Examining the Role of Emotion Regulation in Dialectical Behaviour Therapy Self-Help for Binge-Eating Disorder

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Abstract

Background: Dialectical behavior therapy (DBT) for binge-eating disorder (BED) is based on an emotion regulation (ER) model of BED. This model suggests that individuals with BED struggle with ER and engage in binge-eating in an attempt to manage difficult emotions (e.g., numbing, distracting). Thus, DBT for BED focuses on the development of more adaptive ER skills so that individuals are less likely to binge eat to cope with uncomfortable feelings. While DBT is an evidence-based treatment for BED, little research has examined whether ER acts as a mechanism of change in DBT for BED. The goal of the present study was to examine the role of ER in DBT self-help (DBT-SH) for BED outcome. **Methods:** A secondary analysis of data from a recent randomized controlled trial (RCT) of DBT-SH was conducted. A community sample of 71 adults diagnosed with BED took part in the trial. Participants were randomized to receive either DBT-SH or an active SH control condition for 12 weeks. Assessments of BED symptoms, difficulties in ER, and global distress were conducted at baseline and post-treatment. **Results:** Participants in both conditions demonstrated sizable improvements in binge-eating and medium-magnitude improvements ER from pre-to-post-treatment. However, there were no significant between-group differences in outcome and the associated effect sizes were small. Contrary to expectations, within the DBT-SH group, pre-post ER change did not significantly predict pre-post binge frequency change or post-treatment remission status and treatment condition did not significantly moderate the strength of this relationship. Effect sizes for these analyses were small. **Discussion:** The current study failed to provide evidence that ER is a mechanism of change in DBT-SH. Certain methodological limitations including small sample size and low statistical power

should be considered when interpreting these results. However, it is also possible that other mechanisms of change besides ER explain how DBT-SH works for BED. Clinical implications and future directions are discussed.

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Dedication

To my mom and dad, for always believing in me. I love you.

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List of Abbreviations

Abbreviation	Definition
ANCOVA	Analysis of Covariance
APA	American Psychological Association
AUDIT	Alcohol Use Disorders Identification Test
BED	Binge-Eating Disorder
BN	Bulimia Nervosa
BSI	Brief Symptom Inventory
CBT	Cognitive Behavioural Therapy
CBT-SH	Cognitive Behavioural Therapy Self-Help for Binge-Eating Disorder
DAST	Drug Abuse Screening Test
DBT	Dialectical Behaviorur Therapy
DBT-SH	Dialectical Behavioural Therapy Self-Help for Binge-Eating Disorder
DERS	Difficulties in Emotion Regulation Scale
DSM	Diagnostic and Statistical Manual of Mental Disorders
EDE	Eating Disorder Examination
ER	Emotion Regulation
GSH	Guided Self-Help
GSI	Global Severity Index
RCT	Randomized Controlled Trial
SE	Self-Esteem
SH	Self-Help
USH	Unguided Self-Help

1.0 Introduction

Binge-eating disorder (BED) is an eating disorder characterized by recurrent episodes of binge-eating – eating an objectively large amount of food in a relatively short amount of time (e.g., 2 hours), while experiencing a sense of loss of control (American Psychological Association [APA], 2013). Research has suggested that, for a significant subgroup, BED may develop due to problems with emotion regulation (ER). Research on ER and depression (i.e., a possible indicator of problems with ER) in BED has suggested that individuals may turn to binge-eating in order to cope with intense or uncomfortable emotions (Leehr et al., 2015). However, binge-eating appears to result in further negative emotions such as guilt and shame, leaving one vulnerable to further binge-eating in an attempt to manage these emotions. Dialectical behaviour therapy (DBT) is based on an affect regulation model of binge-eating (Telch, 1997). Research on DBT for BED is limited but promising (e.g., Safer et al., 2010; Telch et al., 2001) and has prompted further research into more disseminable forms of the treatment, such as self-help programs. Self-help adaptations of empirically supported psychotherapy approaches have been identified as promising treatments for a sizable proportion of people with BED. These adaptations may be administered in the form of guided self-help (i.e., completing the self-help program while receiving brief supportive counselling from a therapist) and unguided self-help (i.e., completing the program without a therapist's assistance). To date, only one study has examined dialectical behaviour therapy (DBT) guided self-help as a treatment approach for binge-eating disorder (Masson et al., 2013). While this study yielded promising results, there were multiple limitations, and the researchers did not examine the efficacy of unguided DBT self-help. Moreover, no studies have examined

mediators or moderators of treatment outcome in DBT self-help for BED. Therefore, the mechanism(s) through which DBT self-help treatment produces change, and who may be best suited for this type of intervention is unknown. Investigating mediators of treatment is important as this research could potentially validate the emotion regulation model of BED upon which DBT is based. In addition, it may highlight important treatment targets for clinicians (Baron & Kenny, 1986). Investigating moderators of treatment is important because this will help identify for whom the treatment is most effective (Baron & Kenny, 1986). The present study was a secondary analysis of data from a recent randomized controlled trial that compared DBT guided and unguided self-help interventions to an active control condition in a community sample of adults with BED. The study aimed to address four main research questions: 1) whether significantly greater pre-to-post-treatment improvements in ER occurred in the DBT condition than in the active control condition; 2) if, within the DBT self-help conditions, pre-to-post improvement in ER was significantly associated with pre-to-post improvement in binge frequency; 3) whether, within the DBT self-help conditions, pre-to-post-treatment improvement in ER was significantly associated with BED remission status at post treatment; and 4) whether treatment condition (i.e., DBT versus control) moderated the association between pre-to-post change in ER and pre-to-post change in binge frequency, such that this association was significantly stronger in the DBT self-help condition than in the active control condition.

1.1 Binge-eating Disorder

1.1.1 Definition and history of BED

Binge-eating disorder (BED) is characterized by recurrent episodes of binge-eating (APA, 2013). Binge-eating is defined as eating an objectively large amount of food in a discrete period of time (e.g., 1-2 hours) while experiencing a sense of loss of control. BED is distinguished from bulimia nervosa (BN) by an absence of extreme behaviours to compensate for binge-eating (e.g., self-induced vomiting, laxative misuse) following binge episodes (APA, 2013). While BED was only recognized as a standalone eating disorder in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5; APA, 2013), it was first observed by Stunkard (1959) among a subset of individuals with obesity, who noted that this eating pattern occurred more frequently during stressful periods in the individual's life, and was linked to "self-condemnation" and shame related to the behaviour (p. 289). Subsequently, Spitzer (1991) was the first to coin the term "binge-eating disorder," and developed diagnostic criteria for BED for the publication of the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV; American Psychiatric Association [APA], 1996; Spitzer et al., 1991). However, BED was not given full recognition in DSM-IV, and was included as an example of Eating Disorder Not Otherwise Specified (ED-NOS; APA, 1996). The disorder was not officially recognized as an eating disorder until 2013 with the publication of the DSM-5 (APA, 2013).

To meet diagnostic criteria for BED according to DSM-5, one must report an average of one binge episode per week over the past three months. The episodes must be characterized by at least three of the following: rapid eating; eating until uncomfortably

full; eating large amounts of food when not hungry; eating alone due to embarrassment over the amount of food being eaten; disgust, embarrassment, or guilt following the episode. The individual must also report distress about binge-eating, and must not report regular compensatory behaviours designed to compensate for the binge-eating such as fasting or self-induced vomiting. While the term "regular" is not specifically defined, the individual cannot meet the criteria for BN, which requires that compensatory behaviours occur an average of once a week for three months. DSM-5 includes specifiers with regards to remission status (i.e., partial or full remission) and severity (e.g., mild: 1-3 binges per week; severe: 14 or more binges per week).

1.1.2 Prevalence of BED

BED is the most common eating disorder. An international study found that the mean lifetime prevalence across fourteen countries was 1.9% (Kessler et al., 2013), and an American study revealed a mean lifetime prevalence of 2.8% (Hudson et al., 2012). BED prevalence appears to be higher among individuals with obesity, with one community prevalence study finding that 14.1% of individuals with obesity met criteria for BED (Grucza et al., 2007), and a bariatric surgery study finding that 29.5% of bariatric surgery candidates met BED criteria. Sex differences in BED are less skewed than for the other eating disorders, with one study estimating that 3.5% of females and 2.0% of males in the U.S. will suffer from BED in their lifetime (Hudson et al., 2007).

1.1.3 Impact of BED on Physical Health and Quality of Life

BED shares a strong relationship with obesity. The body mass index (BMI) of people with BED is usually in the overweight or obese range, and people with BED are at significantly higher risk for obesity (Hudson et al., 2007). This poses significant physical

health risks, as obesity has been found to be linked to medical complications such as hypertension (Lavie et al., 2009), insulin resistance (a cause of type II diabetes; Olefsky et al., 1982), arthritis (Grotle et al., 2008), asthma (Strine et al., 2007), and kidney failure (Ejerblad et al., 2006). Moreover, individuals with BED are significantly more likely to have issues with impaired glucose, high triglyceride levels, urinary incontinence, sleep problems, gastrointestinal problems, and insulin resistance compared to non-BED controls after controlling for BMI (Cremonini et al., 2009; Mitchell et al., 2015; Succurro et al., 2015; Trace et al., 2012) suggesting that binge-eating can contribute to physical health issues regardless of adiposity.

BED is also associated with more impairments in quality of life (i.e., work performance, sexual functioning, and self-esteem) than obesity without BED (Rieger et al., 2005). Similarly, compared with obese and non-obese controls, participants with BED have been found to have significantly lower levels of physical activity and physical fitness, and reported worse role functioning, social functioning, and energy levels (Vancampfort et al., 2014).

BED also carries a significant economic burden. For example, a Canadian study found that each female patient with BED costs the health care system an average of $2759.00 per year related to physician visits, medication use (e.g., antidepressant medication for comorbid mood disorders) and medical tests (Grenon et al., 2010).

In summary, findings suggest that BED has a serious negative impact on physical health and quality of life, and represents a high cost to the healthcare system. Moreover, BED has also been found to have a detrimental effect on mental health.

1.1.4 Impact of BED on Mental Health

Hudson and colleagues (2012) found that 78.9% of participants with BED also met criteria for a DSM-IV disorder (Hudson et al., 2012). Of particular relevance to the current study, cross-sectional (e.g., Bittencourt et al., 2012), laboratory (e.g., Peterson et al., 2012), and epidemiological (e.g., Fontenelle et al., 2003; Hudson et al., 2012) research has highlighted the high degree of comorbidity between BED and depressive symptoms. High rates of BED have also been found among individuals with borderline personality disorder (BPD; APA, 2013; Specker et al., 1994; Van Hanswjck de Jonge et al., 2003).

Poor emotion regulation (ER) is a cardinal feature of both BPD (Glenn & Klonsky, 2009; Tebartz van Elst et al., 2003) and depression (Ehring et al., 2010; Quigley & Dobson, 2014). The significant role of ER in these mental health disorders, in concert with their particularly prevalent co-occurrence with BED, suggest that BED may be a disorder characterized by deficits in ER.

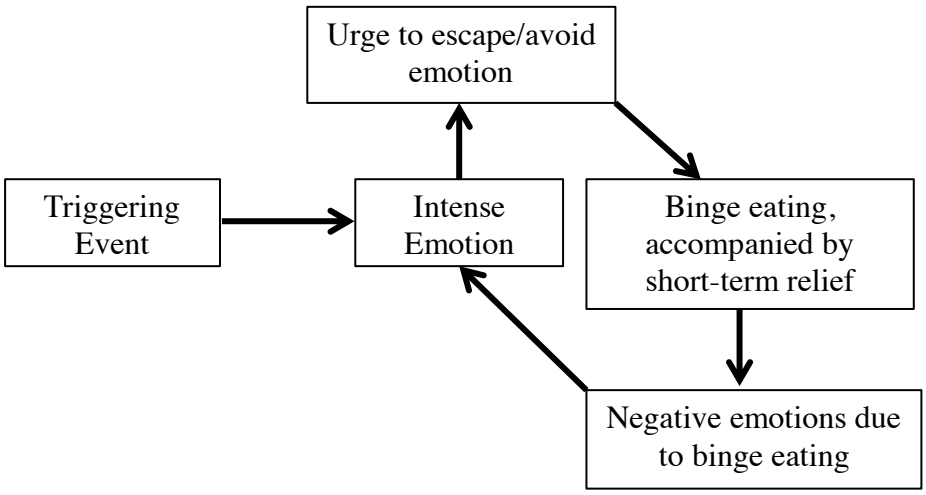
1.2 The Emotion Regulation (ER) Model of BED

Emotion regulation (ER) has been defined as, "[…] the processes by which individuals influence which emotions they have, when they have them, and how they experience and express these emotions" (Gross, 1998, p.275). The ER model of BED (Safer, 2015; Safer et al., 2009; Telch, 1997; Wiser & Telch, 1999) was adapted from conceptions of self-harm in BPD (Linehan, 1993). According to this model, distressing internal or external events prompt emotionally vulnerable individuals with BED to experience intense or uncomfortable emotions. Binge-eating represents an effort to avoid or escape these emotions, with short-term coping benefits (e.g., numbing, distracting).

This short-term relief is followed by feelings of guilt, disgust, and shame, which leaves the individual more vulnerable to binge eat again in the future. Figure 1 illustrates the ER model of BED.

Figure 1

The ER Model of BED



A considerable amount of evidence supports the validity of the ER model of BED (Gianini et al., 2013; Leehr et al., 2015). For example, one study randomized overweight women with and without BED to receive training in cognitive reappraisal (an adaptive ER strategy in which the individual attempts to look at the emotion-inducing situation objectively) or emotion suppression (a maladaptive ER strategy that involves stifling the emotional experience and expression), and then they were asked to employ the skill during a sad mood induction (Svaldi et al., 2014). Following the induction, participants took part in a "taste test" that measured food intake. Participants with and without BED who used emotion suppression in response to the sad mood induction consumed significantly more food than participants engaging in cognitive reappraisal. Further, the

BED group consumed significantly more food than those without BED. Taken together, these findings suggest that maladaptive ER strategies may have the potential to put those with and without BED at risk of overeating, with BED being associated with greater food consumption. Interestingly, a secondary aspect of this study provided participants with a questionnaire gauging their habitual ER strategies used in their day-to-day life. The results showed that participants with BED used significantly more emotion suppression in their lives compared to the control group. In concert with the experimental findings, this could suggest that individuals with BED are inherently more prone to maladaptive ER strategies and, consistent with the ER model of BED, might turn to binge-eating as a way to help them regulate in the absence of helpful ER methods.

Another experimental study exposed obese participants with and without BED as well as normal-weight controls to either a stress-inducing manipulation (i.e., public speaking and working on a difficult math problem in front of an evaluating panel) or neutral manipulation (i.e., reading a magazine; Rosenberg et al., 2013). Pre- and post-experiment cortisol levels and binge-related variables were measured. It was found that the stress-inducing condition increased self-reported desire to binge eat significantly more in the BED group than in the non-BED groups. Furthermore, sweet cravings and desire to binge in the BED group were significantly positively correlated with stress and anxiety levels after the stress-inducing manipulation. Interestingly, the individuals with BED produced less cortisol in response to stress than non-BED participants. This is consistent with a study that measured cortisol levels for two days in women with obesity, with and without BED, and found lower overall cortisol secretion in women with BED (Larsen et al., 2009). The authors suggest that this may be linked to down-regulation of

the hypothalamic-pituitary-adrenal axis, which animal studies have associated with higher stress sensitivity, worse stress regulation, and prolonged stress reactions. Thus, this pattern may reflect inherent difficulties with the regulation of stress and negative emotions in BED, leading susceptible individuals to turn to binge-eating as an ER tool. Therefore, this study provides some biological support for the ER model.

While these studies provide support for the "trigger" component of the ER model, a study by Schulz and Laessle (2010) provided evidence for the "immediate relief" aspect of the model. On two separate mornings, obese individuals with and without BED were exposed to a stress-inducing manipulation and a neutral manipulation. Participants then completed a visual analogue mood scale and a food diary throughout the day. Results were consistent with the ER model, as self-reported mood improved immediately after binge-eating among those with BED. From these results, it appears that, for some individuals, binge-eating may provide immediate but short-term relief from negative emotions. However, the findings related to the "relief" component of the ER model has been relatively less conclusive than findings related to the "trigger" component. For example, ecological momentary assessment studies have gathered data from people with BED on their mood fluctuation in real-time, and have found that negative affect actually worsens directly following a binge episode (Hilbert & Tuschen-Caffier, 2007; Stein et al., 2007; Wegner et al., 2002). For instance, one study equipped participants with BED with portable devices that intermittently had them rate their emotional experience before, during, and after eating. Participants with BED reported a significant worsening in affect following binge-eating (Hilbert & Tuschen-Caffier, 2007). However, it may be that binge-eating in BED is reinforced by possible relief (i.e., numbing or escape from

uncomfortable emotions) during the actual binge episode (Stein et al., 2007). Regardless, research on the "relief" component of the ER model of BED is lacking and requires further study.

Taken together, although the "relief" component of the model requires more study, compelling research findings have provided support for the ER model of the development and maintenance of BED. Thus, researchers have hypothesized that ER-focused therapy would be an effective treatment for BED. Next, the research on existing evidence-based psychological treatment approaches for BED will be reviewed.

1.3 A Review of Psychological Treatment Research on BED

1.3.1 Cognitive Behavior Therapy (CBT)

Since binge-eating is a core feature of both BN and BED (APA, 2013), evidence-supported treatments for BN were the first treatments to be applied to BED in controlled studies. The first intervention that was studied for BED was cognitive-behaviour therapy (CBT), given evidence of its effectiveness with BN (Shapiro et al., 2007). CBT conceptualizes BED as resulting from distorted ideas around weight, shape, and eating (e.g., overvaluation of weight and shape, viewing foods as "good" and "bad") as well as maladaptive eating behaviours (e.g., dietary restraint and restriction). Thus, CBT aims to change these patterns of thoughts, feelings and behaviours to improve body image, stop binge-eating, and promote healthier eating behaviours and attitudes towards food (Fairburn et al., 1993).

To date, thirteen trials have compared group CBT to wait-list control (WLC) groups (Dingemans et al., 2007; Elredge et al., 1997; Marchesini et al., 2002; Peterson et al., 1998; Telch et al., 1990), behavioural weight loss treatment (Fossati et al., 2004;

Grilo et al., 2011; Munsch et al., 2007; Pendleton et al., 2002), antidepressant medication (Agras et al., 1994; Devlin et al., 2005), and group interpersonal therapy (Agras et al., 1995; Wilfley et al., 1993). There have been fewer studies of individual CBT (i.e., one-on-one) for BED, with eight studies comparing individual CBT to WLC groups (Fischer et al., 2014; Lewer et al., 2017), antidepressant medication (Grilo et al., 2005a; Grilo et al., 2012), stimulant medication (Quilty et al., 2019), brief strategic therapy (Jackson et al., 2018) or behavioural weight loss treatment (Castelnuovo et al., 2011; Masheb et al., 2011).

