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## Predictors and moderators of treatment outcome in a randomized clinical trial for adults with symptoms of bulimia nervosa

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#### Abstract

**Objective**—This study examined predictors and moderators of outcome in two treatments for bulimia nervosa (BN).

**Method**—Eighty adults with BN symptoms at one of two sites were randomized to 21 sessions of integrative cognitive-affective therapy (ICAT-BN) or enhanced cognitive behavior therapy (CBT-E). Generalized linear models examined predictors and moderators of improvements in bulimic behavior and eating disorder psychopathology at end of treatment (EOT) and four-month follow-up (FU).

**Results**—At EOT, individuals with higher dietary restraint had greater reductions in bulimic behavior. At FU, individuals with higher weight and shape concern had greater reductions in bulimic behavior, while those with greater baseline depression had less improvement in eating disorder psychopathology. Individuals higher in stimulus-seeking had greater reductions in bulimic behavior and eating disorder psychopathology at follow up in ICAT-BN than CBT-E, whereas individuals lower in stimulus seeking had greater reductions in bulimic behavior in CBT-E than ICAT-BN. Finally, individuals with higher affective lability had greater reductions in eating disorder psychopathology in ICAT-BN than CBT-E, while improvements were comparable across treatments for individuals with lower affective lability.

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**Conclusions**—This study identified three non-specific predictors of outcome (i.e., dietary restraint, weight and shape concern, and depression) and two moderators (i.e., affective lability and stimulus seeking). All moderator effects emerged at FU rather than EOT, suggesting that the moderating effects of treatment were not immediately apparent. These results suggest that individuals with higher affective lability and stimulus seeking may benefit more from treatment with a greater focus on affective states and self-regulation.

#### Keywords

bulimia nervosa; psychotherapy; predictors; moderators; treatment outcome

Bulimia nervosa (BN) is a psychiatric disorder characterized by recurrent binge eating episodes, inappropriate compensatory behaviors, and self-evaluation that is unduly influenced by weight and shape (APA, 2013). Successful treatment of BN is critical because of its association with psychosocial impairment (Crow & Peterson, 2003), medical complications (Mehler, 2011), and high mortality rates (Suokas et al., 2013). However, only about half of those who receive established treatment for BN respond well (Steinhausen & Weber, 2009). Therefore, there is still considerable need for alternative treatments that are more efficacious overall, or that are more efficacious for particular individuals (Kraemer, Wilson, Fairburn, & Agras, 2002).

Cognitive behavior therapy (CBT) for BN has demonstrated significantly greater impact on bulimic symptoms than other psychotherapies (Hay, Bacaltchuk, Stefano, & Kashyap, 2009). An updated "enhanced" version of CBT was developed (CBT-E) (Fairburn, 2008), with exploratory analyses suggesting that abstinence and remission rates are at least comparable to CBT (Fairburn et al., 2009), although those who developed the treatment have suggested that CBT-E is superior to CBT for BN (Murphy, Straebler, Cooper, & Fairburn, 2010). A potential alternative treatment is integrative cognitive affective therapy for BN (ICAT-BN), which performed comparably to CBT-E in a randomized controlled trial (Wonderlich et al., 2014). ICAT-BN places an explicit focus on identifying momentary triggers of emotion dysregulation and the potentially rewarding role that bulimic behavior may play in regulating emotional states.

While preliminary efficacy data indicate no significant differences in outcome between ICAT-BN and CBT-E (Wonderlich et al., 2014), moderators that might inform for whom this type of treatment might be particularly helpful have not yet been examined. Examining predictors and moderators of treatment outcome is critical to better understand how treatments work, and which treatments work best for which patients (Kraemer et al., 2002). Non-specic predictors are baseline factors that have a main effect on outcome (i.e., the factor's effect on outcome is equal across treatments), while moderators provide information about who responds to which treatment (i.e., the factor's effect on outcome differs across treatments). Additional research on non-specific predictors and moderators is critical in order to identify likely prognosis and more appropriately match patients to treatment. Unfortunately, a review of 79 studies revealed poor or inconsistent predictors of treatment outcome (Steinhausen & Weber, 2009).

