

Binge Eating Study

Submission date 23/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/08/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/08/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Binge eating is defined as eating, in a set period of time, an amount of food that is larger than what most people would eat in a similar period of time under the same circumstances while experiencing feelings of being out of control. Binge eating causes severe physical, emotional and psychological problems. Although there are ways to treat binge eating, many people who binge eat drop out of treatment early or continue to binge eat after treatment ends. Given the serious consequences of binge eating, it is important to figure out better ways of helping people stop binge eating. This study aimed to do that by comparing two different types of psychotherapy designed to help people stop binge eating: (1) motivational interviewing (MI), which focuses on increasing motivation to stop binge eating; (2) psychoeducation, which involves providing people who binge eat with information about the causes and consequences of binge eating. There is research that suggests that MI is helpful for treating binge eating because people who binge eat tend to be undecided or hesitant about giving up binge eating. However, it was not previously known whether MI was better than other therapies at helping people with serious binge eating problems. The purpose of this study was to answer help this question by comparing MI to another type of psychotherapy that has been shown to work.

Who can participate?

Men and women over the age of 18 could participate in the study if they had one of two types of eating disorders: Binge Eating Disorder or Bulimia Nervosa.

What does the study involve?

Interested participants answered some brief screening questions online on a secure website and then participated in a 30-minute interview via telephone with the researcher. Once it was determined that they were eligible to participate in the study, participants were invited to come into the laboratory individually. At the laboratory, participants were asked to complete several questionnaires asking about their mood and eating habits. They were then randomly assigned to participate in a 60-minute session of one of the two different therapies (psychoeducation or motivational interviewing). After the session, participants were given a self-help manual for binge eating. About 1 and 4 months later, participants were contacted by email and asked to answer questions online on a secure website about their eating and mood, as well as their use of the self-help manual.

What are the possible benefits and risks of participating?

The direct benefits of participating in this study included a free self-help manual designed to help individuals cut down or stop binge eating, as well as 1 hour of psychotherapy directed at binge eating. Participants were also given information regarding community mental health services. There were no major risks to participating in the study. The only risk was that participants were asked to complete questionnaires and participate in a therapy session, both of which addressed sensitive issues related to eating and mood and therefore had the potential to be upsetting to some participants. To combat this problem, participants were encouraged to discuss their concerns with the therapist and were allowed to refuse to answer specific questions or withdraw from the study at any time. Participants were further provided with a list of community mental health services.

Where is the study run from?

The study was run in the Psychology Department at York University in Toronto (Ontario, Canada).

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

The study started in September 2011 and will run until August 2013.

Who is funding the study?

Partial support for this research was provided by the Social Sciences and Humanities Research Council of Canada (SSHRC).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomized controlled trial of motivational interviewing for binge eating

Study objectives

We hypothesized that one type of therapy, motivational interviewing (MI) followed by a self-help manual, would lead to greater improvements than another type of therapy, psychoeducation followed by a self-help manual, for people who binge eat. Specifically, we hypothesized that MI would lead to great improvements in readiness to change binge eating, confidence in ability to control binge eating, number of binges, eating disorder symptoms, self-esteem, depression, and self-help manual use than would psychoeducation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval for this study was granted on August 19, 2011 by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. Ethics Certificate Number: STU 2011 109.

Study design

Unblinded parallel groups randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Binge eating disorder; Bulimia nervosa

Interventions

Participants in one group participated in a 60-minute therapy session of motivational interviewing (MI) for binge eating, a client-centered therapy designed to increase internal motivation to change binge eating.

The other group participated in a 60-minute therapy session of psychoeducation for binge eating, a therapeutic approach that involves providing scientific information about binge eating.

Following the session, participants in both groups received an evidence-supported cognitive behavioural self-help manual to use on their own.

There is only one 60-minute intervention for participants. Baseline questionnaires took approximately 1 hour to complete. Follow-up questionnaires took approximately 30 minutes to complete and were completed at 1 and 4 months post-intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Changes in binge eating and eating disorder symptoms measured using self-report questionnaires presented in Likert or multiple choice format (Eating Disorder Examination Questionnaire, Binge Eating Scale) at baseline, 1 month, 4 months

Secondary outcome measures

1. Readiness to change binge eating measured using a self-report Likert questionnaire (University of Rhode Island Stages of Change Assessment) at baseline and immediately following the intervention session
2. Confidence in ability to control binge eating measured using a self-report Likert questionnaire (Weight Efficacy Lifestyle Questionnaire) at baseline and immediately following the intervention session
3. Therapeutic relationship measured using a self-report Likert questionnaire (Working Alliance Inventory), measured immediately following the intervention session
Self-Esteem measured using a self-report Likert questionnaire (Rosenberg Self-Esteem Scale) at baseline, 1 month, 4 months
4. Depression measured using a self-report Likert scale questionnaire (Beck Depression Inventory) at baseline, 1 month, 4 months
5. Self-help manual usage measured using a multiple choice questionnaire created for this study at 1 and 4 months

Overall study start date

01/09/2011

Completion date

01/09/2013

Eligibility

Key inclusion criteria

1. Must meet full or subthreshold (defined as a minimum of 1 binge/week for the past 3 months) DSM-IV diagnostic criteria for Binge Eating Disorder or Bulimia Nervosa, Non-Purging Subtype.
2. Age 18 - 47 years, male and female

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Under 18 years of age
2. Substance abuse criteria met
3. Not proficient in English
4. Inconsistent dose of psychiatric medication or have been using psychiatric medication for less than 3 months
5. Active suicidal ideation

Date of first enrolment

01/09/2011

Date of final enrolment

01/09/2013

Locations**Countries of recruitment**

Canada

Study participating centre

Department of Psychology

Toronto

Canada

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Sponsor information

Organisation

York University (Canada)

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Sponsor type

University/education

Website

<http://www.yorku.com>

ROR

<https://ror.org/05fq50484>

Funder(s)**Funder type**

Research council

Funder Name

Partial support for this research was provided by the Social Sciences and Humanities Research Council of Canada (SSHRC) Joseph Armand- Bombardier Canada Graduate Scholarship, awarded to one of the investigators (Rachel Vella-Zarb).

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration