ADAPTED MOTIVATIONAL INTERVIEWING FOR BARIATRIC SURGERY PATIENTS: A PILOT STUDY

by

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Bachelor of Arts Honours, Queen's University, June 2012

A thesis presented to Ryerson University

in partial fulfillment of the

requirements for the degree of

Masters of Arts

in the Program of

Psychology

Toronto, Ontario, Canada, 2014

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ABSTRACT

Adapted Motivational Interviewing for Bariatric Surgery Patients: A Pilot Study

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2014

The current pilot trial examined the efficacy of a single-session Adapted Motivational Interviewing (AMI) protocol for improving outcomes for bariatric surgery patients. Forty-six post-operative patients from the Bariatric Surgery Program at Toronto Western Hospital were randomly assigned to either an AMI group (n = 23) or a wait list group (n = 23). From pre- to post-intervention, paired samples t-tests found that participants reported greater readiness and self-efficacy for change, as well as improvements to binge eating characteristics and to some measures of adherence to dietary guidelines at the 4-week follow-up. Repeated measures ANOVAs found that the behavioural changes were maintained over the 12-week follow-up but mixed model ANOVAs suggest that these changes may not be as marked next to patients receiving standard bariatric care. These preliminary findings suggest that AMI is an acceptable and feasible intervention that might be effective for some bariatric patients. Future research is warranted.

ACKNOWLEDGEMENTS

This thesis would not have been possible without the support from a number of individuals. First and foremost, I wish to extend a very special thank you to my research supervisor, Dr. Stephanie Cassin, for the guidance that she has provided me over the years. She epitomizes the qualities one expects of the best of mentors with her admirable work ethic, commitment to student learning, and dedication to clinically meaningful research. She has been heavily involved in overseeing my thesis from conceptualization through to dissemination, and has been an invaluable source of support throughout my training. I would also like to express my appreciation to my supervisory committee members, Dr. Tae Hart and Dr. Trevor Hart, for their thoughtful review of my thesis and for imparting their extensive knowledge of health research to me. I am grateful to the bariatric team at Toronto Western Hospital, especially Dr. Sanjeev Sockalingam and Dr. Susan Wnuk, for helping me to carry out this collaborative initiative. Many thanks to the Canadian Institutes of Health Research for investing in my academic career and to the Ryerson University Health Research Fund for providing the necessary funds to complete this project. A special thanks is extended to past and present HEAL lab members. In particular, I must thank Molly Atwood and Aliza Friedman for contributing many hours of adherence coding.

I am indebted to my parents who have shown me endless love and support. They have given me the confidence to pursue avenues I did not think possible. Words cannot express how grateful I am to my sister for being my personal 2am support system. I am so appreciative of my friends, especially my fellow Ryerson classmates, for keeping me sane these past two years.

Last, but certainly not least, I would like to extend my gratitude to the bariatric patients I have interviewed over the past year for openly sharing their experiences with me. They have inspired me in countless ways, and have solidified my desire to pursue this line of research.

DEDICATION

To my three best cheerleaders: Graham, Michela, and Natalie. Thank you for your unwavering support and encouragement on this journey, and for reminding me to enjoy the ride.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

INTRODUCTION

According to the Global Burden of Disease Study (Lorano et al., 2012), the first effort to examine the full impact of health-related risk factors and disease on a global scale, rates of obesity (body mass index [BMI] of 30 kg/m^2 or more) have almost doubled worldwide (an 82% increase) from 1980 to 2010, and now constitute a health burden that exceeds that due to malnourishment. In Canada, it is estimated that 18.3% of the adult population is obese, and trend analyses predict that national obesity rates will continue to climb until 2019 (Twells, Gregory, Reddigan, & Midodzi, 2014). Obesity is a serious disease, but its development is not inevitable. For this reason, obesity and obesity-related illness are leading causes of preventable illness and premature death in North America (Danaei et al., 2009).

North Americans who are considered to be at least overweight (BMI of 25 kg/m^2 or more) are at a markedly higher risk of developing health problems (Bray, 2004; Field et al., 2001, Must et al., 1999). Specifically, intra-abdominal visceral adipose depositions that characterize obesity are associated with sharp increases in related medical risk factors and comorbidities (Bray, 2004; Pi-Sunyer, 1993). Elevated insulin concentrations and peripheral insulin resistance, precursors to the development of type 2 diabetes, are highly prevalent in obese individuals (Bray, 2004). Rates of chronic illness, such as coronary heart disease, obstructive sleep apnea, gallbladder disease, and osteoarthritis, are significantly higher among obese men and women (Bray, 2004; Field et al., 2001; Must et al., 1999). Hypertension, hyperlipidemia, and high cholesterol are associated with excess weight, and increase an individual's risk for other medical conditions (Pi-Sunyer, 1993).

In addition to the well-established relationship between obesity and physical health concerns, there is a significant overlap between obesity and mental health epidemics (Taylor et

al., 2012). Obesity is associated with a higher prevalence of anxiety disorders, affective disorders, and eating disorders (Simon et al., 2006; Taylor, et al., 2012). Recent estimates suggest that over one-third of obese individuals seeking weight-loss surgery present with a current Axis I disorder, commonly a mood or eating disorder (Mitchell et al., 2012). More recent longitudinal data suggest that the relationship between obesity and psychopathology is a reciprocal one, whereby weight gain leads to the development and maintenance of many mental disorders, and, in turn, these disorders promote weight gain and act as a barrier to maintaining a healthy weight following weight-loss interventions (Luppino et al., 2010; Sharma, 2012; Taylor et al., 2012). Obesity also has debilitating psychosocial consequences, including discrimination and social bias (Kolotkin, Meter, & Williams, 2001; Stunkard & Wadden, 1992). Increases in weight and obesity-related health problems have been associated with compromised functional status and poor health-related quality of life (Fontaine & Barofsky, 2001).

The medical and economic burden of the obesity epidemic threatens to overwhelm health care services in Canada (Katzmarzyk & Jenssen, 2004). A large proportion of health care spending is a direct or indirect consequence of obesity, with total costs more than 40% higher for obese patients than for those who are of normal weight (Katzmarzyk & Jenssen, 2004). The severity of the health risks associated with obesity underscores the need for cost-effective and efficacious interventions for obesity. Unfortunately, for extremely obese individuals, traditional nonsurgical approaches to weight loss, such as behavioural weight loss programs, have shown limited long-term success (Buchwald et al., 2004; Mun, Blackburn, & Matthews, 2001; Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989). The shortcomings of these traditional weight loss methods, and the escalating economic and social burden associated with obesity and obesity-related illness, have ignited an interest in bariatric surgery nation-wide (Karmali, et al., 2010).

Bariatric Surgery

Bariatric surgery is currently considered the most effective treatment for extreme obesity (Colquitt, Clegg, Loveman, Royle, & Sidhu, 2005). Bariatric surgery refers to a group of surgical procedures performed to facilitate substantial weight loss (Smith, Schauer, & Nguyen, 2011). In Roux-en-Y gastric bypass surgery (RGB), the most frequently performed bariatric procedure in Canada (Colquitt et al., 2005), a small stomach pouch is created and is reconnected to a lower portion of the small intestine (Mechanick et al., 2009). Resulting weight loss is attributed to two primary mechanisms: 1) restrictive effects whereby the reduced size of the stomach limits food intake, and 2) malabsorptive effects whereby food that is ingested bypasses a large portion of the duodenum and the upper small intestine, significantly reducing caloric absorption (Mechanick et al., 2009). RGB is associated with fewer surgical revisions and re-operations, shortened hospital stays, reduced discomfort, quicker recovery times, and, importantly, greater weight loss as compared with other weight loss surgeries (Colquitt et al., 2005; Hell, Miller, Moorehead, & Norman, 2000; Potgieter & Van der Merwe, 2011). In a prospective cohort study, the cost of the pre-surgical eligibility and suitability assessments, the RGB procedure itself, and the follow-up care per patient for 1,035 bariatric patients was less expensive than the aggregate costs of health care services needed to care for 5,765 age- and gender-matched extremely obese Canadians who had not undergone the RGB procedure across a 5-year period (Christou et al., 2004). For these reasons, RGB is currently covered by health insurance plans across Canada for individuals who meet objective patient selection criteria, although wait-times for patients do vary considerably between provinces, from six months in Ontario to seven years in Quebec (Christou, 2011).

Bariatric surgery is a consideration for obese patients at high risk of morbidity and mortality who have been unable to achieve and/or maintain weight loss through lifestyle

interventions and/or medical management (National Institute of Health [NIH], 1991). The World Health Organization (WHO) has agreed upon a standardized classification of obesity based on BMI, a reliable measure of adiposity calculated as weight in kilograms divided by the square of height in meters (2002). Obesity is divided into three categories according to BMI: class I (30 to 34.9 kg/m^2); class II (35 to 39.9 kg/m^2); and class III, or extreme obesity (40 kg/m^2 or greater). The National Institute for Health and Clinical Excellence (2006) in the United Kingdom notes that bariatric surgery should be recommended for individuals with class III obesity, and for individuals with class II obesity who present with a significant obesity-related medical comorbidity (e.g., type 2 diabetes, sleep apnea).

Bariatric surgery is expanding exponentially worldwide across 31 International Federation for the Surgery of Obesity (IFSO) nations (Buchwald & Williams, 2003). In the United States, bariatric surgeries increased more than five-fold from 1992 to 2004 (Colwell, 2005), with more than 200,000 surgeries performed in 2007 alone (American Society for Metabolic and Bariatric Surgery [ASMBS], 2009). It is currently estimated that 5,000 patients undergo bariatric surgery in Canada each year (Karmali et al., 2010). In Canada, facilitating access to bariatric surgery and increasing the quality of bariatric care has become a priority of national health care directives (Canadian Institutes of Health Research [CIHR] Institute of Nutrition Metabolism and Diabetes and The Canadian Obesity Network, 2010).

Bariatric surgery is associated with a wide range of health benefits, including substantial weight loss, resolution of comorbid conditions, and improved quality of life. Buchwald and colleagues (2004) conducted a meta-analysis of bariatric surgery outcome studies and found that patients who received bariatric surgery lost an average of 61.2% of their excess body weight within two to three years. The results from this meta-analysis are striking: bariatric surgery

reversed, eliminated, or considerably decreased obesity-related medical comorbidities in the vast majority of patients. A notable example is that over three quarters of patients with diabetes or impaired glucose tolerance at baseline were able to discontinue their diabetes-related medications and maintain stable blood glucose levels. More than half of those who did not demonstrate this full resolution did show a marked improvement on these outcomes, sometimes within just a few days after surgery or after experiencing only modest weight loss over-time. Additionally, surgically-induced weight loss exceeding 100 pounds improved psychosocial functioning (Waters et al., 1991). For example, surgical-related weight loss has been associated with improved body image, social function, self-confidence, perception of health, and sex life, as well as a reduction in psychopathology (de Zwaan et al., 2002; Maddi et al., 2001; Rand & Macgregor, 1991; Solow, Silberfarb, & Swift, 1974; Sutton & Raines, 2007; van Hout, Boekestein, Fortuin, Pelle, & van Hout, 2006; Waters et al., 1991).

Although bariatric surgery is associated with substantial weight loss and improvements in medical comorbidities and psychosocial functioning, reports show a large variation in treatment outcomes. Early post-operative complications occur in 5% to 10% of patients, and long-term complications, such as nutritional deficiencies, incisional hernias, and gastritis, have been reported in more than a quarter of patients (Pories et al., 1995). Additionally, weight regain remains a pressing issue for many patients. Approximately 20% to 50% of patients begin to regain their weight within the first 18 to 24 months following surgery (Shah, Simha, & Garg, 2006). A well-designed, prospective study found that improvements in medical and psychiatric comorbidities tend to dissipate with weight regain (Sjostrom et al., 2004). For instance, the re-emergence of type 2 diabetes after surgery occurred in 38% of patients who regained a significant percentage of weight (DiGiorgi et al., 2010). It has been argued that, in spite of

impressive immediate weight loss outcomes for the majority of bariatric patients, varied long-term outcomes may be attributed to behavioural and psychological factors that contribute to the development and maintenance of obesity that surgical interventions alone do not address.

Post-Surgical Dietary Guidelines

Post-operative dietary guidelines are in place for two main reasons: 1) to reduce the likelihood of post-surgical complications, and 2) to encourage long-term weight loss following surgery (Parkes, 2006). It is important for patients to develop a true understanding that, contrary to common perceptions, the bariatric procedure alone will not produce sustained weight loss (Brolin, 2001). Multidisciplinary bariatric teams, typically consisting of surgeons, psychiatrists, psychologists, dieticians, nurse practitioners, and social workers, play an important role in the development and implementation of pre- and post-surgical treatment guidelines (Stocker, 2003).

Marcason (2004) provides a comprehensive outline of the dietary recommendations for bariatric patients post-surgery. The majority of the bariatric post-operative guidelines involve a form of dietary control, primarily because the stomach's capacity for food intake is considerably reduced following surgery. While the surgery virtually eliminates the ability to consume a large amount of food during a discrete period of time (i.e., objective eating binges), patients remain susceptible to grazing (consuming a larger number of small servings, regardless of appetite or hunger) and overeating (Saunders, 2004). This can result in 'plugging', whereby food becomes lodged in the upper digestive tract resulting in periods of vomiting. Therefore, patients are advised to consume three small meals and two snacks every day, spaced out every three to four hours. It is also recommended that patients chew food thoroughly and consume meals and fluids slowly (approximately 30 minutes per meal) so that blockages of the stomach entrance can be avoided. Additionally, the consumption of certain foods, particularly those high in sugar or

carbohydrates, leaves patients at risk for 'dumping syndrome', which involves nausea, sweating, faintness, and vomiting when food moves through the small intestine too quickly. Patients are also advised to eliminate carbonated beverages from their diet. The remaining guidelines are in place due to the malabsorptive effects of the surgery. Primarily, there is a need to supplement key nutrients that are often not adequately absorbed after surgery. Failure to consume adequate levels of certain nutrients can lead to a host of post-surgery complications, including constipation, headaches, and hair loss. Therefore, bariatric patients are advised to stick to a regimen of nutritional supplements, and to consume a stipulated amount of protein and fluids daily. Furthermore, the body metabolizes alcohol and caffeine differently following surgery, and hence patients are asked to refrain from consuming these substances. Marcason (2004) notes the lack of standardized guidelines available and emphasizes that post-surgery recommendations can vary by procedure performed, as well as across health care professionals and bariatric facilities.

Bariatric programs consider post-operative monitoring to be critical to long-term success. Bariatric Centers of Excellence within the Ontario Bariatric Network promote patient attendance at follow-up appointments every three months within the first year after surgery, and then once a year for five years. Post-operative dietary counseling provides clients with the opportunity to become familiar with the post-surgery dietary guidelines and the consequences of non-adherence. Despite possessing the knowledge of the follow-up recommendations, being informed about the potential consequences of non-adherence, and having access to support systems within the program, there is increasing evidence that many patients have difficulty adhering to the post-operative dietary guidelines (Hsu et al., 1998).

Adherence to Post-Surgical Dietary Guidelines

Within the context of treatment and disease management, adherence describes the degree to which a patient follows through with previously agreed upon courses of action (Shauer, Brethauer, & Schirmer, 2007). Behaviours deemed non-adherent in previous bariatric care studies focus on the failure to adequately follow the post-surgical dietary guidelines (Poole et al., 2005). Adherence to these guidelines has been found to account for a significant proportion of the variance in long-term bariatric outcomes (Hsu et al., 1998). Bariatric surgery initially imposes physiological constraints that make certain maladaptive eating patterns impossible, or at least uncomfortable (Griffen, 1992). Hence, bariatric surgery has been conceptualized as a forced behaviour modification during the first few months post-surgery (Elkins et al., 2005). Although the initial success rate of the surgery is high, sustained weight loss after the initial 3-month 'honeymoon' period requires strict treatment adherence (Elkins et al., 2005).

Studies have demonstrated that many bariatric patients exhibit suboptimal adherence following bariatric surgery (e.g., Sarwer et al., 2008). It has been reported that over half (57%) of bariatric surgery patients do not adequately follow weight loss instructions (Toussi, Fujioka, & Coleman, 2009). Although unable to consume large quantities of food in one sitting (i.e., an objective binge), many patients still experience a loss of control over eating after surgery (Saunders, 1999). Overeating after bariatric surgery may occur as patients learn how to circumvent the surgical and dietary restrictions (Hsu, Bentancourt, & Sullivan, 1997; Hsu et al., 1998). For instance, a large percentage of patients (70%) report 'grazing' six months after surgery, whereby they continually consume small portions of food throughout the day in the place of meals (Saunders, 1999; Zunker, Karr, Saunders, & Mitchell, 2012). This finding is in line with past research indicating that patients report the greatest difficulty adhering to

recommendations to reduce their excessive snacking behaviour (Elkins et al., 2005). Of 100 post-operative RGB patients, 44% reported being unable to resist grazing patterns at 6 months post-surgery (Elkins et al., 2005). In addition, the introduction of high calorie or fat foods back into patients' diets post-surgery remains a pressing concern. At 2 years post-surgery, 36% of patients continued to consume sweets between meals at least twice a week (Leite, de Oliveria, Pereira, & Kiyomi, 2008). Many patients do not adjust dietary intake accordingly after surgery, consuming the same percentage of calories from fat post-surgery as they did prior to surgery (Rabner & Greenstein, 1991).

Non-adherence to post-operative dietary guidelines can be detrimental to bariatric outcomes. Not only can the patient experience dangerous and distressing post-operative medical complications, but deviation from the dietary guidelines significantly impacts weight loss after surgery (Halverson & Koehler, 1981; Hsu et al., 1997; Kalarchian et al., 2002; Sarwer et al., 2008). Poole and colleagues (2005) found that chaotic adherence to dietary advice results in the emergence (or re-emergence) of eating disorder-type symptoms, such as loss of control over eating, or maladaptive eating patterns, such as emotional overeating. After surgery, the stomach is still able to anatomically and physiologically adapt to increased food consumption over time. Aberrant eating patterns can cause the stomach pouch to expand over time in what is known as 'gastric pouch dilatation', allowing for gradual increases in food consumption (Brolin, 2007). Furthermore, the absorptive capacity of the remaining intestine also increases over time (Scopinaro et al., 1992). Hence, non-adherence to the dietary recommendations can, over time, undo what surgery has achieved (e.g., Hsu et al., 1997; Kalarchian et al., 2002; Rabner & Greenstein, 1991; Sarwer et al., 2008). Indeed, premature weight loss plateaus and weight regain have been associated with poor guideline adherence, including eating too quickly and continuing

to eat when hunger has ceased (Halverson & Koehler, 1981). The adverse impact of non-adherence to dietary guidelines on post-operative weight loss has been observed at follow-ups as long as five years (Wolnerhanssen et al., 2008).

Psychosocial Predictors of Non-Adherence to Post-Surgical Dietary Guidelines

Although effective in reducing weight, surgery alone does not address the underlying psychological factors that often lead to behavioural adherence issues and weight regain (Hsu et al., 1998; Sarwer et al., 2004). Overall, the literature suggests that disordered eating (e.g., Sarwer et al., 2004) and motivation for change (e.g., Rabner and Greenstein, 1991) are two factors that influence non-adherence post-surgery. An understanding of the relationship between post-operative weight loss and these variables can inform the development of interventions to improve outcomes (Devlin, Goldein, Flancbaum, Besller, & Eisenstadt, 2004).

Eating Pathology. Pre-operative psychopathology and maladaptive eating behaviours have been implicated in poor adherence to dietary recommendations after surgery (Shah et al., 2006). Patients who reported disordered eating behaviours such as binge eating prior to surgery were at an increased risk of returning to old patterns post-operatively (Kalarchian et al., 2002; Saunders, Johnson, & Teschner, 1998). Almost 13% of obese individuals seeking bariatric surgery meet criteria for binge eating disorder (BED), 5% of patients will be diagnosed with BED post-surgery, and upwards of 64% of patients will display binge eating symptoms post-surgery, such as loss of control over eating (Sarwer et al., 2004). Grazing was prevalent before surgery (26%) and actually increased after surgery (38%), likely because individuals with pre-operative BED most frequently became grazers after surgery (Colles, Dixon, & O'Brien, 2008). Having a history of binge eating prior to undergoing bariatric surgery has been shown to be associated with poorer post-operative weight loss (Sallet et al., 2007). Maladaptive eating

patterns that re-emerge post-surgery have been shown to worsen over time (Saunders, 2004), and are strongly associated with the extent of weight regain, as well as elevated psychological distress, and feelings of shame, disgust, guilt, and hopelessness (de Zwaan et al., 2002; Kalarchian et al., 2002; Saunders, 2004).

Motivation for Change. In his work with adherence to chronic illness management plans, Shuttleworth (2008) considered motivation "both the key element, as well as the central puzzle, in efforts to change health behaviour" (2001, p. S21). A burgeoning body of research in the field of readiness for change indicates that individuals facing the challenges of making lifestyle changes often demonstrate ambivalence for change (Prochaska, Redding, & Evers, 1994) and exhibit poor self-efficacy for change (Bandura, 2004). Indeed, conviction (i.e. "Do I believe that making this change is important?") and confidence (i.e. "Do I believe I can make this change?") have been found to have practical utility in primary care settings, particularly for diabetes care (Whitlock, Orleans, Pender & Allan, 2002). Understanding bariatric patient conviction and confidence within the broader context of readiness for change can provide a more holistic picture of the role that motivation plays in post-operative outcomes.

The assumption that obese individuals seeking weight loss options are ready to change is often times misguided (Clark, Pera, Goldstein, Thebarge, & Guise, 1996). It has been argued that ambivalence is logical in bariatric surgery patients given the drastic lifestyle change that surgery requires, and may be attributable to: 1) perceived benefits of not making changes, and 2) expectancies of the change process (Shauer, Brethauer, & Schirmer, 2007). First, in a qualitative study of nine bariatric patients, several of the respondents reported missing certain aspects of being obese (Knutsen, Terragni, & Foss, 2013). Commonly reported benefits of obesity include the use of food for emotional comfort and to cope with negative affect (Kral, 2001). In the eating

disorder literature, perceived benefits of the disorder lead to ambivalence about making future behavioural changes (Cassin & von Ranson, 2007), and similarly, the advantages of remaining obese for patients may significantly affect their motivation to make and maintain healthy lifestyle choices after bariatric surgery. Second, bariatric patients often hold unrealistic expectations of surgical weight loss. Patients frequently attribute their successes post-surgery entirely to the surgery-related biological changes, as opposed to crediting their own behavioural changes in the process (Knutsen et al., 2013). Rabner and Greenstein (1991) examined expectations of 33 pre-operative patients and 32 post-operative patients. Over half (55%) of pre-operative patients and 41% of post-operative patients felt weight loss post-surgery was due to 'magic'. Those who grazed excessively after surgery reported that they believed the surgery would prevent them from overeating and that they would still manage to maintain an ideal weight post-surgery. These misconceptions about the mechanisms of change of surgery and/or erroneous expectations of surgery potentially influence how bariatric surgery patients perceive their own agency in the change process, which may, in turn, influence the degree to which they believe change is important for them. The perceived importance of change has implications for the motivation to devote effort and time to change.

Confidence in one's ability to make changes is associated with actual behavioural change (Bandura, 2004). Self-efficacy is predictive of change across a variety of health behaviours, including weight loss maintenance (DePue, Clark, Ruggiero, Medeiros, & Pera, 1995). In a study of the impact of self-efficacy on behaviour change in a weight loss trial, self-efficacy predicted weight loss during treatment, with weight control behaviours (e.g., monitoring caloric intake, physical activity, following meal plan) mediating this relationship (Linde, Rothman, Baldwin, & Jeffery, 2006). Qualitative research detailing nine bariatric patients' experiences reveals how

patients' appraisals of their ability to be successful may affect behaviour change following surgery (Knutsen et al., 2013). Patients reported that their strong fear of post-surgical complications helped encourage dietary adherence during the first 9 months post-surgery. However, as these concerns diminished over time, respondents exhibited doubt in their ability to maintain dietary control and weight loss in the long-term, particularly because of pre-surgery attempts that had failed. Indeed, research has identified a negative association between eating self-efficacy and the duration of follow-up after surgery (Batsis et al., 2009). This correlation between patients' confidence in their ability to control eating and time since surgery is particularly notable considering lower weight self-efficacy in bariatric patients is associated with higher eating disinhibition scores (Delin, Watts, & Basstt, 1995) and less weight loss over time (Batsis et al., 2009). Together, these findings illustrate how self-efficacy for change may influence the degree of dietary adherence following surgery.

Current Interventions for Non-Adherence in Bariatric Patients

Only one study to date has attempted to directly influence patient adherence to post-surgery dietary recommendations (Boeka, Prentice-Dunn, & Lokken, 2010). In that study, the researchers developed a psychoeducation intervention based on the Protection Motivational Theory whereby bariatric candidates listened to an essay containing information about post-operative guidelines. The essay encouraged threat appraisals by presenting the consequences of non-adherence, and self-efficacy appraisals by emphasizing that patients possess the capacity to perform these recommended behaviours. Patients also read testimonials from two bariatric patients who originally struggled with adherence but eventually succeeded with long-term weight loss. The treatment group was no more likely to adhere to dietary guidelines than the control group. The lack of findings provides impetus for the development and testing of

treatments that approach the issue of non-adherence post-surgery from alternative theoretical frameworks.

Theoretical Models of Behaviour Change

Two theoretical models that were developed separately, but have been integrated over the last 20 years to form the conceptual backdrop for interventions that have sought to prompt sustained healthful behaviour change are the Transtheoretical Model and the Social Cognitive Theory. These models of change help delineate how to capitalize on psychological determinants of successful behaviour modification. For the purposes of the current study, they offer a framework for how best to approach long-term management of bariatric patients. As such, these two models are of critical relevance, and are reviewed below.

Transtheoretical Model. Prochaska and DiClemente (1992) developed the Transtheoretical Model to elucidate the process of behaviour change. The model assumes that behaviours persist because they serve important functions. As a result, individuals often feel ambivalent about, and have great difficulty, making changes to their behaviour. According to the Transtheoretical Model, the process of change is divided into five stages: precontemplation, contemplation, preparation, action, and maintenance (Prochaska & DiClemente, 1982). The model postulates that each stage is defined by specific mechanisms that give rise to changes in emotional, cognitive, and behavioural faculties, and predict movement through other stages.

Individuals in the precontemplation stage of change are not yet considering the possibility of change, perhaps because they are unaware that their behaviour is problematic, they are in denial about the behaviour, or they are not ready to change their behaviour. In the contemplation stage, individuals are willing to examine their behaviours and entertain the possibility of change. Ambivalence surrounding change may prevent them from committing to any plans, and hinder

their ability to take the first steps in initiating change. Individuals who identify with the preparation stage have acknowledged the need to change and perhaps want to make a change; however, they are unsure of how to move towards their goals. The action stage involves commitment to change and active engagement in a plan for overcoming the problematic behaviour. Finally, the maintenance stage of change is defined as a period of consistently sustaining behavioural changes, typically for a period of six months or longer. Delays at any of the stages and relapses are conceptualized as part of the natural recovery process.

Originally, the Transtheoretical Model was developed within the field of addictions, but its clinical utility has extended far beyond this domain. For example, the model informs interventions for a range of health behaviours such as smoking, medication compliance, sedentary lifestyles, sun exposure, and high-fat diets (Prochaska & Velicer, 1997). The model is helpful in conceptualizing how treatment provider strategies may or may not be effective in moving patients towards change. For example, treatment efforts that approach all stages of change in a similar fashion risk increasing ambivalence because they do not take into account that some patients may not be contemplating or ready for change, and pushing for change in such patients may paradoxically decrease their readiness for change (Rollnick, Kinnersley, & Stott, 1993). Health care providers tend to respond to treatment non-adherence by attempting to give patients insight, knowledge, skills, or a hard time. However, studies show that patients who are ambivalent about change readily present reasons why they cannot, will not, or are unable to follow treatment plans in response to lecturing or criticisms (Butterworth, 2008).

Social Cognitive Theory. Albert Bandura's Social Cognitive Theory (1977) posits that all individuals have a self-system, comprised of one's attitudes, abilities, and cognitive skills, which plays a lead role in governing behaviour. Self-efficacy, the belief in one's capabilities to

perform goal-directed actions, is at the core of this model. While Bandura perceived individuals as very capable of identifying goals they wish to accomplish, he recognized that many people find initiating and sustaining behaviours that lead to goal achievement challenging. From a social cognitive perspective, an individual's self-efficacy plays a major role in how goals and challenges are approached. For example, an individual high in self-efficacy approaches challenges with mastery, interest, and commitment, and recovers quickly after setbacks. In contrast, low self-efficacy is characterized by an avoidance of difficult tasks, a focus on negative outcomes and past failures, and a belief that many tasks are beyond one's capabilities. Self-efficacy can be enhanced over time through experiences of mastery, social modeling, social persuasion, and psychological responses to situations (Bandura, 1977).

Social Cognitive Theory offers principles on how to motivate people to make healthy behaviour changes (Bandura, 2004). The model posits that in order to achieve desired changes, guidance towards health promotion should be specifically tailored to individuals' self-management capabilities and motivational preparedness. Based on this model, public health initiatives should target self-efficacy to encourage the adoption of healthy habits. Studies have found that health communications that emphasized the consequences of not performing a health-related behaviour (e.g., a breast self-examination) and were framed to enhance self-efficacy were more successful at promoting lifestyle changes compared with those that only highlighted the benefits of performing the behaviour (Meyerowitz & Chaiken, 1987). Research has found that pre-existing beliefs about self-efficacy can be enhanced by messages instilled by health promotion initiatives, resulting in the adoption of healthy eating habits and regular exercise (Maibach, Flora, & Nass, 1991). These results indicate that self-efficacy plays a key role in the

promotion of healthy behaviours, and suggest that self-efficacy can be fostered using strategic forms of communication.

Both the Transtheoretical and Social Cognitive Models are directly applicable to the present study because they provide theoretical underpinnings of Motivational Interviewing (MI; Miller & Rollnick, 2002; 2012), the central therapeutic technique employed in the current pilot trial. Although MI was originally conceived from clinical observation, these two models, amongst others, have been borrowed to provide a theoretical framework (Treasure, 2004).

Motivational Interviewing and its Adaptations

Bariatric surgery programs across the nation are lacking empirically-supported psychosocial interventions based on behaviour change principles to optimize treatment adherence and weight loss outcomes. MI is an innovative approach with the potential to fill this void that has yet to be examined in this context. Literature in the field of addictions posits that modification of even the most engrained, habitual behaviours is dependent upon an individual's readiness and motivation for change. As illustrated in the Transtheoretical Model (Prochaska & DiClemente, 1992), a patient's current stage of change is important in determining the type of guidance required for a natural progression towards sustained behaviour change. Motivation for change does not reside solely within the client, but rather it can be fostered in therapeutic interactions with a clinician (Moyers & Martin, 2006). Miller (1985) developed innovative clinical techniques based upon the notion that a clinician's behaviour can significantly influence a client's motivation for change. MI is a client-centered, yet directive method for enhancing a client's intrinsic motivation for change (Miller & Rollnick, 2002). Motivation for change must emanate from within the individual rather than be cast upon the client by the therapist. MI targets the client's beliefs about the importance of change and his/her ability to make the change

successfully (i.e. self-efficacy) as stipulated in Bandura's Social Cognitive Theory (Bandura, 1977; 2004; Burke, Arkowitz & Menchola, 2003).

MI exerts its effects through the resolution of ambivalence (Phase I) and increase in self-efficacy for change (Phase II), as reviewed in the MI manual (2002). The ultimate goal of behaviour change is accomplished in a number of ways. First, to increase the perceived importance of change, the therapist helps the client reflect on how the problematic behaviour may be interfering with his/her life across a variety of domains, including personal goals and social relationships. The therapist accomplishes this by asking open-ended questions about the ways in which the problematic behaviour impinges upon the client's life, and then juxtaposing this with the client's long-term goals and personal values (Treasure & Ward, 1997). The clinician supports the client through a decisional balance, in which the client is asked to articulate both the 'good' and 'not so good' things about the behaviour, as well as the benefits and costs of changing the behaviour. By encouraging the client to verbally present the advantages and disadvantages of continuing to engage in the behaviour, the clinician emphasizes personal control over decisions for the client. Drawing on Cognitive Dissonance Theory (Festinger, 1957), the clinician prompts the need for change by highlighting the discrepancy between the client's long-term goals and broader personal values, and the restrictions imposed by his or her current behaviour. Furthermore, drawing on Self-Perception Theory (Bem, 1967), the clinician elicits the client's own concerns by having him or her verbally present reasons for change. By placing the responsibility for change with the client rather than advocating for the need for change, the clinician emphasizes autonomy and personal choice in making decisions. Argumentation, lecturing, and combating resistance should be avoided as they serve to jeopardize these mechanisms of change (Miller & Rollnick, 2002).

In this review of the theoretical framework of MI it is imperative to acknowledge that although the Transtheoretical Model and MI have been frequently associated in the literature, the relationship between the two is complex and has evolved over time. As reviewed in Wilson and Schlam (2004), ongoing research in the field of behaviour change has identified numerous conceptual and empirical limitations of the Transtheoretical Model. For example, there is little evidence that AMI actually works by enhancing motivation or readiness for change (Burke et al., 2003). Previous studies (e.g. Cassin et al., 2008) have not found readiness for change to predict behaviour changes post-treatment, suggesting that the construct holds low predictive validity. Furthermore, there is little evidence to support the notion that therapeutic interventions must be matched to clients' stage of change in order to facilitate behavioural change (Wilson & Schlam, 2004). Although MI and the Transtheoretical Model were never explicitly linked, Miller and Rollnick have further separated MI from the model in their new edition of the MI manual (2012) by developing a new four-process model. The lack of a solid theoretical foundation does not detract from the efficacy of MI, but it does make it difficult to gain insight into the mechanisms of effect of MI and its necessary components (Hettema et al., 2005).

Since the development of MI, certain principles have been extracted and combined with other established psychosocial interventions to create adaptations of MI (AMIs; Burke et al., 2003). The most common of these hybrids is motivational enhancement therapy (MET). MET is an adaptation of MI in which clients are provided with personalized feedback on the target behaviour severity and/or frequency as compared with a normative sample (Burke et al., 2003; Hettema, Steele, & Miller, 2005). In the literature, the terms MET and AMI have been used inconsistently. For the purposes of this study, the term AMI will be used to refer to MI

adaptations that provide individual feedback, as well as manualized forms of MI that do not provide this feedback.

Applications of AMI

MI was originally developed as a treatment for addictions. A number of review articles have been published to appraise the evidence for AMI in this field (Noonan & Moyers, 1997; Project MATCH Research Group, 1997; 1998). Over the past two decades, considerable evidence has accumulated highlighting the successful application of AMI beyond the field of addictions. Studies have examined the use of AMI with a variety of disease prevention and chronic illness management interventions (Britt, Hudson, & Blampied, 2004; Emmons & Rollnick, 2001). Several meta-analyses have lent support for the efficacy of AMI techniques in addressing multiple problem behaviours in various clinical populations (Resnicow et al., 2002) including, but not limited to, chronic pain (Jensen, 1996), cardiac rehabilitation (Nolan, 1995), anxiety disorders (Westra & Dozois, 2006), and schizophrenia (Rusch & Corrigan, 2002).

Recently, large studies have been conducted examining the use of AMI strategies in health promotion and health behaviour change. Burke and colleagues (2003) published the first meta-analysis examining the efficacy of AMI in clinical controlled trials across health-behaviour domains, including oral hygiene, smoking, substance use, HIV-risk behaviours, and diet and exercise. This meta-analysis included 30 studies, all of which used face-to-face AMI as the primary therapeutic intervention. Furthermore, all the trials utilized random assignment, control group comparisons, and reliable and valid outcome measures. Despite being an average of 180 minutes shorter, the efficacy of AMI was similar to other active treatments and superior to placebo or no treatment conditions in addressing alcohol use ($d = 0.25$), drug use ($d = 0.56$), dietary and exercise problems ($d = 0.53$). In addition to reducing target symptoms, AMI

improved associated social impact measures, including moderate effects ($d = 0.47$) on social, vocational, and physical problems related to the target behaviour.

Rubak, Sandboek, Lauritzen, and Christensen (2005) conducted the most comprehensive review of AMI to date. They analyzed 72 randomized controlled trials of AMI in the treatment of several disease indicators and health behaviours, such as alcohol abuse, smoking cessation, and weight loss. AMI produced a statistically meaningful effect (95% confidence interval) in 53 (74.0%) of the studies reviewed, with combined estimate effect sizes ranging from 0.30 for blood cholesterol to 72.90 for blood alcohol content. The results support the notion that AMI is superior to traditional advice in changing a broad range of health and behavioural challenges.

AMI for Diet and Exercise Modification. In light of the increasing rates of obesity and obesity-related medical comorbidities, recent research attention has focused on examining the utility and efficacy of AMI in the modification of diet and exercise behaviours (Resnicow et al., 2002). AMI used in combination with psychoeducation was found to be at least moderately efficacious for facilitating dietary change, including reduced energy from fat, reduced sodium consumption, and increased fruit and vegetable intake, over and above standard psychoeducation alone (VanWormer & Boucher, 2004). A review of 24 studies of AMI for diet and/or exercise behaviour change supported the efficacy of AMI as both a stand-alone intervention and as an adjunctive intervention with other treatments, such as behavioural weight loss programs (Martins & McNeil, 2009). Patients who received AMI reported increased self-efficacy related to diet and exercise, increased physical activity, reduced caloric intake, and increased fruit and vegetable consumption. Further, patients who received AMI also demonstrated decreased BMI and increased glycemic control. Taken together, these findings support the clinical utility of AMI in this area of health promotion.

AMI for Disordered Eating. AMI techniques have also been applied to the management of eating disorders, based on the recognition that patients with eating pathology often feel ambivalent about making changes (Cassin & von Ranson, 2007; Vitousek, Watson, & Wilson 1998). Dunn, Neighbors, and Larimer (2006) found that the addition of a single session of AMI to a self-help program for binge eating increased individual's readiness to change, particularly individuals in the pre-contemplation stage (d = 1.52) and contemplation stage (d = 1.10). Furthermore, Cassin, von Ranson, Heng, Brar, and Wojtowicz (2008) conducted the first randomized controlled trial examining the efficacy of AMI for BED. Relative to a control group (i.e., self-help handbook only), the AMI group (i.e., single-session AMI intervention plus the self-help handbook) felt more confident in their ability to reduce binge eating immediately following the intervention (d = 0.96), and they reported greater improvements to their binge eating (d = 0.80), mood (d = 0.64), self-esteem (d = 0.60), and quality of life (d = 0.48) at the 4-month follow-up. A greater proportion of individuals in the AMI group abstained from binge eating (27.8% vs. 11.1%) and no longer met diagnostic criteria for BED (87.0% vs. 57.4%). A recent systematic review concluded that AMI holds promise in this field, particularly with respect to enhancing motivation and readiness for change outcomes, with highly robust findings in the area of AMI for the treatment of BED and binge eating behaviours (Macdonald, Hibbs, Corfield, & Treasure, 2012)

AMI for Treatment Adherence. AMI has been receiving increased interest as a means of promoting treatment adherence. Randomized trials have examined the efficacy of AMI techniques incorporated into adherence programs for chronic illness management. Martins and McNeil (2009) conducted a large systematic review of 10 reviews of published empirical articles utilizing AMI to modify health behaviours. Of the studies reviewed, nine applied AMI to the

management of type 1 and 2 diabetes, focusing primarily on changes to diet and exercise. AMI was effective in improving participants' diet, glucose level management, physical activity levels, and weight loss, both alone and in combination with other interventions. Furthermore, AMI increased patients' self-efficacy and sense of control over diabetes. Similarly, Smith, Heckemeyer, Kratt, and Mason (1997) found that incorporating AMI into a standard behavioural treatment program for obese individuals with type 2 diabetes significantly enhanced adherence to program recommendations, including greater appointment attendance (13.3 versus 8.9 appointments), as well as more frequent completion of food diaries (15.2 versus 10.1 diaries) and blood glucose level recordings (46 versus 32.2 days). These results were replicated with a larger sample of 217 overweight women for a longer follow-up period (West, DiLillo, Bursac, Gore, & Greene, 2007). The AMI group attended more sessions ($d = 0.37$) and completed higher quality food diaries ($d = 0.54$) as compared with the treatment-as-usual group at a 6-month follow-up. The AMI group also lost more weight at the 6-month follow-up (4.7 kg versus 3.1 kg) and the 18-month follow-up (3.5 kg versus 1.7 kg). Statistical analysis for this study placed treatment adherence and engagement as the strongest predictors of long-term weight loss. The addition of AMI as an adjunctive intervention to behavioural weight loss programs yields positive outcomes for adherence to treatment and weight loss (DiMarco, Klein, Clark, & Wilson, 2009; DiLillo, Siegfried, & West, 2003).

Study Rationale and Aims

The current research study examined the efficacy of AMI for improving outcomes for extremely obese (BMI of 40 kg/m^2 or more) individuals who have undergone bariatric surgery. Previous work examining the use of AMI principles and strategies justifies the application of AMI with the bariatric population. Specifically, AMI has been found to: 1) generally improve

dietary and exercise behaviours; 2) enhance self-efficacy for change in eating disorder samples, particularly those with binge eating behaviours; and 3) increase adherence to programs focused on weight loss or chronic disease management.

To our knowledge, this is the first study to examine the efficacy of AMI in a group of bariatric surgery patients. A pilot study examining the feasibility and efficacy of AMI in this population is warranted given the poor adherence rates to the post-operative dietary guidelines and the significant percentage of bariatric patients that exhibit binge eating characteristics. AMI was delivered during the post-operative period in light of research showing increased ambivalence for initiating dietary changes and decreased self-efficacy for sustaining these changes during this period, with the potential for non-adherence and weight regain as a result. The AMI protocol was used as an adjunct to treatment-as-usual bariatric care. Patients were randomly assigned to receive AMI immediately (AMI group), or after a 12-week waiting period (wait list control group). The AMI intervention consisted of a single session, as meta-analytic findings in substance use disorder populations suggest that single session interventions are often as effective as more extensive ones (Burke et al., 2003). Specifically, the purpose of the study was to investigate four research questions:

1) Primary research questions:

a) *Primary Effects of the AMI: Immediate Post-Intervention Changes*. Is one session of AMI efficacious in producing significant immediate post-intervention (i.e., directly following the AMI session) changes to one's perceived importance of change, readiness for change, and confidence in one's ability to change, in a post-operative bariatric sample?

Hypothesis: It is hypothesized that participants will report perceiving a higher importance of change, increased readiness for change, and greater confidence in their ability to change (self-efficacy) from pre- to post-intervention.

b) *Primary Effects of the AMI: Durability of Immediate Post-Intervention Changes*. If immediate changes to importance of change, readiness for change, and confidence in one's ability to change (self-efficacy) are observed from pre- to post-intervention, are these changes durable over a 12-week period?

Hypothesis: It is predicted that the improvements in perceived importance of change, readiness for change, and confidence in one's ability to change (self-efficacy) at post-session will be maintained across the 4-, 8-, and 12-week follow-up time points.

c) *Primary Effects of the AMI: Comparison to a Wait List Control Group*. If immediate changes to importance of change, readiness for change, and confidence in one's ability to change (self-efficacy) are observed from pre- to post-intervention, is this change greater than what would be seen in bariatric patients receiving standard bariatric care over time?

Hypothesis: It is predicted that the AMI group will exhibit a greater improvement on these variables relative to a wait list control group, prior to the latter group receiving the AMI intervention. Furthermore, it is hypothesized that the AMI group will have significantly higher scores on these variables than the wait list control group at each follow-up assessment.

2) Secondary research questions:

a) *Secondary Effects of the AMI: Acute Post-Intervention Changes*. Is one session of AMI efficacious in producing significant behavioural changes, including changes to dietary

guideline adherence and to binge eating characteristics, from pre-intervention to 4 weeks after the intervention?