Page 3

The aim of this exploratory study was to examine predictors and moderators of treatment outcome in a randomized controlled trial comparing CBT-E to ICAT-BN (Wonderlich et al., 2014). The two main outcomes in this trial were frequency of bulimic behavior and overall eating disorder psychopathology (i.e., global score on the EDE). Given that this is the first examination of moderators in a randomized trial comparing these two treatments along with the lack of robust predictors of outcome in BN, these analyses are exploratory and hypothesis-generating rather than hypothesis-testing (Schatzberg & Kraemer, 2000). Therefore, we did not develop *a priori* hypotheses regarding specific predictors or moderators of outcome.

#### Method

Eighty adults with DSM-IV BN (APA, 1994) and BN symptoms not meeting diagnostic criteria (i.e., identical criteria as DSM-IV with subjective rather than objective binge eating episodes) were randomized to ICAT-BN or focused CBT-E at one of two sites. An independent biostatistician randomized participants to treatment in blocks of four, strati ed by site, therapist, and diagnosis. Both treatments were delivered in 21 50-minute individual sessions over 17 weeks by four psychologists (two per site) with extensive experience delivering psychotherapy in randomized trials for eating disorders. Additional details of the clinical trial design are provided in the main outcome report (Wonderlich et al., 2014). ICAT-BN (Wonderlich, Peterson, Smith, Klein, Mitchell, & Crow, 2015) and CBT-E are described in detail elsewhere (Fairburn, 2008). Briefly, ICAT-BN is an emotion-focused behavioral therapy with a targeted emphasis on modifying and tolerating momentary affect. In contrast, the focused form of CBT-E employs psychoeducation, self-monitoring, behavioral exposure, and problem-solving to normalize eating patterns, decrease dietary restraint, and reduce over-evaluation of shape and weight. Although CBT-E does not emphasize negative affect, mood tolerance is included in treatment when eating disorder symptoms are observed to be strongly linked to emotions and persist after implementing other CBT-E interventions (e.g., proactive problem-solving). All participants provided written informed consent. This study was approved by each site's institutional review board.

#### Measures

Trained interviewers administered the Eating Disorder Examination (EDE) (Fairburn, 2008) at baseline, end of treatment (EOT), and four-month follow-up (FU) to assess the two main outcomes in this study—bulimic behavior (i.e., combined 28-day frequency of objective binge eating, vomiting, and laxative misuse) and eating disorder psychopathology (i.e., EDE global score). These two outcomes were selected in order to examine objective behavioral outcomes as well as eating disorder psychopathology more broadly. The EDE global score had Cronbach's alphas of .847, .853, and .885 at baseline, EOT, and FU, respectively.

Additional baseline measures assessed dietary restraint (EDE subscale), weight and shape concern (composite EDE subscale),<sup>1</sup> depressive symptoms (Beck Depression Inventory: BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), anxiety symptoms (Spielberger

 $<sup>^{1}</sup>$ Items from the EDE shape concern subscale and weight concern subscale were combined into one composite subscale; the item that loads on both subscales was included only once in the composite score.

