Mindfulness Based Eating Awareness Training (MB-EAT) for Bariatric Surgery Patients: The Effects of Mindfulness on Psychosocial and Physical Functioning

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Introduction and Rationale: Bariatric surgery is an approved treatment for severe obesity. The roux-en-y gastric bypass has been conducted at the Toronto Western Hospital Bariatric Surgery Program (TWH-BSP) since late 2009. Given that weight loss through bariatric surgery is associated with the improvement or resolution of medical comorbidities as well as improvements in patient-reported quality of life (Odom et al., 2010), weight regain is of primary concern in this population. In one study that followed gastric bypass patients over an average of 28 months, 79% regained some weight after reaching their lowest weight, and 15% experienced a weight increase of 15% of more from their lowest weight (Odom et al., 2010). Psychiatric factors associated with weight regain include binge eating (Mitchell et al, 2001) lack of control over food urges (Odom et al., 2010), and a greater number of psychiatric disorders (Rutledge, Goresz & Savu, 2011). Obese individuals who pursue bariatric surgery report high rates of problematic eating including loss of control over eating, binge eating and chronic overeating (Kalarchian et al., 1998; Rutledge, Goresz & Savu, 2011). Even when individuals do not meet criteria for a clinical eating disorder, these disordered eating patterns may prevent optimal adherence to post-surgical eating guidelines. The first 6 months to 1 year after surgery for most patients is characterized by rapid weight loss and patient satisfaction; however, once patients transition from the active weight loss phase to weight maintenance, pre-surgery eating problems may recur and lead to weight regain.

Mindfulness meditation techniques may address many of the factors related to disordered eating that contributes to weight regain, including negative emotions (Saunders et al., 1998) and cognitive distortions (Shook, 2010). Mindfulness training involves purposeful and sustained attention to internal dialogues, emotions and bodily cues that encourage recognition and toleration of painful emotions in adaptive ways that do not involve problematic behavior like eating. Mindfulness is a well-validated intervention for psychological and medical problems in other patient populations, including anxiety, depression, stress (Baer, 2003; deVibe et al. 2012; Greeson, 2009; Grossman et al. 2004; Hofmann et al. 2010; Khoury et al. 2013) and ruminative thoughts (Jain et al., 2007; Shapiro, Brown, & Biegel, 2007). Mindfulness Based Eating Awareness Training (MB-EAT) is a group program developed by Kristeller and Hallett (2006) that integrates mindfulness meditation and eating meditation with didactics about healthy eating.

Emotion dysregulation is understood to be an important underlying cause of problematic eating. In other words, when experiencing painful emotions, individuals with disordered eating tend to use overeating or impulsive eating as an avoidance strategy (Beck et al., 2012). Excess calories may thus be consumed in an automatic or dissociative manner (Saunders et al., 1998). Repeated past diets that teach people to rely on external rules for eating may lead to the loss of one's ability to recognize, accept or respond to internal cues of hunger, taste, satiety, and fullness (Heatherton & Baumeister, 1991). Cognitive distortions may also be particularly problematic for individuals with problem eating. Beck (1967) defined cognitive distortions as errors in thought processes that alter perceptions of reality, often in a manner that reinforces negative thoughts or emotions. Shook (2010) found that individuals with poor health habits (such as overeating, inactivity, smoking) have higher ratings of cognitive distortions. For example, all or nothing thinking, may lead to a "what the hell" effect and ultimately overeating . O'Connor and Dowrick (1987) found that individuals who are classified as overweight, typically report more extreme, self-defeating food and weight-specific cognitions compared to normal-weight peers. Obese individuals reported higher overall ratings on a measure of cognitive distortions surrounding rigid weight regulation and fear of weight gain ("If I eat a sweet, it will be converted instantly

into stomach fat") and self-esteem ("If my weight goes up, my self-esteem goes down"). A study conducted by Sears and Kraus (2009) found that a reduction in cognitive distortions mediated the intervention effects for reducing anxiety, negative affect, and promoting hope for college students.