Overall, CBT (group or individual) has been shown to produce significant decreases in binge frequency at post-treatment (Agras et al., 1994; Devlin et al., 2005; Grilo et al., 2005; Grilo et al., 2012; Masheb et al., 2011; Munsch et al., 2007; Peterson et al., 1998; Quilty et al., 2019; Telch et al., 1990), with post-treatment remission rates averaging around 50% (Elredge et al., 1997; Grilo et al., 2011; Devlin et al., 2005; Pendleton et al., 2002; Peterson et al., 1998; Quilty et al., 2019). This means that 50% of participants do not experience BED remission with CBT. Further, there are mixed findings with regards to maintenance of change at 1 to 4-year follow-up (Castelnuovo et al., 2011; Fischer et al., 2014; Jackson et al., 2018; Munsch et al., 2007; Ricca et al., 2010). Consequently, researchers began to study other psychological treatments for BED including DBT.

1.3.2 Dialectical Behaviour Therapy (DBT)

DBT was the next evidence-based psychological treatment to be studied for BED and is the focus of the current investigation. Linehan (1993) originally developed DBT for individuals with borderline personality disorder (BPD) who often demonstrate self-

harm behavior and suicidal ideation. The ER model (previously discussed) is central to DBT and conceptualizes maladaptive behaviours such as binge-eating as reflective of ER deficits (Safer et al., 2009; Telch, 1997). DBT aims to teach individuals with BED mindfulness-based coping skills that are intended to replace binge-eating as an ER strategy. DBT works to improve ER with skills training in the following areas: i.) emotion regulation; ii.) mindfulness; iii.) interpersonal effectiveness (e.g., dealing with conflict, increasing assertiveness); and iv.) distress tolerance.

Full DBT treatment requires specialized training, extensive time and finances (e.g., having therapists available by phone at all times, concurrent group and individual treatment), and is not widely available (Zanarini, 2009). Thus, researchers have investigated whether an abbreviated version of DBT that involves group emotion regulation skills training only might be helpful for BED.

1.3.4 A Review of Studies of DBT for BED

To date, one single group study has examined comprehensive DBT treatment for BED, with this sample consisting of individuals with either BED or BN along with comorbid BPD (Chen et al., 2008). All other studies of DBT for BED have examined abbreviated versions of DBT. Specifically, three RCTs have been conducted on group DBT skills training for BED, comparing this treatment to a WLC group (Rahmani et al., 2018; Telch et al., 2001), an active comparison supportive counselling group (Safer et al., 2010), and a brief version of DBT (i.e., self-monitoring and 15-minute support sessions; Klein et al., 2013). In addition, two single group studies have examined group DBT for BED (Klein et al., 2012; Telch et al., 2000). The primary outcomes, sample sizes, and attrition rates for these studies are presented in Table 1.

In summary, all studies – regardless of design and sample size – have shown post-treatment remission rates of at least 50%, with most studies resulting in remission rates over 60% (see Table 1). These improvements tend to be maintained at follow-up. Associated effect sizes have ranged from medium to large, indicating substantial changes in binge-eating behaviour following DBT (Cohen, 1988). Moreover, DBT has been found to improve secondary outcome measures such as eating disorder psychopathology (Klein et al., 2013; Safer et al., 2010; Telch et al., 2001).

While these results are promising, these studies had some methodological limitations. For example, a lack of control groups and randomization in some studies prevents researchers from generating sound conclusions regarding DBT's suitability for BED. In addition, a number of studies included both participants with BN and BED in the same sample (see Table 1). As studies have shown that individuals with BN show higher rates of general psychopathology and different treatment moderators than those with BED (Castellini et al., 2012; Núñez-Navarro et al., 2011), this practice makes it difficult to determine how the DBT intervention influenced those with BED specifically. Moreover, sample sizes have been small, lowering statistical power and increasing the risk of type II error.

One study compared group DBT for BED to an active control condition (Safer et al., 2010). This condition was modeled after supportive counselling for chronic depression (Markowitz & Sacks, 2002) and was designed to control for common factors such as warmth, empathy, therapist contact, and expecting to improve. Despite a lack of significant between-group differences at follow-up, the study found advantages specific to DBT such as faster treatment response, larger improvements in eating disorder

psychopathology, and less attrition. These promising findings indicate that more research comparing DBT treatments for BED to active control conditions is needed.

Table 1

Summary of DBT for BED Treatment Studies

Study	Design	N	AR	Tx	Format (duration)	Mean % ↓ OBE (ES)	% rem. BE at post-tx	Other findings
Telch et al. (2000)	Single-arm uncontrolled trial	11	9.1% (dropped out of 3 and 6-month follow-up)	DBT	Group (20 weeks)	↓95% (*d*=1.9) *Days	82%	80% rem. rate at 3-month follow-up 70% rem. rate at 6-month follow-up
Telch et al. (2001)	RCT	44 (n=22 DBT; n=22 WLC)	22.7% (n=4 in DBT; n=6 in WLC)	DBT WLC	Group (20 weeks)	DBT: ↓ 100.0% WLC: ↓ 39.3% (*d*=1.51) *Days	89% 12.5%	67% of DBT group rem. at 3-month follow up 56% of DBT group rem. at 6-month follow up WLC were not assessed after post-tx

Note. ACGT = Active comparison group treatment. AR = Attrition rate. DBT = Dialectical behaviour therapy. DC = Diary card. ES = effect size. OBE = Objective binge episodes. RCT = Randomized controlled trial. Rem. = Remission. N = Sample size. Tx = Treatment conditions. WLC = Waitlist control. Where applicable, it is noted whether studies measured binge frequency by number of binge episodes (*Episodes) or number of days on which bingeing occurred (*Days).

Study	Design	N	AR	Tx	Format (duration)	Mean % ↓ OBE (ES)	% rem. BE at post-tx	Other findings
Chen et al. (2008)	Single-group within-subjects	8 (n=5 BED and BPD; n=3 BN and BPD)	12.5% (another 12.5% did not complete 6-month follow-up)	DBT	Group Individual 24-hr. telephone coaching (24 weeks)	↓ 67.2% (*d*=.43) *Episodes	50% (40% of participants with BED)	50% abst at 6-month follow-up (60% of participants with BED) ↓ 81.0% OBE frequency from post-tx to 6-month follow-up (*d*=2.00)
Safer et al. (2010)	RCT	101 (n=50 DBT; n=51 ACGT)	18.8%	DBT ACGT	Group (21 weeks)	NR	64% 36%	Significant increase in % rem. in ACGT group from post-tx to 3-month follow-up (53%) Significant decrease in % rem. in DBT group from post-tx to 3-month follow-up (51%) Significant No significant between group differences in remission rates at 3, 6, or 12-month follow-up (DBT: 64%; ACGT: 56%)
Klein et al. (2012)	Single-group within subjects	10 Full or sub-threshold BN/BED (BED: n=4)	50%	DBT	Group (18 weeks)	↓85.3% (*d*=2.45) *Episodes	Not reported	No follow-up data

Study	Design	N	AR	Tx	Format (duration)	Mean % ↓ OBE (ES)	% rem. BE at post-tx	Other findings
Klein et al. (2013)	RCT	36 (n=22 DBT; n=14 DC) Full or sub-threshold BN/BED (BED: n=10 DBT, 30% completed; n=9 DC, 100% completed)	44.4% (63.6% in DBT; 14.2% in DC)	DBT DCs and 15-minute individual support sessions	Group (16 weeks) Individual/self-help (16 weeks)	DBT: ↓100% (*d*=3.11) DC: ↓53.7% (*d*=1.32) *Episodes	DBT: 50% DC: 27% Not statistically significant	No follow-up data
Rahmani et al. (2018)	RCT	60 (n=30 DBT; n=30 WLC)	10.0% (10.0% in DBT; 10.0% in WLC)	DBT	Group (10 weeks)	Not reported	Not reported	DBT associated with significantly greater decrease in self-reported binge frequency than WLC Significant pre-post improvements in ER and BMI. No follow-up data

Taken together, the majority of these studies provide evidence that DBT is an effective treatment for BED. Overall, DBT tends to result in higher response rates than CBT that are better maintained over time. In addition, recent evidence suggests that self-help versions of DBT may also be efficacious for some people with BED.

1.4 Self-help (SH) for BED

1.4.1 Background and Rationale for SH

Self-help (SH), also sometimes referred to as "bibliotherapy," refers to reading a self-help manual (or taking in information via another medium such as a Smartphone application) that teaches skills and strategies to help the recipient cope more effectively with their difficulties (Lewis et al., 2003). Research supports the effectiveness of SH manuals in the treatment of various mental health concerns such as depression (Gualano et al., 2017) and anxiety (van Boeijen et al., 2005). SH manuals may be used independently or with the support of a therapist, known as guided SH (GSH). Originally developed for BED by Carter and Fairburn (1998), GSH is an intervention in which a clinician guides the individual through a SH manual. GSH therapists can provide encouragement, accountability, and clarification in the SH program. Some research suggests that people without specialized therapy training (e.g., family doctors) can facilitate GSH (Grilo, 2007). Independent use of a SH program is referred to as unguided SH (USH).

Research has identified numerous advantages of SH approaches. First, SH aides in disseminating empirically supported treatments (EST) because it is more accessible. However, research has found that those with more severe psychopathology at pre-treatment are less responsive to self-help approaches (Sysko et al., 2010; Wilson et al.,

2010). Therefore, SH may be offered as an early option in a stepped care model where treatment gradually increases in terms of intensity and required resources (e.g., Bower & Gilbody, 2005; Clark et al., 2009). Further, SH treatments could help surpass barriers to treatment such as stigma (Eisenberg et al., 2009; Jackson et al., 2007) and logistical factors (e.g., transportation; Syed et al., 2014).

1.4.2 SH Approaches for BED

CBT is the most widely evaluated SH approach for BED. To date, ten randomized controlled trials of CBT-SH for BED have been conducted. Of note, the current review excludes internet adaptations of CBT-SH for BED (see Section 4.7), and instead focuses on studies that have used SH manuals. This is because certain aspects of many internet-delivered SH programs could potentially influence patient outcomes, such as e-mail contact with GSH therapists as opposed to scheduled GSH sessions via video or telephone, as well as electronic notification and self-monitoring features designed to improve adherence and outcomes as opposed to providing participants with manuals (e.g., Carrard et al., 2011; de Zwaan et al., 2017; Juarascio et al., 2015; Wagner et al., 2016). CBT-SH (guided and unguided) has been compared to WLC groups (Carter & Fairburn, 1998), behavioural weight loss interventions (Grilo & Masheb, 2005; Wilson et al., 2010), weight loss medication (Grilo et al., 2014; Grilo et al., 2005b), usual primary care (Grilo et al., 2013), and individual IPT (Wilson et al., 2010). Four trials directly compared USH and GSH (Carter & Fairburn, 1998; Ghaderi, 2006; Ghaderi & Scott, 2003; Loeb et al., 1999), while two other trials compared the use of therapist-led groups to self-help groups (i.e., with no therapist; Peterson et al., 2001; Peterson et al., 2009;

Peterson et al., 1998). All of these studies employed the SH book *Overcoming Binge-eating* by Fairburn (1995).

The results from CBT-SH trials have been variable. Most studies comparing the efficacy of guided and unguided CBT-SH for BED have found their effects to be relatively similar (Carter & Fairburn, 1998; Ghaderi, 2006; Ghaderi & Scott, 2003; Loeb et al., 1999). Some trials have CBT-SH remission rates similar to those found in group CBT trials (i.e., approximately 50%). However, one study that found that CBT-USH was not significantly different from treatment as usual (i.e., following advice from a primary care physician), with post-treatment remission rates of only 25% (Grilo et al., 2013). It is clear that a significant proportion of participants do not fully respond to CBT self-help and therefore there is a need to develop other effective self-help approaches for BED.

1.4.3 DBT-SH for BED

DBT was the next evidence-based treatment for BED to be adapted into a SH format. To date, there have been two studies of DBT SH for BED (DBT-SH). The first study randomized 60 individuals with BED to DBT-GSH or a WLC condition (Masson et al., 2013). Participants in the GSH condition received six 20-minute support phone calls as they worked through the DBT manual over 13 weeks. The GSH group reported significantly less binge-eating at post-treatment than the WLC, with a 40% remission rate (compared to a 3.3% remission in the WLC group). Binge frequency significantly increased between post-treatment and six-month follow-up, but was still significantly lower at follow-up compared with pre-treatment, indicating sustained improvement in the DBT-GSH group. In addition, GSH participants indicated less eating disorder pathology,

higher quality of life, and better emotion regulation abilities at post-treatment and six-month follow-up compared to the WLC group.

However, this study had a number of limitations. First, the study only examined GSH. It is also important to evaluate whether some individuals can make use of the self-help program independently (i.e., USH). A second limitation was that this study did not have an active comparison condition to control for attention or expectations of improvement. Also, the GSH attrition rate of 36.7% (n=11), compared to ten percent (n=3) in the WLC group, left the GSH group with fewer participants than what is seen as acceptable in psychotherapy trials in terms of statistical power (i.e., n=20; Hsu, 2006), and may have also biased the results if those for whom the treatment wasn't working were disproportionately represented in those who dropped out of the study.

Another limitation related to the GSH intervention is that when conducting support sessions, therapists asked participants a series of standardized questions over the telephone. It is likely that clinicians in practice would take a less-structured, more client-centered approach to GSH, suggesting that the GSH condition may have lacked external validity. Further, there was only one GSH therapist in the study, which may introduce systematic therapist effects, with the specific features of the therapist (e.g., interpersonal style, gender) impacting outcome.

Carter and colleagues (2019a) conducted a randomized controlled treatment study designed to overcome some of these limitations. In this study, 71 individuals with BED were randomized to: a) DBT-GSH (n = 24), in which participants received the DBT-SH program plus six 30-minute support sessions with a therapist delivered via videoconference; b) DBT-USH (n = 24), in which participants completed the DBT-SH

program without support sessions; and c) an active USH comparison condition in which participants received a SH manual on self-esteem (SE-USH) that did not address binge-eating (n = 23). This condition was designed to control for factors such as receiving a SH manual, expecting to improve, and contact with the researchers. Participants were assessed at pre-treatment, 12 weeks and 3-month follow-up.

Participants in all three conditions reported significant reductions in binge-eating from pre-to-post-treatment, with no statistically significant between-group differences. Effect sizes for all three conditions were large. There were also no statistically significant between-group differences in terms of binge frequency at 3-month follow-up. 45% of the DBT-GSH group, 41.9% of the DBT-USH group, and 37.8% of the SE-USH group were in remission from binge-eating at post-treatment, while 30.8% of the DBT-GSH group, 31.3% of the DBT-USH group, and 19.1% of the SE-USH group were in remission at three-month follow-up. A similar pattern of results was also seen for other aspects of eating disorder psychopathology including dietary restraint, body dissatisfaction and overvaluation of weight and shape.

Overall, research on DBT and DBT-SH for BED has suggested that these approaches are effective in improving BED symptoms for a sizable proportion of people. However, there has been limited research on *how* these modalities work, or the mechanisms of change. This concept refers to the way through which a treatment engenders its intended treatment outcomes (Kazdin, 2013). Investigating mechanisms of change can help identify clinically-relevant variables to be emphasized in interventions in order to maximize treatment outcome. According to the ER model of BED, binge-eating occurs due to a lack of adaptive ER strategies (Safer et al., 2001; Telch, 1997; Wiser &

Telch, 1999). As such, DBT aims to improve ER skills to decrease BED symptoms via improvements in ER. In other words, the ER model of BED suggests that improvements in ER is the mechanism through which DBT and DBT-SH reduce BED symptoms.

1.5 Research on the Role of ER in DBT and DBT-SH for BED

Few studies have examined the role of ER in DBT treatment for BED to date. One group DBT study found that DBT was associated with significant pre-post improvements in ER, and that these improvements were greater than those observed in a WLC (no effect size reported; Rahmani et al., 2018). Further, a group DBT for BED trial showed that the DBT condition demonstrated medium-to-large-magnitude reductions in emotional eating in response to anger, anxiety, and depression at post-treatment (within-group significance testing not reported; Telch et al., 2001). However, only the improvement in anger-related emotional eating emerged as significantly greater than a WLC. In addition, while one group DBT for BED trial found that the DBT condition showed decreases in self-reported ER and emotional eating scores, significance testing or effect size calculation for this improvement were not conducted due to a lack of statistical power (Safer et al., 2010). However, effect sizes (without significance testing) were calculated to determine the magnitude of differences in ER outcome between the DBT condition and active control condition. All effect sizes were small, suggesting that the conditions did not significantly differ in ER improvement. One study found large effect sizes regarding the relationship between improvements in perceived ability to manage negative emotions and decreases in emotional eating when feeling angry or anxious (Telch et al., 2000). In addition, a DBT-GSH RCT found that DBT-GSH resulted in significantly greater improvement in ER from pre-to-post-treatment compared to a waiting list control group, and that this

improvement was maintained at six-month follow-up (Masson et al., 2013). Effect sizes for these analyses in the DBT-GSH study were in the medium range.

Thus, there is preliminary evidence to suggest that ER may be associated with BED DBT treatment outcome. Still, it is important to replicate these findings and research is needed to investigate whether improvements in BED symptoms (i.e., binge frequency) occur via improvements in ER, or, in other words, whether ER acts as a mechanism of change within DBT or DBT-SH.

Typically, research into treatment mechanisms is conducted through mediation analyses that determine whether an independent variable exerts influence on a dependent variable through its relationship with a third mediator variable (Baron & Kenny, 1986). A formal mediation analysis consists of a series of regressions in which the dependent variable is regressed on the independent variable, the mediator is regressed on the independent variable, and the dependent variable is regressed on the independent variable and mediator. A significant mediation requires that the strength of the relationship between the dependent and independent variables significantly decrease with the addition of the mediator. To date, there are no formal mediation studies of treatment mediators in the DBT for BED or DBT-SH literature.

Alternatively, although less frequently, hypotheses regarding mechanisms of change can also be tested through moderation analyses (Kazdin, 2007). Moderators are variables that influence the strength or direction of the relationship between the independent and dependent variable (Baron & Kenny, 1986). A formal moderation analysis typically requires the dependent variable to be regressed on the independent variable, the proposed moderator, and an interaction term that represents the product of

the independent variable multiplied by the moderator. A significant moderation occurs when the strength of the relationship between the independent and dependent variables varies as function of change in the moderator variable. In the context of mechanisms of change in psychotherapy research, researchers can structure their analyses to determine whether treatment condition moderates the relationship between a relevant variable and treatment outcome (i.e., determining whether the relationship between a hypothesized mechanism variable and treatment outcome is stronger in the treatment condition than the control condition). Moderator analyses can be especially useful when looking at mechanisms of change when there are no significant differences in outcome between the treatment and control conditions, as is the case for the current trial. This is because, unlike a mediation analysis, a moderation analysis does not require a statistically significant association between the independent and dependent variable to examine the influence of a third variable (i.e. moderator) on the relationship. Thus, moderation analyses can allow for mechanism-of-change research to occur regardless of whether there are significant between-group differences in outcome (Baron & Kenny, 1986; Kazdin, 2007).