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Trait Anxiety Inventory: STAI; Spielberger, Gorsuch, & Lushene, 1970), and emotion dysregulation (Difficulties in Emotion Regulation Scale: DERS; Gratz & Roemer, 2004), all of which had good internal reliability ( $\alpha s = .731, .824, .892, .933, and .850, respectively)$ . Three scales from the Dimensional Assessment of Personality Pathology, Basic Questionnaire (DAPP-BQ; Livesley & Jackson, 2009) were chosen as measures of personality psychopathology. The T-scores for DAPP-BQ affective lability ( $\alpha = .915$ ), stimulus seeking ( $\alpha = .885$ ), and intimacy problems ( $\alpha = .897$ ) scales demonstrated good internal consistency. Affective lability refers to the tendency to frequently experience overly intense and unstable emotions. Stimulus seeking refers to the need for excitement and stimulation, often leading to impulsive behavior without anticipation of the consequences; individuals high in stimulus seeking tend to have difficulty tolerating routines and following established plans. Intimacy problems refer to an individual's fear and avoidance of intimacy. Self-discrepancy was assessed using the Selves Interview (Higgins, Bond, Klein, & Strauman, 1986), from which actual-ideal self-discrepancy and actual-ought selfdiscrepancy were derived. Finally, self-blame and self-control were measured using the Structural Analysis of Social Behavior Intrex Questionnaire (SASB-Intrex; Benjamin, 2000).

#### Statistical analyses

Generalized linear models were conducted to evaluate predictors of two outcomes (i.e., bulimic behavior and eating disorder psychopathology) at EOT and FU, adjusting for baseline level of each variable. Predictors of each outcome included baseline dietary restraint, weight and shape concern (bulimic behavior models only), depression, anxiety, emotion dysregulation, affective lability, stimulus seeking, intimacy problems, actual-ideal self-discrepancy, actual-ought self-discrepancy, self-blame, and self-control. All predictors were centered, including treatment as -0.5 and 0.5. Initial models examined each baseline predictor separately, including the main effect of treatment and its interaction with treatment. Models were based on a negative binomial distribution for bulimic behavior (a count variable) and a normal sampling distribution for eating disorder psychopathology. The alpha cut-off for the initial models was based on Bendel and Afifi's (1977) recommendation for the sequential F-test based on a fixed alpha level for models with five degrees of freedom. Therefore, initial main effects or interactions with *p*-values .15 were entered simultaneously into a second final model, and final effects with *p*-values .05 were interpreted. Pseudo R<sup>2</sup> provided a measure of effect size: small (.02), medium (.13), and large (.26) (Cohen, 1988). Analyses were performed using SPSS version 22.

#### Results

Participants were predominantly female (n = 72, 90%) and White (n = 70, 87.5%), and the majority  $(n = 58, 72.5\%)^2$  met DSM-IV criteria for BN (see Table 1).<sup>3</sup>

<sup>&</sup>lt;sup>2</sup>Using DSM-5, 86.3% (n = 69) participants met diagnostic criteria for BN. Of those who did not meet DSM-5 diagnostic criteria for BN, 92.5% (n = 84) endorsed OBEs during the study period. <sup>3</sup>There were no significant treatment differences on any characteristic at baseline.

J Consult Clin Psychol. Author manuscript; available in PMC 2017 February 01.

#### **Outcomes at End of Treatment**

**Bulimic behavior**—Weight and shape concern (p = .005), intimacy problems (p = .118), and actual-ideal self-discrepancy (p = .098) were included in the final model. After adjusting for baseline bulimic behavior (B = 0.013, SE = 0.003, Wald  $\chi^2 = 20.517$ , pseudo R<sup>2</sup> = .059, p < .0001), the final model accounted for  $\approx 5\%$  of the variance in bulimic behavior at EOT (pseudo R<sup>2</sup> = .048). The main effect of weight and shape concern indicated that individuals high in these concerns had significantly greater reductions in bulimic behavior across treatments (B = -0.384, SE = 0.109, Wald  $\chi^2 = 12.470$ , pseudo R<sup>2</sup> = .024, p = .0004). The main effects of intimacy problems (p = .095), self-discrepancy (p = .080), and treatment (p = .27) were not significant.

**Eating disorder psychopathology**—The main effect of depression (p = .077) was included in the final model but did not significantly predict eating disorder psychopathology at EOT (p = .12). There was no effect of treatment (p = .40). All effect sizes are presented in Table 2.