The body of research evidence for mindful eating interventions is small but promising. A recent review concluded mindfulness approaches can improve outcomes in persons with eating disorders and is also associated with a reduction in overall food consumption, healthier food choices, and practices that slow the eating process (Ganley, 1989). Kristeller and Hallett (1999) in their application of MB-EAT to women with binge eating disorder, found a significant improvement in participants' perceived control of eating and awareness of hunger and satiety cues. In a pilot study of a mindful eating group for obese adults patients reported significant increases in mindfulness and restraint over eating, and significant decreases in weight, binge eating, and negative affect (Dalen et al., 2010). Leahey et al. (2008) integrated mindfulness into cognitive behavioural therapy for post-bariatric surgery patients and found improvements in eating, emotion regulation, and depression. Wnuk et al. completed a small, unpublished feasibility study (n=28) of MB-EAT with post-bariatric surgery patients at the TWH-BSP between 2014-2015. Preliminary non-parametric analyses (chosen because of the small sample size), revealed statistically significant improvements from pre to post-MB-EAT in depression ($z=.01$) and emotion regulation ($z=.02$) and noticeable improvements in means for emotional eating ($p=.07$). In addition, participants rated the helpfulness of each session highly on a 7-point scale, with 7 indicating 'completely helpful', between 5.67/7 (after the first session) to 6.18/7 (after the 8the session). Ratings increased steadily over the course of the treatment. A manuscript for publication is currently being prepared.

There are limitations to this research that the proposed study attempts to address. Except for the study by Leahy at al. and Wnuk et al, mindful eating studies have been conducted with non-bariatric surgery patients. Leahy et al's (2008) study included only seven patients who ranged from two to 11 months post-surgery, making it very difficult to generalize to other bariatric surgery patients. In addition, their treatment was created specifically for their study and appears to be largely CBT-based, making it difficult to conclude whether changes observed were due to the CBT or mindfulness intervention. Finally, in a recent review psychotherapeutic and support group were been associated with greater weight loss post-bariatric surgery, though specific modalities were not found to be more effective (Beck et al., 2012).

Objectives and Hypotheses:

Purpose of Study: This study is to examine the effectiveness of MB-EAT in enhancing psychosocial functioning as an adjunctive treatment to the usual standard of care in bariatric surgery patients. Participants will receive MB-EAT 6 months or more following bariatric surgery. Participants will be randomly assigned to receive MB-EAT one week or 8 weeks following consent. Individuals in the group starting in 8 weeks will serve as a waitlist control group.

The **primary objective** of this study is to examine whether MB-EAT is an effective and feasible adjunctive treatment to the usual standard of care.

Outcome Measures: The primary outcome measures will be changes in self-reported eating pathology, depression, anxiety, and mindfulness. See measures in Appendix.

Hypothesis:

1. MB-EAT will lead to significantly greater improvements in eating pathology, depression, anxiety, emotion regulation, cognitive distortions, body image dissatisfaction and mindfulness as compared to the wait list control group.

Methods

Study design: A pre-post treatment design will be used with a waitlist control. Upon completion of the introductory session, participants will be randomly assigned to either the first or second MB-EAT group. Participants in the second group will act as the waitlist control and complete the pre and post questionnaires simultaneously with the first group. There will be a follow-up at 6 months and 12 months to establish stability of symptoms post-intervention.

Participants: Participants (N = 72; 12 per group) will be recruited from the Bariatric Surgery Program at Toronto Western Hospital. All bariatric surgery candidates who meet the study inclusion/exclusion criteria will be eligible for participation. Six separate groups of 12 participants per group will be run.

Inclusion criteria:

1. Post-bariatric surgery patients recruited from the TWH-BSP who are six months or more post-surgery, are experiencing self-reported difficulties adhering to post-surgery eating guidelines, and can commit to attending the group.
2. Fluent in English.
3. Have the capacity to provide informed consent.

Exclusion criteria:

1. Active suicidal ideation.
2. Active serious mental illness (i.e., psychotic disorder, bipolar disorder).
3. Active severe depression (i.e., current major depressive disorder diagnosis and PHQ-9 score $\geq$ 20 [severe depression]).
4. Active severe anxiety (i.e., current anxiety disorder diagnosis and GAD-7 score $\geq$ 15 [severe anxiety]).
5. Active symptoms of post-traumatic stress disorder (i.e., current diagnosis of post-traumatic stress disorder).