Hypothesis: It is hypothesized that participants will report greater improvements in binge eating characteristics and in behavioural adherence to post-surgical dietary recommendations from pre-intervention to 4-week follow-up. Furthermore, it is predicted that the AMI group will exhibit a greater improvement on these variables relative to the wait list control group.

b) *Secondary Effects of the AMI: Durability of Acute Post-Intervention Changes*. If changes to behavioural adherence and binge eating are observed at the 4-week follow-up assessment, are these changes durable over a 12 week period?

Hypothesis: It is hypothesized that any observed changes in adherence or binge eating characteristics will be maintained at 8- and 12-week follow-up assessments. Furthermore, it is predicted that the AMI group will report significantly greater adherence and lower levels of binge eating characteristics than the wait list control group at each follow-up assessment.

c) *Secondary Effects of the AMI: Comparison to a Wait List Control Group*. If acute changes to behavioural adherence and binge eating are observed at the 4-week follow-up assessment, is this change greater than what would be seen in a seen in bariatric patients receiving standard bariatric care over time?

Hypothesis: It is predicted that the AMI group will exhibit a greater improvement on these variables relative to a wait list control group. Furthermore, it is hypothesized that the AMI group will have significantly higher scores on these variables than the wait list control group at each follow-up assessment.

METHODS

This study received approval from the Research Ethics Boards at the University Health Network and at Ryerson University. The study adheres to the CONSORT reporting guidelines for randomized controlled trials (Appendix G; CONSORT, 2010).

Participants

Patients who had previously undergone bariatric surgery at the Bariatric Surgery Program at Toronto Western Hospital were recruited between August 2013 and March 2014. Toronto Western Hospital is considered a Bariatric Centre of Excellence, and is the centralized assessment and follow-up centre for the University of Toronto Collaborative Bariatric Surgery Program. Recruitment was accomplished through two primary means. First, emails (Appendix A) were sent to patients who had consented to be contacted for potential research participation to invite them to participate in the research study. A member of the bariatric team sent recruitment emails to 292 individuals who met inclusion criteria for the study and whose email addresses were provided in their medical charts. Second, recruitment posters were posted by the elevators and in the waiting room at the Bariatric Surgery Program (Appendix B). A third recruitment strategy was implemented, whereby members of the bariatric team had the opportunity to distribute study posters to patients who were having difficulty adhering to the dietary guidelines at post-operative follow-up appointments. A priori power analyses were not conducted, as there was no reference group demonstrating anticipated effect sizes for AMI applied to bariatric surgery patients in the literature. In total, 66 potential participants were recruited, of which 64 (96.9%) patients responded to the email and 2 (3.1%) patients responded to the posters.

Of the 66 patients who expressed interest in participating, 2 (3.0%) did not meet inclusion criteria for being post-operative, 1 (1.5%) was excluded due to a conflict of interest with the

study therapist, 4 (6.1%) opted not to participate in the study due to study time and travel requirements, and 4 (6.1%) were no longer in contact. Fifty-five participants were invited to take part and consented to participate in the study; of these 4 (7.1%) participants who consented did not complete the baseline questionnaire packet. Ultimately, 51 participants were randomized to the AMI or wait list control group (see summary of participant flow in Figure 1). Fifty of the 51 randomized participants had been recruited through the 292 recruitment emails, providing a response rate of 17.1%.

Measures

Ontario Bariatric Eating Self-Efficacy Scale (OBESE Scale; Cassin, 2013) (Appendix C). The OBESE Scale consists of 28 self-report items designed to measure eating self-efficacy in bariatric populations. This measure is adapted from the Weight Efficacy Lifestyle (WEL) Questionnaire (Clark, Abrams, Niaura, Eaton & Rossi, 1991), a scale that assesses confidence in one's ability to resist overeating in tempting situations. In addition to rating confidence in one's ability to resist overeating in 19 tempting situations (Part I), the OBESE scale includes 9 additional items to assess confidence in one's ability to follow bariatric surgery dietary guidelines (Part II). Respondents are asked to rate their confidence on a Likert-type scale from 1 ("*Not confident*") to 10 ("*Very confident*"). Although the psychometric properties of the OBESE Scale have yet to be examined, the subscales of the WEL Questionnaire demonstrated high internal consistency (α), ranging from .90 for the Social Pressure Scale to .70 for the Positive Activities Scale, and high concurrent validity with the Eating Self-Efficacy Scale (r = .67; Glynn & Ruderman, 1986). Internal consistency (α) of the OBESE scale in the current sample was .97 for Part I (eating self-efficacy) and .80 for Part II (guideline adherence), which is considered to be 'very high' and 'good', respectively.

*Change Ratings (*Miller & Rollnick, 2002) (Appendix C). *Importance Rating:* Participants were asked to respond to the question, "How important is it for you to consistently follow the post-operative bariatric surgery dietary guidelines?" on a visual analogue scale from 0 ("*Not at all important*") to 10 ("*Extremely important*"). *Readiness Rating:* Participants were asked to respond to the question, "How ready are you to consistently follow the post-operative bariatric surgery dietary guidelines?" on a visual analogue scale from 0 ("*Not at all ready*") to 10 ("*Extremely ready*"). *Confidence Rating:* Participants were asked to respond to the question, "If you decide to change, how confident are you that you will be able to consistently follow the post-operative bariatric surgery dietary guidelines?" on a visual analogue scale from 0 ("*Not at all confident*") to 10 ("*Extremely confident*").

Behavioural Adherence Checklist and Visual Analogue Scale (Appendix C). This self-monitoring checklist was developed for the current study in order to assess adherence to post-operative dietary guidelines. Respondents were asked to monitor their ability to comply with the nine prescribed post-operative diet and nutrition guidelines over a 7-day period. Participants were asked to record whether they were (indicated by a checkmark) or were not able to adhere to each of the nine bariatric guidelines on a given day. A visual analogue scale (VAS) was included at the end of the measure to assess self-reported overall adherence to dietary guidelines over the past week. Participants were asked to respond to the following question: "On a scale from 0-100%, how well do you feel that you've been able to adhere to the post-operative dietary guidelines over the past week?"

Binge Eating Scale (*BES*; Gormally, Black, Daston, & Rardin, 1982) (Appendix C). The BES consists of 16 self-report items used to assess thoughts and feelings (e.g., guilt, shame) as well as behaviours (e.g., amount of food consumed) associated with objective and subjective

binge eating. This scale was specifically developed for use with obese individuals. The BES yields a range of scores from 0 to 46, with moderate levels of binge eating corresponding to a threshold score of 18 and severe levels of binge eating corresponding to a threshold score of 27. The scale demonstrated good internal consistency in previous studies (α = .85; Gormally, Black, Daston, & Rardin, 1982) and in the current sample (α = .88). Scores have correlated strongly with independent binge eating measures, such as food records, in several studies (e.g., Timmerman, 1999).

Yale Adherence and Competence Scale-2nd edition (YACS-II, Nuro et al., 2005). To evaluate therapist adherence to the MI protocol, two Master's students in clinical psychology rated 25% of the audiotaped MI sessions using the MI guidelines of the YACS-II. As a component of training for this role, the research assistants were required to read the YACS-II MI guidelines as well as several chapters from *Motivational Interviewing* (Miller & Rollnick, 2002) on principles of MI. There are nine key domains of MI explicitly defined in the YACS-II manual that were coded: 1) MI style; 2) Open-ended questions; 3) Affirmation of strengths and self-efficacy; 4) Reflective statements; 5) Fostering a collaborative atmosphere; 6) Motivation to change; 7) Heightening discrepancies; 8) Pros, cons, and ambivalence; and 9) Change plan discussion. Assessors rate each domain on a scale from 1 ("*Not at all present during the session*") to 7 ("*Extensively present during the session*"). Similar to a previous study on MI that used the YACS-II (Cassin et al., 2008), the threshold for demonstrating treatment adherence in the current study was set as a score of at least 5 on this 7-point scale, indicating that each of the MI dimensions was present 'quite a bit' during the MI sessions.

Procedure

Phone Screen. Once in contact with the researchers, further information regarding the study protocol was provided and eligibility was assessed via telephone by the primary investigator and study therapist (L. David). Inclusion criteria were as follows: 1) Post-operative bariatric surgery patients registered at the Toronto Western Hospital Bariatric Surgery Program, 2) at least 18 years of age, 3) fluent in English, 4) able to attend one AMI appointment, and 5) have Internet access. The researcher discussed the study consent form to eligible participants (Appendix D) over the phone and prospective participants had the opportunity to ask questions. Individuals who chose to participate provided verbal informed consent after reading an online version of the consent form. Participants who consented were then asked a series of demographic questions (as listed in Measures).

Baseline Assessment. Consenting participants were e-mailed a link to the questionnaire packet for the baseline assessment. Baseline questionnaires included the OBESE Scale, change ratings, behavioural adherence self-monitoring checklist and VAS, and the BES. All questionnaire packets were hosted on *Qualtrics,* an online survey platform that facilitates the creation and administration of questionnaires (Qualtrics, Provo, UT). Participants inputted their individual study code into the survey to maintain confidentiality. Prior to completing any questionnaires, participants were prompted to read an online version of the study's consent form and were required to indicate that they agreed to partake in the study before responding.

Randomization. The remaining participants were randomly assigned, matched by months since surgery to one of two groups: 1) the Adapted Motivational Interviewing (AMI group); or 2) wait list (control group), using a web-based random number generator (www.randomization.com). Randomization was conducted after receiving the baseline

assessment in order to eliminate any influence group assignment may have had on reporting for these questionnaires. Individuals randomly assigned to the AMI Group were invited to immediately schedule an appointment at the Ryerson University Healthy Eating and Lifestyle (HEAL) Laboratory for the AMI session. Individuals who were assigned to the wait list control group were invited to receive the AMI session following the 12-week waiting period, during which time they completed the same follow-up questionnaires (labeled 'post-baseline' questionnaires for clarity) as the AMI group despite not having received the intervention. All participants were retained in the study regardless of whether they sought out additional treatment at any point during their participation in the study.

Study Visit and Post-Intervention Assessment. Once participants have arrived for the scheduled AMI session (immediately after the baseline assessment for the AMI group and following the 12-week post-baseline assessment for the wait list control group), full written consent was obtained so the participants and researcher would have a hard copy of the signed consent form for their records. Compensation of $20.00 was provided to participants who attended the in-person session to help offset the costs of transportation. Immediately following the session, participants were asked to complete hard copies of the OBESE Scale and the change ratings to examine the baseline to post impact of the intervention. Post-intervention measures were only administered to those actively receiving the intervention (i.e. the wait list control group did not complete this assessment until they received the AMI session). The interviewer left the room while participants completed these questionnaires.

Follow-up Assessments. All participants completed follow-up questionnaires at 4, 8, and 12 weeks following the AMI intervention. Follow-up questionnaire packets included the OBESE Scale, change ratings, behavioural adherence self-monitoring checklist and VAS, and the BES.

Electronic links to the online questionnaires were sent out one week prior to their completion due date as per the follow-up timeline. If participants did not respond within 4 days, a reminder email was sent out every 2 to 3 days thereafter. Phone calls were made to participants who did not respond to four reminder emails. Questionnaires that were not completed within 2 weeks of the link being sent out were not used in the current study.

Study Completion. At the 12-week follow-up, a letter of appreciation (Appendix E) was sent by mail, accompanied by $30.00 compensation for individuals who had completed the 12-week follow-up questionnaire.

AMI Intervention

The AMI session took place at the HEAL Laboratory at Ryerson University. Participants were asked if they would be comfortable with audio recording the session, as it was not explicitly required on the consent form. No participants refused the recording of the session. Participants participated in an individual face-to-face AMI session. Participants were notified of the limits of confidentiality before the session.

The AMI protocol was adapted from the single-session AMI protocol that was developed by one of the study investigators for a previous study on AMI for BED (Cassin et al., 2008; Appendix F). This protocol was based on a book entitled *Getting Better Bit(e) by Bit(e): A Survival Guide for Sufferers of Bulimia Nervosa and Binge Eating Disorder* by Treasure and Schmidt (1997). Minor modifications were made to the intervention for the purposes of the present study for use with bariatric patients. The original protocol was focused on BED, and hence the session was centered on the participants' thoughts and feelings concerning their binge eating behaviours. For the purpose of the current study, more exploratory questions were employed to gain a sense of the area of non-adherence the participant wanted to focus on, such as

"Can you tell me more about how you became interested in participating in this study" and "I'm wondering what difficulties you have been experiencing since the surgery". The specific focus of the session was not determined prior to speaking with each participant, although the topic of the session was limited to the broad domain of dietary changes following surgery.

The goal of the AMI session was to encourage the participant to reflect upon his/her difficulties in making and sustaining healthy lifestyle changes post-surgery, consider both the benefits and consequences of adhering to the dietary guidelines, resolve ambivalence, and then consider the possibility of change. The protocol is considered AMI (and not MET) because personalized feedback of assessment results is not provided to participants. The AMI protocol is semi-structured, such that certain questions were asked of all participants but follow-up questions were tailored to the content of participants' answers. The intervention incorporated the four basic principles of MI: (1) expressing empathy; (2) developing discrepancy; (3) rolling with resistance; and (4) supporting self-efficacy (Miller & Rollnick, 2002). Throughout the intervention, the interviewer expressed acceptance and affirmation, reframed the client's thoughts to amplify motivational statements and minimize non-motivational statements, elicited the client's self-motivational statements (e.g., expressions of problem recognition, concern, desire, intention to change, and ability to change), and affirmed the client's freedom of choice and self-direction (Treasure & Schmidt, 2001).

The AMI protocol included the following elements (see Appendix F):

- Discussion of interest in study
- Eliciting concerns about various areas of adherence to post-surgery guidelines (e.g., protein/vitamin intake, avoiding overeating or snacking, consuming fluids) and how these areas impact on physical health, mental health, social life, and interpersonal relationships.

There was no pre-determined focus of the session, and this discussion was used to determine the dietary guideline that the participant was having the greatest difficulty adhering to.

- Exploration of ambivalence - Discussion of 'good' things and 'not so good' things about not adhering to post-surgery guidelines
- Discussion of Transtheoretical Model of change (Prochaska & DiClemente, 1992) and brief assessment of client's stage of change, while also normalizing ambivalence and lapses
- Written decisional balance (i.e., pros and cons of staying the same versus changing)
- Bolster self-efficacy – Encourage client to recall past experiences in which she has shown mastery in the face of difficulties and challenges
- Values exploration – Exploration of dissonance between actual life and ideal life, ponder the future with and without adherence to the post-surgery dietary guidelines
- Assessment of readiness and confidence for change
- Written list of possible actions – "If you were considering change, how would you go about making changes?"
- Elicit ideas for possible behavioural alternatives to non-adherence
- Work collaboratively on devising a change plan consisting of small, manageable steps (adapted from Treasure & Schmidt (1997))
- Complete "Plans for Change" worksheet (Treasure & Schmidt, 1997)
- Foresee and forestall difficult times – Work with client to identify and prepare for obstacles (adapted from Treasure & Schmidt, 1997)

The study therapist was a Master's level clinical psychology student at Ryerson University (L. David) who was trained in delivering the AMI protocol. As part of her training, she attended a MI workshop hosted by a leading expert in the field, read chapters from

Motivational Interviewing (Miller & Rollnick, 2002; 2013), watched MI professional training videotapes (Hettema, 2009; Miller & Rollnick, 1998), and practiced multiple videotaped role-plays. She also received regular supervision from a Registered Clinical Psychologist with expertise in MI (Dr. S. Cassin). Each AMI session for the study was audio recorded so that clinical supervision could be provided and fidelity to treatment could be assessed in order to prevent drift from the protocol or deviation from the spirit of MI. A Registered Clinical Psychologist was available in case participants wished to privately discuss issues that were brought up during the session, and participants were also reminded that members of the Toronto Western Hospital Bariatric Surgery Psychosocial Team were available to them if needed (e.g., to discuss dietary issues or psychological concerns).

Wait List Condition

All participants were informed that the current trial involved a wait list control group, and informed consent included an agreement to undergo a 12-week period of routine questionnaires prior to receiving the AMI session for those who were assigned to the wait list control condition. During the wait list period, these participants continued to receive standard bariatric care. Bariatric Centers of Excellence within the Ontario Bariatric Network, including Toronto Western Hospital, promote patient attendance at follow-up appointments approximately every three months within the first year after surgery, and then once a year thereafter for five years. Additionally, bariatric patients at Toronto Western Hospital have access to additional services as needed, including support groups, cognitive-behavioral therapy (CBT), and dietary consultations, as well as ongoing research studies, including mindfulness eating. All participants in the current study, including those assigned to both the AMI and wait list groups, were not restricted from accessing these additional bariatric services.

RESULTS

Randomization and Attrition

Participant flow can be seen in Figure 1. Fifty-one participants were randomly assigned to either the AMI group (n = 23) or the wait list control group (n = 28). The current study continued ongoing 'running' recruitment across a 9-month period. The original matching randomized assignment strategy placed participants into the AMI group and wait list group at a 1:1 ratio; however, the higher attrition rate in the wait list group during the post-baseline period meant that the AMI group was retaining a higher number of participants. To account for further attrition and to ensure balanced group sizes, a new randomization strategy was implemented 4 months into the recruitment period. Participants were randomized to the AMI and wait list groups at a 1:2 ratio, respectively. For every one participant placed in the AMI group, two were placed in the control group. Of the 28 participants assigned to the wait list group, 8 participants (28.6%) did not receive the in-person AMI session: 4 (14.3%) withdrew after completing the baseline questionnaire packet, 1 (3.6%) withdrew after completing the 4-week post-baseline questionnaires, and 3 (10.7%) withdrew after completing the 12-week post-baseline questionnaire but before receiving the AMI session. Data from the three participants who completed all of the post-baseline questionnaires were retained (with their consent) solely for the AMI versus wait list control group comparison analyses.

Of the 13 participants who discontinued their participation in the current study after consenting, 4 (30.8%) had yet to be assigned to a group, and 9 (69.2%) had been assigned to the wait list control group. No participants assigned to the AMI group withdrew from the study. Chi-square tests found that client attrition was indeed related to group assignment, $\chi^2 = 7.79, p < .01$, whereby those assigned to the wait list control condition were significantly more likely to

discontinue participation. The three participants who completed the wait list assessment period but did not receive AMI were included as 'completers' for the purposes of the original completer versus dropout analyses, as their data were retained in the study for certain statistical analyses. To examine whether there was differential attrition across groups, independent t-tests were performed to compare completers and dropouts on demographic variables (e.g., age, time since surgery) and baseline characteristics (e.g., self-efficacy, change ratings, adherence, binge eating characteristics). Across groups, the completers ($n = 45$) did not differ from the dropouts ($n = 6$) on any demographic variables or baseline level of outcome variables (Table 2), suggesting no differential attrition. However, when the three participants who completed the post-baseline wait list assessment period were included in this analysis as dropouts, the age of completers ($n = 42$) and dropouts ($n = 9$) was significantly different, $t(49) = 2.46$, $p < .05$, whereby the participants who discontinued the study ($M = 42.1$, $SD = 8.5$) were younger on average than those who completed the study ($M = 50.1$, $SD = 8.4$). Given that this was an initial study of a new treatment, all subsequent analyses were first performed with completers only ($n = 44$; Lavori, 1996). In order to remove any potential bias that may result from restricting analyses to completers only, the results were then reanalyzed using the intention-to-treat (ITT) approach, in which the last observed response of dropouts is carried forward ($n = 46$; Gupta, 2011). The results of the study remained very consistent across completer and ITT analyses performed (Table 9; Table 10; Appendix H).

The mean age of study participants was 49.2 years (range 30 to 66 years). The sample was predominantly female ($n = 40$; 87.0%). On average, study participants were just over 2 years post-surgery ($M = 26.4$ months; range 6 to 44 months). Despite randomization of participants into groups, the presence of pre-existing differences between participants in the AMI and wait

list control groups was examined. Chi-square (χ^2) tests and independent t-tests were used to compare the AMI group and the wait list control group on demographic variables (e.g., age, gender, time since surgery) and baseline characteristics (e.g., self-efficacy, change ratings, adherence, binge eating characteristics). The AMI and control groups did not differ with respect to demographic variables (Table 3). Chi-square tests indicate that there were no significant differences in the gender composition of each group, $\chi^2 = 0.17, p = .68$. The groups did not differ on the majority of the baseline characteristics, including their eating and adherence self-efficacy, change ratings, adherence levels on the self-monitoring checklist, and binge eating behaviours (Table 3). However, the wait list control group was significantly more adherent to the guidelines based on the self-report VAS at baseline as compared with the AMI group (Table 3).

Post-hoc power analyses were conducted using G*Power software. These analyses indicated that in evaluating the immediate pre-post changes in primary outcomes (within-subjects, $n = 43$) and the acute pre-intervention to 4-week follow-up changes in secondary behavioural outcomes (within-subjects, $n = 42$) there was a high power level of .89 to identify a medium effect size ($d = 0.50$). Durability of these changes across the 12-week follow-up period (within-subjects, $n = 37$) obtained a power of .93 to obtain a moderate effect. For the mixed model analyses (n = 44; 2 groups), a power of .98 was obtained to find an interaction (within-between subjects) with a moderate effect size and main effect for time (within-subjects) and a power of .54 to identify a main effect for group (between-subjects).

Treatment Adherence

It was decided a-priori that treatment adherence coding would be conducted on at least one quarter of the AMI session tapes selected at random. Twelve (27.9%) AMI sessions were rated on 9 MI dimensions by 2 adherence raters. Means and standard deviations were computed

to assess how frequently the MI dimensions were present during the AMI sessions (Table 4). The minimal threshold for demonstrating treatment adherence in the current study was set as 5 on a 7-point scale, indicating that each of the MI dimensions was present 'quite a bit' during the AMI sessions. All of the tapes exceeded this cut-off. The intraclass correlation coefficient of the AMI scores provided by the coders was .66, $p < .05$, which means the two coders had moderate inter-rater reliability. The sessions were 107 minutes on average.