To date, there has been one moderator study of treatment outcome in group DBT for BED (Robinson & Safer, 2012). This study used data from the RCT by Safer and colleagues (2010) to examine whether the association between treatment condition (i.e., group DBT and an active control condition) and post-treatment binge frequency was moderated by demographic, eating disorder (e.g., overvaluation of weight and shape), or general psychopathology (e.g., depression, ER) pre-treatment variables. Through moderation analysis, this study aimed to identify subgroups of individuals that may

respond better to one treatment rather than another based on pre-treatment characteristics. While ER did not emerge as a significant treatment moderator, the results showed that the presence of avoidant personality disorder, as diagnosed using a structured clinical interview, as well as both above-average BMI and dieting behavior prior to age fifteen, moderated treatment outcome. The presence of these characteristics predicted lower binge frequency at post-treatment within the DBT condition compared to those in the active comparison group treatment. These findings provide partial support for the ER model of BED. Specifically, avoidant personality disorder – a personality disorder in which individuals avoid interpersonal relationships due to intense fears of rejection or humiliation (APA, 2013) – has been linked to ER deficits (e.g., maladaptive ER strategies such as emotion suppression and avoidance; Gratz & Tull, 2012; Gratz et al., 2013; Taylor et al., 2004). The authors hypothesized that those with avoidant personality disorder may benefit from the ER strategies introduced in DBT, as they could be employing both avoidance and binge-eating as maladaptive ER strategies (Safer & Robinson, 2012). With regards to the results regarding early above-average BMI and dieting behavior predicting post-treatment binge frequency, it is possible that these findings reflect earlier eating-related ER strategies that may be effectively targeted by DBT. This hypothesis is supported by research linking frequent dieting to increased negative emotionality and maladaptive coping strategies (Ackard, et al., 2002; Polivy et al., 1994).

While the study by Robinson and Safer shed light on potential subgroups of individuals with BED who may respond better to DBT, there have been no formal mediation or moderation analyses of mechanisms of change in DBT for BED. One study

approximated a mechanism of change analysis, but did not use a formal mediation or moderation procedure (Wallace et al., 2014). Instead, the authors used binary logistic regression analyses to determine if pre-to-post-treatment ER change predicted binge abstinence (i.e., no binge episodes in the preceding 28 days) at four-, five-, and six-month follow-up. It was found that larger pre-to-post-treatment improvements in ER scores were associated with a greater likelihood of binge-eating remission at post-treatment and follow-up, with small associated effect sizes. This pattern suggests that pre-to-post-treatment ER change had a significant, albeit small-magnitude, effect on DBT-GSH outcome. However, formal mediation and moderation analyses are needed to confirm the role of ER in DBT-SH outcome. Another limitation of this study is the use of a categorical outcome variable to define remission status. According to the ER model of BED, binge-eating occurs in the absence of effective ER strategies, while DBT aims to replace binge-eating with more adaptive ER tools. As such, one may hypothesize that the degree of ER change directly predicts the degree of binge frequency reduction, as the two constructs are directly linked in the model. However, a categorical outcome variable (i.e., whether the participant was or was not in remission) does not allow assessment of whether the amount of ER change is proportional to the degree of change in binge frequency. Thus, further research is needed in order to gain a more nuanced understanding of the complex relationship between ER and BED symptoms. In addition, the researchers did not control for global psychological distress (e.g., negative emotionality) in their analysis. Thus, it is impossible to determine how much of the variance was influenced by negative emotions themselves, as opposed to how these emotions and psychological distress were managed.

In summary, preliminary research suggests that DBT and DBT-SH are associated with improvements in participants' ER capabilities. Further, one study found preliminary evidence that ER might act as a mechanism of change in DBT-SH for BED (Wallace et al., 2014). However, this study was limited by the use of categorical outcome variables, as well as a lack of formal mediation or moderation analyses. While research on ER as a mechanism of change in DBT for other disorders is sparse, existing research on DBT for BPD suggests that ER improvement via DBT skill usage leads to improved outcomes such as decreased suicide attempts and depression (Lynch et al., 2010; Neasciu et al., 2010). As such, it may be that this pattern is reflected in DBT-SH for BED, in that improvement in ER will decrease maladaptive ER strategies such as binge eating.

1.6 The Current Study

The present study aimed to examine the role of ER difficulties in DBT self-help for BED by investigating whether improvements in BED symptoms with DBT are mediated by improvements in ER. Research on whether improvement in ER skills helps improve BED symptoms in DBT-SH has important clinical implications. Findings may help both therapists and SH users understand how DBT treatments for BED exerts change, and pinpoint areas to focus on during DBT to maximize treatment effects.

1.7 Research Objectives and Hypotheses

The present study involved a secondary analysis of data from a recent RCT examining the efficacy of DBT-SH compared to an active control condition (Carter et al., 2019a). The current author helped to coordinate the RCT, assisted with recruitment by screening potential participants, conducted baseline assessments, and served as a GSH therapist for the trial. In one sense, using these data to investigate whether ER skills are

related to a reduction in binge-eating is not ideal because outcome for the DBT conditions (which target ER skills) did not differ from the active control condition (which did not target ER skills) in the trial. Nevertheless, there was a significant, large decrease in binge-eating over the course of these treatments. Therefore, through focused analyses, it is possible to investigate the link between ER and binge-eating that could exist despite this lack of group differences. In particular, the current study aimed to address four research questions:

1. The first objective was to determine whether DBT-SH was associated with significantly greater pre-to-post-treatment improvement in ER skills than the SE-USH active control condition, after controlling for global psychological distress. It was hypothesized that DBT-SH would be associated with significantly greater improvements in ER than the SE-USH condition.

2. The second objective was to examine whether, within the DBT-SH group, greater pre-post improvements in ER skills were associated with greater pre-post reductions in binge frequency after controlling for global psychological distress. It was predicted that greater improvements in ER would be associated with larger decreases in binge frequency.

3. The third objective was to replicate the findings of Wallace and colleagues (2014) while also controlling for global distress. It was hypothesized that, within the DBT-SH condition, greater pre-post improvement in ER would significantly predict post-treatment BED remission status.

4. The final objective was to examine whether treatment group (DBT-SH vs. SE-USH) moderated the association between pre-post improvements in ER and pre-post

improvements in BED symptomatology, after controlling for psychological distress. A moderation analysis was employed instead of a mediation analysis given the lack of significant between-group differences in outcome in the trial– a requirement for a mediation analysis (Baron & Kenny, 1986; Kazdin, 2007). It was hypothesized that treatment group would significantly moderate this relation, such that the strength of the correlation between pre-post change in ER would be significantly stronger in the DBT-SH group than in the SE-USH group.

2.0 Methods

2.1 Ethics Approval

Full ethics approval for this study was obtained from the Health Research Ethics Board at Memorial University (reference number: 20170592).

2.2 Sample Size and Power Calculation

This study was a secondary analysis of data from an RCT examining the efficacy of DBT-GSH, DBT-USH, and an active control condition for BED (Carter et al., 2019a). The final sample size for the larger trial was 71. See Appendix A for a study protocol of the RCT.

For the current study, G*Power was used to conduct a post-hoc power analysis for a moderation analysis. Given a sample size of 71 participants, an error rate (α) of 0.05, and assuming a medium effect size (i.e., $R^2 = 0.13$), the current analysis was underpowered, with power ($1 - \beta$) equal to 0.710. A sample size of 153 would be needed in order to detect an effect size within the small-to-medium range (i.e., $R^2 = 0.075$) with 80% power. A subsequent sensitivity analysis revealed that, with 80% power, the current

study could detect an effect between medium and large (i.e., $f^2 = 0.18$). This finding further suggests that the present analysis was statistically underpowered.

2.3 Participants

Data for the present study were collected from a community sample of 71 adults meeting DSM-5 criteria for BED as determined by a semi-structured interview, the Eating Disorder Examination 17.0 (EDE; Fairburn et al., 2013; Appendix B). Participants were also required to meet the inclusion and exclusion criteria for the larger trial. Namely, they were required to have regular, private access to an internet-enabled device with a screen and video camera, be proficient in English, and have a high school diploma. Prospective participants on antidepressants or sleep medication were eligible to take part if they were on a stable dose for at least 3 months. In addition, individuals could not participate in the study if they were currently receiving psychological treatment for an eating disorder with a registered psychologist, had already received specialized eating disorder treatment, had a medical illness impacting eating or weight (e.g., diabetes), were pregnant during recruitment, or scored above the cut-off on the Drug Abuse Screening Tool (DAST; Skinner, 1982; Appendix C) and Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993; Appendix D). Individuals were also excluded if they reported six or more occurrences of compensatory behaviour over the past six months (e.g., self-induced vomiting, laxative misuse, fasting).

2.4 Recruitment

Participants for the trial were recruited from the community via diverse methods including posters displayed around the city, brochures in doctor's offices, advertisements on a local radio station website, and in church bulletins and newspapers. Provincial media

outlets also expressed interest in our study, and wrote stories on the project for local news sources. Lastly, the primary investigator of the larger trial was interviewed on local radio shows to discuss binge-eating disorder and to give contact information for the study (while keeping the study details confidential so as not to compromise the integrity of the study).

2.5 Study Conditions

In the larger trial, participants were randomized to DBT-GSH, DBT-USH, or an active comparison condition (SE-USH) for twelve weeks. Participants randomized to either DBT-GSH or DBT-USH conditions received the SH manual *An Emotion Regulation Approach for Binge-eating* (published as *The DBT Solution to Emotional Eating*) by Safer and colleagues (2018). Participants assigned to DBT-GSH also took part in six 30-minute videoconference sessions with one of three psychology graduate students. Sessions took place weekly for the first two weeks, with three subsequent bi-weekly sessions, and a final session during the last week of treatment. Therapists were graduate students in psychology who were trained in GSH by a doctoral-level registered clinical psychologist with extensive experience working with individuals with eating disorders. GSH therapist training emphasized common therapeutic factors such as validation and rapport-building, as well as DBT-GSH-specific skills such as skill review and problem-solving. Therapists attended weekly group supervision with the registered clinical psychologist throughout the course of GSH sessions to review recorded sessions, discuss clinical issues, and receive feedback. The team member who conducted the participant's baseline assessment was not permitted to be their GSH therapist so that all participants would meet their therapist for the first time upon beginning GSH.

Participants randomized to the active comparison condition received the self-help book *Self Esteem: A Proven Program of Cognitive Techniques for Assessing, Improving, and Maintaining Your Self-Esteem* (McKay & Fanning, 2016), a CBT SH manual on self-esteem improvement, with no mention of binge-eating (SE-USH). Participants were told that people with BED tend to have low self-esteem and that improving self-esteem may reduce binge-eating. The condition was designed to control for factors such as hearing a plausible treatment rationale, receiving a self-help manual, and expecting to improve (Kazdin, 2013).

2.6 Measures

2.6.1 Demographic Information

Participants completed a demographic form at pre-treatment that asked them to report their biological sex at birth, gender, age, relationship status, ethnicity, and education level (Appendix E). The demographic form also asked about current weight and height as well as their lowest and highest past body weight. In addition, participants were asked to disclose age at which they began binge-eating and to describe any past treatment for binge-eating. Participants gave their mailing address so that the researchers could mail the SH manual to them.

2.6.2 BED Diagnosis, Binge Frequency, and BED Remission

The *Eating Disorder Examination 17.0* (EDE; Fairburn et al., 2014; Appendix B) is a semi-structured interview that assesses behavioural and cognitive eating disorder symptoms. For this study, an abbreviated interview containing only BED diagnostic items and compensatory behavior items (i.e., self-induced vomiting, laxative misuse, diuretic misuse, excessive exercise, fasting, other compensatory behaviours) was administered via

telephone. This interview takes approximately 20-30 minutes. The EDE was used to confirm BED diagnosis, measure binge frequency, and determine post-treatment BED remission status. The researchers were trained by an experienced clinician on EDE administration, and received supervision during the study (e.g., interview observation and feedback). The EDE has shown high inter-rater agreement and test-retest reliability (Rizvi et al., 2000), as well as high discriminative validity (Wilfley et al., 2000).

2.6.3 Emotion Regulation

The *Difficulties in Emotion Regulation Scale* (DERS; Gratz & Roemer, 2004) is a 36-item self-report measure of ER difficulties in adolescents (e.g., Weinberg & Klonsky, 2009) and adults (e.g., Bardeen & Fergus, 2014). The DERS includes six subscales in addition to an overall score: i.) Non-acceptance of Emotional Responses (i.e., feeling secondary negative emotions in response to negative emotions, such as being angry with onself for feeling upset); ii.) Difficulties Engaging in Goal-Directed Behaviour (i.e., impaired focus and productivity when distressed); iii.) Impulse Control Difficulties (i.e., feeling as though one is out of control when highly emotional; negative emotionality leading to impulsive behaviour); iv.) Lack of Emotional Awareness (i.e., dearth of attention paid to current feelings); v.) Limited Access to Emotion Regulation Strategies (i.e., not being able to employ coping skills; believing emotions cannot be effectively managed); and vi.) Lack of Emotional Clarity (i.e., impaired ability to identify and understand one's emotions). All items are rated on a 5-point Likert scale, with 1 being "almost never" and 5 being "almost always". The DERS has been shown to have strong internal consistency, test-retest reliability, and predictive and construct validity (Gratz & Roemer, 2004). Internal consistency in the present study was excellent for the overall

score (Cronbach's α = .94), Non-acceptance of Emotional Responses (Cronbach's α = .91), Difficulties Engaging in Goal-Directed Behaviour (Cronbach's α = .91), Lack of Emotional Awareness (Cronbach's α = .90), and good for Impulse Control Difficulties (Cronbach's α = .88), Limited Access to Emotion Regulation Strategies (Cronbach's α = .89), and Lack of Emotional Clarity (Cronbach's α = .86).

2.6.4 General Psychopathology

The Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983) is a 53-item self-report questionnaire that assesses how much psychological distress was experienced over the past week (Appendix G). In the current study, the time frame was changed to "over the past 4 weeks" so that the measure would align with the timeframe specified in the EDE (i.e., measuring binge episodes in the preceding 28 days). Items are rated on a 5-point Likert scale, from 0 ("not at all") to 4 ("extremely"). The BSI yields nine symptom scales: somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, paranoid ideation, phobic anxiety, and psychoticism. It also gives three summary scores: positive symptom total, positive symptom distress scale, and global severity index (GSI), an index of overall psychopathology. Research shows that the BSI has strong internal consistency, test-retest reliability, as well as construct and convergent validity (Boulet & Boss, 1991; Derogatis & Melisaratos, 1983). Only the GSI was used in the present study, with internal consistency being excellent for this index (Cronbach's α = .95).

2.7 Procedure for the Larger Trial

Prospective participants for the trial completed an online questionnaire that assessed inclusion and exclusion criteria (Appendix H), as well as the AUDIT and DAST.

Those who were eligible were invited to participate in the abbreviated EDE via telephone. Those who were ineligible were sent a standardized email providing them with local eating disorder resources. Those who were eligible were sent an email with an attached consent form (Appendix I), along with a link to the demographic and pre-treatment questionnaires (including the DERS and BSI). The email asked the participant to carefully review the consent form prior to completing the questionnaires. The consent form itself instructed participants to imply consent through completion of the pre-treatment questionnaires. All study questionnaires were administered online via Qualtrics. A research team member then randomized participants to one of the three conditions (i.e., DBT-GSH, DBT-USH, SE-USH). Block randomization (Arifin, 2012) was conducted by an individual separate from the research team, so that the researchers remained blind to the randomization sequence.

Following randomization, participants were sent a SH manual in the mail along with an email asking them to read the manual and follow its advice over the following twelve weeks. Participants were re-administered the DERS and BSI twelve weeks later (i.e., post-treatment), completed a questionnaire assessing the number of chapters read in their respective SH manual, and also completed another telephone EDE at this time (see Appendix J for post-treatment EDE script). To avoid interviewer bias, an interviewer who was blind to participants' treatment conditions conducted these interviews.

2.8 Statistical Analyses

The dataset from the RCT (Carter et al., 2019a) used in the current study employed intention-to-treat analysis. This means that all randomized participants were included in the final analysis including those who dropped out. Multiple imputation was

used to estimate missing data at post-treatment (Enders, 2017; Ruben, 1987). This procedure accounts for any missing data (e.g., participants not completing post-treatment assessments) by estimating these values based on the distribution of the extant data (i.e., by replacing missing data points with values that align with the pattern of present data). Multiple imputation uses an iterative process based on regression analysis to create several different estimates of missing values, with this procedure providing multiple alternate approximations of the original database. Data analyses are carried separately on each iterated dataset and are then pooled to create a single estimate. The multiple imputation procedure in the current study generated 20 iterations. This procedure has been shown to be suitable for studies with data missing-not-at-random as is the case with drop-out from randomized clinical trials (O'Kelly & Ratitch, 2014). Multiple imputation is considered a superior approach to missing data handling than single imputation or listwise deletion as it uses an iterative process to provide multiple estimates of missing values. Other approaches tend to provide single estimates based on observed data (i.e., replacing missing values with estimates based on completer results), leading to potentially biased statistics (van Ginkel et al., 2019).

Data were primarily analyzed using IBM SPSS Software Version 21 (Armonk, NY). However, as SPSS only provides individual *F*-test values (i.e., analysis of variance, regression model fit) for each imputed iteration, as opposed to pooled statistics, the "miceadds" package (Robitzsch et al., 2019) within R Version 3.6.1 (R Core Team, 2019) was used through RStudio Version 1.2.1335 (RStudio Team, 2015) to pool F-test values when necessary. Significance was determined at $p < .05$ unless otherwise indicated.

In terms of data screening, relevant variables were screened to ensure that they met required assumptions for analysis of variance and regression analyses. Specifically, data were assessed for linearity, homogeneity of regression slopes, homoscedacity, homogeneity of variances, and normality (i.e., analysis of variance assumptions), as well as multicollinearity, presence of outliers, and normal distribution of residuals (i.e., regression assumptions). In addition, the binge frequency variables were log transformed due to significant skewness and kurtosis. Data screening using the Mahalanobis distance method revealed no multivariate outliers in the current dataset.

Next, descriptive statistics were run on demographic variables for each condition to yield means and standard deviations for continuous demographic variables (i.e., body mass index [BMI; kilograms/metres^2], age), and frequencies and percentages were calculated for categorical variables (i.e., sex, education level, relationship status, ethnicity). In addition, means and standard deviations were calculated for all pre-treatment clinical variables including DERS total score, BSI GSI, and binge frequency as measured by the EDE. Next, a series of independent samples *t*-tests were run to determine whether continuous pre-treatment demographic or clinical variable means significantly differed between conditions. Chi-square analyses were performed to examine between-group differences on pre-treatment categorical variables.

Given the lack of significant differences in outcome between the DBT-GSH and DBT-USH groups in the trial (Carter et al., 2019a), these two conditions were collapsed into one DBT-SH condition for the purposes of the present study. Thus, between-group analyses examined differences between the DBT-SH and SE-USH conditions.