Participants will be screened for eligibility over the phone by administering the PHQ-9 (depression) and GAD-7 (anxiety) verbally. This screening will be completed once the participant has expressed interest in participating, prior to attending the first session. Of note, patients in the Bariatric Surgery Program who have active suicidal ideation, serious mental illness, severe depression, or severe anxiety do not receive bariatric surgery until their psychiatric symptoms stabilize. Thus, the vast majority patients who are currently post-bariatric surgery will be eligible for participation in this study. In the event that participants develop

significant mental health issues (e.g., active suicidal ideation, serious mental illness) during the research study, a consultation will be arranged with one of the staff psychiatrists in the program.

Treatment: Participants will receive one introductory information session about the program, as well as 8 MB-EAT scheduled consecutively over eight weeks. Each session is approximately two hours in length. During MB-EAT, participants will practice an approach to eating designed to change their relationship with food and improve their decision making abilities in regards to food, through a variety of mindful eating practices and guided mindfulness meditations. Through MB-EAT, participants will learn to address mindless or out-of-control eating, which can lead to weight gain. Homework will include daily meditations and mindful eating exercises. Participants will also receive weekly take-away documents, which may include: (1) key information from the session; (2) relevant articles; (3) poems; (4) homework exercises. All participants will continue to receive the routine standard of care provided to all patients of the TWH-BSP while participating in the study.

Both MB-EAT groups will be co-facilitated by two of three clinicians who work in the TWH-BSP: Susan Wnuk, Ph.D., C. Psych., a clinical psychologist, Chau Du, M.Sc., a psychometrist, and Katie Warwick, R.D. All facilitators have completed MB-EAT training with J. Kristeller (the primary developer of MB-EAT) and A. Lieberstein (a clinician with extensive experience facilitating MB-EAT) and have provided clinical care in the TWH-BSP for between 4-6 years. Susan Wnuk and Chau Du have clinical experience with mindfulness and eating disorders and extensive clinical experience with mindfulness-based interventions. Susan Wnuk and Chau Du will supervise the research assistant.

Procedure: Of the 3977 patients currently enrolled in the TWH-BSP, 28% reside within 20 km, yielding an estimated 1114 patients who could potentially be recruited during the course for the proposed study. Patients will be recruited through the following means, which were successfully employed during 2014-2015 feasibility study (REB protocol #13-7006-BE):

1. Flyers will be posted in the Bariatric Surgery Department with contact information for the study investigator. Patients who are interested in participating can self-refer and contact the investigator directly, who will address the potential participant's questions and arrange to obtain signed consent, if applicable.
2. Announcements will be made at the twice monthly TWH-BSP patient support group for the duration of the recruitment phase. Announcements will be made by study staff or a member of the TWH-BSP to the group of assembled patients (usually 30-40 patients per support group). Staff members take turns facilitating and organizing support group sessions. The following script will be used to make the announcement: *"We are currently recruiting patients who are six or more months post-bariatric surgery for a study on a mindful eating group called 'Mindfulness Based Eating Awareness Training.' The group is 8 weeks long and there are up to 10 participants per group. The purpose of the group is to see if it helps patients become more aware of their eating patterns and triggers for unhealthy eating behaviours, and to learn skills for managing these. If you're interested, please take one of the flyers (i.e. MB-EAT recruitment flyer) and contact the study staff listed on it. You can also write your contact information on the form provided (i.e. MB-EAT recruitment form) if you'd prefer to have a study staff person contact you"*

3. When patients who are six months or more post-surgery attend their routine follow-up assessments at the TWH-BSP as the standard of care, TWH-BSP clinicians will inform them of the study using the script provided above. Study staff will ensure that these clinicians are provided sufficient copies of the MB-EAT recruitment flyer and recruitment form. They will provide the potential participant the MB-EAT recruitment flyer and/or ask the potential participant to provide their contact information on the MB-EAT recruitment form. Other clinicians in the patient's circle of care who are outside of the TWH-BPS such as family physicians or specialists, will not be involved in recruitment.

