2019

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] 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 24, 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 UCL 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 counter conditioning, counter conditioning alone, or memory reactivation alone. Counter conditioning involves learning new associations between food cues and unpleasant outcomes.

What are the possible benefits and risks of participating?
Possible benefits from participating include a potentially natural improvement in symptoms through trial participation and consistent food-intake monitoring. The research is considered to be low risk. Short-term side effects include experiencing an unpleasant taste after consuming the harmless but extremely bitter-tasting substance, Bitrex. This is the substance added to household products to prevent children from consuming them. Although very bitter, the taste

does not last long after sucking on a mint and using a mouthwash, which will be provided. Some people experience mild nausea after consuming Bitrex, but again, this is short-lived.

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 trial is March 2019. Including all follow-up measures, the approximate duration of the trial will be 15 months, from March 2019 to July 2020.

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Study information

Scientific Title
The effects of counterconditioning alone vs. during the reconsolidation of binge-eating memories in binge-eating young adults

Study objectives
1. 'Active' disgust counterconditioning, (where binge food images are paired with disgusting images and bitter liquids) will be more effective than 'sham' counterconditioning (where binge food cues are paired with neutral images and liquids) at reducing subsequent approach biases and reactivity to binge food images.
2. Counterconditioning will be more effective in reducing approach biases and cue reactivity when conducted following retrieval and destabilisation of binge food memories (BMR + Counterconditioning), than with counterconditioning alone.
3. If counterconditioning is sufficient to produce behavioural reductions in self-reported binge episodes, associated calorie intake and disordered eating, this effect will be significantly greater when counterconditioning is conducted shortly after reactivation of binge eating-relevant memories, consistent with reconsolidation-updating mechanisms.
4. Exploratory: Response to counterconditioning and memory reactivation will be positively associated with the level of 'prediction error' or 'surprise' engendered during the memory reactivation procedure and moderated by blood glucose level and hunger ratings prior to memory retrieval.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2017, University College London Research Ethics Committee, (University College London, 2 Taviton St., London, WC1E 6BT; +44 2076798717, ext: 28717; ethics@ucl.ac.uk), ref: 3901/004

Primary study design
Interventional

Study design
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.

For full details see our Open Science Framework entry https://osf.io/82c4r/.

Study type(s)
Other

Health condition(s) or problem(s) studied
Binge eating behaviour

Interventions
Following our previous procedures showing successful reactivation of ingrained associative drinking memories in heavy drinkers, we aim to reactivate maladaptive binge-eating memories through brief cue-driven binge memory retrieval with omission of an expected high palatability food reward.

During the 'reconsolidation window' following this memory retrieval procedure, we will perform an experimental counterconditioning procedure, which involves pairing cues that were previously associated with rewarding outcomes with negative outcomes. We will pair highly palatable binge food images with disgusting images from the IAPS database and a diluted solution of Bitrex (denatonium benzoate). During sham counterconditioning, highly palatable binge food images will be paired with neutral IAPS images and water.

Participants are evenly and randomly allocated to one of three experimental groups: 1) Binge memory reactivation (BMR) + counter conditioning (CC) (BMR+CC; N = 30), 2) Non-binge memory reactivation + CC (NR+CC; N = 30); 3) Binge memory reactivation+ sham CC (BMR + sham CC; N= 30).

Full pre-registered details on Open Science Framework website https://osf.io/reytv/ (study title: The Effects of Counter Conditioning Alone vs. During the Reconsolidation of Binge-Eating Memories in Binge-Eating Young Adults)

Intervention Type
Behavioural

Primary outcome(s)
Eating behaviour measured by:
1. Binge frequency/food diary: Daily food consumption will be logged via an online diet app (MyFitnessPal), using anonymised login codes. On each day, participants will also log subjective binges. From these diaries, experimenters will extract frequency of subjective binges and consumption information (caloric volume of binge foods and non-binge foods consumed). The outcomes will thus be 1) frequency of subjective binge episodes in the pre-intervention (baseline) period, post-intervention (test) period and follow-up 2) average (mean, or median if high skew is present) corresponding macronutrient intake over these same periods. This outcome is assessed on Day 1, Day 14 and the first follow up (28 days after Day 1)
2. Eating Disorders Examination-Questionnaire (EDE-Q) This is a questionnaire version of the Eating Disorders Examination (EDE) and is used to assess disordered eating. This is assessed on Day 1 and 14 and at follow up at 28 days, 3 months, 6 months and 9 months.
3. Binge Eating Scale (BES) This is a questionnaire-based measure of specific binge eating symptomatology severity. This is assessed on Day 1 and 14 and at follow up at 28 days, 3 months, 6 months and 9 months.
4. Food Craving Questionnaire State/Trait (FCQ-T/FCQ-S): This is a measure of desire to eat one or more specific foods. The trait version assesses generally experienced food craving and the

state form momentary craving. The state version will be used to assess momentary craving evoked by exposure to binge food images and in-vivo high-palatability food at baseline (pre-intervention) and test (post-intervention). FCQ-T assessed on Day 1 and 14 and at follow up at 28 days, 3 months, 6 months and 9 months. FCQ-S is assessed on Day 1, 2 (48-72 hr after Day 1) and Day 14.

Key secondary outcome(s)

These measures are potentially important covariate or cofounding factors that we wish to assess for similarity between groups at baseline, but which are not outcomes for study. No specific predictions are made about changes in these 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 CC/sham CC 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).

Additional details contained on Open Science Framework website https://osf.io/reytv/.

Completion date

01/12/2021

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)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
24 Years

Sex
All

Total final enrolment
79

Key exclusion criteria
1. Pregnant or breastfeeding, or likely to become pregnant during the study
2. Currently seeking treatment for binge eating or any other psychiatric condition
3. Suffer from any major psychiatric or physical health disorder
4. 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. BMI < 18.5
11. High blood pressure (> 140/90 mmHg)
12. Unable to abstain from drugs and alcohol for 24 hours prior to each session
13. Vegan diet

Date of first enrolment
11/02/2019

Date of final enrolment
01/02/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Psychopharmacology Unit
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Sponsor information

Organisation
University College London

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		21/01/2019	15/08/2022	No	No