2.8.1 Is DBT self-help associated with significantly greater improvements in DERS than SE-USH?

It was predicted that the DBT-SH condition would be associated with significantly greater pre-post improvements in DERS total score than the SE-USH condition. To test this hypothesis, a 2 (time) x 2 (condition) repeated measures analysis of covariance (ANCOVA) was run with pre-post DERS total score change as the dependent variable. This procedure allowed for psychological distress (i.e., pre-post BSI-GSI score) to be held constant, to ensure that the analysis captured group differences in DERS change, as opposed to negative emotionality. The difference in DERS improvement between the two groups would be reflected in the test of the time by condition interaction. Partial eta squared values (η^2_p) were generated as effect size values for this analysis.

2.8.2 Within the DBT-SH condition, are greater pre-to-post-treatment improvements in DERS associated with greater reductions in binge-eating frequency from pre-to-post-treatment?

It was hypothesized that, within the DBT-SH group, greater pre-post improvements in DERS total score would predict greater pre-post improvements in binge frequency. To test this hypothesis, a hierarchical linear regression was conducted with pre-post BSI-GSI in the first block (to control for global distress), pre-post change in DERS total score entered in the second block, and pre-to-post-treatment change in binge frequency as the criterion variable. Change in R^2 values were calculated as estimates of effect size for this analysis.

2.8.3 Within the DBT-SH condition, are greater pre-to-post-treatment improvements in DERS predictive of BED remission status at post-treatment?

It was hypothesized that the current study would replicate the findings from Wallace and colleagues (2014), and that pre-post change in DERS would significantly predict post-treatment remission status. For this objective, a hierarchical logistic regression was run with pre-post GSI in the first block (to control for global distress), pre-post change in DERS total score in the second block, and post-treatment remission status as the criterion variable. Odds ratios and confidence intervals were used as estimates of effect size.

2.8.4 Does treatment condition significantly moderate the strength of the correlation between improvements in DERS and improvements in binge frequency?

Due to the lack of significance in binge-eating outcome between conditions in the larger trial (Carter et al., 2019a), it was not feasible to conduct a mediation analysis to determine whether changes in DERS total score mediated the relationship between condition and pre-post change in binge frequency. However, as previously discussed, a moderation analysis may be used in place of a mediation analysis to study mechanisms of change in instances when there are no significant between-group differences in outcome, as moderation analyses explore the strength and direction of associations, as opposed to whether relationships are statistically significant and do not require, as a prerequisite, a statistically significant difference between the groups (Kazdin, 2007). In other words, although the DBT-SH and SE-USH had similar decreases in binge-eating frequency, it is possible that is the decrease in binge-eating was due to an increase in ER skills in the DBT-SH group but due to something else in the SE-USH group. Thus, the final analysis

was a Baron and Kenny (1986) moderation analysis to explore whether the strength of the relationship between change in DERS and change in binge frequency depended on treatment condition. It was hypothesized that the relationship between change in DERS and binge frequency would be significantly stronger in the DBT-SH group than the SE-USH group.

To test this hypothesis, a hierarchical linear regression analysis was run with pre-to-post-treatment change in binge frequency as the criterion. Pre-post BSI-GSI change score was entered into the first block to control for global distress. Next, pre-post change in DERS score and treatment condition were added into the second block. The interaction term (i.e., the product of the respective DERS score variable multiplied by the dummy-coded treatment condition variable) was entered into the third block. Change in R^2 was calculated as a measure of effect size. A significant moderation would be reflected by the interaction term significantly predicting pre-post change in binge frequency.

3.0 Results

3.1 Participant Flow and Attrition

Five hundred and fifty-eight individuals completed the screening questionnaire for the larger RCT. Of these, 298 people appeared to meet the study inclusion criteria and were offered a telephone EDE interview. One hundred and seventy-five EDE telephone interviews were conducted, with 75 individuals meeting criteria for BED. Seventy-four of these individuals consented to take part in the study. During the study, three participants disclosed information that no longer made them eligible to participate (i.e., type II diabetes, pregnancy, learning disability in reading) and their data were removed. The final sample thus consisted of 71 participants (93% female). Twenty-four participants

were randomized to the DBT-GSH condition, 24 to the DBT-USH condition, and 23 to the SE condition.

Of these 71 participants, 46 (64.8%) completed the post-treatment questionnaires. Ten individuals dropped out of the DBT-GSH condition (41.7%), four from the DBT-USH condition (16.7%), and 11 from the SE condition (47.8%). A chi-square analysis revealed that the DBT-USH condition retained significantly more participants at post-treatment than the other two conditions, $\chi^2(1, n = 71) = 5.471$, $p = .019$. Across the collapsed DBT-SH conditions, 29.2% of participants dropped out by post-treatment. There was no significant difference between pre-to-post-treatment attrition between the DBT-SH condition and SE-USH condition, $\chi^2(1, n = 71) = 2.373$, $p = 123$. In terms of treatment adherence, a post-treatment questionnaire assessing number of chapters read indicated that, on average, DBT-SH participants read between eight and nine chapters out of thirteen total chapters of the DBT-SH manual (i.e., $M = 8.432$, $SD = 4.253$), while participants in the SE-USH condition read between six and seven chapters of the 17 chapters in the SE-USH book (i.e., $M = 6.571$, $SD = 6.211$).

3.2 Baseline characteristics

Tables 2, 3, and 4 present the baseline demographic and clinical characteristics for the conditions. For reference, the mean provincial age in NL according to the 2016 Census was 43.7. In terms of relationship status, 62.2% of the adult population reported being married or in a common-law relationship, 96.2% reported their ethnicity as Caucasian, and 61.7% indicated completing post-secondary education. These statistics are similar to those of the current sample, suggesting that the community sample is representative of the general NL population.

A series of chi-square analyses were run to compare the conditions on demographic variables. There were no significant between-condition differences at baseline with regards to gender, $\chi^2(1, n = 71) = 0.377$, $p = .539$, education, $\chi^2(3, n = 71) = 3.154$, $p = .369$, or relationship status, $\chi^2(3, n = 71) = 3.378$, $p = .337$. A chi-square test of independence showed a significant difference between the conditions in terms of ethnicity, as two individuals within the SE-USH group reported ethnicities other than caucasian, $\chi^2(1, n = 71) = 4.25$, $p = .038$, Cramer's $V = .246$. However, as the expected cell frequency for two of the cells was less than five, a two-sided Fisher's exact test was run to further explore between-group difference in ethnicity, and was not significant, $p = .102$. This finding suggests that the proportion of the different ethnicities in the sample was independent of condition. Furthermore, independent-sample *t*-tests with condition as the independent variable demonstrated that the DBT-SH and SE-USH conditions did not significantly differ in terms of baseline age, $t(69) = -0.171$, $p = .864$, or BMI, $t(69) = -1.337$, $p = .186$ (Table 3).

This pattern was consistent with regards to clinical variables. The conditions did not significantly differ on baseline number of binge episodes in the past 28 days, $t(69) = -0.736$, $p = .464$, DERS total score, $t(69) = -0.105$, $p = .917$, or BSI-GSI, $t(69) = -0.512$, $p = .610$. Of note, the current mean values for baseline DERS scores are similar to pre-treatment mean DERS total scores found in previous BED treatment (Masson et al., 2013; Safer et al., 2010) and cross-sectional studies (Harrison et al., 2016; Robinson et al., 2015). Further, the current mean DERS scores for each condition are approximately one standard deviation above the means presented in the initial paper on the development and validation of the DERS, which reported on data from a large, non-clinical undergraduate

sample (Gratz & Roemer, 2004). This pattern of findings suggests that the current participants were experiencing above-average difficulties with ER at baseline.

Table 2

Age and BMI of Participants in the Sample

	Age		
	Mean	*SD*	Range
DBT-SH	40.54	11.91	42 (21-63)
SE-USH	41.04	10.73	37 (25-62)
	BMI		
	Mean	*SD*	Range
DBT-SH	36.30	8.82	39.87 (20.17-60.05)
SE-USH	39.49	10.60	45.65 (19.74-65.39)

Note: Lowest and highest ages and BMI values in the sample are given in brackets next to the range value.

Table 3

Demographic Characteristics of the Sample

	DBT-SH *n* (%)	SE-USH *n* (%)
Gender		
Female	44 (91.7%)	22 (95.7%)
Male	4 (8.3%)	1 (4.3%)
Ethnicity		
Caucasian	48 (100.0%)	21 (91.3%)
Other	0 (0.0%)	2 (8.7%)
Relationship status		
Single	14 (29.2%)	10 (43.5%)

Married/Common Law	29 (60.4%)	13 (56.5%)
Divorced	3 (6.2%)	0 (0.0%)
Separated	2 (4.2%)	0 (0.0%)
Education level		
High school	6 (12.5%)	0
College	18 (37.5%)	10 (43.5%)
Undergraduate degree	17 (35.4%)	9 (39.1%)
Graduate degree	7 (14.6%)	4 (17.4%)

Table 4

Clinical Characteristics of Participants in the Sample

	DBT-SH		SE-USH	
	Mean	*SD*	Mean	*SD*
Binge frequency	14.89	10.52	21.73	25.52
DERS	97.90	23.15	98.51	21.95
GSI	1.08	.60	1.15	.48

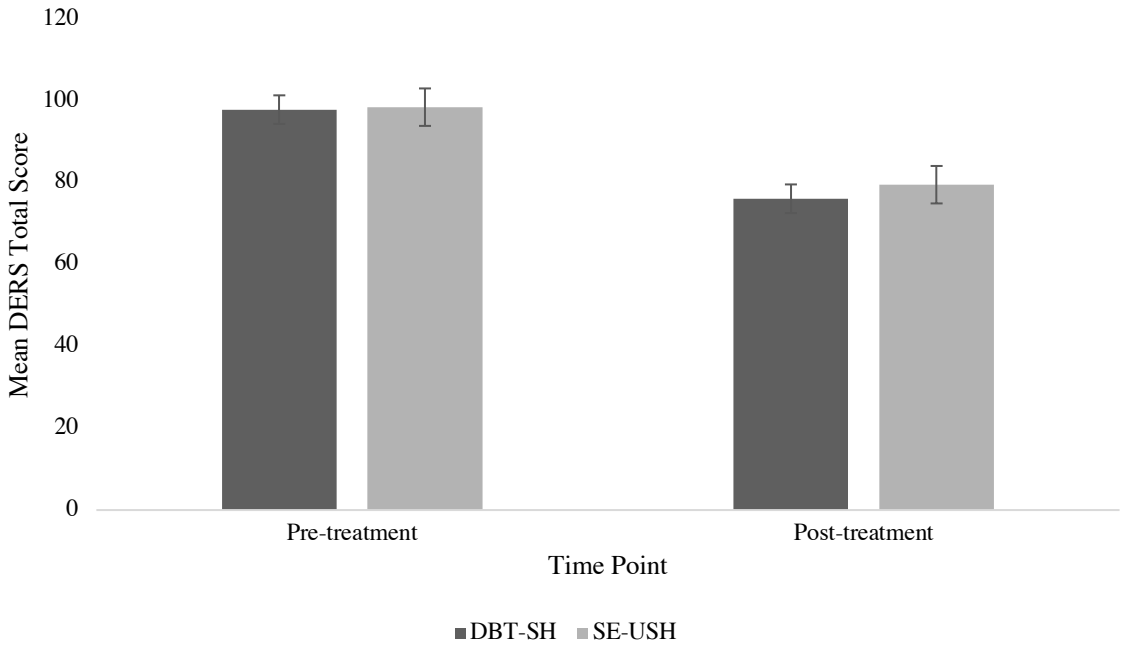
3.3 Is DBT self-help associated with significantly greater improvements in DERS than SE-USH?

The results of the two-way repeated measures ANCOVA revealed a significant main effect of time, $F(1, 243.77) = 4.862$, $p = .028$, $\eta^2_p = 0.094$. However, the main effect of condition, $F(1, 15932.32) = 0.222$, $p = .638$, $\eta^2_p = 0.004$, and the time x condition interaction, $F(1, 976.47) = 0.445$, $p = .505$, $\eta^2_p = 0.010$, were not significant. These findings suggest that all groups showed medium-magnitude improvement in DERS from

pre-treatment to post-treatment. However, the results indicate that there was no between-group difference in pre-post DERS change. The effect size associated with the between-group analysis was small, suggesting that there was minimal difference in pre-post DERS change between groups in the current study. Figure 2 summarizes change in DERS across the two time points for the two conditions.

Figure 2

Mean DERS Total Score at Pre-treatment and Post-treatment for DBT-SH and SE-USH Conditions



3.4 Within the DBT-SH condition, are greater improvements in DERS associated with greater reductions in binge-eating frequency from pre-to-post-treatment?

The hierarchical linear regression analysis was not significant when pre-post BSI-GSI was entered into the first block, $F(1, 184.54) = 1.091$, $p = .297$, $R^2 = .043$, or when pre-post DERS total score were entered into the second block, $F(2, 314.25) = 0.630$, $p = .533$, $\Delta R^2 = .005$ (see Table 4). As these findings were non-significant with small effect

sizes, this suggests that pre-post DERS change was not a strong predictor of pre-post binge frequency change within the DBT group.

Table 5

Results of the Hierarchical Linear Regression Analysis with Pre-Post Binge Frequency Change Score as the Criterion

	Unstandardized Coefficients			
	B	*SE*	*t*	*p*
Model				
1				
GSI	.154	.160	.964	.337
2				
DERS	.001	.005	.237	.813
GSI	.126	.212	.597	.552

3.5 Within the DBT-SH condition, does pre-to-post-treatment improvement in DERS predict BED remission status at post-treatment?

Similar to the linear regression analysis, the hierarchical logistic regression analysis was not significant with pre-post BSI-GSI change score in the first block, $\chi^2(1, n = 48) = 0.228$, $p = .664$, $OR = 1.376$, or with pre-post DERS change score in the second block, $\chi^2(2, n = 48) = 0.294$, $p = .836$, $OR = 1.002$. All odds ratios were of small magnitude (Chen, et al., 2010). Thus, the current study did not find evidence to suggest that pre-post change in DERS was a significant predictor of post-treatment remission status.

Table 6

Coefficients for the Hierarchical Logistic Regression Analysis with BED Remission Status as the Criterion

	Unstandardized Coefficients					
	B	*SE B*	*Wald* χ^2	*p*	*OR*	*95% CI*
Model 1						
GSI	.319	.780	.228	.683	1.376	.298-6.535
2						
DERS	.002	.016	.820	.914	1.002	.971-1.003
GSI	.270	.993	.224	.786	1.310	.187-9.203

3.6 Does treatment condition significantly moderate the strength of the correlation between improvements in DERS and improvements in BED symptomatology?

The Baron and Kenny (1986) moderation method was employed to examine whether DBT-SH participation moderated the association between DERS improvement and binge frequency improvement. Overall, the regression model was not significant at steps one (i.e., BSI-GSI as predictor), $F(1, 85.34) = 1.756$, $p = .189$, $R^2 = .056$, two (i.e., DERS total pre-post score and condition added as predictors), $F(1, 122.14) = 0.671$, $p = .571$, $\Delta R^2 = .011$, or three (i.e., the interaction between condition and pre-post change in DERS total score added as a predictor), $F(1, 113.93) = 0.487$, $p = .745$, $\Delta R^2 = .008$.

Consistent with findings from the previous objectives, pre-to-post-treatment change in DERS total score did not significantly predict change in binge frequency (see Table 3). Similarly, condition did not predict pre-post change in binge frequency. Further, DBT-SH participation did not significantly moderate the relationship between change in DERS total score and binge frequency (see Figure 3). Taken together, as the pre-post DERS change and condition interaction was not significant and was accompanied by a low effect size, it appears that condition did not act as a moderator of the relationship between pre-post DERS change and pre-post binge frequency.

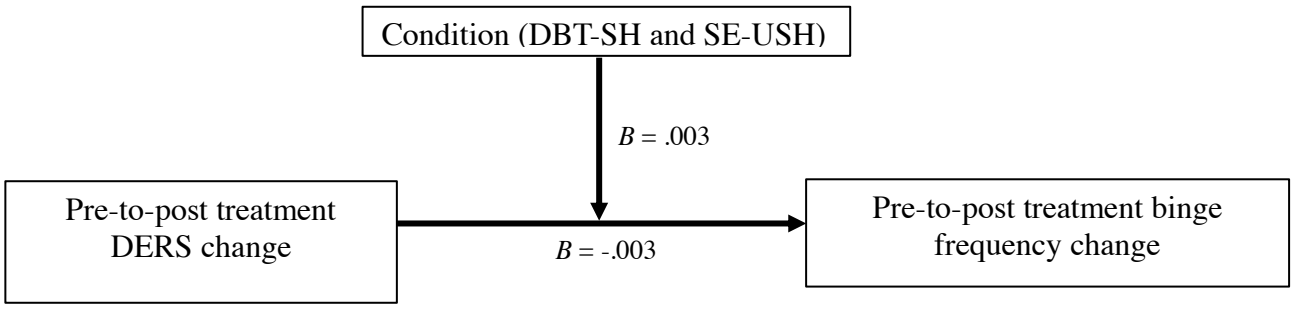
Table 7

Results of the DERS x Condition Moderation Analysis with Pre-Post Binge Frequency Change Score as the Criterion

	Unstandardized Coefficients			
	B	*SE*	*t*	*p*
Model				
1				
GSI	.196	.143	1.367	.175
2				
DERS	.002	.004	.402	.688
Condition	-.033	.159	-.205	.838
GSI	.158	.188	.838	.405
3				
DERS	-.003	.009	-.304	.761
Condition	-.099	.206	-.483	.629

DERS x Condition	.003	.007	.483	.629
GSI	.163	.186	.879	.382

Figure 3



Results of the DERS x Condition Moderation Analysis

4.0 Discussion

4.1 Summary of the Findings

DBT is based on the emotion regulation model of BED. This model theorizes that BED results from a deficit in ER, such that vulnerable individuals with BED use binge-eating as a way to modulate uncomfortable emotions (e.g., numbing, soothing, distracting, etc.). Thus, DBT aims to improve individuals' ER abilities so that they do not turn to binge-eating as a way to cope with distress. However, limited research has evaluated the role of ER in DBT for BED. Therefore, the purpose of the present thesis was to examine the role of ER in treatment outcome in DBT-SH – a SH adaptation of traditional DBT for BED. The present study was a secondary analysis of data that were collected as part of a randomized controlled trial that compared DBT-GSH and DBT-USH to an active USH control condition designed to control for non-specific factors (SE-USH; Carter et al., 2019).

The first objective of the present study was to determine if the combined DBT-SH groups were associated with significantly greater pre-to-post-treatment improvements in ER than the active control condition (SE-USH). It was hypothesized that DBT-SH would be associated with significantly larger improvements in ER than SE-USH. The results showed that both DBT-SH and SE-USH conditions showed large-magnitude improvements in ER from pre-to-post-treatment. Contrary to expectations, there were no between-group differences in pre-post ER change. These non-significant between-group differences were associated with small effect sizes.

The second research question was whether, within the combined DBT-SH conditions, the degree of pre-post ER change would predict the degree of pre-post binge frequency change. Consistent with the ER model, it was hypothesized that larger improvements in ER would significantly predict larger decreases in binge frequency. However, the results revealed no significant relationship between these two variables with a small effect size.