Primary Effects of the AMI

Immediate Post-Intervention Changes. To examine whether AMI increased eating and adherence self-efficacy as well as ratings of importance of change, readiness for change, and confidence in one's ability to change, paired-samples t-tests were performed to compare all participants' scores on the OBESE Scale and change ratings from pre-intervention (baseline/post-waitlist) to post-intervention. Results are displayed in Table 5. Participants' eating and adherence self-efficacy were significant higher immediately following the AMI session. Additionally, participants reported greater readiness for change and greater confidence in their ability to change immediately following the AMI session. Participants did not report significant changes with respect to the perceived importance of change. Effect sizes were computed from the t-tests (Thalheimer & Cook, 2002). Effect sizes (*ES*) of .2, .5, and .8 correspond to small, medium, and large effects, respectively (Cohen, 1992).

Durability of Immediate Changes. To examine the durability of observed immediate intervention changes in self-efficacy and readiness for change across the follow-up period, a one-way (time: post-intervention, 4-week follow-up, 8-week follow-up, 12-week follow-up) repeated measures ANOVA was conducted. Mauchly's W, indicating the presence of sphericity, was monitored. If the test was significant at the .05 alpha level, signifying sphericity of the data, the

Greenhouse-Geisser (GG) adjusted F statistic was employed to obtain a more conservative estimate of effect. Effect sizes (partial eta-squared; η^2_p) were computed from the F-tests (Fritz, Morris, & Richler, 2012). Effect sizes (*ES*) of .02, .13, and .26 correspond to small, medium, and large effects, respectively (Fritz, Morris, & Richler, 2012).

Results are displayed in Table 6. Immediate improvements to eating self-efficacy and readiness for change remained stable from post-intervention to 4, 8, and 12 weeks after the intervention. Immediate gains in adherence self-efficacy were not consistent across the 12-week follow-up period. Post-hoc paired-samples t-tests, using the Bonferroni correction ($\alpha = .0125$), indicated a significant decrease in adherence self-efficacy from post-intervention ($M = 8.3$, $SD = 1.3$) to the 4-week follow-up ($M = 7.9$, $SD = 1.7$), $t(36) = 2.65$, $p < .05$, but levels at the post-intervention assessment did not differ from those at the 8-week follow-up ($M = 8.1$, $SD = 1.4$), $t(36) = 2.11$, $p = .041$, or at the 12-week follow-up ($M = 8.0$, $SD = 1.5$), $t(36) = 1.38$, $p = .033$. Participants' confidence in their ability to change also fluctuated across the follow-up period. Follow-up paired-samples t-tests, using the Bonferroni correction ($\alpha = .0125$), indicated that participants' confidence in their ability to change decreased significantly from post-intervention ($M = 8.2$, $SD = 1.7$) to the 4-week follow-up ($M = 7.4$, $SD = 2.0$), $t(36) = 3.44$, $p < .01$. As was the case with adherence self-efficacy, confidence ratings at the post-intervention assessment were not significantly different from ratings at the 8-week follow-up ($M = 7.7$, $SD = 1.6$), $t(36) = 2.22$, $p = .034$, or the 12-week follow-up ($M = 7.5$, $SD = 2.0$), $t(36) = 2.50$, $p = .026$. In summary, the majority of the acute treatment changes, including improvements in eating self-efficacy and readiness for change, were maintained across a 12-week follow-up. Both adherence self-efficacy and confidence in ability to change declined at the 4-week follow-up before increasing again for the remainder of the follow-up period.

Comparison to a Wait List Control Group. A 2 (Group: AMI vs. wait list control) x 4 (Time: baseline, 4-week follow-up/post-baseline, 8-week follow-up/post-baseline, 12-week follow-up/post-baseline) mixed model (repeated measures and between subjects comparisons) ANOVA was performed to examine group differences on self-efficacy and change ratings across the follow-up/wait list time period. The inclusion of the wait list (post-baseline) assessments in this analysis allows testing of how any effects of treatment compare with potential changes on outcome measures that may occur over time or over the course of multiple assessments (i.e. the study questionnaires). For all analyses conducted, Levene's test was non-significant, indicating that the assumption of homogeneity for the between groups factor was not violated. Additionally, Box's M was non-significant for all mixed-model ANOVAs and follow-up repeated measures ANOVAs conducted, meaning that the equality of variances assumption was not violated for the repeated measures factor. The assumption of sphericity was assessed for using the Mauchly's W test and, where necessary, corrected for statistically using the Greenhouse-Geisser (GG) adjusted F statistic. Effect sizes (partial eta-squared; η^2_p) were computed from the F-tests (Fritz, Morris, & Richler, 2012). Effect sizes (*ES*) of .02, .13, and .26 correspond to small, medium, and large effects, respectively (Fritz, Morris, & Richler, 2012).

When examining eating self-efficacy, there was a significant Group x Time interaction (Table 8; Figure 2). A significant main effect for time was also found but there was no main effect for group (Table 8; Figure 2). A one-way (baseline, 4-week, 8-week, 12-week) repeated measures ANOVA for each of the two levels of the grouping factor (i.e. follow-up time points for the AMI group and post-baseline time points for the wait list group). The AMI group demonstrated a main time effect, $F(3, 60) = 6.79$, $p < .01$. Post-hoc paired-samples t-tests within the AMI group, using Bonferroni corrections, found significant improvements between eating

self-efficacy scores from baseline ($M = 6.4$, $SD = 2.2$) to the 4-week follow-up ($M = 7.2$, $SD = 2.0$), $t(20) = 2.60$, $p < .05$. The wait list group produced no main effect for time, $F(3, 66) = 0.56$, $p = .64$. Additionally, independent sample t-tests did not find a significant difference between the groups at any assessment points ($p > .0125$ with the Bonferroni correction).

When comparing the AMI and wait list groups on adherence self-efficacy scores, no interaction was identified between Group and Time (Table 8). However, there was a significant main effect for time (Table 8). A one-way repeated measures ANOVA for the AMI group demonstrated a main effect for time, $F(3, 60) = 5.92$, $p < .01$, and post-hoc paired-samples t-tests found a significant increase in scores from baseline ($M = 7.0$, $SD = 1.6$) to the 4-week follow-up ($M = 7.6$, $SD = 1.8$), $t(20) = 2.98$, $p < .01$. A repeated measures ANOVA for the wait list control group also identified a main effect for time, $F(3, 66) = 3.28$, $p < .05$. Post-hoc paired-samples found the same increase between scores at baseline ($M = 7.3$, $SD = 1.6$) and the 4-week follow-up ($M = 7.8$, $SD = 1.3$), $t(22) = 2.12$, $p < .05$, but this was non-significant with the Bonferroni correction ($\alpha = .017$).

Perceived importance of change and readiness for change showed no interaction or main effects (Table 8). Confidence in ability to change, however, showed a significant Group x Time interaction (Table 8; Figure 3). A main effect for time was also identified but no main effect was observed for group (Table 8; Figure 3). A follow-up one-way repeated measures ANOVA found that the AMI group demonstrated a main effect for time, $F(3, 60) = 7.81$, $p < .001$. Post-hoc paired-samples t tests found a significant increase in scores from baseline ($M = 6.0$, $SD = 2.3$) to the 4-week follow-up ($M = 7.0$, $SD = 2.4$), $t(20) = 2.72$, $p < .05$. The post-hoc ANOVA did not indicate a main effect for time in the wait list control group $F(3, 66) = 0.32$, $p = .81$.

Additionally, independent sample t-tests did not identify a significant difference between the groups at any assessment points ($p > .0125$ with the Bonferroni correction).

To summarize, the significant interaction between groups and time points for eating self-efficacy and confidence in one's ability to change signifies that the AMI and wait list control groups differ in the way that they improve on these outcome measures across time. Follow-up tests indicated that it was the AMI group, not the wait list group, which showed significant improvements on outcome measures over time, likely driving the significance of the omnibus test. Specifically, these improvements in the AMI group occurred between the baseline and 4-week follow-up assessments. However, although it was found that the AMI group improved more dramatically over time as compared with the wait list control group, these changes were not marked enough for the AMI group to differ significantly from the wait list control group at any post-intervention time point. Furthermore, both the AMI group and wait list group showed improvements in adherence self-efficacy from pre- to post-intervention, although the wait list group improvements did not reach statistical significance when the alpha was adjusted using the Bonferroni correction.

Secondary Effects of the AMI

Acute Post-Intervention Changes. To examine whether AMI improved participants' guideline adherence and binge eating behaviours, paired-sample t-tests were performed to compare scores on the self-reported adherence checklist and VAS as well as on the BES from pre-intervention (baseline/12-week post-baseline) to the 4-week follow-up. Results are displayed in Table 7. As compared with the pre-intervention assessment, participants reported significantly greater adherence to the dietary guidelines, but only as assessed by the VAS. In contrast, scores on the adherence checklist did not show significant improvement at the 4-week follow-up.

Participants reported significantly fewer binge eating characteristics, as measured by the BES, 4 weeks following the AMI session. Effect sizes were computed from the t-tests (Thalheimer & Cook, 2002). Effect sizes (*ES*) of .2, .5, and .8 correspond to small, medium, and large effects, respectively (Cohen, 1992).

Durability of Acute Changes: To examine the durability of acute treatment changes to adherence and binge eating across the 12-week follow-up period, a one-way (Time: 4-week follow-up, 8-week follow-up, 12-week follow-up) repeated measures ANOVA was conducted. The assumption of sphericity was assessed for using Mauchly's W test and, where necessary, corrected for statistically using the Greenhouse-Geisser (GG) adjusted F statistic. Acute gains demonstrated in behavioural adherence, as measured by the VAS, and binge eating behaviours, as assessed by the BES, 4 weeks after the AMI intervention were maintained 8 and 12 weeks following the intervention (Table 6). In summary, all of the secondary behavioural gains in guideline adherence and binge eating behaviours reported at the 4-week follow-up were maintained across the 12-week follow-up. Effect sizes (partial eta-squared; η^2_p) were computed from the F-tests (Fritz, Morris, & Richler, 2012). Effect sizes (*ES*) of .02, .13, and .26 correspond to small, medium, and large effects, respectively (Fritz, Morris, & Richler, 2012).

Comparison to a Wait List Control Group. A 2 (Group: AMI vs. wait list control) x 4 (Time: baseline, 4-week follow-up/post-baseline, 8-week follow-up/post-baseline, 12-week follow-up/post-baseline) mixed model (repeated measures and between subjects comparisons) ANOVA was performed to examine group differences in guideline adherence and binge eating behaviours across the follow-up/wait list period. The inclusion of the wait list assessments in this analysis allows testing of how any effects of treatment compare with changes on behavioural outcome measures that may occur over time or over the course of multiple assessments (i.e. the

study questionnaires). The results of these analyses and calculated effect sizes (*ES*; Thalheimer & Cook, 2002). are depicted in Table 8. For all analyses conducted, Levene's test and Box's M were non-significant, indicating that the homogeneity and the equality of variances assumptions were not violated. The assumption of sphericity was assessed for using Mauchly's W test and, where necessary, corrected for using the Greenhouse-Geisser (GG) adjusted F statistic. Effect sizes (partial eta-squared; η^2_P) were computed from the F-tests (Fritz, Morris, & Richler, 2012). Effect sizes (*ES*) of .02, .13, and .26 correspond to small, medium, and large effects, respectively (Fritz, Morris, & Richler, 2012).

Scores on the adherence checklist did not indicate a Group x Time interaction or main effects for time or group (Table 8). Adherence VAS levels, however, did demonstrate a significant Group x Time interaction (Table 8; Figure 4). A main effect for time was also found but there was no group main effect (Table 8; Figure 4). A follow-up a one-way (baseline, 4-week, 8-week, 12-week) repeated measures ANOVA for each of the two levels of the grouping factor (i.e. 'follow-up' time points for the AMI group and 'post-baseline' time points for the wait list group) was conducted. The AMI group had a main effect for time, $F(3, 60) = 4.95, p < .01$, and post-hoc paired-samples t tests, with a Bonferroni correction, showed a significant increase in VAS scores from baseline ($M = 57.0$, $SD = 24.6$) to the 4-week follow-up ($M = 68.6$, $SD = 23.7$), $t(20) = 3.17, p < .01$. The repeated measures ANOVA did not indicate a main effect for time in the wait list group $F(3, 66) = 2.51, p = .067$. Additionally, independent sample t-tests showed a significant difference between the groups at baseline, as reported earlier, but not at other assessment points ($p > .0125$ with the Bonferroni correction).

There was a significant Group x Time interaction for BES scores (Table 8; Figure 5). A significant main effect for time was also found but there was no group main effect (Table 8;

Figure 5). A follow-up one-way repeated measures ANOVA found a main effect for time in the AMI group, $F(3, 60) = 5.28$, $p < .01$, and post-hoc paired-samples t-tests indicated a significant decrease in BES scores from baseline ($M = 16.1$, $SD = 8.6$) to the 4-week follow-up ($M = 13.9$, $SD = 10.5$), $t(20) = 2.64$, $p < .01$. The repeated measures ANOVA did not indicate a main effect for time in the wait list control group $F(3, 66) = 0.87$, $p = .46$. Independent sample t-tests did not find a significant difference between the groups at any assessment points ($p > .0125$ with the Bonferroni correction).

To summarize, the significant interaction between groups and time points for binge eating characteristics signifies that the AMI and wait list control groups differ in the way that they improve on these outcome measures across time. Follow-up tests indicated that it was the AMI group, not the wait list group, which showed significant improvements on the BES over time, likely driving the significance of the omnibus test. Specifically, these improvements in the AMI group occurred between the baseline and 4-week follow-up assessments. However, although it was found that the AMI group improved in binge eating more dramatically over time as compared with the wait list control group, these changes were not marked enough for the AMI group to differ significantly from the wait list control group at any post-intervention time point.

DISCUSSION

The present study examined the effect of a single-session AMI protocol for post-operative bariatric patients in order to investigate its feasibility and efficacy as a brief intervention for patients exhibiting difficulties in initiating and maintaining adherence to dietary guidelines after surgery.

Acute Treatment Effects. In line with the original hypotheses, the addition of one AMI session to standard bariatric care significantly improved patient outcomes with respect to primary psychological outcomes related to readiness for change and self-efficacy for making changes, as well as secondary behavioural outcomes related to dietary guideline adherence and binge eating characteristics. Immediately post-intervention, moderate improvements were reported in both eating self-efficacy and adherence self-efficacy, as well as moderate increases in ratings of readiness for change and large increases in confidence in one's ability to change. At the 4-week follow-up, small behavioural effects were reported, including decreases in binge eating behaviours and some evidence for improvement to guideline adherence. Despite these impressive results observed, comparisons between the AMI and wait list control groups paint a less optimistic picture of the efficacy of AMI for bariatric patients, as discussed later.

Contrary to the initial study hypotheses, participants' perceived importance of change did not improve immediately following the AMI intervention. These results are similar to the randomized controlled trial of AMI for BED (Cassin et al., 2008), where it was found that, in comparison to a self-help book control, a single session of AMI did not produce higher perceived importance of change or readiness for change ratings at post-intervention. A ceiling effect may have contributed to this finding, as participants reported high baseline scores regarding the perceived importance of change (M = 9.1 out of a possible 10). The high perceived importance of

change reported by the current sample at baseline may be a result of the intensive preparatory courses and assessments that pre-operative patients are mandated to attend prior to receiving the surgery, or of the reminders they receive from the Bariatric Surgery Psychosocial Team during their post-operative follow-up appointments. It appears that a strength of AMI may lie in its ability to enhance confidence in one's ability to change, at least for patients who already recognize the importance of adherence following surgery. Bariatric surgery patients generally report low self-efficacy for initiating and maintaining healthy dietary changes due to an extensive history of unsuccessful attempts to lose weight prior to surgery.

Another finding of the current study that opposes the original hypotheses is the lack of improvement in dietary adherence as assessed by the self-monitoring checklist at post-intervention. This finding is particularly difficult to interpret given the improvements seen in adherence as assessed by the VAS. The self-monitoring checklist and VAS were included in the study to holistically measure adherence, but the differential results produced by these two measures imply that they were not necessarily tapping into the same construct. There are a number of factors that could have compromised the validity and reliability of the assessment of adherence in the current study. First, checkmark responses, as used on the adherence checklist, are an 'all-or-nothing' form of responding. In this way, scores relied heavily on participants' subjective judgment of what adherence and non-adherence encompassed for each of the nine guidelines on any particular day (e.g., knowing how many grams of protein they should be consuming daily, as well as knowing the actual protein content of the foods they are consuming). Furthermore, participants' recall of eating patterns may have been subject to retrospective recall bias or inaccurate reporting, as it has been reported in the literature that maladaptive eating patterns are associated with guilt, shame, and embarrassment (de Zwaan et al., 2002; Kalarchian

et al., 2002; Saunders, 2004). Second, the 7-day period of self-monitoring would likely not capture the true state of the participants' dietary patterns over the long-term. Finally, in concordance with the spirit of MI, the AMI session and subsequent measures of adherence remained broadly applicable to any of the nine post-operative dietary guidelines by grouping adherence across guidelines into an overall score. Taken together, these factors introduce between-subject variability and reduce reliability, which could have contributed to differential results between the two measures of adherence in the current study.

Maintenance of Acute Treatment Effects. The majority of the acute treatment changes, including improvements in eating self-efficacy and readiness for change, were maintained across a 12-week follow-up evaluation period. In addition, all of the secondary behavioural gains in guideline adherence and binge eating behaviours reported at the 4-week follow-up were maintained across the 12-week follow-up period. In contrast, post-intervention improvements in adherence self-efficacy and confidence in one's ability to change, two different measures of a similar construct, both demonstrated similar fluctuations across the follow-up period. Both outcomes showed large improvements from pre- to post-intervention, but decreased from post-intervention to the 4-week follow-up. Interestingly, ratings on both outcomes increased between the 4-and 8-week follow-ups, and remained stable until the 12-week follow-up. One of the more plausible explanations for this temporary reduction in adherence self-efficacy is that by the 4-week follow-up period, participants had had time to attempt dietary changes that were discussed in the AMI session. The experience of tackling foreseen obstacles or facing new difficulties associated with change may have impacted self-efficacy levels until changes had been implemented for a longer period of time or until obstacles had been overcome. It is important to note that these trends do not directly converge with results seen in eating self-efficacy, whereby

participants' confidence in their ability to resist overeating across various tempting situations improved post-intervention, and stayed improved over the 12-week follow-up period. As of yet, there is no literature on the relationship between self-efficacy for resisting overeating versus self-efficacy for adhering to the guidelines in post-operative bariatric patients. Prior to the OBESE Scale being developed, there were no self-efficacy measures geared specifically towards bariatric surgery patients. Part II of the OBESE Scale refers to a host of dietary changes other than overeating that encompass adherence post-surgery, and hence it may be speculated this discrepancy may be due to participants' wavering confidence in their ability to be adherent to dietary guidelines that do not involve overeating, such as consuming adequate amounts of protein or fluids. The field of bariatrics would benefit from future research exploring the descriptive data on changes in eating self-efficacy post-surgery and the identification of areas in which bariatric patients are reporting low self-efficacy. It could also be hypothesized that the consequences of certain areas of non-adherence are more apparent or distressing for bariatric patients than the consequences of non-adherence in other areas. For example, overeating after surgery is often associated with dumping syndrome, plugging, early weight loss plateaus or weight regain, and other physical complications, whereas failure to follow other guidelines often does not result in such salient effects. Therefore, patients may find it more difficult to diligently and consistently follow these other bariatric guidelines.

Wait List Control Comparisons. Changes on outcome measures observed in the AMI group during the 12-week time period following the AMI intervention were compared to changes experienced by the wait list control group during the same 12-week period. It was anticipated that the AMI group would report greater improvements on all primary and secondary outcome variables than the wait-list control group. Significant group by time interactions were reported

for eating self-efficacy, confidence in one's ability to change, and binge eating characteristics. One interpretation of these findings is that the AMI group is improving differently on eating self-efficacy, confidence in one's ability to change, and binge eating characteristics as compared with the wait list control group. The AMI group reported improvements on these three outcomes between the baseline and 4-week follow-up, whereas the wait list group did not report improvements, showing that the AMI group improved to a greater extent than the wait list controls. However, the improvements reported by the AMI group were not marked enough for the AMI group to differ significantly from the wait list control group at any follow-up time point.

Adherence self-efficacy showed a different pattern compared with eating self-efficacy, whereby both the AMI and wait list groups improved significantly in adherence self-efficacy from baseline to 4 weeks post-intervention. The finding that participants assigned to no treatment conditions show improvements is not uncommon in the literature on randomized controlled psychotherapy trials (e.g., Hesser, Weise, Rief, & Anderrson, 2011; Steketee, Frost, Tolin, Rasmussen, & Brown, 2010; Troeung, Egan, & Gasson, 2014; Zernicke, et al., 2013). One noteworthy study is a randomized controlled trial examining CBT for Posttraumatic Stress Disorder (PTSD) in children and adolescents which found that an unexpectedly high percentage (42%) of wait list participants no longer exhibited symptoms that met criteria for a PTSD diagnosis (Smith et al., 2007). Although the mechanisms underlying wait list improvement remain unclear, potential explanations have been offered in the literature. First, it has been proposed that wait list changes may reflect spontaneous remission over time (Smith et al., 2007). In the current study, however, the observed improvement in the wait list control group contradicts research on the long-term patterns of dietary non-adherence in bariatric surgery patients (Sarwer et al., 2004). Unlike the high recovery rates for individuals with BED without

treatment (Fairburn et al., 2000), the emergence of maladaptive eating patterns post-surgery tend to progressively worsen over time (Sarwer et al., 2004). Second, the therapeutic effect of systematic monitoring of symptoms itself may lead to improvements in outcomes. Indeed, wait list control participants in the current study, like their AMI group counterparts, were required to complete study questionnaires, where they responded to questions about their thoughts and feelings post-surgery, and self-monitored their adherence to the post-operative guidelines. Pre-intervention scores may have been influenced by these assessments and self-monitoring—a strategy used in CBT to increase patient insight and encourage behaviour change. Finally, it has been argued that the expectation of future treatment may trigger a placebo effect, and improve outcomes (Frank & Frank, 1991). Wait list participants in the current study were aware that they would be receiving an intervention in 12 weeks, potentially leading to improvements while they anticipated treatment.