#### **Outcomes at Four-Month Follow-up**

**Bulimic behavior**—Dietary restraint (p = .145), stimulus seeking (p = .030), stimulus seeking x treatment (p = .001), and affective lability x treatment (p = .020) were included in the final model. After adjusting for baseline bulimic behavior (B = 0.017, SE = 0.003, Wald  $\chi^2 = 31.116$ , pseudo R<sup>2</sup> = .064, p < .0001), the final model accounted for 4% of the variance in bulimic behavior at FU (pseudo  $R^2 = .040$ ). The main effect of restraint indicated that individuals higher in dietary restraint had greater reductions in bulimic behavior across treatments (B = -0.235, SE = 0.085, Wald  $\chi^2 = 7.640$ , pseudo R<sup>2</sup> = .009, p = .006). The main effect of stimulus seeking (B = -0.031, SE = 0.012, Wald  $\chi^2 = 6.609$ , pseudo R<sup>2</sup> = .003, p = .010) and its interaction with treatment were significant (B = 0.071, SE = 0.024, Wald  $\chi^2 =$ 9.183, pseudo  $R^2 = .016$ , p = .002), indicating that individuals high in stimulus-seeking had greater reductions in bulimic behavior in ICAT-BN than in CBT-E, whereas individuals low in stimulus seeking had greater reductions in bulimic behavior in CBT-E than in ICAT-BN (Figure 1). The affective lability x treatment interaction was significant (B = 0.044, SE =0.022, Wald  $\chi^2 = 4.016$ , pseudo R<sup>2</sup> = .007, p = .045), indicating that individuals high in affective lability had greater reductions in bulimic behavior in ICAT-BN than in CBT-E, whereas individuals low in affective lability had comparable reductions across treatments (Figure 2). The main effects of affective lability (p = .42) and treatment (p = .87) had no significant effect on outcome.

**Eating disorder psychopathology**—Depressive symptoms (p = .150), stimulus seeking x treatment (p = .055), and affective lability x treatment (p = .055) were included in the final model. After adjusting for baseline eating disorder psychopathology (B = 0.176, SE = 0.101, Wald  $\chi^2 = 2.925$ , pseudo R<sup>2</sup> = .039, p = .087), the final model accounted for approximately 8% of the variance in eating disorder psychopathology at FU (pseudo R<sup>2</sup> = .083). Individuals with greater depressive symptoms had lesser improvements in eating disorder psychopathology at FU (B = 0.039, SE = 0.012, Wald  $\chi^2 = 11.489$ , pseudo R<sup>2</sup> = .049, p = .001). The stimulus seeking x treatment interaction was also significant (B = 0.039, SE = 0.001, Wald  $\chi^2 = 4.060$ , pseudo R<sup>2</sup> = .019, p = .044), such that individuals higher in

stimulus seeking had greater reductions in eating disorder psychopathology at FU in ICAT-BN than in CBT-E, whereas those with lower stimulus seeking had comparable outcomes across treatments (Figure 3). Finally, the main effect of affective lability (B = -0.040, SE =0.014, Wald  $\chi^2 = 7.949$ , pseudo R<sup>2</sup> = .037, p = .005) and its interaction with treatment were significant (B = 0.041, SE = 0.020, Wald  $\chi^2 = 4.103$ , pseudo R<sup>2</sup> = .019, p = .043), such that individuals with higher affective lability had greater reductions in eating disorder psychopathology at FU in ICAT-BN than in CBT-E, while improvements were comparable across treatments for those with lower affective lability (Figure 4). The main effects of treatment and stimulus seeking were not significant (ps > .10).