Third, this study aimed to replicate an analysis from the only previous study that examined the relationship between pre-post ER change and remission from binge-eating following DBT treatment outcome (Wallace et al., 2014). Based on the previous findings, it was hypothesized that pre-post change in ER would significantly predict BED remission (i.e., no reported binge episodes in the past 28 days) at post-treatment in the present study. However, the present analysis revealed a small effect size and no significant relationship between pre-post ER and binge remission. Furthermore, pre-post ER change scores did not differ significantly between those who achieved binge remission at post-treatment and those who did not, with a small effect size.

Lastly, the present study aimed to determine whether pre-post change in ER acted as a mechanism of change in DBT-SH more so than in SE-USH. A moderation analysis was conducted to examine whether treatment condition (i.e., DBT-SH or SE-USH) significantly moderated the strength of the relationship between pre-post change in ER and pre-post change in binge frequency. That is, the analysis aimed to determine whether the relationship between binge frequency and ER was significantly stronger in the in the DBT-SH condition than in the SE-USH condition. Contrary to the hypothesis, treatment condition was not a significant moderator of this relationship, with a small effect-size.

4.2 DBT self-help was not associated with significantly greater pre-post improvements in ER than active SE-USH control.

As expected, participants in DBT-SH reported a large and statistically significant improvement in their difficulties with ER from pre-to-post treatment. This is consistent with the results of previous RCTs that have similarly found that individuals with BED who received DBT interventions improved from pre-to-post-treatment in terms of ER abilities (Masson et al., 2013; Safer et al., 2010; Telch et al., 2001). The improvement demonstrated in the DBT-SH group adds to growing evidence suggesting that DBT-based interventions are effective for improving ER in BED (Lavender, 2015). On a broader scale, this finding aligns with research suggesting the effectiveness of SH interventions in decreasing eating disorder symptoms (Aardoom et al., 2016a; Aardom et al., 2016b).

However, contrary to expectations, the current study found no difference in pre-post ER improvement between DBT-SH and the active control condition, and the associated effect size was small. This stands in contrast to previous studies that compared DBT-GSH (Masson et al., 2013) and group DBT for BED (Telch et al., 2001) to WLC

conditions. Yet, these two studies feature a significant difference from the present study in that this study used an active control condition to control for non-specific factors, as opposed to a WLC in which participants did not receive any treatment. Therefore, it is to be expected that the difference in ER change will be larger – and that statistical power will be higher – when comparing a DBT-based intervention to no intervention than when comparing DBT to an active intervention (Kazdin, 2013). Interestingly, the results of the current study are in line with the findings of a previous trial that compared group DBT for BED to an active control condition (Safer et al., 2010). Similar to the present findings, Safer et al. (2010) also found small effect sizes for group differences in ER between the DBT condition and active control condition at post-treatment. While research is limited, these findings suggest that certain non-specific factors (e.g., contact with researchers, expecting to improve, hearing a plausible treatment rationale) could lead to meaningful ER improvements in BED. This possibility is supported by the fact that the SE-USH group reported reading considerably less of the self-help manual than the DBT-SH group, possibly suggesting that non-specific factors, distinct from the material in the SE-USH book, may explain changes within this condition.

4.3 Within the combined DBT-SH condition, greater improvements in ER were not associated with greater reductions in binge-eating frequency from pre-to-post-treatment.

In contrast to the hypothesis, pre-post change in ER within the DBT-SH group did not significantly predict pre-post binge frequency change. Subsequent analysis revealed a small effect size, suggesting that there was no meaningful association between ER change and binge frequency change. To date, no previous longitudinal or treatment studies have

examined the association between pre-post ER change and pre-post binge frequency change as continuous variables. However, the current results are inconsistent with experimental studies that have found a negative association between ER and binge-eating (e.g., Rosenberg et al., 2013; Schulz & Laessle, 2010; Svaldi et al., 2014). For example, one study found that, compared to a weight-matched control group without BED, participants with BED who reported higher induced negative emotionality were more likely to engage in a self-reported binge following the negative mood induction (Telch & Agras, 1996). Similarly, a cross-sectional study found that, compared to individuals with obesity and without BED, as well as individuals of normal weight, those with BED reported higher daily levels of emotional distress, and demonstrated significantly stronger associations between negative emotionality and overall desire to eat (Zeeck et al., 2011).

The discrepancy between the current findings and past research on the association between ER and binge-eating may be related to methodological factors such as low statistical power given the relatively small sample size. However, the small effect size obtained for this relationship suggests that there was no meaningful connection between pre-post change in ER and binge frequency in the current study. One possibility is that a third variable accounts for the association between ER and binge-eating. For instance, it may be that the relationship between ER and binge-eating is explained by depressive symptoms and that, without self-reported negative emotionality, there may not be a significant association between ER and binge-eating. This idea is supported by a recent cross-sectional study that found a significant positive relationship between binge-eating and ER but only among those who reported higher levels of depression (Kenny et al., 2017). Thus, it is possible that binge frequency may fluctuate more as a function of

negative emotionality as opposed to the manner in which those emotions are regulated. In other words, it may be that DBT-SH leads to a decrease in distress, leading individuals to experience fewer negative emotions that could make them vulnerable to binge eating.

4.4 Within the combined DBT-SH condition, greater pre-post improvements in ER did not predict remission status at post-treatment.

In contrast to the findings of Wallace and colleagues (2014) who found that pre-post change in ER predicted remission from binge-eating at post-treatment, we found that pre-post ER change did not predict remission from binge-eating in the current study. This relationship was associated with a small effect size suggesting no meaningful association between pre-post ER change and post-treatment remission status. A secondary analysis also showed no significant difference in ER scores between participants who achieved remission from binge-eating and those who did not with a small effect size.

This discrepancy between the current findings and those of Wallace and colleagues (2014) may be related to certain methodological and statistical differences between the two studies. First Wallace and colleagues employed a sample of sixty participants, while the current analysis (DBT-SH condition only) contained thirty-eight participants. Further, Wallace and colleagues were able to detect a series of small effects, while effects of similar magnitude went undetected in the current study. As greater statistical power is required to detect smaller effects as significant, this pattern suggests that the current study lacked statistical power.

Another methodological difference between the two studies was that, although the Wallace and colleagues (2014) study used a dataset with a similar rate of missing data (Masson et al., 2013) as the current data set (Carter et al., 2019), the former study

replaced missing data by carrying the last observation forward (LOCF) for each participant with missing data, as opposed to multiple imputation (MI) which was used in the current dataset. LOCF is widely considered limited as it assumes that the variable in question does not change over time (Kenward, 2013; Lachin, 2016; Shoop, 2015). This assumption can bias results as it has the potential to both obscure treatment effects that exist, and present treatment effects that are not valid. For instance, if a portion of the participants experienced worse ER following drop-out, but were assumed to remain static on this construct, subsequent analyses using the last-observation-carried-forward method could bias the results in favour of the treatment (Molnar et al., 2008). Multiple imputation is widely considered to be a superior approach and may have led to a more valid representation of the relationship between pre-post ER change and post-treatment remission as it takes into account change over time, leading to less bias (O'Kelly & Ratitch, 2014; see Section 4.6).

4.5 Treatment condition did not significantly moderate the strength of the relationship between pre-post improvements in ER and pre-post improvements in binge frequency.

The final objective of the current study was to examine pre-post ER improvement as a potential mechanism of change within DBT-SH. Mediation analyses are frequently used to examine mechanisms of change, and determine whether a relationship between an independent and dependent variable occurs through the independent variable's relationship with a mediating variable (Baron & Kenny, 1986). However, in the present study, the independent and dependent variables (i.e., condition and pre-post change in binge frequency, respectively) were not significantly associated, making it impossible to

conduct a mediation analysis. Thus, mechanism of change was examined using moderation analysis, as this analysis does not require a significant relationship between the independent and dependent variables. Instead, a moderation analysis examines whether the strength of the correlation between two variables (i.e., in this case, change in binge-eating and change in ER difficulties) significantly varies at different levels of the moderator variable (i.e., treatment condition; Kazdin, 2007). The current results indicated that treatment condition (i.e., DBT-SH versus SE-SH) was not a significant moderator of the relationship between pre-post ER change and pre-post binge frequency improvement. Further, the effect size associated with the moderation relationship was small, suggesting that ER was not a mechanism of change within DBT-SH.

Few longitudinal or treatment studies exist that explored the relationship between ER and BED. The only longitudinal study to use a formal moderation analysis to examine the link between ER and BED found that baseline ER did not moderate treatment outcome in group DBT for BED (i.e., those with more ER difficulties at baseline did not respond better to DBT; Robinson & Safer, 2012). This non-significant finding aligns with the lack of significance found in the present study's moderation analysis, and provides another example of the ER model of BED not being supported through longitudinal treatment research. Taken together, the ER model has been repeatedly supported through cross-sectional and experimental studies, but has not been validated through longitudinal treatment studies (e.g., Carter et al., 2019; Robinson et al. 2012; Safer et al. 2010), leading to overall mixed findings in support of the model.

There may be various reasons for the mixed findings in the literature regarding the ER model of BED. One possibility is that there are different subgroups of individuals

within the BED population (and in these study samples) that reflect different underlying mechanisms relevant to the maintenance – and thus, treatment- of the disorder. This hypothesis is supported by a cross-sectional study that found that self-reported depression ratings significantly moderated the association between binge frequency and reported difficulties with ER, with these two constructs being significantly associated in those with higher, but not lower, levels of depression (Kenny et al., 2017). This suggests that there may be different mechanisms at play in individuals who meet criteria for BED but experience relatively less difficulties with ER than those who correspond to the ER model of BED. Further, while preliminary evidence suggests that group DBT-based treatments are promising interventions for BED, a significant portion of individuals do not respond to this intervention, as evidenced by post-treatment and follow-up abstinence rates of approximately 60% (Carter et al., in press; Chen et al., 2008; Klein et al., 2013; Masson et al., 2013; Safer et al., 2010). These findings from treatment studies point towards the possibility that some individuals with BED respond better to DBT treatments that treat difficulties with ER as the primary underlying mechanism in BED, while others may show less improvement perhaps because this treatment does not target mechanisms relevant to their disorder.

Research has shed light on various other mechanisms that may contribute to the development and maintenance of BED. One of these factors is dietary restraint, or an individual's intentional effort to restrict their caloric intake to manage weight and shape, often in the form of rigid dietary rules (Polivy, 1976; Polivy & Herman, 1985). Individuals who hold these rigid rules in an "all-or-none" manner are prone to binge-eating. When these rules are challenged through events such as stress or the presentation

of palatable food, the individual may "break" their rule and engage in disinhibited (i.e. binge) eating. A subsequent binge can then lead to distress, thus prompting further restraint that puts the individual at risk for a future binge episode (Polivy & Herman, 1985; Wilson, 1993). Research has shed light on the relationship between dietary restraint and BED. Studies have found that approximately half of individuals with BED report significant histories of dietary restraint via dieting prior to the onset of BED (e.g., Grilo & Masheb, 2000; Reas & Grilo, 2007; Spurrell et al., 1997). Further, dietary restraint has been found to significantly predict binge-eating across eating disorders (Jacobi et al., 2004). In one study, greater decreases in rigid dietary restraint predicted significantly higher probability of post-treatment abstinence from binge-eating following CBT-GSH for BED (Blomquist & Grilo, 2011). Thus, as DBT does not address dietary restraint, this research suggests that these individuals may respond better to a CBT treatment approach that explicitly discusses dietary restraint (e.g., Fairburn, 1995).

Another conceptualization of BED is a model centered around the concept of "food addiction". This refers to the idea that certain highly palatable foods (e.g., calorie-dense, highly processed foods) can provoke a process similar to substance addiction (e.g., alcohol use disorder) in certain individuals, with features such as tolerance and withdrawal (Gearhardt et al., 2009). Research has accumulated both validating the model (for review, see Carter et al., 2016) and suggesting its importance in BED. For instance, one study found that individuals with BED endorsed significantly higher levels of food addiction than a sample with no history of an eating disorder, with approximately three quarters of the sample endorsing severe food addiction symptoms (Carter et al., 2019b). Moreover, BED has been shown to be associated with various mechanisms associated

with substance use disorders such as reward dysfunction, craving, and impulsivity (for review, see Schulte et al. , 2016). Multiple studies have found that approximately 50% of their BED samples to meet criteria for "food addiction" (e.g., Gearhardt et al., 2013; Gearhardt et al., 2012). Thus, this research points towards the existence of a subset of individuals with BED whose experience aligns with a food addiction model, and who might respond better to a treatment similar to those used with substance-use disorders (Schulte et al., 2016).

Another potential explanation for the current findings is that ER is not the mechanism of change within DBT. For example, mindfulness is a pivotal component of DBT, and many DBT skills aim to decrease BED symptoms by enhancing mindfulness (Linehan, 1993). For instance, mindful eating aims to increase awareness and satisfaction through eating via encouraging mindful awareness during food consumption (Safer et al., 2018). Thus, it may be the case that DBT improves BED symptoms via enhancing mindfulness, as opposed to ER. In addition, factor analysis research has revealed that there are multiple facets to emotion regulation such as awareness and acceptance of emotions, as well as impulsivity (Gratz & Roemer, 2004). It is possible that, while overall ER as measured by the DERS does not act as a mechanism of change, specific aspects of ER – reflected in the DERS subscales that were not examined in the current study – are more influential on treatment outcome. Certain DBT skills target these individual ER elements. For instance, DBT for BED works with people to enhance their ability to accept uncomfortable emotions as opposed to avoiding the experience via binge-eating (Safer et al., 2018). Thus, specific ER dimensions such as emotional acceptance could be key mechanisms in DBT for BED.

4.6 Methodological Strengths

This study had a number of methodological strengths. First, the Eating Disorder Examination 17 (EDE; Fairburn et al., 2014) was used to assess and diagnose participants with BED at pre-treatment, and to gauge binge frequency at pre- and post-treatment. The EDE is a semi-structured interview that has been well-validated in community samples and is considered to be the "gold standard" eating disorder diagnostic tool (Berg et al., 2012; Mond et al., 2004). Further, interviewers received extensive training and supervision in EDE administration and scoring with a senior clinical psychologist who specializes in eating disorders. These factors combined lend confidence that participants were accurately diagnosed with BED, and that binge frequency data were accurately assessed. Further, the post-treatment EDE interviews were conducted by a research assistant who was blind to the participants' treatment conditions in an effort to minimize interviewer bias (e.g., observer-expectancy or confirmation bias).

This study also employed psychometrically sound self-report questionnaires. For example, in addition to the BSI having strong overall psychometric properties (Derogratis & Melisaratos, 1983), factor analysis research suggests that the BSI is particularly adept at validly capturing general psychological distress in community samples (Urban et al., 2014). Studies have also found that the DERS possesses strong validity and reliability when used with community samples (e.g., Victor & Klonsky, 2016), as well as eating disorder populations (Wolz et al., 2015). Of note, factor analysis in the latter study found that DERS results across eating disorder diagnoses aligned with the original conceptualization of the measure, further suggesting its ability to accurately capture ER difficulties in people with eating disorders.

Another strength of the current study was that we recruited a community sample of adults with BED. While samples recruited from clinics or treatment centers are generally considered easier to recruit and maintain over longitudinal clinical studies (Kazdin, 2013), a study by Wilfley and colleagues (2001) found that clinic samples of adults with BED report significantly more psychopathology and higher binge frequency than community BED samples. As such, the present results may be more generalizable to the general population than the results of studies employing clinic samples. This consideration is especially relevant to a study of self-help interventions given that stepped care conceptualizations indicate that individuals in the community with less complex psychopathology might benefit from lower-intensity treatments such as SH, as opposed to more intensive in-clinic treatments (Bower & Gilbody, 2005; Clark et al., 2009). Of note, the current sample was similar to community samples from other studies in terms of baseline age, gender ratio, and binge frequency (Masson et al., 2013; Safer et al., 2010), which suggests that the current sample was representative of the BED population within the larger community.

An additional methodological strength was that the trial from which the data for the current study were obtained used intention-to-treat analysis. This means that all randomized participants were included in the outcome analysis. Further, multiple imputation (MI) was used to estimate missing data at post-treatment. MI – as outlined by Ruben (1987) and Enders (2017) – is a procedure for replacing missing data in clinical trials that uses an iterative process to provide multiple estimates for each missing data point, as opposed to other commonly used methods, such as last observation carried forward, that provide a single estimate (McKnight et al., 2007; van Ginkel et al., 2018).

MI allows for analyses to be run on these separate datasets, and then pools these separate results to create a single estimate. MI was appropriate for the current study as it considers missing data points to be systematically different than observed data points, which is often the case in clinical trials (e.g., individuals dropping out of treatment due to factors such as motivation, perceived acceptability and accessibility of treatment, etc.; O'Kelly & Ratitch, 2014). In addition, the iterative process in MI that provides multiple estimates for each missing data point is considered superior to other methods that provide a single estimate for a missing data point (McKnight et al., 2007; van Ginkel et al., 2018). These single imputation methods tend to provide estimates based on observed data, which can lead to biased statistics (e.g., replacing all missing data points with variable means derived from completers, leading to unrepresentative statistics; van Ginkel et al., 2018). As such, multiple imputation is designed to provide realistic outcome estimates for participants who have left the study, suggesting that the current results are a strong estimate of actual outcome.

Another strength of the current study lies in the use of moderation analysis to examine the relationship between pre-post change in ER, pre-post change in binge frequency, and treatment condition. This procedure allowed the current study to examine the degree to which treatment condition impacted the relationship between pre-post change in ER and binge frequency. While the study by Wallace and colleagues (2014) used a series of logistic regressions to explore whether pre-post change in emotion regulation predicted binge abstinence, a limitation of logistic regression is that it only examines the link between two variables, one of which is a categorical variable (i.e., change in ER and binge abstinence). The moderation analysis used in the current study

explored both the bidirectional association between ER change and binge frequency, as well as whether treatment condition influenced this relationship.

4.7 Methodological Limitations

The present study also had a number of methodological limitations. First, the sample was quite homogenous with most participants being university educated, female, and Caucasian. This limits the generalizability of the findings. Second, there was a considerable attrition rate of 35%. Although multiple imputation is considered a sound and evidence-based method for replacing missing data in clinical trials (O'Kelly & Ratitch, 2014; van Ginkel et al., 2018), it is possible that the imputed data are not entirely representative of actual outcomes of those who dropped out given the relatively high drop-out rate. This study had an attrition rate that was higher than some other studies of SH for BED, with certain CBT-SH trials showing drop-out rates of approximately 20% or lower (e.g., Carter & Fairburn, 1998; Grilo & Masheb, 2005; Grilo et al., 2005; Grilo et al., 2014). However, it is important to note that the current attrition rate is comparable to previous trials assessing SH interventions for BED. For example, the previous DBT-GSH trial had an attrition rate of 30% in their treatment group (Masson et al., 2013) and a CBT-GSH trial also had a similar drop-out rate of 32.5% (Loeb et al., 2001). Of note, a meta-analysis of SH trials for both BN and BED noted that attrition is highly variable across trials, and is a noted challenge in SH research (Beinter et al., 2014).