Self-reported guideline adherence was an important secondary behavioural outcome in the current study, given the theoretically-driven hypothesis that improvements in readiness to change and self-efficacy would translate into behaviour change. Interestingly, the wait list control group reported significantly higher VAS adherence than the AMI group at baseline. The cause of the initial discrepancy in VAS adherence ratings between the two groups is unclear, as the baseline assessment was conducted prior to randomization. This baseline difference between groups disappeared within 4 weeks of the AMI group receiving the intervention. However, there was a discrepancy between the pattern of results for guideline adherence, as an interaction was not identified on the self-monitoring checklist. These results provide additional evidence for the inadequate reliability and validity of the two measures of guideline adherence employed in the current study. The interpretation of post-intervention changes to adherence in the present trial is

problematic given the conflicting evidence provided by these two assessment measures. The effect of AMI on bariatric guideline adherence warrants future study with a special consideration for accurate assessment.

Binge eating was regarded as a variable of interest in this study, given that it has been found to affect post-surgical outcome (Hsu et al.,1997; 1998) and has also been a target of AMI treatment in previous research (e.g., Cassin et al., 2008). Not surprisingly given the reduced size of the stomach with RGB, the majority of patients who received the surgery reported no objective eating binges. Patients are unable to eat objectively large amounts of food, yet 39% of patients report experiencing loss of control over eating 24 months post-surgery (White et al., 2010). These factors render the assessment of binge eating behaviours following bariatric surgery challenging. The current study employed the BES, which captures the presence of binge eating characteristics that can still be exhibited by bariatric patients, such as loss of control over eating. The results indicate that AMI exerted a small effect on reducing binge eating characteristics, which was maintained for 12 weeks after the intervention. However, binge eating characteristics in the AMI group were not significantly different from those in the wait list control group at any of the follow-up time points. A comparison between the current study's findings to results seen in the binge eating and BED literature may shed light on the clinical significance of these findings. Cassin and colleagues (2008) found that the AMI group reduced the frequency of participants' objective binge eating to a greater extent than the control group at all follow-up assessment points. The largest effect on binge eating frequency was identified at the end of the follow-up period, 16-weeks post-AMI ($d = 0.80$). This significant trend, whereby improvements in binge eating continue to increase across the follow-up period, may suggest that

the 12-week follow-up utilized in the current study was not sufficient to capture meaningful long-term behaviour changes in binge eating post-AMI.

Generally, there is conflicting evidence regarding the durability of health-related behaviour changes following AMI. Rubak and colleagues (2005) found in their review that studies that included a prolonged follow-up period increased the percentage of studies showing a significant effect. For example, 36% (4/11) of studies with a 12-week follow-up period reported a significant effect compared with 81% (26/32) of studies with a follow-up period of 1 year or longer. However, meta-analytic findings reported that the benefits of AMI decreased significantly as follow-up times increased, whereby large effects were indicated rapidly ($d = 0.77$ at 4 weeks), but gradually declined over time ($d = 0.39$ at 4 to 12 weeks and $d = 0.31$ at 12 to 24 weeks; Hettema et al., 2005). Given conflicting evidence regarding the durability of improvements following AMI, it is difficult to determine whether the current study's follow-up period was adequate to observe changes in binge eating characteristics.

There are numerous potential explanations for the lack of group differences in the current study. First, although post-hoc analyses show that the study was adequately powered to detect at least moderate effect sizes for the between-subjects factor ($d = 0.50$) given the exploratory nature of the study, it is acknowledged that the current study is underpowered to identify between-group differences. A larger sample size would have provided more power to identify meaningful differences between the groups (reducing Type II error). Second, the two groups did demonstrate significant differences in self-reported guideline adherence at baseline, whereby the wait list control group reported being more adherent to the dietary guidelines at the outset of the study. Analysis of Covariance (ANCOVA) is a statistical technique designed to estimate the effect of a dependent variable across levels of an independent variable while controlling for effects that are

not of primary interest. This analysis would typically be employed to control for the baseline group differences observed in the current study, however, for the purposes of the current study, the use of an ANCOVA to control for the effect of VAS adherence scores is inappropriate given the fact that this outcome measure was affected by the intervention. As reviewed in Miller and Chapman (2001), Elashoff (1969) argued that in cases where the covariate is expected to be influenced by the treatment, the regression adjustment in the ANCOVA may remove a portion of the treatment effect or produce an erroneous effect. Without the ability to control for this baseline group difference statistically, the possibility remains that a significant group effect for adherence to dietary guidelines may have been detected across time if the wait list group not reported higher VAS scores at baseline. Third, as previously discussed, improvements in the wait list group would have diminished any between group effects expected. The use of a wait list control group attempts to control for the passage of time and repeated assessment, increasing the internal validity of the study and allowing for greater confidence that the effects found were most likely accounted for by the AMI session. The primary implication of systematic changes seen in the wait list control group is that confidence that systematic changes seen in the AMI group are due to the AMI intervention is reduced—it may be that AMI produces changes that may occur in the absence of this specific intervention. Furthermore, wait list data was not collected at a time point that could be considered equivalent to the immediate post-intervention time point, and hence post-intervention data was not included in wait list comparison analyses. The 4-week follow-up data point from the AMI group was the first time point after the AMI session that was included in these analyses. This limitation is significant given that decline in two outcomes was seen in the AMI group from post-intervention to the 4-week follow-up.

The current study utilized parametric statistics, such as t-tests and Analyses of Variance (ANOVAs), to analyze the results; however, other possible methods could have been employed. A mixed model regression is a more powerful analysis to test both between- and within-group differences as it accounts for the shared variance in hierarchically structured data and accommodates missing data. A disadvantage of this analysis is that it requires large sample sizes for adequate power, which presents an ambitious task for the purposes of a pilot study. Additionally, a Multivariate ANOVA (MANOVA) may have provided results in a more integrative manner, as it facilitates the comparison of multiple dependent variables across a single independent variable. The statistical methods applied in the current study facilitated comparisons with other AMI outcome studies and other research in the bariatric field, but it is important to consider how various statistical approaches may have affected the study's findings.

The non-completion rate in the current study was 19.6%. The increased rate of attrition in the wait list control group is logical given the three additional questionnaire packets the wait list group was required to complete and the 12-week wait-time prior to receiving the intervention. When considering that the dropout rate was only 4.7% for those who actually received the AMI intervention, an advantage in retention is noted. Difficulties with patient attrition in bariatric programs have been noted in the literature (Sarwer et al., 2005). Studies of long-term post-operative psychosocial follow-up in bariatric programs have reported retention rates of approximately 58% (Wolf et al., 2000) to 73% (Choban, Onyejekwe, Burge, & Flancbaum, 1999). Dropout rates ranging from 30% to 34% have been reported by studies examining AMI for eating disorders (Dunn et al., 2006; Feld et al., 2001). Ongoing psychotherapy pilot trials at the Toronto Western Hospital Bariatric Surgery Program have even reported retention rates as low as 50%. Retention rates may have been higher in the present study because the follow-up

assessments were conducted entirely online, reducing the burden placed on participants. Furthermore, the client-centered approach of AMI may be more acceptable to patients. Overall, the relatively large sample recruited over an 8-month period and high retention rate speak to the acceptability of the AMI protocol to bariatric patients and the feasibility of incorporating a one-session intervention of this nature into bariatric surgery programs.

Limitations

Several limitations of the current study warrant discussion. The majority of the study's limitations reflect the fact that the current study was designed as a pilot study. First, it is acknowledged that certain patient demographics were underrepresented in the current study sample, and hence the degree to which findings can be generalized beyond the current sample is restricted. For instance, the current sample was predominantly female, which is typical among bariatric surgery programs (Arkinson, Ji, Fallah, Perez, & Dawson, 2010). Also, the type of bariatric surgery performed in the current sample was primarily RGB (93.0%), which may be problematic given the different physiological effects of RGB versus other bariatric procedures. Furthermore, only 50 participants responded to the 292 recruitment emails that were sent out. This response rate (17.1%) may signify that the current study's sample was subject to nonresponse bias whereby patients who opted to participate in the study may differ from those who did not respond to the email. Two possible reasons that are of particular relevance to the currently study include: a) patients who opted to participate were in need of help, whereas patients who perceived that they were doing well following surgery would not be likely to respond, or b) patients who took the initiative to voluntarily participate may have already been considering change and patients who did not seek out this intervention were less motivated to change or seek help. An interesting direction for this field of work is to examine the effect of

AMI for post-operative patients who do not voluntarily seek help, including individuals brought to the attention of health professionals due to weight regain post-surgery. In addition, the results of the ITT analysis (Appendix I) indicated poorer durability of post-intervention improvements to adherence self-efficacy and confidence in ability to change over the follow-up period relative with the completer analysis. These findings suggest that dropouts fared worse on these outcomes prior to ending participation in the study. The exclusion of dropouts from the present analyses may have resulted in a biased sample of post-operative patients who were more ready to seek help or make changes, which is a commonly cited critique of completer analyses (Gupta, 2011). Overall, the current results should be interpreted as preliminary evidence in support of the acceptability and feasibility of AMI that warrant further investigation with a larger, more representative sample.

Second, the current study did not control for participants' seeking treatment outside of the AMI intervention. All of the participants were currently within the 5-year window for routine follow-up at Toronto Western Hospital. The program mandates a number of routine follow-up appointments with the interdisciplinary team, and offers additional services, such as CBT and dietary consulting, on an as-needed basis. This presents a threat to the internal validity of the study, as participants in the AMI or wait list control group may have been receiving other interventions throughout the study.

Third, despite training in the spirit of MI and in the administration of the protocol, the study therapist was MI trained, but not a MI expert. Independent proficiency in MI requires, at minimum, attendance at intensive MI workshops and regular feedback from experts (Miller, Yahne, Moyers, Martinez, & Pirritano, 2004). Similarly, the adherence raters were not MI experts, and thus were not able to assess therapist competence. However, the effect of MI in a

systematic review and meta-analysis was not found to be dependent on the therapist's professional or educational background (Rubak et al., 2005). Furthermore, the use of a non-expert therapist serves to enhance the external validity of the study, given that most members of bariatric care teams are not MI experts.

Finally, the psychometric properties of the OBESE scale, one of the primary outcome measures, have not yet been assessed. This limitation is not specific to the current study; the field of psychosocial bariatric research remains relatively new, and the literature needed to support the development and testing of new measures that are applicable to bariatric surgery patients remains in its infancy. The OBESE scale was, however, adapted from a psychometrically-sound measure (the WEL Questionnaire; Clark et al., 1991) and was specifically designed for use with bariatric patients for the current study due to lack of an existing measure. The good internal consistency of both parts of the scale in the current sample speaks to its preliminary reliability and validity.

Conclusions and Future Research

Bariatric surgery is currently considered the most effective treatment for weight loss (Colquitt et al., 2005). However, for some patients, post-surgical weight loss is less than optimal. The reasons for weight regain or pre-mature weight loss plateaus are not yet well understood, but studies have demonstrated that disordered eating patterns and poor adherence to the prescribed post-surgical dietary guidelines are related to sub-optimal weight loss following surgery (Sarwer et al., 2008). Strict adherence to the dietary guidelines as well as the reduction of post-surgical eating disturbances may be required to achieve the desired long-term effects. Limitations notwithstanding, the current study provides preliminary support that AMI is an acceptable and feasible brief intervention that may help some bariatric patients feel more ready and able to change their dietary patterns after surgery as compared with before the intervention, and which

may translate into behavioural changes across a 12-week evaluation period. The results of the current pilot study suggest that AMI might not have a significant advantage over a wait list control group; however, these findings should be replicated in a sample that is equivalent on all outcome measures at baseline and sufficiently powered to detect between-group differences. The current study's strong recruitment of post-operative patients (n = 66 over 8 months) and high retention in the study (76.8% after consent; 97.7% after the AMI session) speaks to the acceptability and feasibility of integrating AMI into standard bariatric care if future studies should find AMI to improve outcomes following bariatric surgery.

This study represents the first attempt to apply AMI to increase adherence to post-surgical dietary guidelines in bariatric patients. Some positive results of the present study provide an impetus to pursue this line of research; however a lack of group differences between the AMI and wait list groups signify that the immediate next step should be to replicate the current study while addressing its limitations to learn more about the efficacy of AMI in this application to bariatric patients prior to conducting a larger randomized controlled trial. For example, the first step to build upon the results of this study may be to implement a methodology that will control for extraneous variables. One proposed design is to examine data from post-operative patients who receive AMI in comparison to routinely collected post-surgical follow-up data from bariatric programs as well as data from wait list controls. This approach would allow researchers to isolate any effect that the anticipation of receiving AMI had on the scores during the waiting period. Furthermore, the adherence checklist utilized in the current study could be removed in order to increase confidence that any effect observed was due to AMI and not self-monitoring.

Additionally, future studies should examine the role that AMI plays in overall treatment for post-operative patients. Given the versatility of AMI, it may be implemented into bariatric

care in a number of ways. Not only could AMI be used as a adjunct to bariatric care as it was in the current study, but the approach has shown success when employed as an additive component or prelude to more specific action-oriented empirically-supported treatments. One notable finding from the current study is the high retention rate of participants, as it is in stark contrast to reports in the literature and at Toronto Western Hospital of poor attendance at routine program follow-up appointments. As time after surgery increases, the percentage of patients attending post-surgical evaluations has been shown to decrease. For example, one study reported that attendance at post-operative follow-up appointments decreased from 89% at 3 months to 68% at 24 months (Wolf et al., 2001), and attendance rates of 50% have been reported at 24-month follow-up appointments at Toronto Western Hospital (Sockalingam et al., 2013). Non-attendance at post-operative appointments has consistently been associated with diminished weight loss post-surgery (Dymek, le Grange, Neven, & Alverdy, 2001; Halverson & Koehler, 1981). AMI may hold promise as an adjunct to standard bariatric care to improve attendance at follow-up appointments, which may have implications for improved weight loss. Furthermore, results from an ongoing telephone CBT trial at Toronto Western Hospital have reported dropout rates as high as 50%. AMI as a prelude to CBT, a skill-oriented approach, has been shown to be a promising therapeutic partnership in previous studies (e.g., Westra & Dozois, 2006), and could be a consideration for future bariatric research.

Next, it would be beneficial to determine whether a higher dose of AMI is more efficacious for post-operative patients. The present study provided only one AMI session to participants, and future research may benefit from examining whether the effect of the intervention may be enhanced by booster sessions. Although there are numerous reports in the literature that argue AMI can be delivered in small doses for the purposes of inciting dietary

changes and reducing eating pathology (e.g., VanWormer & Boucher, 2004; Cassin et al., 2008), a meta-analysis found a positive relationship between length of treatment and outcomes, suggesting that MI exerts a dose-response effect (Lundahl. Kunz, Brownell, Tollefson, & Burke, 2010). Furthermore, for complex adherence issues, as those seen in bariatric patients, more than a single session may be required to effectively target problem behaviours. AMI was designed to be a scalable treatment for flexible implementation across health care settings in this way.

An important avenue for future research involves replicating the current study with the addition of more objective outcome measures. The current pilot study relied solely on self-report measures, and yet systematic reviews (e.g., Rubak et al., 2005) show that MI can effect change on both indirect measures, such as questionnaires, and direct measures, such as BMI, glycemic control, and blood pressure. When possible, future studies should bolster reliability of the results by using these objective measures to help measure treatment effects.

Finally, the next generation of bariatric research should work towards operationalizing post-operative success, and developing tools to assess for these outcomes. This field remains relatively new, and, at present, divided on the issue of defining important parameters of success after surgery. The lack of agreement on what constitutes post-operative success and the dearth of standardized assessment tools developed for this unique patient population may contribute to a literature that offers little information about how to improve post-operative outcome (Sarwer, Wadden, & Fabricatore, 2005). Of particular relevance to the current study is the fact that no gold standard criteria exist for evaluating adherence in the context of bariatric surgery. The identification of a threshold between what may be considered an acceptable versus harmful level of non-adherence to the post-operative dietary guidelines would facilitate a full appreciation for the meaningfulness of the treatment effect observed in studies such as the present one.

Table 1

Timing of Assessments

Measures/Interventions	Baseline	Post Intervention[a]	Post-baseline and follow-up		
			4-week	8-week	12-week
Demographics	X				
OBESE Scale	X	X	X	X	X
Change Ratings	X	X	X	X	X
Binge Eating Scale	X		X	X	X
Behavioural Adherence	X		X	X	X

[a] *Post-intervention measures were only administered to those actively receiving the intervention.*

Table 2

Comparison of Completers and Dropouts at Baseline

Variable	Completers (n = 45) *M (SD)*	Dropouts (n = 6) *M (SD)*	t(49)
Age[a]	49.2 (8.9)	46.0 (8.6)	0.76
Months since surgery	26.7 (10.6)	29.4 (6.1)	0.55
OBESE Scale			
Part I	6.7 (2.1)	7.2 (2.7)	0.45
Part II	7.1 (1.6)	6.5 (.7)	0.83
Change Ratings			
Importance of Change	9.0 (1.1)	8.8 (1.3)	0.37
Readiness for Change	7.8 (1.6)	8.0 (2.3)	0.54
Confidence for Change	6.4 (2.1)	7.0 (2.9)	0.25
Behavioural Adherence			
Self-monitoring checklist	5.5 (1.2)	5.4 (.8)	0.09
VAS	63.4 (23.1)	49.6 (27.7)	1.24
Binge Eating Scale	15.4 (9.2)	17.2 (10.5)	0.41

Note. Independent-samples t-tests were performed. The completers and dropouts did not differ significantly from one another on any variable.

[a]When the three wait list participants who completed all of the post-baseline questionnaires but did not receive the AMI were included in these analyses as 'dropouts' rather than as 'completers', an age difference between completers (n = 42) and dropouts (n = 9) was identified whereby dropouts were more likely to be younger (M = 42.1, SD = 8.5) compared with completers (M = 50.1, SD = 8.4), t(49) = 2.46, p = .018.

Table 3

Comparison of AMI and Wait List Control Groups at Baseline

Variable	AMI (n = 23) *M (SD)*	Control (n = 23) *M (SD)*	$t(44)$
Age	49.9 (8.4)	48.3 (9.5)	0.58
Gender			
Female	n = 20 (87.0%)	n = 19 (82.6%)	
Male	n = 3 (13.0%)	n = 4 (17.4%)	
Months since surgery	28.2 (10.9)	25.5 (10.2)	0.96
OBESE Scale			
Part I	6.39 (2.2)	7.07 (1.9)	1.15
Part II	7.0 (1.6)	7.3 (1.6)	0.61
Change Ratings			
Importance of Change	8.8 (1.1)	9.2 (1.2)	1.04
Readiness for Change	7.7 (1.6)	7.9 (1.6)	0.27
Confidence for Change	6.0 (2.3)	6.9 (1.9)	1.37
Behavioural Adherence			
Self-monitoring	5.53 (1.2)	5.39 (1.2)	0.40
VAS	56.4 (24.3)	70.5 (20.3)	2.12*
Binge Eating Scale	17.9 (9.0)	12.9 (8.9)	1.90

Note. Independent-samples t-tests were conducted to compare groups on demographic variables and on baseline variables. The two groups did not differ on any demographic or study variable at baseline except for the adherence VAS rating. OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale.

* $p < .05$

Table 4

Means (and Standard Deviations) of AMI Adherence Ratings

Adherence Rating Dimension	Rater 1	Rater 2
Motivational Interviewing	6.17 (.58)	6.33 (.65)
Open-Ended Questions	6.42 (.67)	5.58 (.67)
Strengths & Self-Efficacy	6.25 (.62)	6.42 (.67)
Reflective Statements	6.92 (.29)	6.58 (.52)
Fostering Collaboration	5.83 (.58)	5.67 (.49)
Motivation to Change	6.33 (.49)	6.42 (.52)
Heightening Discrepancies	5.42 (.67)	5.17 (.72)
Pros, Cons, & Ambivalence	6.58 (.52)	6.33 (.65)
Change Plan Discussion	6.67 (.65)	6.33 (.89)

Note. 12 tapes (27.9%) of adapted motivational interview sessions were randomly selected for the adherence ratings. Ratings were made on a 7-point scale from 1 (not at all present during session) to 7 (extensively present during session).

Table 5

Primary Changes Immediately Following the AMI Intervention

Variable	Pre-AMI *M (SD)*	Post-AMI *M (SD)*	*t*(42)	*ES* (*d*)
OBESE Scale				
Part I	6.72 (2.1)	7.67 (1.5)	3.53***	0.53
Part II	7.13 (1.6)	8.31 (1.3)	5.55***	0.70
Change Ratings				
Importance of Change	9.07 (0.9)	9.35 (0.9)	1.74	0.38
Readiness for Change	7.98 (1.4)	8.56 (1.5)	2.31*	0.43
Confidence for Change	6.49 (2.2)	8.13 (1.7)	6.43 ***	0.79

Note. Paired-samples t-tests were conducted to compare participants' responses (n = 46) before and immediately after the AMI intervention. ES = effect size (.2 = small effect, .5 = medium effect, .8 = large effect; Cohen, 1992). Effect sizes were computed from the t-tests (Thalheimer & Cook, 2002). AMI = Adapted Motivational Interview, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale.

* $p < .05$; ** $p < .01$; *** $p < .001$

Table 6

Durability of Acute Primary and Secondary Effects Over the 12-Week Follow-up Period

	Post-AMI (n = 37)	4-week follow-up (n = 37)	8-week follow-up (n = 37)	12-week follow-up (n = 37)		
Primary Effects	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*F(3, 108)*	*ES* (η^2_P)
OBESE Scale						
Part I	7.7 (1.6)	7.4 (1.8)	7.8 (1.6)	7.5 (2.1)	2.29	.060
Part II	8.3 (1.3)	7.9 (1.7)	8.1 (1.4)	8.0 (1.5)	3.19*	.081
Change Ratings						
Importance of Change	9.5 (0.9)	9.0 (1.2)	9.2 (1.1)	9.2 (0.9)	--	
Readiness for Change	8.6 (1.6)	8.5 (1.6)	8.5 (1.1)	8.3 (1.2)	0.72	.021
Confidence for Change	8.2 (1.7)	7.4 (2.0)	7.7 (1.6)	7.5 (2.0)	5.52**	.133
Secondary Effects	--	*M (SD)*	*M (SD)*	*M (SD)*	*F (2, 72)*	*ES*
Behavioural Adherence						
Checklist	--	5.7 (1.2)	5.7 (1.3)	5.9 (0.9)	--	
VAS	--	71.6 (21.3)	70.6 (22.5)	72.5 (23.3)	0.26	.007
Binge Eating Scale	--	13.0 (10.2)	11.6 (9.2)	11.4 (9.9)	2.16	.057

Note. One-way repeated measures ANOVAs were conducted to compare the maintenance of acute treatment effects over the 12-week follow-up. No acute changes were seen in Importance of Change post-intervention or in the adherence checklist at 4-weeks post-AMI, and thus ANOVAs were not conducted on these variables. Effect sizes (partial eta-squared; η^2_P) were computed from the F-tests

(Fritz, Morris, & Richler, 2012). *ES* = effect size (.02 = small effect, .13 = medium effect, .26 = large effect; Fritz, Morris, & Richler, 2012). AMI = Adapted Motivational Interview, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale.