#### Discussion

In the original study of this randomized clinical trial comparing CBT-E and ICAT-BN study (Wonderlich et al., 2014), there were no differences in primary or secondary outcomes between treatment groups at EOT, nor were any moderators found at EOT in the present study. There were again no differences in outcome between treatment groups at four-month FU, but affective lability and stimulus seeking moderated the effect of treatment on bulimic behavior and eating disorder psychopathology (i.e., EDE global) at FU. For those with higher affective lability or higher stimulus seeking, ICAT-BN was associated with greater improvement than CBT-E across both outcomes at FU. For those with lower stimulus seeking or lower affective lability, both treatments were comparable in reducing eating disorder psychopathology at FU, but CBT-E performed better than ICAT in reductions of bulimic behaviors at FU. Finally, three non-specific predictors (i.e., effects held constant across treatments) were identified. Individuals with higher weight and shape concern and higher dietary restraint had greater reductions in bulimic behavior at EOT and FU, respectively. Second, greater depression predicted lesser reductions in eating disorder psychopathology at FU, which is consistent with other outpatient psychotherapy studies in BN (e.g., Bøgh, Rokkedal, & Valbak, 2005; Claussen, 2008). Effects were small for predictors and moderators, except for the small-to-medium non-specific effect of depressive symptoms.

Although previous adult BN studies have not identified moderators of treatment outcome, ICAT-BN was specifically developed to impact different hypothesized mechanisms than CBT-E. ICAT-BN targets aspects of affect-related impulsive behavior with a momentary focus, such as behavioral skill training to manage momentary urges and rash behaviors while experiencing negative emotional states. Hence, individuals with higher stimulus seeking may have benefitted more at FU from ICAT-BN's emphasis on concrete momentary strategies for high risk situations. More emphasis on affect regulation may also account for better improvements at FU across both outcomes in ICAT-BN than CBT-E for individuals with higher affective lability. In contrast, CBT-E targets dietary restraint and over-evaluation of weight and shape. Individuals with low stimulus seeking may have preferred the weight and shape focus in CBT-E rather than broader emotional experiences, facilitating greater reductions in bulimic behavior at FU. However, weight and shape concern (EOT) and dietary restraint (FU) emerged as non-specific predictors of bulimic behavior, possibly because both treatments address them. In addition, because both ICAT-BN and CBT-E include strategies for affective tolerance (although to a different extent), these non-specific

predictors may reflect overlaps between treatments. Differential outcomes by treatment are not apparent at EOT since moderators only emerged at FU, which suggests that patienttherapy match is more important for maintenance of gains or continued improvement, perhaps because the use of therapy-specific strategies becomes differentially easier and more helpful for certain patients compared to others. Alternatively, analyses of outcomes at FU may have had increased power due to larger treatment effect sizes and greater variability in outcome.

These data may be helpful in refining existing psychological treatments for BN and matching patients to treatments. Nevertheless, several limitations warrant discussion. First, our modest sample (N = 80) limited power to detect effects, so null findings do not necessarily indicate the absence of meaningful effects but rather effects that were not large enough to be detected. On the other hand, significant effects are likely robust given limited power. Due to limited power, only a relatively small number of predictors could be reasonably examined, precluding a more nuanced examination of several predictors (e.g., emotion dysregulation). Second, conclusions about potential mechanisms of change are not possible because mediators were not examined. Future research is needed to examine specific treatment mechanisms, which will help to clarify why certain individual characteristics predicted better outcomes in one treatment versus the other. Third, moderator effects at FU may be influenced by unknown factors occurring after EOT that are unrelated to treatment. Fourth, these findings cannot be generalized to the broad version of CBT-E, which includes additional modules on clinical perfectionism, core low self-esteem, and interpersonal problems. Finally, treatments were delivered in a highly-controlled settings by psychologists with expertise in delivering manualized treatment for eating disorders, and participants had to agree to random treatment assignment. While this design maximized internal validity in this initial comparison of ICAT-BN and CBT-E in adults with BN symptoms, future studies are needed to examine whether these results will be replicated when treatments are delivered in non-research community settings.