Related to drop out and sample size, a post-hoc power analysis revealed that the current study was underpowered. Specifically, a sample size of approximately 137 participants would have been needed to detect the effect sizes found in the moderation analysis as statistically significant. However, statisticians have begun to question the

utility of traditional statistical significance in mediation and moderation analyses. For example, one study simulated power analyses for four different methods of mediation analyses, and found that all methods needed large sample sizes to achieve a .80 power level, with the Baron and Kenny (1986) mediation method requiring sample sizes greater than 400 when either the relationship between the mediator and either the independent or dependent variable was of small magnitude (Fritz & Mackinnon, 2007). Moreover, multiple simulation studies have documented the challenges of detecting moderation effects as significant, and have specified the need for large sample sizes as a particular barrier facing researchers conducting moderation research (Aguinis & Stone-Romero, 1997; Shieh, 2009). As such, researchers have advocated for an increased focus on effect sizes as opposed to *p*-values in RCT mediation and moderation analyses, as these statistics are more reflective of the magnitude of observed changes, and are not hindered by small sample sizes (Kraemer, 2008; Kraemer, 2013; Kraemer, 2016; Kraemer et al., 2002). However, although the present results were underpowered, they were also consistently accompanied by low effect sizes. While non-significant results for large effect sizes could mean statistically under-powered tests, the small effect sizes obtained in the current study may mean that there was no meaningful moderation effect of treatment condition.

Relevant to the issues of power and effect size is the current study's use of an active control condition. The majority of DBT-BED and DBT-SH trials have employed waiting list control conditions (e.g., Masson et al., 2013; Telch et al., 2001). The active control condition in the current study was designed to control for nonspecific factors such as hearing a plausible treatment rationale, reading a self-help manual, contact with

researchers, and multiple assessments. One caveat of including an active control condition in an RCT design is that differences in outcome between the experimental and control conditions tend to be smaller than when a waiting list (i.e., no treatment) control is used. Thus, it follows that a larger sample size would be required to detect a statistically significant difference between an experimental and an active control condition than between an experimental condition and a waiting list control condition.

Related to the inclusion of an active control condition, it is important to consider how the nature of the active control SE-USH manual in the current study may have impacted the results. Although the SE-USH group reported reading less of their respective SH manual than the DBT-SH condition, it may be that the SE-USH manual somehow helped participants learn strategies to improve their ER skills and binge-eating. In other words, it is possible that the active control condition used in the larger trial was in a sense "too active" in that it may have resulted in improved ER and binge frequency through the content in the manual, and did not solely work to control for non-specific factors as intended. This may have inflated ER and binge frequency outcome in the SE-USH and decreased the magnitude of between-group differences. Although the connection between SE and ER in the general population has not been studied extensively, certain studies have found evidence suggesting that those with better ER abilities possess higher rates of SE (Bajaj et al., 2016; Garofalo et al., 2016; Orth et al., 2016). Moreover, research has found significant positive correlations between self-criticism and binge frequency (Duarte et al., 2014; Starrs et al., 2015), and there exists preliminary evidence for the use of self-compassion training as a way to decrease binge frequency in BED (Kelly & Carter, 2015). Thus, it is important to consider that providing

the active control condition with a SE-USH intervention may have improved difficulties with ER and binge frequency experienced by these individuals, leading to meaningful improvements in these domains that were comparable to the DBT-SH group.

4.7 Clinical Implications of the Findings

The current findings have a number of potential clinical implications. The present study showed that DBT-SH was associated with a medium-magnitude pre-post improvement in ER alongside a large reduction in binge-eating behaviour. Although we failed to demonstrate that the improvements in ER mediated the reductions in binge-eating, the current findings add to existing evidence suggesting that DBT-SH may be a helpful intervention for some people with BED (Carter et al., 2019; Masson et al., 2013).

Self-help interventions have the potential to provide greater access to empirically-supported treatments. Empirically-supported specialized in-person treatments for BED, such as DBT, are not widely available. Therapist-delivered DBT programs require extensive therapist training and are expensive to deliver (Zanarini, 2009). Further, research suggests that many clinicians do not provide empirically-supported treatments such as DBT to patients with eating disorders, instead opting for alternate approaches without strong research support (von Ranson & Robinson, 2006; Wallace & von Ranson, 2012). Thus, by translating empirically-supported treatments into SH formats, individuals have greater access to proven interventions for BED, even when they do not have access to in-person empirically supported treatments. Further, empirically-supported SH approaches such as DBT may help overcome a number of barriers to in-person mental health care such as stigma, shame, logistical barriers such as transportation, and cost (Eisenberg et al., 2009; Hart et al., 2011; Jackson et al., 2007; Syed et al., 2014).

It is also important to consider the ways in which SH interventions, such as DBT-SH, may be delivered. While most SH for BED studies to date have involved in-person GSH, there has been extensive discussion in the SH literature about the feasibility of delivering empirically-supported SH programs through technology and this is just beginning to be studied. The majority of SH programs for BED that have been adapted for use through technology to date are CBT programs that are available through online websites (e.g., Carrard et al., 2011; de Zwaan et al., 2017; Wagner et al., 2016). As an example, a 16-week online intervention program designed by Wagner and colleagues (2016) delivered CBT through resources on a website, as well as through e-mail communication with a therapist. This online program retained many of the key elements of CBT for BED such as self-monitoring, regular eating, and cognitive restructuring. The program resulted in large-magnitude decreases in binge-eating, eating disorder psychopathology, and depression. Between-group analyses showed that the program was significantly superior to a WLC in terms of these outcomes, with large associated effect sizes for these analyses. While some evidence indicates that online CBT-SH for BED does not yield as large improvements as in-person therapist delivered CBT (de Zwaan et al., 2017), research suggests that this intervention is a widely acceptable low-intensity treatment for BED and therefore holds the potential to reach a lot more people than in-person treatments (Carrard et al., 2011; Wagner et al., 2016). A review by Beintner and colleagues (2014) found that internet-based SH programs for BED demonstrated the best adherence rates compared to other forms of SH (e.g., bibliotherapy). As such, researchers should consider evaluating internet-based DBT-SH programs that may further enhance treatment accessibility for people with BED. For instance, it may be that designing a

website based on the DBT principles and providing e-mail or text-based support for participants working through the website would be a suitable way for people with BED to significantly improve their ER and binge-eating symptoms.

DBT-SH may also be relevant to stepped care approaches to treatment. At present, even when empirically-supported treatments are available, many public mental health services are difficult to access due to significant wait times (Canadian Mental Health Association, 2017). As previously discussed (see Section 1.3.1), the stepped-care model of mental health care posits that intervention should be delivered on a graded-intensity scale based on initial level of psychopathology (Bower & Gilbody, 2005; Clark et al., 2009). For example, those with low-level symptoms may benefit from a lower-intensity treatment such as SH. Eventually, people with more severe symptoms may then engage in a higher-intensity treatment such as group therapy. Generally, one-on-one mental health care is considered the apex of the stepped care model in terms of intensity. With this information in mind, it may be helpful for individuals awaiting BED treatment to receive access to SH interventions, such as DBT-SH, while on waitlists for mental health care. Research suggests that some of these individuals may demonstrate clinically meaningful response to SH interventions, including DBT-SH (Beintner et al., 2014; Carter et al., 2019; Masson et al., 2013; Vocks et al., 2010), and may not need in-person services thereby decreasing the number of individuals on waitlists. While this research also suggests that not all individuals will respond to SH interventions, giving these resources to people struggling with BED while they await in-person treatment may provide them with psychoeducation about BED to help prepare them for treatment (Fairburn & Patel, 2017).

In addition to using empirically-supported SH programs such as DBT-SH prior to in-person treatment, it may also be possible to use SH interventions during in-person therapy as an adjunct to the material covered in therapy sessions (Fairburn & Patel, 2017). While research on the use of SH as part of in-person therapy is limited, a review by Clough and Casey (2011) found evidence that online SH adjuncts to in-person treatment such as relaxation modules can improve adherence and engagement in therapy. There are many ways that SH could theoretically be used in conjunction with in-person treatment. For example, reviewing DBT material both through SH and during in-person sessions could potentially help people consolidate knowledge about DBT skills. Alternatively, some clients may benefit from learning DBT skills through SH, while in-person sessions may be dedicated to practicing the skills, or delivering other psychotherapy approaches. Further, as clients may be progressing at a faster pace with both SH and in-person therapy, this could potentially reduce the number of sessions needed for certain clients, thus allowing clinicians to see more people awaiting services.

4.8 Directions for Future Research

There are a number of directions for future research on DBT-SH approaches. First, the current study should be replicated with a larger sample size in order to ensure adequate statistical power. Given previous findings indicating that people find SH programs more acceptable when delivered via internet (Macdonald et al., 2007; Knowles et al., 2014; Todd et al., 2013), it would be interesting to see if adapting the DBT-SH manual (Safer et al., 2018) to an online format such as a website would increase participants' engagement in the program, thus decreasing drop-out.

Second, it will be important for researchers to determine who is most likely to respond to DBT-SH. From a stepped-care perspective, some research evidence suggests that SH interventions are best suited for individuals with less complex psychopathology (Bower & Gilbody, 2005; Clark et al., 2009). To build on the current study, future research should investigate whether those with less severe symptoms (e.g., binge frequency, ER, comorbid psychopathology) respond better to DBT-SH than those with more complex psychopathology. This line of research could help clinicians further identify who is a good fit for DBT-SH, while also answering questions about the utility of applying a stepped-care model in BED (i.e., whether those with less BED symptoms respond sufficiently to a lower-intensity treatment). It would also be interesting to examine whether program completion (e.g., chapters read, activities finished) is significantly linked to treatment outcome. Findings from this research could help clinicians determine how much of the program is needed to produce meaningful improvement, and could emphasize the importance of promoting adherence to the program.

In addition to symptom severity, researchers should also identify other characteristics of individuals who are more likely to respond to SH approaches. A number of different underlying mechanisms have been implicated in the development and maintenance of BED including emotion dysregulation, reward dysfunction and dietary restraint. In addition, it would be beneficial for researchers to examine other potential mechanisms of change in DBT-SH besides emotion regulation. This line of research could also help determine which individuals are best suited for this intervention. It may be that certain individuals' experience of BED aligns more with the dietary restraint

model (Polivy, 1976; Polivy & Herman, 1985) or the food addiction model (Davis & Carter, 2014; Gearhardt et al., 2009) of BED rather than the ER model, and this would have important implications for treatment. Taken together, more research on mechanisms of change in DBT-SH could help further discern who is best suited for this approach.

Due to the relatively small sample size, only the DERS overall score was examined in the current study. However, research has determined that ER is a multi-faceted construct with a variety of components such as impulsivity, goal-directed behaviour, emotional awareness, and acceptance of emotional responses (Gratz & Roemer, 2004). This is reflected through the various DERS subscales, which all possess strong psychometric properties (Gratz & Roemer, 2004). As such, future studies on mechanisms of DBT-SH should examine all of the DERS subscales, in addition to the total score to obtain more information on whether certain aspects of ER are mechanisms of change in DBT-SH for BED. Another possible mechanism of change in DBT-SH is mindfulness. Mindfulness is considered to be the core component of DBT and provides the foundation on which the other (DBT) skills are built (Safer et al., 2017). Mindfulness has yet to be studied as a mechanism of change in DBT.

An additional research topic with relevant clinical implications would investigate the utility of pairing in-person therapy for BED with DBT-SH. As both group DBT for BED and DBT-SH have demonstrated effectiveness in treating BED, it is possible that combining these two approaches could help boost outcome or reduce the number of in-person sessions required (Clough & Casey, 2011). For example, it may be that some individuals would gather psychoeducation through the use of the SH manual, thus leaving more space in group DBT sessions for discussion, clarification, and refinement of skill

use. Alternatively, using a DBT-SH manual as an adjunct may complement the use of another approach for in-person treatment. For instance, emotion-focused therapy (Greenberg & Paivio, 1997) is an evidence-based, process-oriented treatment approach that encourages individuals to explore the meaning, functions, and origins of their emotions. It is possible that the behavior-focused DBT-SH would complement emotion-focused therapy, as individuals would be learning to both regulate and make meaning of their emotions.

Lastly, the use of an active control condition in the larger trial highlights the challenge of designing an active treatment condition that controls for non-specific factors and does not conceptually overlap with the treatment being studied. Thus, it would be interesting to replicate this study using a different active control condition. For example, it may be that using a purely psychoeducational program with no intervention component (e.g., skills, self-monitoring) could better control for relevant common factors such as receiving a manual and contact with the researchers. Further, given that the SE-USH manual was linked to significant and meaningful improvement in ER from pre-to-post-treatment, it may be interesting to study the potential utility of integrating SE-enhancing approaches with DBT for BED as a way to further enhance treatment outcome.

5.0 Conclusion

The results of the current study failed to provide evidence that ER is a mechanism of action in the improvement of binge-eating frequency in DBT-SH. Pre-post ER change within the DBT-SH group did not predict pre-post binge frequency or post-treatment remission status, and associated effect sizes were small. In addition, treatment condition did not significantly moderate the strength of the correlation between pre-post ER change

and pre-post binge frequency change, and the effect size of the moderation relationship was small, suggesting that ER did not act as a mechanism of change in the current study. It may be that the ER model does not apply to all individuals with BED and that different subsets of people with BED possess different underlying mechanisms such as dietary restraint (Polivy & Herman, 1976) or food addiction (Gearhardt et al., 2011). More studies are needed to determine who is best-suited for DBT-SH. In addition, researchers should investigate other potential mechanisms of change in DBT-SH for BED, such as specific facets of ER, mindfulness, or other potential mechanisms relevant to different models of BED (e.g., dietary restraint, food addiction). Taken together, this line of research will help improve our overall understanding of the nature of BED. Studies such as these will also increase our knowledge about who will benefit most from DBT-SH, and could help clinicians better pair individuals with BED with treatments that meets their needs.

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Appendix A

Protocol for Randomized Controlled Trial (Carter et al., 2019a)

A Randomized Controlled Study of a Dialectical Behaviour Therapy Guided Self-Help Intervention for Binge-eating Disorder

BACKGROUND

Binge-eating disorder (BED) is characterized by recurrent binge-eating in the absence of extreme compensatory weight control behaviors. Binge-eating refers to eating significantly more food in a short period of time than most people would eat under similar circumstances coupled with a subjective sense of loss of control [1]. The body weight of individuals with BED is typically in the obese range (i.e., body mass index [BMI] $\geq$ 30). BED is associated with substantial impairments in psychosocial and physical health related quality of life [2]. The prevalence of BED is estimated at 4-8% among obese individuals in community samples [3]. Given that NL has the highest rate of obesity in Canada (34%), BED is a serious public health concern in the province. Despite the existence of evidence-supported interventions for BED, there are currently no publically funded specialized treatment services for BED in NL. Further, many people in NL live in rural areas where they do not have access to specialized psychological services. Thus, research on novel ways of disseminating evidence-based treatment for people with BED in NL is urgently needed.

Dialectical Behavior Therapy (DBT) is an evidence-supported psychological treatment for BED [4, 5]. It is based on an affect regulation model of BED and conceptualizes binge-eating as a behavioral attempt to cope with painful emotions [6]. However, DBT is a specialized treatment that requires extensive training, is costly and not widely available. Recently, a self-help version of DBT for BED has been developed by two of our co-investigators (DS and SA) and is to be published by the Guilford Press. In a recent pilot study, this DBT self-help manual was tested in a guided self-help (GSH) format using telephone support sessions and compared to a waiting list control condition [7]. GSH refers to following a self-help manual while receiving a several brief support sessions with a therapist who may be a non-specialist. While the results of this pilot study were promising, further research on DBT-GSH is needed to determine whether this

intervention represents an effective way of disseminating treatment to individuals with BED. Using video-calling, instead of telephone support, may be one way of enhancing the effectiveness of DBT-GSH while retaining its portability. In addition, it is important to determine whether some people with BED can effectively use the DBT self-help manual independently. However, to date, unguided DBT self-help (DBT-USH) has not yet been studied.

Given the psychological and neurobiological overlaps between BED and substance use disorders, it has been argued that it may be useful for clinicians to integrate an addiction perspective into current treatments for BED [8]. Therefore, we will measure the impact of treatment on "food addiction" symptoms in this trial. Also, given that sleep disturbance among obese individuals has been shown to be associated with binge-eating [9, 10], we will include measure of sleep disturbance in this trial as well.

STUDY OBJECTIVES AND HYPOTHESES

The primary objective of this randomized controlled trial is to compare the effectiveness of two methods of administering a Dialectical Behavior Therapy (DBT) self-help intervention in a community sample of individuals with BED in the province of NL: guided DBT self-help (DBT-GSH) and unguided DBT self-help (DBT-USH). In addition, in order to control for non-specific factors (such as attention, receiving a self-help manual, and expecting to improve), a third condition will be included. This condition is meant to serve as an attention-control condition. Participants randomized to this condition will received unguided self-help that is focused on improving self-esteem, but does not address binge-eating specifically (NS-USH).

METHODS

Sample size calculation

Power analysis was based on the primary outcome variable: frequency of binge-eating episodes. Assuming the three randomized groups (DBT-USH, DBT-GSH and NS-USH) are equivalent at baseline, a between groups ANOVA will be used to compare them at post-treatment. Based on the findings of Masson et al. (2013) [7], assuming an effect size of 0.40 and Type 1 error rate equal to .05, a sample size of at least 21 participants per group will yield 80% power. Assuming an attrition rate of 20%, we will require 25 participants per group.

Procedure

Recruitment. Participants will be recruited from the community in the province of NL. Family doctor practices around the province will be informed about the study and brochures/posters will be sent to them. Posters advertising the study will be posted in hospitals, colleges, medical clinics, community centres, and universities. Advertisements will be placed on the VOCM website and the PI will attempt to obtain an interview on VOCM and CBC radio about binge-eating disorder and will advertise the study by stating during the interview that we are currently conducting a treatment study on BED. In addition, she will provide the study website where interested listeners can obtain more information about the study. [1] In rural NL, the study will be advertised in church bulletins and community halls. The content of these advertisements will be identical to the study posters. The HOPE program (day treatment program for eating disorders in St. John's, NL), which does not treat BED, and the Eating Disorder Foundation of NL (EDFNL) will also be given information about the study and asked to refer any individuals who they believe may be suitable for the study. In addition, an advertisement, including a link to the screening questionnaire, will be posted on the EDFNL website. Interested individuals will be instructed to go to a website where they will fill in an initial screening questionnaire via Qualtrics. Those who appear to meet the study inclusion criteria will be scheduled for an interview via telephone to confirm their eligibility (see "Telephone Screening Interview" in Attachments).

Study inclusion/exclusion criteria (see Screening Questionnaire in Attachments).