* $p < .05$; ** $p < .01$; *** $p < .001$.

Table 7

Secondary Changes 4 Weeks Following the AMI Intervention

Variable	Pre-AMI *M (SD)*	4-week follow-up *M (SD)*	*t*(41)	*ES* (*d*)
Behavioural adherence				
Checklist	5.32 (1.5)	5.66 (1.1)	1.64	0.18
VAS	61.83 (23.9)	70.83 (21.3)	3.41**	0.35
Binge Eating Scale	15.63 (9.4)	13.0 (10.0)	2.87*	0.33

Note. Paired-samples t-tests were conducted to compare participants' responses ($n = 42$) before and 4 weeks after the intervention. Effect sizes were computed from the t-tests (Thalheimer & Cook, 2002). *ES* = effect size (.2 = small effect, .5 = medium effect, .8 = large effect; Cohen, 1992). AMI = Adapted Motivational Interview, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale.

* $p < .05$; ** $p < .01$; *** $p < .001$.

Table 8

Primary and Secondary Effects in the AMI and Wait List Control Groups During the 12-Week Follow-Up/Post-Baseline Period

	OBESE Scale		Change Ratings			Guideline Adherence		BES
	Part I	Part II	Importance	Readiness	Confidence	Checklist	VAS	
Time	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*
AMI Group (*n* = 21)								
Baseline	6.4 (2.2)	7.0 (1.6)	8.8 (1.1)	7.6 (1.6)	6.0 (2.3)	5.4 (1.7)	57.0 (24.6)	16.1 (8.6)
4 week follow-up	7.2 (2.0)	7.6 (1.8)	8.7 (1.4)	8.1 (2.0)	7.0 (2.4)	5.4 (1.3)	68.6 (23.7)	13.9 (10.5)
8 weeks follow-up	7.8 (1.6)	7.8 (1.5)	9.1 (1.1)	8.3 (1.2)	7.5 (1.8)	5.5 (1.5)	66.7 (25.2)	12.9 (8.9)
12-week follow-up	7.4 (2.3)	7.8 (1.7)	9.0 (11)	8.0 (1.2)	7.3 (2.2)	5.8 (.09)	71.6 (26.3)	12.7 (10.1)
WLC Group (*n* = 23)								
Baseline	7.1 (1.9)	7.3 (1.6)	9.2 (1.2)	7.8 (1.7)	6.9 (1.9)	5.4 (1.9)	70.5 (20.3)	12.9 (8.8)
4-week post-BL	7.4 (1.8)	7.8 (1.3)	8.9 (1.6)	8.0 (1.7)	7.0 (1.8)	5.9 (0.9)	70.6 (21.4)	11.9 (7.9)

8-week post-BL	7.2 (1.7)	7.7 (1.3)	8.9 (1.7)	7.8 (2.0)	6.8 (2.6)	5.7 (1.2)	64.0 (25.9)	13.1 (8.7)
12-week post-BL	7.2 (1.4)	7.6 (1.3)	9.0 (1.3)	7.7 (2.0)	7.1 (1.9)	5.5 (1.3)	72.2 (22.8)	13.3 (8.1)
Mixed Model ANOVA	*F (3, 126)*	*F (3, 126)*	*F (3, 126)*	*F (3, 126)*	*F (3, 126)*	*F (3, 126)*	*F (2.7, 111.6)*	*F (3, 126)*
Time ME	5.05**	8.23**	0.65	1.13	4.67**	0.85	4.35**	3.25*
ES (η^2_P)	.107	.164	.015	.026	.100	.021	.094	.072
Group ME	0.07	0.005	0.11	0.20	0.00	0.09	0.28	0.26
ES (η^2_P)	.00	.00	.003	.005	.000	.002	.007	.006
Group x Time effect	3.16*	1.23	0.81	1.32	3.91**	1.28	3.81**	4.17**
ES (η^2_P)	.07	.029	.019	.031	.085	.03	.083	.090

Note. Mixed model ANOVAs were conducted to test for Group x Time interactions, as well as for Time and Group main effects across outcome variables. Effect sizes (partial eta-squared; η^2_P) were computed from the F-tests (Fritz, Morris, & Richler, 2012). *ES* = effect size (.02 = small effect, .13 = medium effect, .26 = large effect; Fritz, Morris, & Richler, 2012). AMI = Adapted Motivational Interview group, WLC = wait list control group, BL = baseline, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale, BES = Binge Eating Scale, ME = main effect.

- $p < .05$; * $p < .01$; ** $p < .001$***.

Table 9

Durability of Acute Primary and Secondary Effects Over the 12-Week Follow-up Period Using Intention-to-Treat Analyses

	Post-AMI (n = 43)	4-week follow-up (n = 43)	8-week follow-up (n = 43)	12-week follow-up (n = 43)		
Primary Effects	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*F(3, 120)*	*ES* (η^2_P)
OBESE Scale						
Part I	7.7 (1.6)	7.4 (1.8)	7.7 (1.6)	7.4 (2.1)	2.02	.048
Part II	8.3 (1.3)	7.9 (1.6)	8.0 (1.4)	7.9 (1.5)	3.65*	.084
Change Ratings						
Importance of Change	9.4 (0.9)	9.0 (1.2)	9.2 (1.1)	9.2 (0.9)	--	--
Readiness for Change	8.6 (1.5)	8.4 (1.5)	8.5 (1.1)	8.3 (1.2)	0.77	.019
Confidence for Change	8.1 (1.7)	7.3 (2.1)	7.6 (1.8)	7.4 (2.0)	7.11***	.151
Secondary Effects	--	*M (SD)*	*M (SD)*	*M (SD)*	*F (2, 80)*	*ES*
Behavioural Adherence						
Checklist	--	5.6 (1.1)	5.7 (1.2)	5.9 (0.9)	--	--
VAS	--	70.7 (21.3)	70.2 (22.5)	71.8 (23.3)	0.23	.006
Binge Eating Scale	--	13.2 (10.1)	11.8 (9.2)	11.5 (9.6)	3.11	.072

Note. One-way repeated measures ANOVAs were conducted to compare the maintenance of acute treatment effects over the 12-week follow-up. No acute changes were seen in Importance of Change at post-intervention or in the adherence checklist at 4-weeks post-AMI, and thus ANOVAs were not conducted on these variables. Effect sizes (partial eta-squared; η^2_P) were computed from the F-tests

(Fritz, Morris, & Richler, 2012). *ES* = effect size (.02 = small effect, .13 = medium effect, .26 = large effect; Fritz, Morris, & Richler, 2012). AMI = Adapted Motivational Interview, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale.

- $p < .05$; ** $p < .01$; *** $p < .001$.

Table 10

Primary and Secondary Effects in the AMI and Wait List Control Groups During the 12-Week Follow-Up/Post-Baseline Period Using Intention-to-Treat Analyses

	OBESE Scale		Change Ratings			Guideline Adherence		BES
	Part I	Part II	Importance	Readiness	Confidence	Checklist	VAS	
Time	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*
AMI Group (*n* = 23)								
Baseline	6.4 (2.2)	7.0 (1.6)	8.8 (1.1)	7.6 (1.6)	6.0 (2.3)	5.3 (1.6)	56.4 (24.3)	17.0 (8.8)
4 week follow-up	7.1 (2.0)	7.6 (1.8)	8.7 (1.4)	8.1 (2.0)	7.0 (2.4)	5.4 (1.2)	66.9 (24.0)	14.8 (10.4)
8 weeks follow-up	7.6 (1.7)	7.7 (1.5)	9.1 (1.1)	8.3 (1.2)	7.5 (1.8)	5.5 (1.4)	65.9 (25.5)	13.4 (8.9)
12-week follow-up	7.1 (2.4)	7.7 (1.7)	9.0 (11)	8.0 (1.2)	7.3 (2.2)	5.8 (0.9)	70.1 (26.6)	12.9 (9.8)
WLC Group (*n* = 23)								
Baseline	7.1 (1.9)	7.3 (1.6)	9.2 (1.2)	7.9 (1.7)	6.9 (1.7)	5.4 (1.2)	70.5 (20.3)	12.9 (8.9)
4-week post-BL	7.4 (1.7)	7.8 (1.3)	8.9 (1.6)	8.0 (1.7)	7.0 (1.8)	5.9 (0.9)	70.7 (21.4)	11.9 (7.9)

8-week post-BL	7.2 (1.7)	7.7 (1.3)	8.9 (1.7)	7.8 (2.0)	6.8 (2.6)	5.7 (1.2)	64.0 (25.9)	13.4 (8.7)
12-week post-BL	7.2 (1.4)	7.6 (1.3)	9.0 (1.3)	7.7 (2.0)	7.1 (1.9)	5.5 (1.3)	72.2 (22.8)	13.3 (8.1)
Mixed Model ANOVA	*F (3, 132)*	*F (3, 132)*	*F (3, 132)*	*F (3, 132)*	*F (3, 132)*	*F (3, 132)*	*F (3,132)*	*F (3, 132)*
Time ME	3.83*	7.42***	0.75	0.92	4.15**	1.03	4.19**	3.85*
ES (η^2_P)	.080	.144	.017	.020	.086	.023	.087	.08
Group ME	0.13	0.07	0.06	0.56	0.029	0.18	0.51	0.34
ES (η^2_P)	.003	.002	.001	.008	.001	.003	.011	.17
Group x Time effect	2.15*	0.65	0.73	1.20*	3.60*	1.56	3.87*	5.27**
ES (η^2_P)	.047	.015	.017	.027	.076	.034	0.81	.12

Note. Mixed model ANOVAs were conducted to test for Group x Time interactions, as well as for Time and Group main effects across outcome variables. Effect sizes (partial eta-squared; η^2_P) were computed from the F-tests (Fritz, Morris, & Richler, 2012). *ES* = effect size (.02 = small effect, .13 = medium effect, .26 = large effect; Fritz, Morris, & Richler, 2012). AMI = Adapted Motivational Interview, WLC = wait list control group, BL = baseline, OBESE = Ontario Bariatric Eating Self-Efficacy, VAS = Visual Analogue Scale, BES = Binge Eating Scale, ME = main effect.

* $p < .05$; ** $p < .01$; *** $p < .001$.

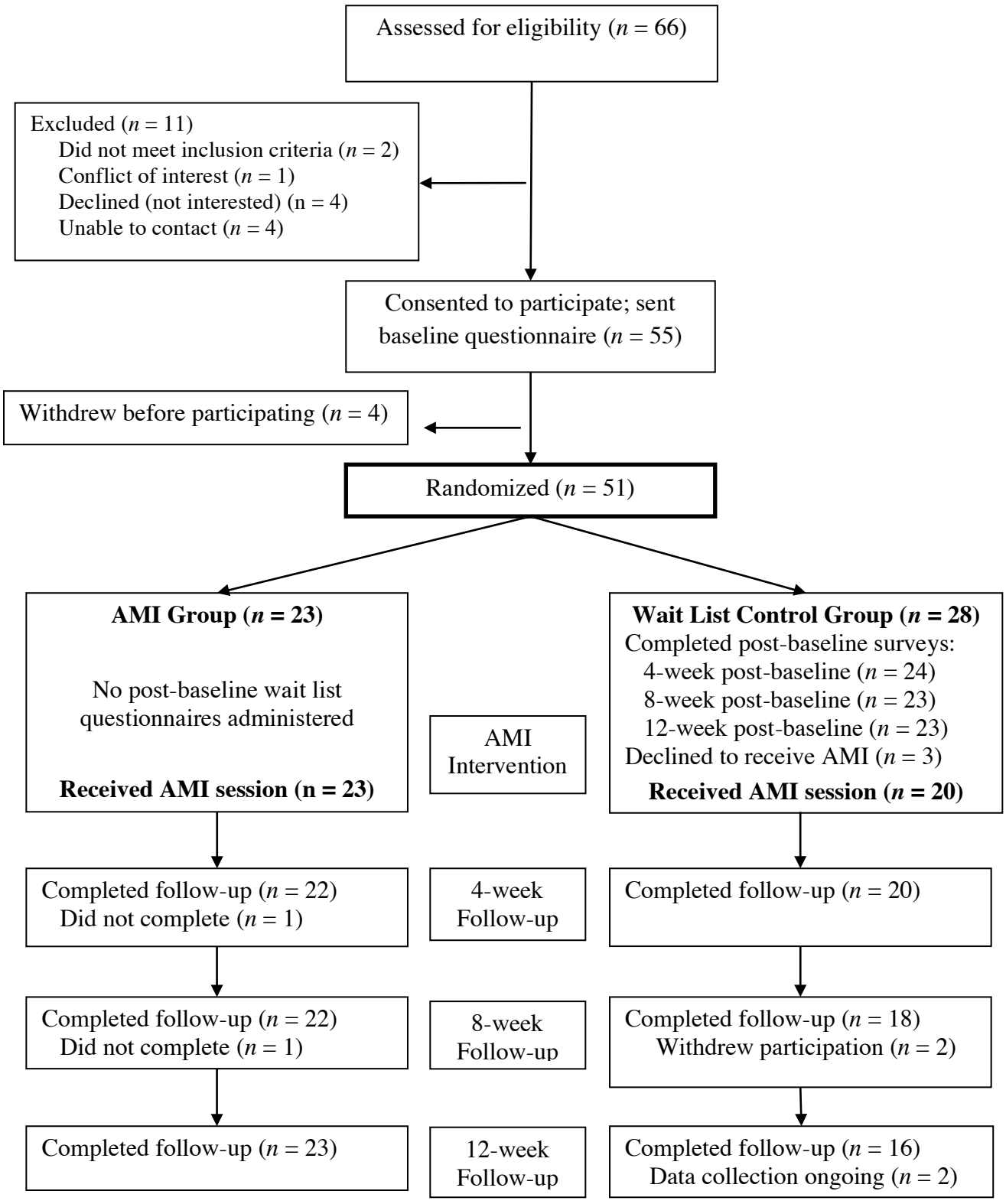


Figure 1. Summary of participant flow. AMI = Adapted Motivational Interview

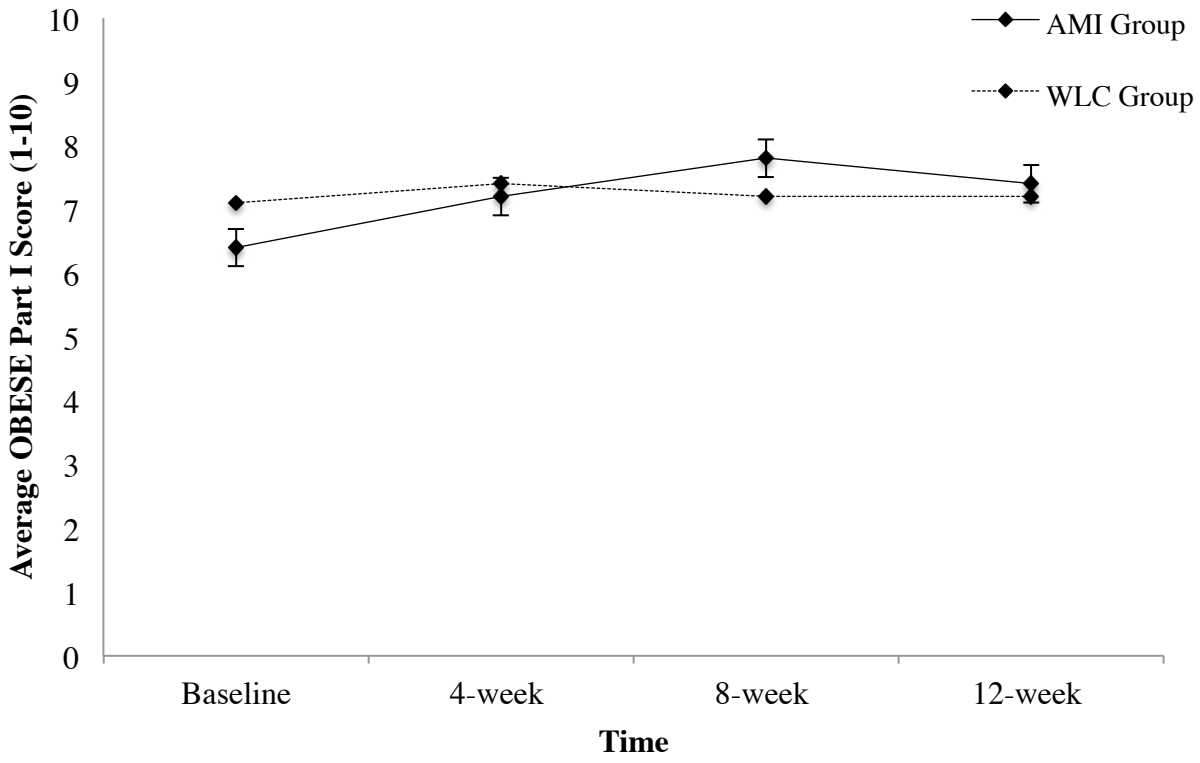


Figure 2. Group by Time Interaction on Eating Self-Efficacy Over the 12-Week Follow-Up/Post-Baseline Period. Group differences are not observed at any of the time points. The AMI group improved significantly from baseline to the 4-week follow-up while the wait list group did not show any significant changes across post-baseline time points. Error bars represent standard errors. AMI = Adapted Motivational Interview, WLC = wait list control.

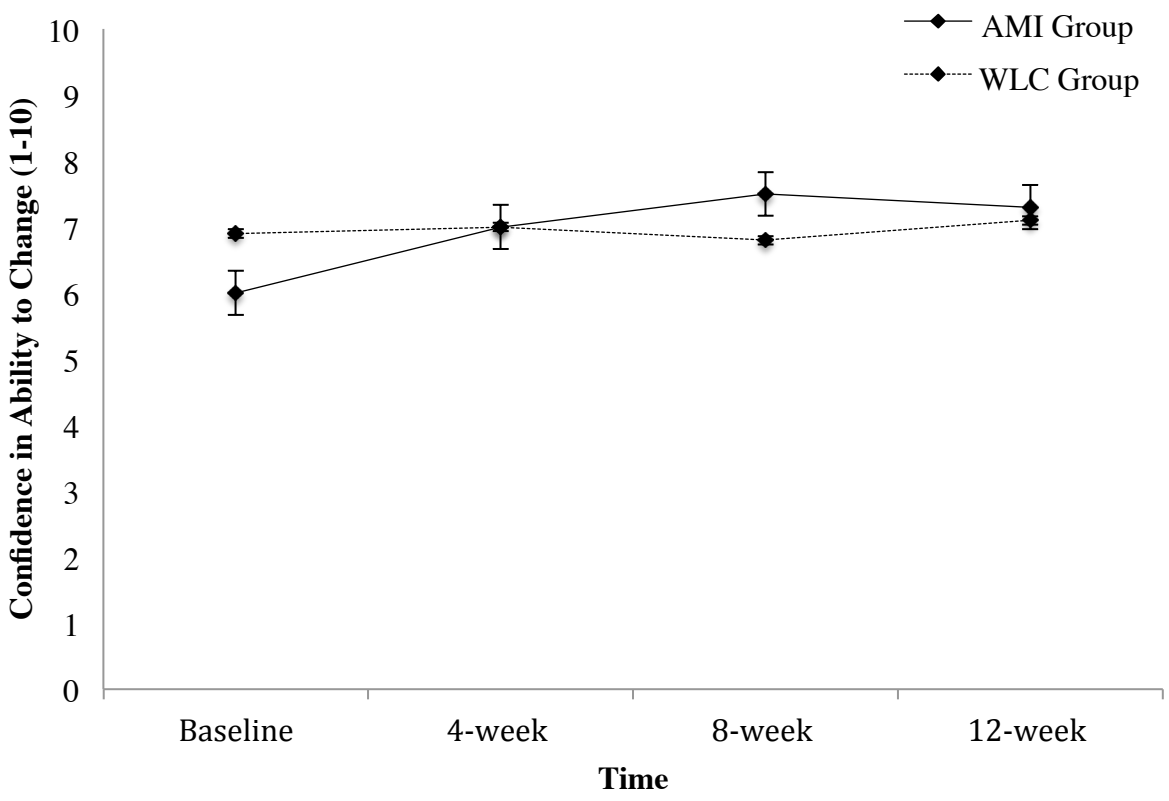


Figure 3. Group by Time Interaction on Confidence in Ability to Change Over the 12-Week Follow-Up/Post-Baseline Period. Group differences are not observed at any of the time points. The AMI group improved significantly from baseline to the 4-week follow-up while the wait list group did not show any significant changes across post-baseline time points. Error bars represent standard errors. AMI = Adapted Motivational Interview, WLC = wait list control.