These findings advance our understanding of efficacious treatments for individuals with BN and provide preliminary information about which patients may benefit most from which treatment (i.e., CBT-E might be more suitable for those with low stimulus-seeking, while ICAT-BN may be preferred for those with high affective lability). Given the exploratory nature of this study, replication in future studies with larger and more heterogeneous samples, along with an examination of mediators, is needed. The hypotheses generated from this study may guide future (hypothesis-testing) research by providing a rationale for the hypotheses to be tested.

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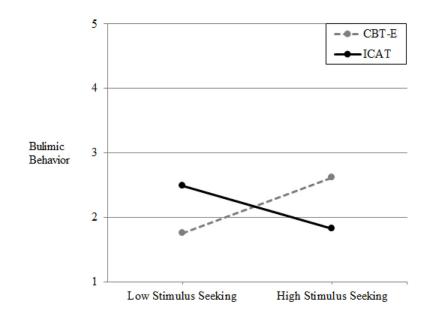
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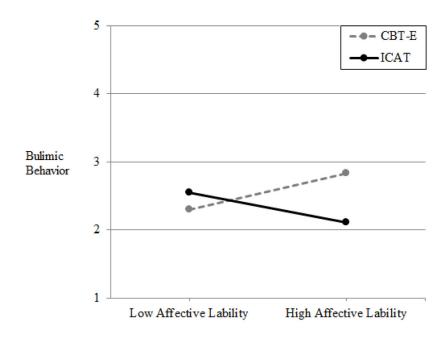
#### Public health significance

This study suggests that for individuals with high affective lability and stimulus seeking, integrative cognitive-affective therapy may be a more efficacious psychological treatment for bulimia nervosa than enhanced cognitive behavior therapy. Furthermore, additional treatment may be indicated for individuals with greater depressive symptoms, regardless of treatment type received. However, the hypotheses generated through this exploratory study require direct testing and replication.



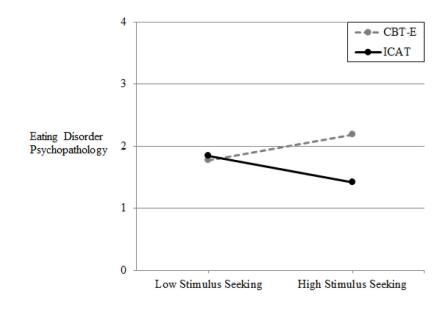
#### Figure 1.

Bulimic behavior (count of objective binge episodes and purging behaviors in the past 28 days) at four-month follow-up by treatment and level of stimulus seeking (high = 1SD above the mean, low = 1SD below the mean).



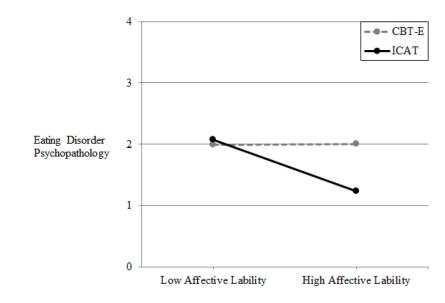
#### Figure 2.

Bulimic behavior (count of objective binge episodes and purging behaviors in the past 28 days) at four-month follow-up by treatment and level of affective lability (high = 1SD above the mean, low = 1SD below the mean).



#### Figure 3.

Eating disorder psychopathology at four-month follow-up by treatment and level of stimulus seeking (high = 1SD above the mean, low = 1SD below the mean).



#### Figure 4.

Eating disorder psychopathology at four-month follow-up by treatment and level of affective lability (high = 1SD above the mean, low = 1SD below the mean).