Inclusion criteria: Participants will be male or female aged 19 and older who meet the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria for BED based on Eating Disorder Examination (Version 17) [11]. Additional inclusion criteria will include: 1) body mass index (BMI; kilograms/meters^2) of at least 18.5; 2) ability to read English; 3) high school graduate or equivalent; and 4) access to a computer, tablet or smart phone (with camera and microphone) and to high speed internet in order to facilitate therapy sessions via video conferencing. Individuals on a stable dose

[1] We have had good success with this method of recruitment in a previous community-based study on obesity.

of antidepressant medication and/or sleep medication for at least 3 months will be eligible to take part.

Exclusion criteria: Participants will be excluded for the following reasons: 1) current psychological treatment with a registered psychologist specifically for binge-eating disorder; 2) major medical illness that would interfere with treatment (e.g., cancer); 3) current pregnancy; 4) current acute suicidal risk as assessed using the BDI-II[2]; 5) current substance use disorder; 6) current psychotic symptoms[2].

Randomization. Participants recruited from the community will be randomized to one of the three conditions: Unguided Dialectical Behaviour Therapy Self-Help [DBT-USH], Guided Dialectical Behaviour Therapy Self-Help [DBT-GSH], or Non-Specific Unguided Self-Help [NS-USH]) for 12 weeks using block randomization, with a block size of 7. Two randomization lists will be prepared, one for females and one for males to ensure an equal number of males and females in each condition. Since no reliable predictors of binge-eating disorder (BED) outcome have been identified to date, we will not stratify the groups by any other variable. The randomization lists will be prepared by a research assistant not involved in this study. The list will be transferred to a numbered sequence of opaque envelopes. Each time a new participant completes the baseline assessment, the next envelope will be opened by the research assistant who will inform the participant of their treatment assignment. To ensure that treatment assignment is communicated in a neutral and consistent manner [so as not to influence expectations about treatment effectiveness], this information will be communicated via e-mail using a standardized format (see Attachments). Next, participants will be sent the self-help program by mail and those assigned to guided self-help (GSH) will be contacted by a therapist to book an appointment for the first therapy session.

Interventions. Treatment will last 12 weeks in all three conditions. Participants in both DBT conditions will be provided with the DBT self-help manual "An Emotion Regulation Approach to Stop Binge-eating" by Safer, Adler & Masson (2016). This manual is a self-help version of the therapist-administered DBT treatment manual used in previous trials of DBT for BED (e.g. [5]). It consists of 13 chapters (nine modules) that

[2] Potential participants who are judged to be at risk of suicide or psychotic symptoms will be assessed by the PI who is a registered clinical psychologists and will be referred to the appropriate services.

aim to teach three skills to help participants stop binge-eating: mindfulness, distress tolerance and emotion regulation. In the guided self-help (GSH) condition, participants will receive six 30-minute GSH sessions via a secure web-based video-calling program (Bluejeans) with a clinical psychology doctoral student therapist. These sessions will take place weekly for the first two weeks followed by three biweekly sessions and a wrap-up session at 12 weeks. A "Guided Self-Help (GSH) Therapist Manual" will be used to guide these sessions (see Attachments). The Bluejeans video-calling program allows GSH sessions to be recorded for supervision and treatment monitoring purposes. Therapists will have weekly supervision meetings with the PI to discuss any questions or challenges that arise. In the two unguided self-help (USH) conditions, participants will be asked to do their best to follow the advice in the self-help manual independently over the next 12 weeks.

Therapist Training and Supervision. After completing preparatory readings, therapists will attend a half-day training workshop with the PI. Thereafter, therapists will meet weekly with the PI for group GSH supervision to ensure competence and adherence to the GSH therapist manual.

Guided Self-Help (GSH) Therapist Manual (see Attachments). This manual was used in three previous GSH trials, including one by the PI. It was adapted for the present study to guide therapists' Dialectical Behaviour Therapy GSH sessions.

Therapist Adherence to the GSH Therapist Manual. A random sample of 2/6 video-taped GSH sessions will be reviewed by an independent rater to ensure adherence to the Therapist Manual.

Participant drop-out

Consistent with an intention-to-treat approach, participants who decide not to continue with their guided self-help therapy sessions will be invited to continue to participate in the study assessments. Study assessments will take place at mid-treatment, post-treatment and 3-month follow-up. At these time points, participants will be sent a weblink to the study assessment questionnaires. If there is no response, we will send one email to remind participants of the study assessments and if they do not respond, they will be considered withdrawn from the study and will not be contacted again. To assess participant adherence to the self-help program, we will ask participants to report the

number chapters read and the amount of time per day and per week spent on the self-help program.

The number of eligible individuals who: decline to participate, are randomized, begin the study, or drop out of the study (and the week at which this occurs) will be recorded.

Assessment Measures (See Attachments for "Table of Measures and Assessment Schedule")

Except for the initial assessment interview, which will be conducted via telephone, all study measures will be administered on-line via the survey software Qualtrics. Measures will be administered at baseline (Week 1), post-treatment (Week 12) and 3-month follow-up (Week 24). In addition, a subset of measures will be administered at mid-treatment (Week 6).

Demographic Information:

Age, body weight, height, weight history, dieting history, marital status, education level, ethnicity, age of onset of binge-eating, and treatment history will be collected at baseline. Body weight will also be re-assessed at mid- and post-treatment, as well as 3-month follow-up.

The following measures are presented and described in the Attachments section of the HREB application:

Eating Disorder Symptoms:

- Eating Disorder Examination Interview, Version 17 (EDE; BED section only) [11].
- Eating Disorder Examination Questionnaire (EDE-Q 6.0) [12].
- Male Body Attitudes Scale (MBAS) [13].

General Psychological Distress

- Brief Symptom Inventory (BSI) [14].
- Beck Depression Inventory–II (BDI-II), Suicidal Screening Item at baseline only [15].
- Insomnia Severity Index (ISI) [16].
- STOP-Bang [17].
- Short Form Health State Classification (SF-6D) [18].

Emotion Regulation

- Difficulties with Emotion Regulation Scale (DERS) [19].

Food Addiction Symptoms

- Yale Food Addiction Scale Version 2.0 (YFAS-2) [20].

Impulsivity

- UPPS-P Impulsivity Scale [21]

Mindfulness

- Five Facet Mindfulness Questionnaire – Short Form (MMFQ-SF) [22]

Treatment Suitability and Expectancy (TSE)

- Perceived treatment suitability and efficacy expectations will be measured at baseline using two likert scales.

Statistical analyses

The primary analysis will focus on the main outcome variable - number of binge-eating episodes over the previous 28 days. If, after randomization, the three groups (i.e., DBT-GSH, DBT-USH and NS-USH) are equivalent at baseline, then ANOVA will be used to compare the groups on binge-eating frequency at mid-treatment, post-treatment and follow-up. Impact on eating disorder psychopathology (EDE-Q), food addiction symptoms, sleep disturbance, general psychological distress (BSI), quality of life (SF-6D), and difficulties with emotion regulation (DERS) will also be examined. Consistent with an intention-to-treat approach, all randomized participants will be included in the final data analyses. Missing data will be imputed using multiple imputation.

Significance of the Research

The establishment of an evidence-based self-help intervention for BED that can be disseminated widely will contribute to the improvement of the physical and psychosocial health of the people of the province of NL.

Dissemination of Findings

Efforts will be taken to disseminate the study findings locally, nationally and internationally. Locally, the findings will be shared with the NL Eating Disorders Foundation as well as the NL Department of Health and Community Services. More broadly, we will present our results at national and international scientific meetings, and manuscripts will be prepared for publication in peer-reviewed journals.

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Appendix B

Eating Disorder Examination 17.0 (EDE; Fairburn et al., 2014)

Pre-Treatment Telephone Screening Interview Script

EDE-17.0

Hello [participant's name]. My name is [researcher's name], and I'm a researcher at Memorial University. I'm a part of the study on overeating that you have expressed interest in.

Thank you for your interest in taking part. Is this a convenient time for me to tell you a few things about the study and to make sure you match the criteria for the study?

Here's what we're going to do [today/this evening]. To see whether you meet the criteria to participate in this study, I am going to go through a few questions with you that ask about your eating habits, with a focus on overeating.

You participation is voluntary and you can discontinue this interview at any time. Also, completing this interview does not commit you to taking part in this study. All information that you disclose in this interview is confidential, and will be not be shared with anyone except the research team. Do you have any questions?

Please let me know if you have any questions. After the interview is finished, there will be a chance for you to ask any questions you haven't asked yet. After the interview, we will assess your answers and send you an email regarding your eligibility to participate. The email will also contain more information on the study.

As these interviews are designed in a certain way, it is important that I read the instructions as they have been written by the authors. Are you ready to begin?

EATING DISORDER EXAMINATION (Edition 17.0D)

THE INTERVIEW SCHEDULE ORIENTATION TO THE TIME PERIOD

What we are going to do is a partially structured interview in which I will ask you about your eating habits. Because a standard set of questions is going to be asked, please note that some may not apply to you. Most of the questions focus on the past three months, but there will be some that cover the previous six months. I know this will test your memory because the weeks tend to blend together. So the past four weeks go from yesterday (day and date) to (day and date). And two months before that go from (date) to (date). And to help you remember these periods, I have noted down the holidays (e.g., Canada Day, Thanksgiving).

What I would like you to do now is tell me about any events that have happened in the past 28 days since this will help us discuss these four weeks. Have there been any events out of the ordinary ..... such as celebrations of any type, trips away or days off work? [Make a note of these.]

QUESTIONS FOR IDENTIFYING BINGE EPISODES [See preceding section "Guidelines for Proceeding Through the Overeating Section". The asterisked questions should be asked in every case.]

Main Probe Questions (to get the overall picture)

***I would like to ask you about any episodes of overeating, or loss of control over eating, that you might have had over the past four weeks.**

***Different people mean different things by overeating. I would like you to describe any times when you have felt that you have eaten, or might have eaten, too much at one time.**

***And any times you have felt you have lost control over eating?**

Additional Probe Questions

***Have there been any times when you have felt that you have eaten too much, but others might not agree?**

***Have there been any times when you have felt that you have eaten an ordinary amount of food but others might have regarded you as having overeaten?**

Subsidiary Probe Questions (to classify any episodes of overeating) To assess the amount of food eaten:

Typically what have you eaten at these times?

Did you view this amount as excessive?

To assess the social context:

What were the circumstances?
What were others eating at the time?

To assess "loss of control":

Did you have a sense of loss of control at the time?
Did you feel you could have stopped eating once you had started?

Did you feel you could you have prevented the episode from starting?

[For objective binge episodes, the following two ratings should be made:

i) Over the past 4 weeks (28 days), on how many of the days did you have an overeating episode like this? number of days (rate 00 if none)
ii) number of episodes (rate 000 if none)

In general, it is best to calculate the number of days first and then the number of episodes. Rate 777 if the number of episodes is so great that their frequency cannot be calculated.

[Episodes of subjective overeating are not rated.]

Objective binge episodes

days [ ][ ]

episodes [ ][ ][ ]

[Ask about each of the preceding two months referring back to the relevant dates and any events of note. For objective binge episodes, rate the number of episodes over the preceding two months and the number of days on which they occurred. Rate 0s if none and 9s if not asked.]

Objective bulimic episodes

days - month 2 _____

month 3 _____

episodes – month 2 _____

month 3 _____

[Also rate the longest continuous period in weeks free (not due to force of circumstances) from objective binge episodes over the past three months. Rate 99 if not applicable.]
[ ][ ]

BINGE-EATING DISORDER MODULE
(Diagnostic items)

[Only enter this module if at least 12 objective binge episodes have been present over the preceding 12 weeks. Otherwise rate 9. Use a respondent-based interviewing style, rather than the investigator-based style of the EDE.]

Features Associated with Binge-eating
During these episodes (refer to objective binge episodes that are representative of those over the past three months)**, have you *typically* .....**

... Eaten much more rapidly than normal? [ ]
... Eaten until you have felt uncomfortably full? [ ]
... Eaten large amounts of food when you haven't felt physically hungry? [ ]
... Eaten alone because you have felt embarrassed about how much

you were eating? [ ]

... Felt disgusted with yourself, depressed, or very guilty? [ ]

[Rate each feature individually using the binary scheme below.]

0 - Feature not present

1 - Feature present

Distress about Binge-eating

In general, over the past three months how distressed or upset have you felt about these episodes (refer to objective bulimic episodes that are representative of those over the past three months)**?**

[Rate the presence of marked distress about the binge-eating. This may stem from the actual behaviour itself or its potential effect on body shape and weight.]

0 – No marked distress

1 – Marked

SELF-INDUCED VOMITING (Diagnostic item)

***Over the past six months have you made yourself sick as a means of controlling your shape or weight, or to compensate for overeating?**

[Rate the number of discrete episodes of self-induced vomiting. If the participant denies that the vomiting is under his or her control, determine whether it has the characteristics that would be expected were it not self-induced (e.g., unpredictability, occurrence in public). If the available evidence suggests that the vomiting is under the participant's control (i.e., it is self-induced), then rate it as such. Accept the participant's definition of an episode. Rate 777 if the number of episodes is so great that it cannot be calculated. Rate 000 if no vomiting.]

[ ][ ][ ]

LAXATIVE MISUSE (Diagnostic item)

***Over the past six months have you taken laxatives as a means of controlling your shape or weight, or to compensate for overeating?**

[Rate the number of episodes of laxative-taking as a means of controlling shape, weight or body composition. This should have been the *main* reason for the laxative-taking, although it may not have been the sole reason. Only rate the taking of substances with a true laxative effect. Rate 00 if there was no laxative use or there is doubt whether the laxative-taking was primarily to influence shape, weight or body composition.]

[ ][ ][ ]

DIURETIC MISUSE (Diagnostic item)

***Over the past six months have you taken diuretics as a means of controlling your shape or weight, or to compensate for overeating?**

[Rate the number of episodes of diuretic-taking as a means of controlling shape, weight or body composition. This should have been the *main* reason for the diuretic-taking, although it may not have been the sole reason. Only rate the taking of substances with a true diuretic effect. Rate 00 if there was no diuretic use or there is doubt whether the diuretic-taking was primarily to influence shape, weight or body composition.]

[ ][ ][ ]

DRIVEN EXERCISING (Diagnostic item)

***Over the past six months have you exercised as a means of controlling your weight, altering your shape or amount of fat, burning off calories, or to compensate for overeating?**

***Have you felt driven or compelled to exercise?**

Typically, what form of exercise have you done? How hard have you exercised? Have you pushed yourself?

Have you exercised even when it might interfere with other commitments or do you harm?

Have there been times when you have been unable to exercise for any reason? How has this made you feel?

[Rate the number of days on which the participant has engaged in "driven" exercising. Such exercising should have been intense in character and have had a "compulsive" quality to it. The participant may describe having felt compelled to exercise. Other indices of this compulsive quality are exercising to the extent that it significantly interferes with day-to-day functioning (e.g. such that it prevents attendance at social commitments or it intrudes on work or exercising when it might do one harm (e.g., when possibly injured). Another suggestive feature is having a strong negative reaction to being unable to exercise. **Only rate driven exercising that was *predominantly* intended to use calories or change shape, weight, or body composition.** Exercising that was exclusively intended to enhance health or fitness should not be rated. Rate 00 if no such driven exercising.]

[ ][ ]

[Rate the *average* amount of time (in minutes) per day spent exercising in this way. Only consider days on which the participant has exercised. Rate 999 if no such exercising.]

[ ][ ][ ]

[Ask about the preceding two months. Rate the number of days on which the participant has exercised in this manner over each of the two preceding months. If not asked, rate 99.]

month 2 [ ][ ]
month 3 [ ][ ]

OTHER EXTREME WEIGHT-CONTROL BEHAVIOUR (Diagnostic item)

***Over the past six months have you done anything else to control your shape or weight, or to compensate for overeating?**

[Rate other noteworthy (i.e., potentially effective) dysfunctional forms of weight-control behaviour (e.g., spitting, insulin under-use, thyroid medication misuse). Rate number of days and nature of the behaviour. Rate 99 if no such behaviour.]

month 1 [ ][ ]
month 2 [ ][ ]
month 3 [ ][ ]

AVOIDANCE OF EATING (Restraint subscales) *Over the past six months have you gone for periods of eight or more waking hours without eating anything?
Has this been to influence your shape or weight or to compensate for overeating?

[Rate the number of days on which there has been at least eight hours abstinence from eating food (soup and milkshakes count as food, whereas drinks in general do not) during waking hours. It may be helpful to illustrate the length of time (e.g., 9 a.m. to 5 p.m.). The abstinence must have been at least partly *self- imposed* rather than being due to force of circumstances. It should have been intended to influence shape, weight or body composition, or to avoid triggering an episode of overeating, although this may not have been the sole or main reason (i.e., fasting for religious or political reasons would not count). Note that the rating should be consistent with those made earlier for "Pattern of eating".]

[ ][ ][ ]

END OF EDE

Thank you for taking part in this interview today. All of your answers are confidential and will be stored securely and without any identifying information.
In terms of next steps, we will next review your answers and then we will then send you an email very soon to let you know whether you are eligible to take part in the study. If you are eligible to take part, then we will then give you more information about the study. Do you have any questions?
Thank you so much for your time today. If you have any questions that you didn't get to ask, don't hesitate to contact us at [PHONE]. Enjoy your [day/evening]. We'll be in touch soon.

END OF TELEPHONE INTERVIEW

Appendix C

Drug Abuse Screening Test (DAST; Skinner, 1972)

In the past 12 months... Circle			
1.	Have you used drugs other than those required for medical reasons?	Yes	No
2.	Do you abuse more than one drug at a time?	Yes	No
3.	Are you unable to stop abusing drugs when you want to?	Yes	No
4.	Have you ever had blackouts or flashbacks as a result of drug use?	Yes	No
5.	Do you ever feel bad or guilty about your drug use?	Yes	No
6.	Does your spouse (or parents) ever complain about your involvement with drugs?	Yes	No
7.	Have you neglected your family because of your use of drugs?	Yes	No
8.	Have you engaged in illegal activities in order to obtain drugs?	Yes	No
9.	Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	Yes	No
10.	Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)?	Yes	No
Scoring: Score 1 point for each question answered "Yes," except for question 3 for which a "No" receives 1 point.		**Score:**	

Appendix D

Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993)

Questions	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
3. How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7 How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily

8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year

Appendix E

Demographics Questionnaire

Page 1

Hello! Thank you for taking part in the *MUN Stop Overeating Study*.
Before we can randomize you to one of the study self-help programs, we need you to please fill in the questionnaires below. These should take about 60 minutes to complete. Once you have submitted your responses you will get an email from a member of our team. This email will tell you more about the program you will be following for the next twelve (12) weeks.
We would like to take this time to remind you that all of your responses are ***confidential***, and will only be seen by the research team for this study.
We look forward to working with you to help you overcome your overeating.

Page 2

How old are you (in years)? _____

What was your biological sex at birth?

- ☐ Male
- ☐ Female

What gender do you identify as?

- ☐ Male
- ☐ Female
- ☐ Other

What is your marital status?

- ☐ Single
- ☐ Married/Common Law
- ☐ Divorced
- ☐ Widowed
- ☐ Separated

What is your level of education?

- ☐ High School
- ☐ College
- ☐ Undergraduate
- ☐ Graduate

What is your ethnicity?