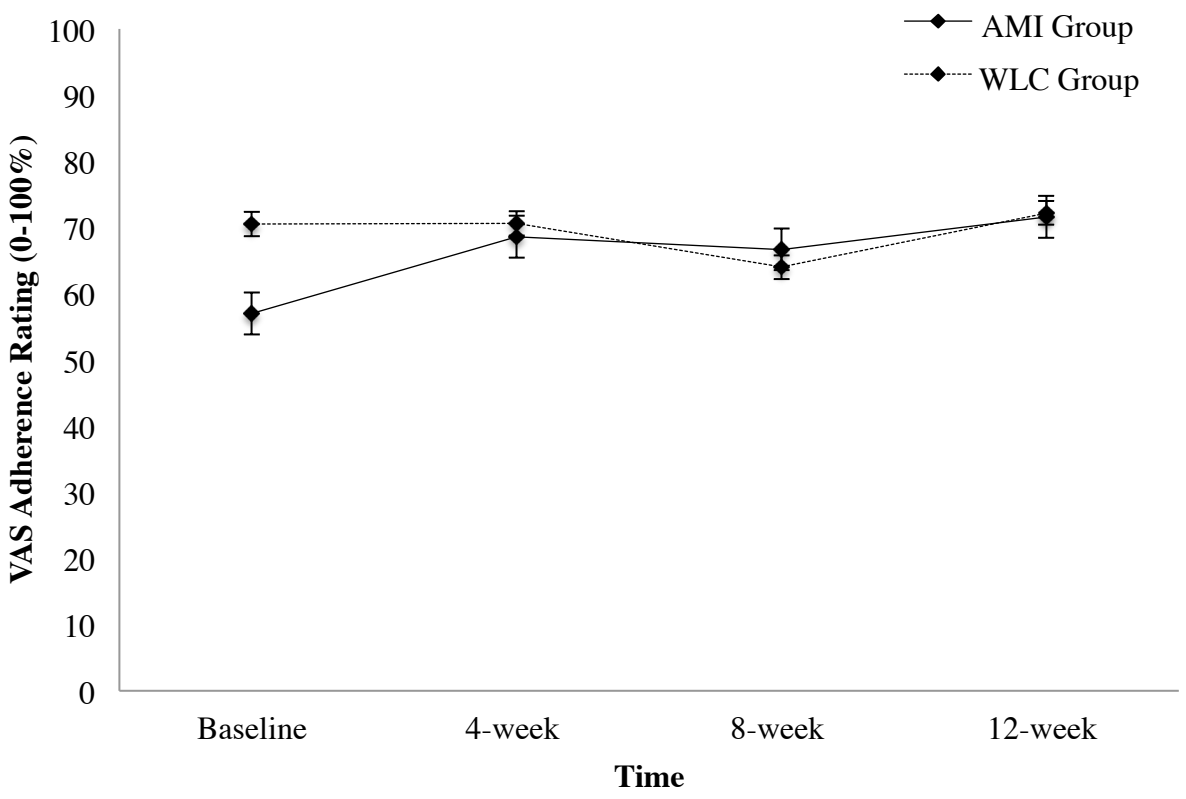


Figure 4. Group by Time Interaction on Self-Reported Guideline Adherence Over the 12-Week Follow-Up/Post-Baseline Period. Group differences are observed at baseline, but are not seen at any of the post-intervention follow-up points. The AMI group improved significantly from baseline to the 4-week follow-up while the wait list group did not show any significant changes across post-baseline time points. Error bars represent standard errors. AMI = Adapted Motivational Interview, WLC = wait list control.

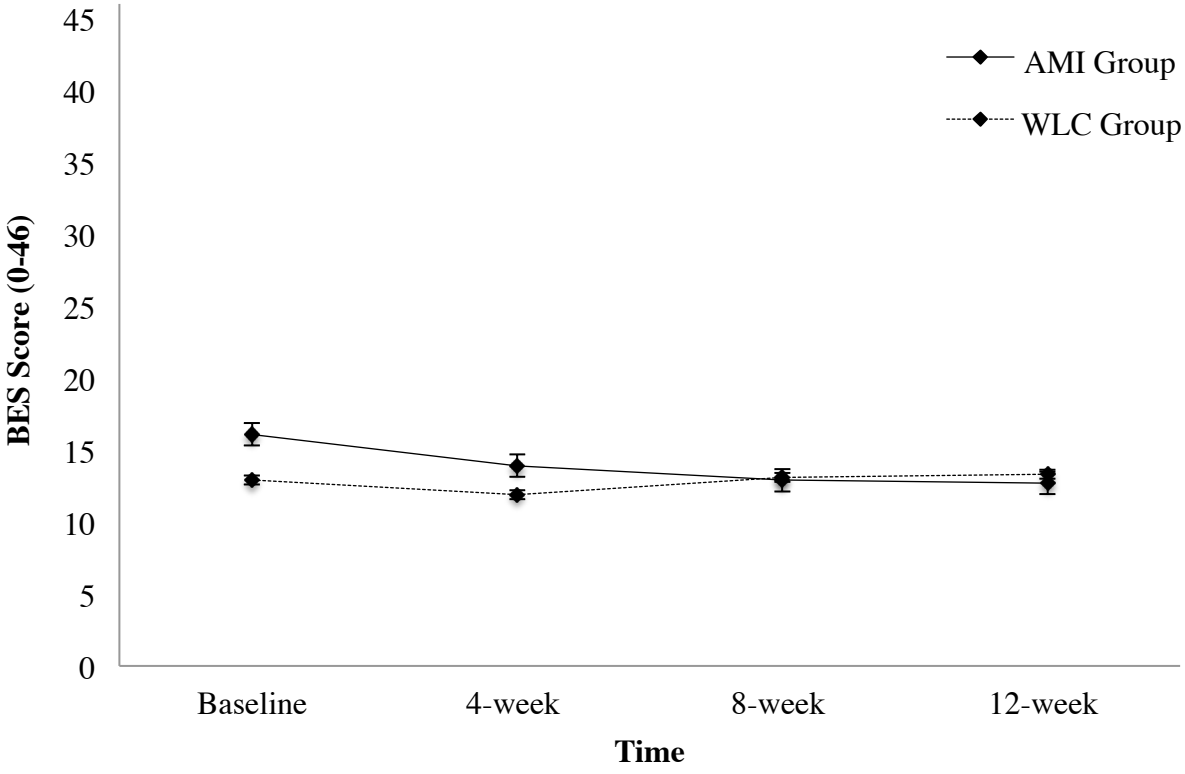


Figure 5. Group by Time Interaction on Binge Eating Characteristics Over the 12-Week Follow-Up/Post-Baseline Period. Group differences are not observed at any of the time points. The AMI group reduced binge eating characteristics significantly from baseline to the 4-week follow-up while the wait list group did not show any marked changes across post-baseline time points. Error bars represent standard errors. AMI = Adapted Motivational Interview, WLC = wait list control.

Appendix A

Invitation to Participate in Research Study Email

Hello,

I am contacting you to introduce you to researchers at Ryerson University who are currently recruiting bariatric surgery patients registered with the Toronto Western Hospital Bariatric Surgery Program. During one of your past visits at the Bariatric Program you agreed to be contacted by researchers about upcoming studies. Dr. Stephanie Cassin (Assistant Professor in the Department of Psychology, and a former Psychologist at the Bariatric Surgery Program) and Lauren David (graduate student), together with Dr. Sanjeev Sockalingam (Director of the Toronto Western Hospital Bariatric Surgery Psychosocial Program), are conducting a study to examine the helpfulness of specific interview techniques in improving peoples' ability to make healthy lifestyle choices and meet weight loss goals after surgery.

For more information about this research study and to participate, please see the attached study brochure. You don't need to fill in the information on the second sheet of the brochure if you're interested in participating, simply contact the Ryerson research team via telephone at 416-979-5000 x. 3232 or by email at heal@ryerson.ca.

Please be advised that e-mail is not a secure form of communication and sensitive personal information should not be disclosed in emails.

Thank you for your consideration,

[inset health practitioner/clinical staff]

Appendix B

Recruitment Poster

BARIATRIC SURGERY PARTICIPANTS WANTED

ARE YOU HAVING DIFFICULTY MAKING OR MAINTAINING HEALTHY CHANGES FOLLOWING BARIATRIC SURGERY?

- *Would you be interested in participating in a research study designed to examine techniques that may enhance one's ability to make healthy lifestyle adjustments and to meet weight loss goals post-surgery?*

The study requires participants to complete:

- An **interview** - focused on your experiences sticking to dietary recommendations and making lifestyle changes after surgery
- A **questionnaire packet** – includes questions about eating behaviours and emotional functioning (completed online at your convenience)

You will be compensated for your time and reimbursed for travel expenses

Location: Toronto Western Hospital and/or Ryerson University
Investigators: Dr. Sockalingam, Dr. Cassin, & L. David.

For more information on this study, please contact:

heal@ryerson.ca* (416) 979-5000 ext. 3232

*Please note that email correspondence is not guaranteed to be secure and personal sensitive information should not be communicated via email

Appendix C

Measures Used in the Current Study

Ontario Bariatric Eating Self-Efficacy Scale (OBESE Scale)

Bariatric surgery requires significant changes to your dietary habits, some of which are very challenging for many people to make. We would like to know how confident you are that you will be able to make these changes following bariatric surgery. **Please answer honestly** so we can identify areas that you might require additional help with in order to adapt to the changes afterwards.

Part A Instructions:

On a scale from 1 (not at all confident) to 10 (extremely confident), rate how confident you feel right now that you would be able to resist overeating in each of the situations below. In other words, pretend that you are in each of the situations below right now.

Not at all confident Extremely confident

1 2 3 4 5 6 7 8 9 10

I FEEL CONFIDENT THAT:

1. I can resist overeating when I feel anxious or stressed out.	1 2 3 4 5 6 7 8 9 10
2. I can resist overeating on the weekends.	1 2 3 4 5 6 7 8 9 10
3. I can resist overeating when I feel physically run down.	1 2 3 4 5 6 7 8 9 10
4. I can resist overeating when I feel stuck on a problem.	1 2 3 4 5 6 7 8 9 10
5. I can resist overeating when I am watching TV.	1 2 3 4 5 6 7 8 9 10
6. I can resist overeating when I am alone.	1 2 3 4 5 6 7 8 9 10
7. I can resist overeating when I feel depressed (or down).	1 2 3 4 5 6 7 8 9 10
8. I can resist overeating when I have a headache.	1 2 3 4 5 6 7 8 9 10
9. I can resist overeating when I feel overworked.	1 2 3 4 5 6 7 8 9 10
10. I can resist overeating when I am reading.	1 2 3 4 5 6 7 8 9 10

11. I can resist overeating when I feel angry (or irritable).	1 2 3 4 5 6 7 8 9 10
12. I can resist overeating when I am at a party.	1 2 3 4 5 6 7 8 9 10
13. I can resist overeating when I have conflict with others.	1 2 3 4 5 6 7 8 9 10
14. I can resist overeating when I feel bored.	1 2 3 4 5 6 7 8 9 10
15. I can resist overeating when I am in pain.	1 2 3 4 5 6 7 8 9 10
16. I can resist overeating just before going to bed.	1 2 3 4 5 6 7 8 9 10
17. I can resist overeating when I have experienced failure.	1 2 3 4 5 6 7 8 9 10
18. I can resist overeating when I feel lonely.	1 2 3 4 5 6 7 8 9 10
19. I can resist overeating when my favourite foods are available.	1 2 3 4 5 6 7 8 9 10

Part B

Instructions: On a scale from 1 ("*Not at all confident*") to 10 ("*Extremely confident*"), rate how confident you feel right now that you would be able to follow the dietary recommendations below.

Not at all confident Extremely confident

1 2 3 4 5 6 7 8 9 10

I FEEL CONFIDENT THAT:

20. I can consume three small meals and two snacks daily.	1 2 3 4 5 6 7 8 9 10
21. I can consume my meals/snacks every 3-4 hours daily.	1 2 3 4 5 6 7 8 9 10
22. I can consume all of my meals and snacks slowly (e.g., 30 minutes).	1 2 3 4 5 6 7 8 9 10
23. I can consume the recommended amount of protein daily.	1 2 3 4 5 6 7 8 9 10
24. I can consume the recommended amount of fluids daily.	1 2 3 4 5 6 7 8 9 10
25. I can consume the recommended amount of nutritional supplements	1 2 3 4 5 6 7 8 9 10
26. I can limit my consumption of alcoholic beverages.	1 2 3 4 5 6 7 8 9 10
27. I can resist drinking fluids with my meals.	1 2 3 4 5 6 7 8 9 10
28. I can resist consuming carbonated beverages (e.g., pop).	1 2 3 4 5 6 7 8 9 10

Self-Monitoring Behavioural Adherence Checklist

Instructions:

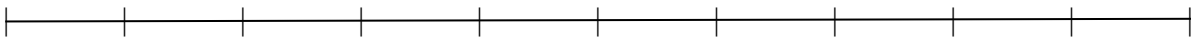
a) The following checklist is designed to help us get a better understanding of your dietary patterns over the **past week**. Please respond as honestly as possible so we have an accurate understanding of your dietary patterns.

If the statement is true, place a check mark in the box: ☑

	Mon	Tues	Wed	Thur	Fri	Sat	Sun
I consumed three small meals and two snacks.							
I consumed my meals/snacks every 3-4 hours.							
I consumed all of my meals and snacks slowly (e.g., 30 minutes per meal).							
I consumed the recommended amount of protein.							
I consumed the recommended amount of fluids.							
I consumed the recommended amount of nutritional supplements.							
I limited my consumption of alcoholic beverages.							
I did not drink fluids with my meals.							
I did not consume carbonated beverages.							

Adherence Visual Analogue Scale

b) How well do you feel that you've been able to adhere to the post-operative dietary guidelines over the past week?



0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Change Ratings

Instructions:

Please circle the appropriate number for each question, according to how you feel **at this moment** about changing your eating.

1. How important is it for you to consistently follow the post-operative bariatric surgery dietary guidelines? (circle one)

0	1	2	3	4	5	6	7	8	9	10
Not at all Important										Extremely Important

2. How confident are you that you will be able to consistently follow the post-operative bariatric surgery dietary guidelines? (circle one)

0	1	2	3	4	5	6	7	8	9	10
Not at all Confident										Extremely Confident

3. How ready are you to consistently follow the post-operative bariatric surgery dietary guidelines? (circle one)

0	1	2	3	4	5	6	7	8	9	10
Not at all Ready										Extremely Ready

Binge Eating Scale

Instructions:

Below are groups of numbered statements. Read all of the statements in each group and **circle the one** that best describes the way you feel about your eating behaviour.

1.

1. I don't feel self-conscious about my weight or body size when I'm with others.
2. I feel concerned about how I look to others, but it normally does not make me feel disappointed with myself.
3. I do get self-conscious about my appearance and weight which makes me feel disappointed in myself.
4. I feel very self-conscious about my weight and frequently, I feel intense shame and disgust for myself. I try to avoid social contacts because of my self-consciousness.

2.

1. I don't have any difficulty eating slowly in the proper manner.
2. Although I seem to "gobble down" foods, I don't end up feeling stuffed because of eating too much.
3. At times, I tend to eat quickly and then, I feel uncomfortably full afterwards.
4. I have the habit of bolting down my food, without really chewing it. When this happens I usually feel uncomfortably stuffed because I've eaten too much.

3.

1. I feel capable to control my eating urges when I want to.
2. I feel like I have failed to control my eating more than the average person.
3. I feel utterly helpless when it comes to feeling in control of my eating urges.
4. Because I feel so helpless about controlling my eating I have become very desperate about trying to get in control.

4.

1. I don't have the habit of eating when I'm bored.
2. I sometimes eat when I'm bored, but often I'm able to "get busy" and get my mind off food.
3. I have a regular habit of eating when I'm bored, but occasionally, I can use some other activity to get my mind off eating.
4. I have a strong habit of eating when I'm bored. Nothing seems to help me break the habit.

5.

1. I'm usually physically hungry when I eat something.
2. Occasionally, I eat something on impulse even though I really am not hungry.
3. I have the regular habit of eating foods, that I might not really enjoy, to satisfy a hungry feeling even though physically, I don't need the food.
4. Even though I'm not physically hungry, 1 get a hungry feeling in my mouth that only seems to be satisfied when I eat a food, like a sandwich, that fills my mouth. Sometimes, when I eat the food to satisfy my mouth hunger, I then spit the food out so I won't gain weight.

6.

1. I don't feel any guilt or self-hate after I overeat.
2. After I overeat, occasionally I feel guilt or self-hate.
3. Almost all the time I experience strong guilt or self-hate after I overeat.

7.

1. I don't lose total control of my eating when dieting even after periods when I overeat.
2. Sometimes when I eat a "forbidden food" on a diet, I feel like I "blew it" and eat even more.
3. Frequently, I have the habit of saying to myself, "I've blown it now, why not go all the way" when I overeat on a diet. When that happens I eat even more.
4. I have a regular habit of starting strict diets for myself, but I break the diets by going on an eating binge. My life seems to be either a "feast" or "famine."

8.

1. I rarely eat so much food that I feel uncomfortably stuffed afterwards.
2. Usually about once a month, I eat such a quantity of food, I end up feeling very stuffed.
3. I have regular periods during the month when I eat large amounts of food, either at mealtime or at snacks.
4. I eat so much food that I regularly feel quite uncomfortable after eating and sometimes a bit nauseous.

9.

1. My level of calorie intake does not go up very high or go down very low on a regular basis.
2. Sometimes after I overeat, I will try to reduce my caloric intake to almost nothing to compensate for the excess calories I've eaten.
3. I have a regular habit of overeating during the night. It seems that my routine is not to be hungry in the morning but overeat in the evening.

4. In my adult years, I have had week-long periods where I practically starve myself. This follows periods when I overeat. It seems I live a life of either "feast or famine."

10.

1. I usually am able to stop eating when I want to. I know when "enough is enough."
2. Every so often, I experience a compulsion to eat which I can't seem to control.
3. Frequently, I experience strong urges to eat which I seem unable to control, but at other times I can control my eating urges.
4. I feel incapable of controlling urges to eat. I have a fear of not being able to stop eating voluntarily.

11.

1. I don't have any problem stopping eating when I feel full.
2. I usually can stop eating when I feel full but occasionally overeat leaving me feeling uncomfortably stuffed.
3. I have a problem stopping eating once I start and usually I feel uncomfortably stuffed after I eat a meal.
4. Because I have a problem not being able to stop eating when I want, I sometimes have to induce vomiting to relieve my stuffed feeling.

12.

1. I seem to eat just as much when I'm with others (family, social gatherings) as when I'm by myself.
2. Sometimes, when I'm with other persons, I don't eat as much as I want to eat because I'm self-conscious about my eating.
3. Frequently, I eat only a small amount of food when others are present, because I'm very embarrassed about my eating.
4. I feel so ashamed about overeating that I pick times to overeat when I know no one will see me. I feel like a "closet eater."

13.

1. I eat three meals a day with only an occasional between meal snack.
2. I eat 3 meals a day, but I also normally snack between meals.
3. When I am snacking heavily, I get in the habit of skipping regular meals.
4. There are regular periods when I seem to be continually eating, with no planned meals.

14.

1. I don't think much about trying to control unwanted eating urges.
2. At least some of the time, I feel my thoughts are pre-occupied with trying to control my eating urges.

3. I feel that frequently I spend much time thinking about how much I ate or about trying not to eat anymore.
4. It seems to me that most of my waking hours are pre-occupied by thoughts about eating or not eating. I feel like I'm constantly struggling not to eat.

15.

1. I don't think about food a great deal.
2. I have strong cravings for food but they last only for brief periods of time.
3. I have days when I can't seem to think about anything else but food.
4. Most of my days seem to be pre-occupied with thoughts about food. I feel like I live to eat.

16.

1. I usually know whether or not I'm physically hungry. I take the right portion of food to satisfy me.
2. Occasionally, I feel uncertain about knowing whether or not I'm physically hungry. At these times it's hard to know how much food I should take to satisfy me.
3. Even though I might know how many calories I should eat, I don't have any idea what is a "normal" amount of food for me.

Appendix D

Informed Consent Form

University Health Network

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title	Adapted Motivational Interviewing for Bariatric Surgery Patients: A Pilot Study
Investigator	Dr. Sanjeev Sockalingam Bariatric Surgery Program Toronto Western Hospital Phone: (416) 340-3762
Co-Investigators	Dr. Stephanie Cassin Department of Psychology, Ryerson University Phone: (416) 979-5000 ext.3007
	Lauren David Department of Psychology, Ryerson University Phone: (416) 979-5000 ext.3232
Sponsor	Ryerson University Health Research Fund

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

You are being asked to participate in this research study because you are a patient in the Bariatric Surgery Program at Toronto Western Hospital. Previous research has demonstrated that

adherence to post-surgical dietary guidelines is difficult for most bariatric patients. Over half of patients do not properly follow dietary guidelines, including abstaining from alcohol and caffeine, eating healthy meals, eating smaller portions, eating slowly, and consuming vitamin supplements. These recommendations were implemented to reduce the likelihood of post-surgical complications and to encourage long-term weight loss. Not surprisingly, suboptimal adherence to these guidelines has been associated with poorer weight loss and greater weight regain following bariatric surgery.

Despite this finding, psychological interventions are not routinely offered in Bariatric Surgery Programs to address non-adherence to post-surgery recommendations. Preliminary evidence in non-bariatric surgery populations suggests that a psychological intervention called Motivational Interviewing (MI) and its adaptations (Adapted Motivational Interviewing; AMI) might be effective in improving adherence to treatment, eating behaviours, and psychological functioning. The current study will examine whether the addition of one session of Motivational Interviewing to the usual standard of care is more effective than standard bariatric care alone. As a participant in the study, you will be randomly assigned to receive the intervention immediately (AMI condition) or to receive the intervention in approximately 14 weeks (Wait List condition). A total of 60 patients from the Bariatric Surgery Program at Toronto Western Hospital will participate in this study (30 per group).

Study Visits and Procedures

Baseline Assessment: The study team needs to find out about your functioning before you receive Adapted Motivational Interviewing so they can examine the impact of the intervention. This is called the Baseline Assessment. You will be asked to complete a questionnaire packet that asks questions about your eating behaviours, mood, readiness for change, self-esteem, quality of life, social support, trust in treatment team, and perceived involvement in care. You can refuse to answer any questions that you wish. The questionnaire packet should take approximately 30 minutes to complete. Additionally, you will be asked to monitor your current behaviours with respect to how well you were able to stick to each of the nine bariatric guidelines over the course of a week.

Randomization: You will be randomly assigned to receive either Adapted Motivational Interviewing or be placed in a Wait List Control Group. Whether you receive Adapted Motivational Interviewing in 1 week or in 14 weeks will be decided randomly (by chance) like flipping a coin.