A research assistant will collect MB-EAT recruitment forms and contact patients by phone who express interest in participating to explain the study. The research assistant will describe the study (i.e., the information covered in the study consent form) and answer any questions potential participants might have. Consent will be obtained at the introductory information session. Ample time will be given prior to the commencement of the session so that potential participants have an opportunity to review it before consenting to take part in the research study.

Mindfulness-Based Eating and Awareness Training (MB-EAT): Eight sessions of Mindfulness Based Eating and Awareness Training (MB-EAT) will be delivered once per week over the course of 8 weeks, based on a protocol developed by Kristeller et al. with minor modifications to accommodate the typical dietary restrictions encountered by post-surgery patients. For example, due to abdominal discomfort experienced by post-surgery patients when consuming sugar and fat, sugar-free/fat-free food items will be made available for mindful eating exercises that involve sweet foods. The primary focus of treatment is the use of general mindfulness meditation and eating meditation to help participants bring greater awareness and understanding to their relationship with food. One introductory information session will be offered prior to the start of the 8-session MB-EAT protocol. The purpose of this information session is to explain the intervention and expectations for participation. It will be facilitated by the leaders of the 8 week protocol. Homework consists of weekly mindfulness exercises. Many of these exercises involve listening to an audio recording of a guided meditation, which will be emailed to participants. Since email will be used throughout the study for contact purposes, a separate consent form for email communication for the study will be administered. If participants do not have email they will be provided a data key loaded with the mindfulness exercise audio recordings.

Taped Sessions: For the purpose of supervision and also as a measure of adherence to the MB-EAT protocol, all sessions will be audiotaped. The sessions will be reviewed for adherence to the protocol, according to a checklist that outlines the main goals of each session and to ensure inter-rater reliability between therapists.

Assessment: Participants will be administered measures pre-treatment, post-session, post-treatment and six months and one year post-treatment.

Measures:
<u>Pre-Group Only (please see attached)</u>
Demographics: Age, gender, ethnicity, education, work status, marital status.

Pre, Post and Follow-up Measures (please see attached)

Pre-treatment questionnaires will be completed during the first information session, and post-questionnaires will be completed during the last MB-EAT session. Follow-up questionnaires will be completed during regular standard of care clinical visits if feasible, or a separate appointment will be made with participants for the purpose of completing questionnaires, or they will be mailed questionnaires with sufficient return postage

Anthropometric and Physical measures: Anthropomorphic (height and weight) and physiological measurements (blood pressure measured by mm Hg, taken using standardized measurement techniques and validated electronic upper arm blood pressure monitors) will be obtained at the TWH-BSP by Wei Wang, a TWH-BSP nurse practitioner and co-investigator. Gastrointestinal symptoms will be assessed by Wei Wang using a clinician-administered rating scale, the Gastrointestinal Symptom Rating Scale.

Patient Health Questionnaire (*PHQ-9*; Kroenke et al., 2001). The PHQ-9 is a 9-item self-report measure of depression severity. Respondents are asked to rate the frequency with which they have experienced depressive symptoms over the last two weeks on a scale ranging from 0 (not at all) to 9 (nearly every day). Scores on the PHQ-9 can range from 0 to 27, and mild, moderate, moderately severe, and severe levels of depressive symptoms correspond to cut-off scores of 5, 10, 15, and 20 respectively.

Generalized Anxiety Disorder Questionnaire (*GAD-7;* Spitzer et al., 2006). The GAD-7 is a 7-item self-reported measure of anxiety severity. It was originally developed to diagnose generalized anxiety disorder, but it has also proved to be a good screening instrument for other disorders including panic disorder, social phobia, and post-traumatic stress disorder. Respondents are asked to rate the frequency with which they have experienced anxiety symptoms over the last two weeks on a scale ranging from 0 (not at all) to 9 (nearly every day). Scores on the GAD-7 can range from 0 to 21, and mild, moderate, and severe levels of anxiety symptoms correspond to cut-off scores on 5, 10, and 15 respectively.