- ☐ Caucasian/White
- ☐ Hispanic
- ☐ Black
- ☐ Asian
- ☐ Other

Page 3

What is your current height? _____

What is your current weight? (please weigh yourself before answering) _____
What is the highest weight you've been as an adult? _____
When did you reach that weight? _____
How long did you stay at that weight? _____
What was your lowest adult weight? _____
When did you reach that weight? _____
How long did you stay at that weight? _____
Page 4
To the best of your memory, how old were you when you began binge-eating? _____
Have you ever received treatment for binge-eating?

- ☐ Yes
- ☐ No

If yes, when? _____
Do you currently consider yourself to be overweight?

- ☐ Yes
- ☐ No

If yes, to the best of your memory how old were you when you were first overweight? _____
Have you previously gone on diets to control your weight (it does not matter if you consider them successful or not)?

- ☐ Yes
- ☐ No

If yes, to the best of your knowledge how old were you when you first went on a diet? _____

Appendix F

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004)

Please indicate how often the following 36 statements apply to you by writing the appropriate number from the scale above (1 – 5) in the box alongside each item.

	1 Almost never	2 Sometimes	3 About half the time	4 Most of the time	5 Almost always
I am clear about my feelings					
I pay attention to how I feel					
I have no idea how I am feeling					
I am attentive to my feelings					
I care about what I am feeling					
When I'm upset, I acknowledge my emotions					
When I'm upset, I become embarrassed for feeling that way					
I experience my emotions as overwhelming and out of control					
I have difficulty making sense out of my feelings					
I know exactly how I am feeling					
I am confused about how I feel					
When I'm upset, I become angry with myself for feeling that way					
When I'm upset, I have difficulty getting work done					
When I'm upset, I become out of					

control					
When I'm upset, I believe that I will remain that way for a long time					
When I'm upset, I believe that I'll end up feeling very depressed					
When I'm upset, I believe that my feelings are valid and important					
When I'm upset, I have difficulty focusing on other things					
When I'm upset, I feel out of control					
When I'm upset, I can still get things done					
When I'm upset, I feel ashamed with myself for feeling that way					
When I'm upset, I know that I can find a way to eventually feel better					
When I'm upset, I feel like I am weak					
When I'm upset, I feel like I can remain in control of my behaviours					
When I'm upset, I feel guilty for feeling that way					
When I'm upset, I have difficulty concentrating					
When I'm upset, I have difficulty					

controlling my behaviours					
When I'm upset, I believe that there is nothing I can do to make myself feel better					
When I'm upset, I start to feel very bad about myself					
When I'm upset, I lose control over my behaviours					
When I'm upset, I take time to figure out what I'm really feeling					
When I'm upset, my emotions feel overwhelming					

Appendix G

Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983)

Below is a numbered list of problems and complaints. For each of these numbered statements circle the number on the right whch best describes how much discomfort the problem has caused you over the PAST SEVEN DAYS. Please do not skip any items. Thank you.

0 = Not at all
1 = A little bit
2 = Moderately
3 = Quite a bit
4 = Extremely

OVER THE PAST SEVEN DAYS HOW MUCH HAVE YOU BEEN DISTRESSED BY:

OVER THE PAST 7 DAYS HOW MUCH HAVE YOU BEEN DISTRESSED BY:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Nervousness or shakiness inside	0	1	2	3	4
2. Faintness or dizziness	0	1	2	3	4
3. The idea that someone else can control your thoughts	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	0	1	2	3	4
5. Trouble remembering things	0	1	2	3	4
6. Feeling easily annoyed or irritated	0	1	2	3	4
7. Pains in the heart or chest	0	1	2	3	4
8. Feeling afraid in open spaces or on the streets	0	1	2	3	4
9. Thoughts of ending your life	0	1	2	3	4
10. Feeling that most people cannot be trusted	0	1	2	3	4
11. Poor appetite	0	1	2	3	4
12. Suddenly scared for no reason	0	1	2	3	4
13. Temper outbursts that you could not control	0	1	2	3	4
14. Feeling lonely even when you are with people	0	1	2	3	4

15. Feeling blocked in getting things done	0	1	2	3	4
16. Feeling lonely	0	1	2	3	4
17. Feeling blue	0	1	2	3	4
18. Feeling no interest in things	0	1	2	3	4
19. Feeling fearful	0	1	2	3	4
20. Your feelings being easily hurt	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	0	1	2	3	4
22. Feeling inferior to others	0	1	2	3	4
23. Nausea or upset stomach	0	1	2	3	4
24. Feeling that you are watched or talked about by others	0	1	2	3	4
25. Trouble falling asleep	0	1	2	3	4
26. Having to check and double-check what you do	0	1	2	3	4
27. Difficulty making decisions	0	1	2	3	4
28. Feeling afraid to travel on buses, subways, or trains	0	1	2	3	4
29. Trouble getting your breath	0	1	2	3	4
30. Hot or cold spells	0	1	2	3	4
31. Having to avoid certain things, places, or activities because they frighten you	0	1	2	3	4
32. Your mind going blank	0	1	2	3	4
33. Numbness or tingling in parts of your body	0	1	2	3	4
34. The idea that you should be punished for your sins	0	1	2	3	4
35. Feeling hopeless about the future	0	1	2	3	4
36. Trouble concentrating	0	1	2	3	4
37. Feeling weak in parts of your body	0	1	2	3	4
38. Feeling tense or keyed up	0	1	2	3	4

39. Thoughts of death or dying	0	1	2	3	4
40. Having urges to beat, injure, or harm someone	0	1	2	3	4
41. Having urges to break or smash things	0	1	2	3	4
42. Feeling very self-conscious with others	0	1	2	3	4
43. Feeling uneasy in crowds, such as shopping or at a movie	0	1	2	3	4
44. Never feeling close to another person	0	1	2	3	4
45. Spells of terror or panic	0	1	2	3	4
46. Getting into frequent arguments	0	1	2	3	4
47. Feeling nervous when you are left alone	0	1	2	3	4
48. Others not giving you proper credit for your achievements	0	1	2	3	4
49. Feeling so restless you couldn't sit still	0	1	2	3	4
50. Feelings of worthlessness	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	0	1	2	3	4
52. Feeling of guilt	0	1	2	3	4
53. The idea that something is wrong with your mind	0	1	2	3	4

Appendix H

Screening Questionnaire for BED Self-Help Study

Page 1

Hello! Thank you for your interest in the *MUN Stop Overeating Study*.

This study is being conducted by Dr. Jacqueline Carter-Major (Registered Psychologist) and her students in the Department of Psychology at MUN.

Please fill out the short survey below to find out whether or not you are eligible to take in this study. All of your responses are confidential, and will only be seen by the researcher team for this study.

Thank you for your interest in this study. Once we have a chance to review your responses, we will be in touch with you as soon as possible.

Page 2

Please provide an email address and a phone number below. This is important so that we can tell you whether or not you are eligible to take part. A member of our research team will be in touch with you within a few days to inform you of your eligibility status. Remember, your contact information will not be shared with anyone, it will only be used by the researcher to let you know if you are eligible.

Please provide an email that you can be reached at:

_____

Please provide a telephone number that you can be reached at:

_____

Please let us know how you heard about our study:

_____

Page 3

Do you consider English to be your first language?

- ☐ Yes
- ☐ No

If no, are you able to communicate (read and write) fluently in English?

- ☐ Yes
- ☐ No

What is the highest level of education that you have COMPLETED?

- ☐ Lower than grade 12
- ☐ High school diploma or equivalent
- ☐ College diploma
- ☐ Bachelor's degree
- ☐ Graduate degree

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Do you own (or have regular access to) a computer, tablet or smartphone with microphone and camera?

- ☐ Yes

- ☐ No

Do you have access to high speed internet in a private location (i.e., somewhere that you would be comfortable/able to communicate openly with one of our researchers)?

- ☐ Yes
- ☐ No

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What was your biological sex at birth?

- ☐ Male
- ☐ Female

What gender do you identify as?

- ☐ Male
- ☐ Female
- ☐ other

Please provide your current weight: _____

Please provide your height (for example, if you are 5 feet 6 inches please enter 5'6")?

_____

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Are you currently receiving treatment for any medical conditions?

- ☐ Yes
- ☐ No

If yes, please list your medical conditions below:

Are you currently taking any medications?

- ☐ Yes
- ☐ No

If yes, please list all medications below:

If yes, how long have you been taking these medications? _____

Page 7

Have you had surgery to promote weight loss (i.e., gastric bypass)?

- ☐ Yes
- ☐ No

Do you intend to have surgery to promote weight loss within the next 12 months (i.e., gastric bypass)?

- ☐ Yes
- ☐ No

Are you currently taking any medications or supplements to promote weight-loss?

- ☐ Yes
- ☐ No

If yes please describe:

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Have you ever been diagnosed with an eating disorder?

- ☐ Yes
- ☐ No

If yes, please explain your diagnosis, when you were diagnosed and by whom (i.e., family doctor, psychologist, etc.):

Are you currently receiving treatment or counselling (i.e., HOPE Centre, psychologist, dietitian, etc.) for a "binge-eating" problem?

- ☐ Yes
- ☐ No

If yes please describe:

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Over the past three (3) months, have there been any times when you have eaten what most people would regard as an unusually large amount of food given the circumstances?

- ☐ Yes
- ☐ No

If yes, on average, how many episodes of overeating like this have you had per week?

_____

During how many of these episodes of overeating did you feel 'out of control' over your eating? _____

During these overeating episodes, do you find yourself (check all that apply):

- ☐ Eating faster than usual?
- ☐ Eating until uncomfortably full?
- ☐ Eating large amounts of food when not physically hungry?
- ☐ Eating alone because of feeling embarrassed about how much you eat?
- ☐ Feeling disgusted with yourself, depressed or guilty about how much you eat?

Do your eating habits cause you distress?

- ☐ Yes
- ☐ No

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Over the past three (3) months, have you made yourself throw up (vomit) to control your weight?

- ☐ Yes

- ☐ No

If yes how many times? _____

Over the past three (3) months, have you taken laxatives or diuretics to control your weight?

- ☐ Yes
- ☐ No

If yes how many times? _____

Over the past three (3) months, have you engaged in any other weight control behaviours?

- ☐ Yes
- ☐ No

If yes please describe:

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Thank you for completing the screening survey for the *MUN Stop Overeating Study*. We will review your responses and get in touch with you soon.

Appendix I

Consent Form

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TITLE: **SELF-HELP FOR BINGE-EATING: A RANDOMIZED CONTROLLED STUDY**

PRINCIPAL INVESTIGATOR: Dr. Jacqueline Carter-Major
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Information about the current study

You have been invited to take part in a research study. Participation is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to withdraw from the study at any time.

Before you decide, you need to understand what the study is for, what risks you might take, and what benefits you might receive. This information form explains the study.

Please read this information form carefully. Take as much time as you like. Mark anything you do not understand, or want explained better. After you have read this form, if you want to take part in the study, you can give your consent by email. Please ask questions about anything that is not clear. At any point during this study, if you have any questions or concerns, please do not hesitate to contact a member of our research team.
The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

1. **Why am I being invited to take part in this study?**
   You are invited to take part in this study because you reported problems with binge-eating.

2. **What is the purpose of this study?**
   The purpose of this study is to compare the helpfulness of three self-help programs for binge-eating.
3. **What is the background for this study?**
   Binge-eating refers to eating a large amount of food in a short period of time while feeling out of control. It can have a negative effect on people's lives and can cause problems like weight gain and emotional distress. There are helpful treatments for binge-eating, but they can be costly and are not widely available. Recently, research has shown that self-help programs can be helpful for many people who binge eat. Sometimes people follow a self-help program on their own, and sometimes they follow a self-help program with brief support from a therapist.
4. **How many people will take part in this study?**
   75 people in the province of Newfoundland and Labrador will be invited to take part.
5. **How long will I be in this study?**
   Your participation in this study will be for 6 months. The self-help program will last 3 months. Then, after you complete the self-help program, we will ask you to complete some follow-up forms 3 months later.
6. **How is the study being done?**

   <u>Self-Help Programs:</u>
   - If you decide to take part in this study, you will be randomly assigned (i.e., by chance, like tossing a coin) to one of three self-help programs.
   - All of the self-help programs involve reading a self-help manual and learning skills that might help you to stop binge-eating.
   - Two of the programs involve following a self-help program on your own, and one involves following a self-help program with some support from a therapist. Therapist support will be provided via video-calling using a computer, tablet or smart phone.
   - All self-help programs will last three months. All support sessions will be video-recorded to allow monitoring of therapy quality.
   - All support sessions are confidential and will be supervised by the principal

investigator, Dr. J. Carter-Major.

Study Forms:
In order to find out if the self-help program is helpful for you, you will be asked to fill in a series of forms asking about your eating habits and mood four times during study. The researchers will email these forms to you and you can fill them in on-line using a computer, tablet or smart phone. This should take about 45 minutes or so. You will be asked to fill in these forms before and after you complete the self-help program. We will also ask you to fill in a two of these forms mid-way through the self-help program. Finally, we will ask you to fill in the forms again three months after you complete the program.

7. **Are there any possible risks or discomforts?**
It is possible that some of the forms may ask about topics that are uncomfortable. If you feel upset while answering these questions, you will have the opportunity to talk to the Principal Investigator, Dr. J. Carter-Major (telephone 790-864-8118).
If you report that you are at risk of committing suicide, the research team is required to report this to Dr. Carter-Major. In this case, Dr. Carter-Major, who is a registered psychologist, has a duty to act in a reasonable manner to prevent you from harming yourself. This may include contacting you to assess your risk of suicide and/or disclosing this information to other health care professionals.
8. **Are there any possible benefits?**
You may reduce your binge-eating by taking part in this study. However, we cannot guarantee that this study will help you.
9. **Will there be any payment for taking part?**
You will not receive any payment for taking part in this study. However, you will receive a self-help program free of charge.

10. **Liability statement:**
By agreeing to take part in this study via e-mail and completing the study forms online you are implying your consent. This tells us that you understand the information outlined above about this study and are willing to take part. When you agree to take part and complete these forms, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

11. **Withdrawal of consent**
It is possible for you to withdraw your information up until the point when you have submitted your responses to the on-line forms. After this time, your data will be entered anonymously into our database and it will be impossible to identify which data is yours. You may withdraw from the self-help program or decide not to complete future forms at any time.

12. **What about my privacy and confidentiality?**
Protecting your privacy and confidentiality is an important part of this study. Every effort to protect your privacy will be made.

When you respond to this email with your consent to take part in this study, you give us permission to:

- Collect information from you
- Share information with the people conducting the study
- Use information for dissertations and publications in group format without identifying anyone who took part

Storage of Records

Information collected and used by the research team (including video-recordings of therapy sessions) will be encrypted and stored in a password-protected database. After you have completed the online forms, any identifying information about you (i.e., name or email address) will be removed from the file. Your data will be stored *anonymously*. The primary investigator (Dr. J. Carter-Major) is responsible for the security of these files.

Access to records

The members of the research team will have access to the study records. After you have submitted the forms, however, there will be no identifying information (i.e., name or email address) stored with the data. Other people may need to *look* at the study records. This might include the health research ethics board. You may ask to see the list of these people. They can look at your records only when supervised by a member of the research team. The records will not identify you in any way.

Use of your study information

The research team will collect and use only the information they need for this research study.

This information will include your

- age
- biological sex at birth
- medical history
- medications
- information from study interviews and forms

Your name and contact information will be kept secure by the research team at Memorial University until you have completed the study. Once you have submitted the study forms your data will be stored anonymously. Your information will not be shared with others outside of our research team without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will be kept securely for ten years. No identifying information (i.e., your name or email address) will be stored with your data. After the ten-year period these electronic files will be magnetically erased or overwritten so that it cannot be recovered.

Your access to records

If you are interested in seeing the information collected by our team, you may

contact the principal researcher (or another member of the team) prior to submitting your responses to the questionnaires. We will set up a telephone or video interview to go through your information with you. If you do not contact the investigators prior to submitting your responses, it will be impossible for us to identify your data.

13. Questions or problems:

If you have any questions about taking part in this study, you can contact a member of our research team at: munstopovereating@gmail.com

Alternatively, you may contact the primary investigator:

Dr. Jacqueline Carter-Major at 709-864-8118
jacquelinec@mun.ca

If you would like to talk to someone who is not involved in the study and can advise you on your rights as a participant in a research study you can contact:

Ethics Office at 709-777-6974
info@hrea.ca

This study has been reviewed and given ethics approval by the Newfoundland and Labrador Health Research Ethics Board. We encourage you to retain this information form so that you are aware of your rights throughout this study.

Checklist

Before deciding to participate in this study, we encourage you to go through this checklist to ensure that you are aware of your rights as a participant and that all of your questions have been answered.

Study title: **SELF-HELP FOR BINGE-EATING: A RANDOMIZED CONTROLLED STUDY**

Name of principal investigator: Dr. Jacqueline Carter-Major

Please check as appropriate:

I have read the information form. Yes { } No { }

I have had the opportunity to ask questions/to discuss this study. Yes { } No { }

I have received satisfactory answers to all of my questions. Yes { } No { }

I have received enough information about the study.
Yes { } No { }

I have been in contact with a member of the research team and s/he has answered my questions. Yes { } No { }

I understand that I am free to withdraw from the study Yes { }
No { }

- at any time
- without having to give a reason

I understand that it is my choice to be in the study and that I may not benefit. Yes { }
No { }
I understand that I may experience discomfort while filling out the study forms and that, if I experience discomfort, I will have the opportunity to talk Dr. J. Carter-Major. Yes { }
No { }
I understand how my privacy is protected and my records kept confidential. Yes { }
No { }

If you agree to take part in this study, please send us an e-mail letting us know that you would like to take part.

Thank you,

MUN Eating Behaviours Laboratory
e-mail: munstopovereating@gmail.com
Memorial University of Newfoundland
St. John's, NL

Appendix J

Post-treatment Script for EDE Interviews

Hello [participant's name]. My name is Lily, and I'm a researcher in the psychology department at Memorial University. I'm a part of the study on overeating that you have been participating in for the past three months.

Thank you for your continued involvement in our study. Is this a convenient time for us to talk? Are you in a private space where you feel comfortable speaking openly?

Before I proceed, it's very important that you do not tell me the book that you have received. It is important that I am blind to the book that you have received, as this will ensure that I do not influence your responses in any way while doing the interview. This will help us get an honest and accurate picture of your eating habits. Do you have any questions about that?

Here's what we're going to do [today/this evening]. We want to see how you have been doing with regards to your eating habits since receiving their books. To do this, I am going to ask you a few questions about your eating habits, with a focus on overeating. These are the same questions that you answered during your previous telephone interview three months ago. I know that this can be difficult to discuss but it is really important for our study that we get a clear picture of your eating habits.

All information that you disclose in this interview is confidential, and will be not be shared with anyone except the research team. Do you have any questions before we begin?

As these interviews are designed in a certain way, it is important that I read through the full instructions as they have been written by the authors. Also, I just wanted to let you know that the interview will be very focused on specific episodes of overeating. Lastly, if there are any periods of silence on my end, it is because I am taking detailed notes. Do you have any questions before we start?