Individuals who are randomly assigned to receive Adapted Motivational Interviewing will begin treatment approximately one week after consenting to participate in the research study. The longest follow-up time point in this study is 12 weeks after the Baseline Assessment, however, when considering the one week period needed to complete these assessments, the total participation will last approximately 14 weeks from the time that they provide consent.

Individuals who are randomly assigned to the Wait List Control Group will be asked to complete the questionnaire packet again approximately 14 weeks after consenting to participate in the research study, and then will receive the Adapted Motivational Interviewing session approximately 1 week after providing consent.

Intervention: Regardless of whether you are randomly assigned to receive Adapted Motivational Interviewing now or 14 weeks from now, you will receive one indiviual Adapted Motivational Interviewing session that will take approximately 60-90 minutes. The time and location of the session will be scheduled at your convenience, either taking place at Toronto Western Hospital or at Ryerson University. The session will focus primarily on your current eating patterns and difficulties you might be experiencing with adhering to post-surgery dietary guidelines. The intervention will be provided by a Ryerson University Clinical Psychology graduate student who has been trained in the manualized treatment protocol, and will be supervised by Dr. Stephanie Cassin (Co-Investigator).

Post-Intervention Assessments: You will be asked to complete some of the same questionnaires that you completed during the Baseline Assessment at four time points following the Adapted Motivational Interviewing session (immediately following the session, as well as 4, 8, and 12 weeks following the session). In total, all of these questionnaires across these time points will likely take approximately 120 minutes to complete. This will allow the study team to see if you have experienced any changes as a result of receiving an Adapted Motivational Interviewing session. All of the questionnaires can be completed from a computer for your convenience. Upon completion of the study, you will be asked to partake in a brief interview over the phone to inquire about your experiences with the Adapted Motivational Interviewing session.

Risks Related to Being in the Study

There are no known risks associated with receiving Adapted Motivational Interviewing. You will be asked to reflect upon some personal issues and your psychological health (e.g., eating habits, mood, quality of life) during the intervention and while completing the questionnaires that may cause you discomfort, embarrassment, or sadness. You may choose to discontinue Adapted Motivational Interviewing or to refuse to answer questions at any time if you experiece discomfort.

Benefits to Being in the Study

Research has shown that Motivational Interviewing can help some individuals lose weight and improve mental and physical health conditions As such, some participants may experience weight loss or quality of life benefits from the intervention. However, no research to date has examined whether Motivational Interviewing is effective for bariatric surgery patients. Information learned from this study may help inform psychosocial interventions that serve to enhance bariatric outcomes for future patients.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care in the Bariatric Surgery Program. You may refuse to answer any questionnaire item you do not want to answer, or not answer a question during the Adapted Motivational Interviewing session by saying "pass".

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Alternatives to Being in the Study

You do not have to join this study to receive Adapted Motivational Interviewing. This intervention is also offered in the community to influence change across a variety of health-related behaviours, such as smoking. You may also choose not to receive Adapted Motivational Interviewing or any other treatments. Anybody associated with this study (e.g., the research coordinator, your therapist) can discuss any of these options with you.

Confidentiality

If you agree to join this study, the study doctor and the study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

name,
address,
date of birth,
new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. All e-mail correspondence will be sent from a University Health Network or Ryerson University e-mail account. However, please note that the security and confidentiality of information sent

through e-mail correspondence cannot be guaranteed. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for the Adapted Motivational Interviewing that you receive as part of this study. You will be reimbursed $20 to attend the Adapted Motivational Interviewing session at Toronto Western Hospital or Ryerson University to help offset the cost of transportation (public transportation, gas, parking). Furthermore, you will be compensated $30 for completing all of the questionnaires associated with this study and a brief telephone interview at the end of the study focused on your experience of participating in the study.

Conflict of Interest

Ryerson University (Health Research Fund), the sponsor of this study, will cover some of the costs associated with doing this study. The interests of the sponsor and the study investigators should not influence your decision to participate in this study. You should not feel pressured to join this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. Sanjeev Sockalingam at (416) 340-3762, Dr. Stephanie Cassin at (416) 979-5000 x.3007 or the Ryerson University Research team at (416) 979-5000 x. 3232.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at (416) 581-7849. The REB is a group of people who oversee the ethical conduct of research studies.These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

_____

Print Study Participant's Name

_____ _____

Signature Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_____

Print Name of Person Obtaining Consent

_____ _____

Signature Date

Appendix E

Letter of Appreciation

[Date]

Dear ***[insert participants' name]***,

We would like to thank you for your participation in our study entitled Adapted Motivational Interviewing for Bariatric Surgery Patients: A Pilot Study. As a reminder, the purpose of this study is to examine the effectiveness of a single session of Adapted Motivational Interviewing in a bariatric surgery population to improve patients' confidence in their ability to improve adherence to post-surgical dietary recommendations and actually begin to make those behavioural changes.

We wanted to take the time to express our appreciation for your openness and honesty throughout the study. The data collected through the questionnaires, motivational interviewing session, and final satisfaction interview will contribute to a better understanding of how this intervention may benefit bariatric surgery patients in post-surgery care. If our hypotheses are supported, this study could justify the need for more research support surrounding the development and implementation of psychological services in Bariatric Surgery Programs nationwide.

Please remember that any data pertaining to you as an individual participant will be kept confidential. Once all the data are collected and analyzed for this project, we plan on sharing this information with the community of researchers and health care professionals through seminars, conferences, presentations, and journal articles. If you are interested in receiving more information regarding the results of this study, or would like a summary of the results, please e-mail us at heal@ryerson.ca, and when the study is completed (anticipated by August 2014), we will send you the information. In the meantime, if you have any questions about the study, please do not hesitate to contact us by email (heal@ryerson.ca) or telephone (416-979-5000 x.3232).

Best,

Lauren David, BAH
Masters Student in Clinical Psychology
Ryerson University

(On behalf of the research team, including Dr. Stephanie Cassin at Ryerson University and Drs. Sanjeev Sockalingam and Susan Wnuk at Toronto Western Hospital)

Appendix F

Adapted Motivational Interviewing (AMI) Protocol

Review informed consent (including permission to audiotape) with participant.

Discuss turning on audiotape – *I will now turn on the audiotape. Some of the tapes will be reviewed to ensure that the therapists are doing what they are supposed to, but your name isn't associated with the tape.*

Exploration of Behaviour/Elicitation of Self-Motivational Statements

I'd like to start off by hearing a little bit about your experience with making changes to your eating and other lifestyle changes following bariatric surgery (Probe for some of the difficulties noted on the Self-Monitoring Behavioural Checklist if they aren't mentioned spontaneously).

Okay, now I want to find out a little more about your concerns about _____.

[If participants hints at the need for change] *What makes you think you need to change something about_____?*

Before we talk more about some of the not so good things about_____, what are some of the good things about_____? What do you get out of _____? What else?.

And what are some of the not so good things about _____? What else? (Elicit impact on physical health, mental health, finances, romantic relationships, family relationships, social life, etc.

[If he/she implies that behaviour is not problematic, use amplified reflection] – *You don't feel that this is a problem at all* – or paradox – *It doesn't seem like you have many concerns. I'm not sure how you would benefit from changing behaviour* OR *It seems like you really like to _____. Do you like it too much to consider change?*

Summarize Benefits and Costs of Behaviour

From what you've said so far, some of the good things about _____are….

But you're worried about (or wondering about)….

Does that sound about right? Am I missing anything?

Life Areas Affected by Behaviour

I want to ask some more questions about how _____has affected your life. I will ask you to rate each question in 2 ways—first using words, then using numbers from 0 (not at all affected) to 10 (severely affected).

In what ways, if any, has _____affected your physical health?

Rating (0-10)? _____

In what ways, if any, has _____affected your mental health?

Rating (0-10)? _____

In what ways, if any, has _____affected your relationships (e.g., romantic, family, social life)?

Rating (0-10)? _____

Looking at these answers, it seems that you have noticed the greatest effect in the area of …and the least effect in the area of …

Does this fit with how you think about the impact of _____?

What do you make of this?

Have you noticed _____having an effect in any other areas of your life that I haven't asked you about already (e.g., some mention occupational or spiritual)*?*

Stage of Change

Have you ever heard of the Stages of Change Model?

[If yes]: **What do you recall about the Stages of Change Model?** ***If client only has a vague recollection of the model, describe the model as below.***

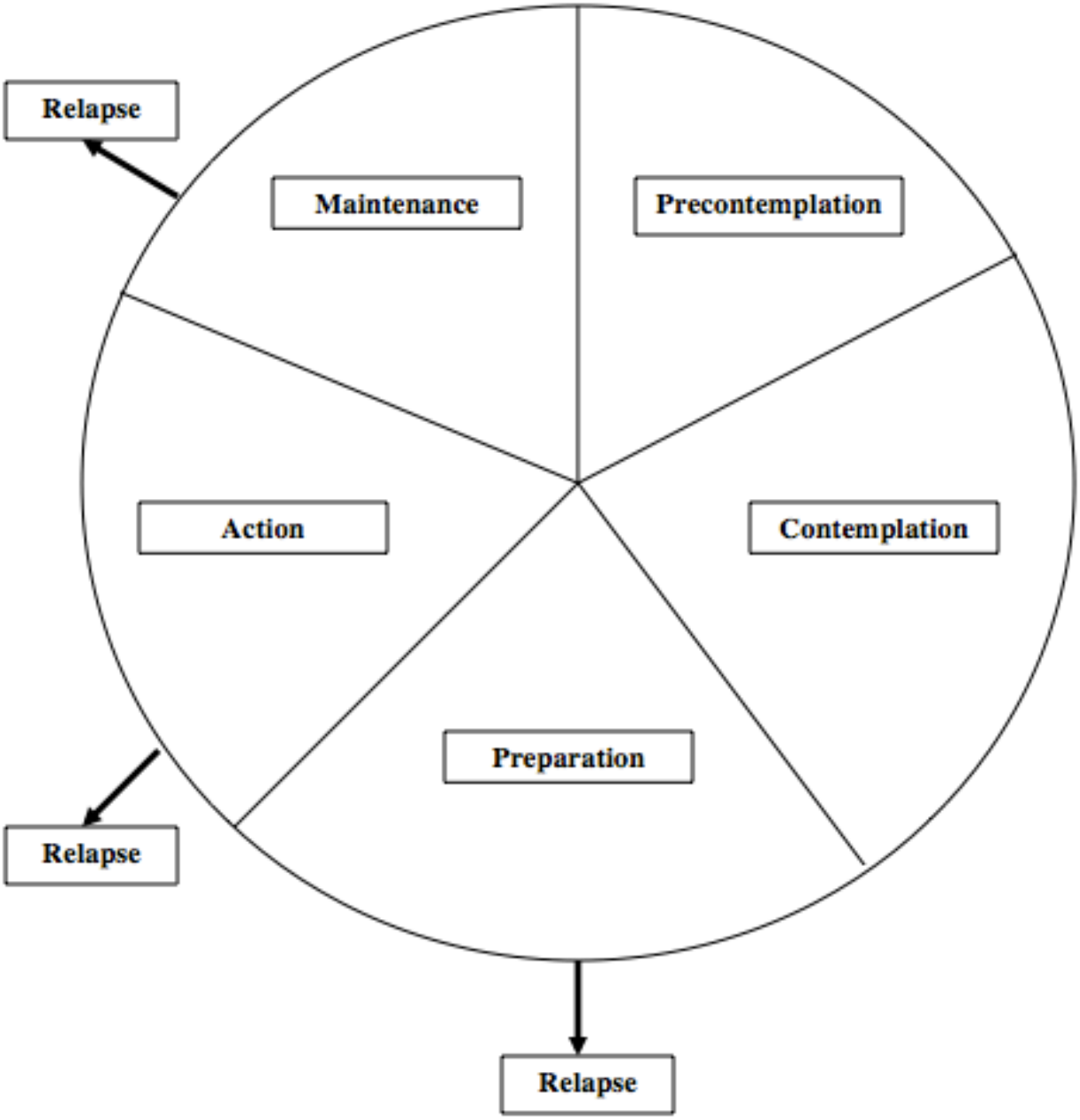
[If no]: Show the participant a diagram of the Stages of Change Model. Briefly discuss each of the stages of change and emphasize that relapse (or a 'lapse') is a natural part of the recovery process in which learning occurs. It does not mean that the individual has to go all the way back to square 1 (precontemplation). Instead, person can have a single lapse (i.e., one binge) and then renew commitment to change. Rather than beating oneself up over a lapse, remember that valuable learning has occurred. At a minimum, person knows what didn't work and can try some different strategies next time.

In the precontemplation stage: People who score highest in this area are just beginning to wonder if they should make a change. Some people aren't quite sure if they have a problem that needs changing. Other people in this area feel like they should make a change, but aren't sure they want to do so right now, or might not feel they are ready. Does that sound like you?

In the contemplation stage: People who score in the contemplation stage are usually thinking about making some kind of change. They may have already made plans to change. Does that sound like you?

In the action stage: People in this stage have decided they want to make a change and they are doing some things to make the change happen. Does that sound like you? Reflect/discuss some of the things they have been doing to facilitate change.

Stages of Change



Decisional Balance

Complete the decisional balance to summarize the benefits and costs of staying the same vs. changing– *I have something else here we can look at to help get a picture of how you're feeling about _____right now. It looks at _____ in terms of the benefits and costs of _____, and the benefits and costs of* ***changing*** *_____. In order to be successful in changing _____, it's important to recognize both the benefits and costs of _____.*

We can start by looking at some of the things you said were good about _____(give examples from previous discussion). *They would go under "Benefits of staying the same".*

The concerns you talked about (give examples from previous discussion) *would go under "Costs of staying the same".*

What are some of the things you are concerned about when you think of changing _____? They would go under "Costs of changing".

What are some of the things that you think might be better if you changed _____? They would go under "Benefits of changing".

(In all segments, keep probing for more examples and remind participant of information they talked about earlier if necessary).

Upon completion of the decisional balance: *Do you notice anything when you look at the benefits and costs of changing vs. staying the same?* (Usually they will notice that there are more reasons to change, but emphasize to the participant that it's not just the number of reasons that's important, but also the strength or importance of the reasons. They may also notice that the behaviour is associated with fast-acting short-term gains whereas changing is associated with positive long-term changes that take longer to obtain. If appropriate, bring this to the participant's attention (i.e., delay of gratification).

You can take this sheet with you when we're finished the interview. I really encourage you to continue working on it during the week as you think about more benefits and costs.

If the participant has not been able to generate many statements and is not presently willing to contemplate changing anything about_____, leave the decisional balance until later in the interview. Instead, engage in a hypothetical exercise.

You've told me you're not interested in making any changes right now. I was wondering if you know what might make it different. What might make you decide you want to make some changes? OR *If you decided to make some changes sometime in the future, what might you do? What might that be like?*

DECISIONAL BALANCE

BENEFITS OF STAYING THE SAME	**COSTS OF STAYING THE SAME**
COSTS OF CHANGING	**BENEFITS OF CHANGING**

Self-Efficacy

So far we've been talking quite a bit about the idea of making changes. Have you made changes in other areas of your life? Have you stopped or cut down drinking, smoking, or using drugs? Have you decided to change a job or relationship? Have you tried to learn something new, such as driving, which required you to take risks and tolerate mistakes in the beginning until you got the hang of it? Get details of personal examples.

What kinds of things did you do when you decided to change?

[If participant hasn't made any changes]: *Do you know other people who have changed some behaviour? What kind of things did they do?*

What about times when you wanted to_____, but didn't? What did you do differently then?

Looking to the Future

I was wondering how you see the future if you decide ***not*** *to change your behaviour?*

How do you see the future if you decide to change your behaviour?

What is your ideal life? How does _____ fit in?

These are some questions you may want to think more about after the interview. Some people find it helpful to write letters—one to a friend in 5 years describing your life if behaviour continues and another letter if behaviour stops.

Readiness and Confidence for Change

We've been talking a lot about _____ —about the good and not so good things, and about the possibility of making some changes. This is another way to get an idea of how you're feeling about _____.

If we had a ruler in front of us, and 0 on the ruler was "not at all ready to change anything about _____" and 10 on the ruler was "extremely ready to change _____"—where would you put yourself right now?

Rating (0-10): _____

Discuss choice—*why X? Why not 0? How did you decide? What would it take to move it up a bit? What would it take to move it to 9?*

Okay, now we're going to do the same for confidence. If you decided you did want to make changes, how confident are you that you would be successful? If 0 means that you are "not at all confident" and 10 means that you are "extremely confident if you set your mind to it"—where would you put yourself right now?

Rating (0-10): _____

Discuss choice—*why X? Why not 0? How did you decide? What would it take to move it up a bit? What would it take to move it to 9?*

Making a Change

[If participant seems willing to consider change]: *We've talked a lot about things related to _____today. On the one hand….* (list benefits of bingeing)*, but on the other hand ….* (list costs of bingeing)

What do you think about all this?

What kinds of things do you think you could do to change_____? (gather options –telling others of plan, social support, reminders, etc.)

[If participant asks for a lot of suggestions]: *I can't tell you exactly what to do because you are the person who knows what works for you.* OR *I can give you some ideas of what some other people have tried, but I really don't know what will work best for you. You are the expert on yourself.*

Do you anticipate any difficulties? What obstacles might get in the way? How could you overcome them?

Plan for Change

Complete Plan for Change Sheet and send it home with participant.

[If participant seems unwilling to consider change]: *We've talked a lot about _____today. It seems like you have some worries* (list costs), *but you've also told me* (list benefits). *You are the person who knows best about you and your life.*

I was wondering if you have any ideas about the kinds of things that might make it important for you to think about changing your behaviour sometime.

How do you see things going in 5 years if things stay the same as they are now?

How has it been for you to talk about _____today?

Plans for Change

The changes I want to make are:

The most important reasons why I want to make these changes are:

The steps I plan to take in changing are:

The ways other people can help me are:

Person	**Possible ways to help**

I know that my plan is working if:

Some things that could interfere with my plan are:

Terminate Interview

[If participant is considering change]: *I hear that you really want to do something about your_____, and that you'd like to get going right away. We talked about things you could do differently and you think that it would be best to … Is that correct? It really sounds like you want to make changes in your life.*

[If participant is still ambivalent about change]: *This interview gives people a chance to think about _____. You have thought of some things you might want to change about* _____(review possible changes). *Does that sound about right?*

For all participants: *Do you have any last thoughts about what we've talked about today?*

We've been talking about a lot of things today. I hope it's been helpful to you to take the time to look at _____.

Appendix G

CONSORT Checklist of Items to Include When Reporting a Randomized Trial

PAPER SECTION And topic	Item	Description	Reported on Page #
TITLE & ABSTRACT	1	1a. Identification as a randomized trial in the title 1b. Structured summary of trial design, methods, results, and conclusions	iii
INTRODUCTION Background and objectives	2	2a. Scientific background and explanation of rationale 2b. Specific objectives or hypotheses	1-26
METHODS Trial design	3	3a. Description of trial design (such as parallel, factorial) including allocation ratio 3b. Important changes to methods after trial commencement (such as eligibility criteria), with reasons	23-24, 30-32
Participants	4	4a. Eligibility criteria for participants 4b. Settings and locations where the data were collected	27-28, 30-31
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	33-36, Appendix F
Outcomes	6	6a. Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b. Any changes to trial outcomes after the trial commenced, with reasons	28-32

Sample size	7	7a. How sample size was determined 7b. When applicable, explanation of any interim analyses and stopping guidelines	27, 39
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size)	31-32, 37
Randomization -- Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	31-32
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	27, 31
Blinding	11	11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how 11b. If relevant, description of the similarity of interventions	N/A
Statistical methods	12	12a. Statistical methods used to compare groups for primary and secondary outcomes 12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses	40-47, 57
RESULTS Participant flow	13	13a. For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary	27-28, 37-39, 78

		outcome 13b. For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14	14a. Dates defining the periods of recruitment and follow-up. 14b. Why the trial ended or was stopped.	27
Baseline data	15	Baseline demographic and clinical characteristics of each group.	38-39, 65-66, 68, 71
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups.	33, 35-36, 38-46, 68-76
Outcomes and estimation	17	17a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended	40-47, 68-76
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group	113
DISCUSSION Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	58-60

Generalizability	21	Generalizability (external validity, applicability) of the trial findings	58-60
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	48-58
OTHER INFORMATION Registration	23	Registration number and name of trial registry	N/A (pilot trial)
Protocol	24	Where the full trial protocol can be accessed, if available	Appendix F
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	iv

Appendix H

Intent-to-Treat Analysis

Summary of Differences Between Intent-to-Treat versus Completer Analyses

The results of Intent-to-Treat (ITT) analyses are presented in Tables 9 and 10. The complete data set was available for the examination of acute primary and secondary treatment effects at post-intervention and at the 4-week follow-up, and thus these data were not re-analyzed using an ITT approach. The results were nearly identical regardless of whether completer or ITT analyses were performed. Of all the analyses conducted, there was only one notable difference between the two analyses. When analyzing the durability of acute treatment effects across the 4-, 8-, and 12-week follow-ups, the reported declines in both adherence self-efficacy and confidence across the follow-up period did not resolve when ITT analyses were conducted. In the completer analyses, these levels returned to post-intervention levels by the 8-week follow-up, whereas these levels remained lower in the ITT analysis. The ITT analyses found that, compared with the post-intervention assessment, adherence self-efficacy ratings were significantly lower at the 4-week follow-up, $t(42) = 2.64$, $p < .05$, the 8-week follow-up, $t(42) = 2.00$, $p < .05$, and the 12-week follow-up, $t(42) = 2.45$, $p < .05$. Additionally, compared with the post-intervention assessment, confidence in ability to change was significantly lower at the 4-week follow-up, $t(42) = 3.43$, $p < .01$, the 8-week follow-up, $t(42) = 2.60$, $p < .05$, and the 12-week follow-up $t(42) = 3.33$, $p < .01$, when analyzed using an ITT approach. These findings would suggest that dropouts likely reported lower adherence self-efficacy and confidence in ability to change prior to terminating participation in the current study. The implications of this finding are explored in the *Discussion*.

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