The Three Factor Eating Questionnaire –R18 (TFEQ-R18; de Lauzon et al., 2004). The TFEQ-R18 is an 18 item measure developed in an obese population to investigate 3 aspects of eating behaviour: cognitive restraint, uncontrolled eating, and emotional eating.

Five Facets of Mindfulness Questionnaire (FFMQ; Baer et al, 2006). The FFMQ is a 39-item self-report measuring mindfulness on five scales: Observing, Describing, Act with Awareness, Nonjudging, and Nonreactivity. .

Self-Compassion Scale (SCS; Neff, 2003). The SCS is a 26-item measure tapping self-kindness, self-judgment, common humanity, isolation, mindfulness, and over-identification. Participants respond to various items about ‘‘how I typically act toward myself in difficult times’’ on a 5-point scale, with higher total scores indicating greater self-compassion.

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004). The DERS is a 36 item questionnaire that measures general difficulties in emotion regulation. Items are rated on a 5 point scale with higher scores indicating better emotion regulation. Six subscales are computed: nonacceptance of emotional reactions; difficulties engaging in goal directed behaviour; impulse control difficulties; lack of emotional awareness, and limited access to emotion regulation strategies.

Body Parts Satisfaction Scale (BPSS; Berscheid et al., 1973*)*. The original BPSS is a 23-item measure that assesses satisfaction on a 6-point Likert scale ("extremely satisfied, somewhat satisfied, somewhat dissatisfied, quite dissatisfied, extremely dissatisfied") on individual body parts (i.e., hips, teeth, etc.). The present scale is a modified version that eliminates unrelated items (i.e., size of sex organs) in order to relieve patient burden. Additionally, there is one added question assessing satisfaction with loose skin, which is a common concern for post-bariatric surgery patients.

Body Satisfaction Questionnaire (BSQ; Cooper at al., 1987*).* The BSQ is a valid and reliable measure that assesses body shape concerns and body dissatisfaction. The scale asks participants to indicate on a 6-point Likert scale the subjects state over the past 4 weeks ("never, rarely, sometimes, often, very often, always").

The Dichotomous Thinking Scale (DTS; Byrne et al., 2008) The DTS is a 16-item scale that measures the cognitive distortion of dichotomous, or "black and white," thinking. Six items are specifically surrounding cognitive distortions related to food, dieting, and weight, while the remaining ten items more broadly measure dichotomous thinking.

The Obesity Cognitions Scale; O'Connor et al., 1987*)* The Obesity Cognitions Scale is a measure of 15 items that measures cognitive distortions surrounding food, weight, and shape that are more typical for individuals classified as obese.

Gastrointestinal Symptom Rating Scale (GSRS); Svedlund et al., 1988). The GSRS is a 15 item clinician administered scale that assesses a variety of symptoms on a point likert scale to assess severity of symptoms. The scale has been shown to be useful in comparing the effectiveness of treatments in previous clinical trials.

<u>Group Session Evaluation Questionnaires (please see attached)</u>

Helpfulness of session just completed. This is a one item questionnaire developed for this study to evaluate participants' overall rating of the session.

Homework Monitoring Form. Participants record how many days per week and minutes per day they practiced their mindfulness homework. This item was developed for this study.

Working Alliance Inventory-Short Form (*WAI-short form*; Tracey & Kokotovic, 1989) – The WAI-short form is a 12-item self-report measure that assesses the alliance between patient and therapist. Respondents are asked to rate the frequency with which they feel each statement describes the alliance they have with their therapist on a scale from 1 (never) to 7 (always). The WAI consists of 3 subscales reflecting goals, bond, and tasks.

Group Climate Questionnaire (GCS; MacKenzie, 1983). The GCS is a 12-item self-report measure that assesses the degree to which participants feel the group has a positive atmosphere and constructive interpersonal interactions. It includes 3 subscales: engagement, avoidance and conflict and items are rated on a scale from 0 (not at all) to 6 (extremely).

Post-Group Individual Participant Interview (please see attached).

The Client Change Interview (Elliott et al., 2001). The Client Change interview is an hour-long semi-structured interview. The major topics of this interview are any changes patients have noticed since therapy began, what you believe may have brought about these changes, and helpful and unhelpful aspects of the therapy. The main purpose of this interview is to allow patients to tell us about the therapy and the research in their own words. This information will help researchers to understand better how the therapy works; it will also help us to improve the therapy. This interview is audio-recorded for later transcription.