#### Table 1

#### Participant characteristics at baseline.

Characteristic	M (SD) or N (%)
Age (years)	27.3 (9.6)
Gender (female)	72 (90.0%)
Race/ethnicity	
White	70 (87.5%)
Asian	5 (6.3%)
Hispanic	2 (2.5%)
Other	3 (3.9%)
Never married	55 (68.8%)
College degree	36 (45.0%)
DSM-IV BN	58 (72.5%)
BMI (kg/m <sup>2</sup> )	23.9 (5.5)
Objective binge episodes*	22.8 (20.2)
Subjective binge episodes*	12.7 (16.3)
Vomiting*	29.2 (29.4)
Laxative misuse*	1.3 (3.7)
EDE Global Score	3.3 (1.1)
BDI Total	18.7 (11.6)
STAI Total	51.6 (12.4)
DERS Total	98.0 (26.3)
DAPP-BQ subscales	
Affective lability	52.3 (10.4)
Stimulus seeking	52.4 (10.7)
Intimacy problems	55.7 (10.5)
Selves Interview	
Actual-ideal self-discrepancy	-0.4 (2.6)
Actual-ought self-discrepancy	-0.6 (2.0)
SASB-Intrex self-directed style	
Self-blame	7.5 (2.8)
Self-control	3.1 (1.7)

Note: Using DSM-5 diagnostic criteria, 69 (86.3%) participants met criteria for BN.

\* Frequency of episodes in last month

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# Table 2

Effect sizes (pseudo R<sup>2</sup>) of predictors and moderators at end of treatment and four-month follow-up.

		END	END OF TREATMENT	ENT	FUUK-I	FOUR-MONTH FOLLOW-UP	LOW-UP
<b>Baseline predictor</b>	Outcome	Classification	Main effect	Interaction x treatment	Classification	Main effect	Interaction x treatment
Dietary Restraint	Bulimic Behavior	irrelevant	.003	.001	non-specific predictor+	*600.	< .001
Weight and Shape Concern	Bulimic Behavior	non-specific predictor+	.024*	.002	irrelevant	.008	< .001
Depression	Bulimic Behavior	irrelevant	.003	< .001	irrelevant	.003	< .001
	EDE Global	irrelevant+	.012	.004	non-specific predictor+	.049*	.001
Anxiety	Bulimic Behavior	irrelevant	<.001	< .001	irrelevant	< .001	.002
	EDE Global	irrelevant	.004	.003	irrelevant	.011	< .001
Emotion dysregulation	Bulimic Behavior	irrelevant	<.001	.002	irrelevant	< .001	< .001
	EDE Global	irrelevant	<.001	.002	irrelevant	.006	< .001
Affective lability	Bulimic Behavior	irrelevant	.001	< .001	moderator++	< .001	.007*
	EDE Global	irrelevant	< .001	< .001	moderator++	.037*	.019*
Stimulus seeking	Bulimic Behavior	irrelevant	.004	.003	moderator++	.003*	.016*
	EDE Global	irrelevant	.001	< .001	moderator++	.019	.019*
Intimacy problems	Bulimic Behavior	irrelevant+	.022	< .001	irrelevant	.011	.002
	EDE Global	irrelevant	.020	.001	irrelevant	.011	.002
Actual-ideal self-discrepancy	Bulimic Behavior	irrelevant+	.006	< .001	irrelevant	.002	.003
	EDE Global	irrelevant	<.001	.002	irrelevant	.002	.002
Actual-ought self-discrepancy	Bulimic Behavior	irrelevant	<.001	.003	irrelevant	< .001	.002
	EDE Global	irrelevant	.004	< .001	irrelevant	.005	.005
Self-blame	Bulimic Behavior	irrelevant	.040	< .001	irrelevant	.030	< .001
	EDE Global	irrelevant	.026	< .001	irrelevant	.029	< .001
Self-control	Bulimic Behavior	irrelevant	.041	< .001	irrelevant	.025	.001
	EDE Global	irrelevant	.035	.005	irrelevant	.028	.005

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 $^{++}\operatorname{Both}$  main effect and interaction with treatment included in final model,

\* p-value less than .05.

<sup>+</sup>Only the main effect was included in final model,