Assessment Timeline:

Measure	Baseline	Sessions 1 to 8	Post-Treatment	6 & 12 Months Post Treatment
Demographics	X			
Anthropomorphic Measures	X		X	X
Patient Health Questionnaire	X		X	X
Generalized Anxiety Disorder Questionnaire	X		X	X
Three Factors of Eating Questionnaire Revised-18	X		X	X
Emotional Eating Scale	X		X	X
Five Facets of Questionnaires	X		X	X
Self-Compassion Scale	X		X	X
Difficulties in Emotion Regulation	X		X	X

Scale				
Personal Questionnaire	X		X	X
Body Parts Satisfaction Scale	X		X	X
Body Satisfaction Questionnaire	X		X	X
Obesity Cognitions Scale	X		X	X
Dichotomous Thinking Scale	X		X	X
Helpfulness of Session		X		
Homework Monitoring Form		X		
Working Alliance Inventory		X		
Group Climate Questionnaire		X		
The Change Interview			X	

Statistical Analysis: Analysis of variance will be conducted in the case of continuous variables, and chi square analyses will be conducted in the case of categorical variables to compare the groups on demographic and baseline clinical variables. If there are significant differences between groups on demographic or clinical variables measured at baseline, or on session measures, these variables will be entered as covariates in the statistical analyses. A repeated measures analysis of variance will be conducted to compare the groups on each of the outcome variables and Cohen's effect sizes will be computed for each of the primary outcome variables.

Privacy and Confidentiality: E-mail correspondence will be sent from a secure UHN e-mail account. Participants will be notified that security and confidentiality of information cannot be guaranteed through e-mail correspondence. All rating scales and forms used at each assessment will use a single coding system, with only the research ID number and study name written on it. Personal health information is required for determining participant eligibility for the study and to contact the participant during the study for MB-EAT sessions. The master code will be kept by the research coordinator for the duration of the study and will be kept separately from the research data (i.e., participant files). Contact information will be used throughout the course of the study and correspond to the master code. All data and personal health information will be stored in a locked room in a locked cabinet. Contact information, demographic data, and computerized rating scales will be stored on a password-protected computer on a secure network drive. A login name and password will be required to access these files and the computer will be located in a locked office. Similarly, audio recordings of MB-EAT sessions will be stored on these password-protected computers on a secure network drive in a locked office. Participants will be referred to by their first names only in the audio tapes and participants will be advised not to disclose any personal identifying information during the recording to further maintain their privacy. Only individuals involved in the research project will have access to these tapes and all data will be destroyed after 5 years.

In the event of inappropriate release of personal health information, after further release of information is stopped and any information that could be retrieved is retrieved, the UHN Privacy Office and REB will be notified. Then, further actions on informing participants might be taken according to recommendations from the UHN Privacy Office and REB.

Risks Related to being in the Study: There are no known risks associated with receiving Mindfulness-Based Eating and Awareness Training. Participants will be asked to reflect upon

some personal issues and their psychological health (e.g., eating habits, mood, anxiety, quality of life) during Mindfulness-Based Eating and Awareness Training and while completing the questionnaires. They may choose to discontinue Mindfulness-Based Eating and Awareness Training or to refuse to answer questions at any time if they experiece discomfort.

Benefits to being in the Study: There is some evidence that Mindfulness-Based Eating and Awareness Training is effective in improving eating habits, depression, and emotional eating for individuals with binge eating and after bariatric surgery. Participants may or may not receive any direct benefit from being in this study. Information learned from this study may help other bariatric surgery patients in the future.

Implications: If MB-EAT is found to be effective with bariatric surgery patients and is feasible to deliver, the treatment could become the standard of care in the Bariatric Surgery Program at Toronto Western Hospital. In addition, the Toronto Western Hospital MB-EAT protocol could be used to deliver MB-EAT to bariatric centers across the province and perhaps beyond, thus providing cost-effective psychosocial care.

Conflicts of Interest: There are no known conflicts of interest.

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