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Clinical Moderators and Predictors of Cognitive-Behavioral Therapy by Guided-Self-Help Versus Therapist-led for Binge-eating Disorder: Analysis of Aggregated Clinical Trials

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Abstract

Objective: Cognitive-behavioral therapy (CBT) – therapist-led (CBTth) and guided-self-help (CBTgsh) – has efficacy for binge-eating disorder (BED) but many patients do not benefit sufficiently. We examined predictors and moderators for these two CBT methods.

Methods: Data were aggregated from randomized controlled trials (RCTs) testing psychosocial treatments for BED in the U.S. Predictors and moderators of outcomes (treatment completion and binge-eating remission) were examined in N=457 participants who received either CBTgsh (N=164) or CBTth (N=293).

Results: Analyses, adjusting for demographic/clinical variables, indicated CBTth was significantly superior to CBTgsh for treatment completion (odds ratio [OR]=20.0) and remission (OR=14.6). For remission, analyses revealed significant predictors (age, treatment length, Weight Concern), a moderator (Weight Concern [OR=5.13]), and a significant interaction between CBT-type and treatment length (OR=2.66). For CBTgsh, longer treatment was associated with less remission, whereas for CBTth, longer treatment was associated with greater remission. For CBTgsh, 44.1% with low Weight Concern versus 56.3% with high Weight Concern achieved remission whereas for CBTth, 43.5% with high Weight Concern and 61.0% with low Weight Concern achieved remission.

Discussion: Analyses of aggregated RCT BED data, adjusting for demographic/clinical characteristics, indicated superiority (large effect-sizes) in treatment outcomes of CBTth over CBTgsh and that Weight Concern moderated outcomes.

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Keywords

binge-eating disorder; eating disorders; guided self-help; cognitive-behavior therapy; treatment; moderators; predictors

INTRODUCTION

Binge-eating disorder (BED), the most prevalent eating disorder in U.S. adults (Udo & Grilo, 2018), is associated with elevated medical/psychiatric comorbidity and psychosocial impairment (Udo & Grilo, 2019). Research supports effectiveness of cognitive-behavioral therapy (CBT) for BED (Grilo, 2017; Hilbert et al., 2019; Linardon, 2018). Empirical support for CBT – for both therapist-led (CBTth) and guided-self-help (CBTgsh) methods (Wilson & Zandberg, 2012) has led some professional guidelines to recommend it as "treatment-of-choice" for BED (NICE, 2017). NICE (2017) recommends that patients with BED start with CBTgsh, and if they do not benefit after one month, to switch to CBTth. NICE (2017) recommendations follow evidence that: (1) CBTgsh outperforms "pure" self-help-CBT (Wilson & Zandberg, 2012); (2) although CBTth seems superior to CBTgsh (51.7% versus 33.3% remission rates; [Peterson et al. 2009]), many patients benefit from CBTgsh and it is more readily available and less costly (Wilson & Zandberg, 2012); and (3) rapid response to CBTgsh predicts good outcomes (Masheb & Grilo, 2007).

Randomized controlled trials (RCTs) find approximately 50% of patients do not achieve binge-eating abstinence with CBTth (Linardon, 2018) and this figure is greater for CBTgsh (Peterson et al., 2009). Identification of patient variables that predict or moderate responses to treatment could enhance clinical decision-making about treatment recommendations in addition to informing research on refining treatments (Kraemer, Wilson, Fairburn, & Agras, 2002; Wilson, Grilo, & Vitousek, 2007).

Available research on prognostic indicators of treatment outcomes for BED has produced few reliable predictors and nearly no significant moderators (i.e., for whom specific treatments work better [Kramer et al., 2002]) other than body-image constructs (Linardon, la Piedad, & Brennan, 2017; Vall & Wade, 2015). Some research suggests that patients with BED with higher weight/shape concerns are more likely to remit from binge-eating with CBTgsh than behavioral weight-loss treatment (Sysko et al., 2010) and with CBTth than pharmacotherapy (Grilo, Masheb, & Crosby, 2012). Lower weight/shape concerns predicted greater reductions in binge-eating frequency (but not remission) in integrative cognitive-affective therapy (ICAT) than CBTgsh (Anderson et al., 2020).

The current study, the first to examine predictors/moderators of CBTth and CBTgsh for BED, used aggregated RCT data from "Clinical Trials of BED" (CT-BED)(Franko et al., 2012). CT-BED aggregated data from RCTs testing psychosocial treatments to examine racial/ethnic (Thompson-Brenner et al., 2013) and sex (Shingleton et al., 2015) differences in BED and to examine predictors/moderators of outcomes. Thompson-Brenner et al. (2013) reported race/ethnicity did not moderate outcomes of psychosocial treatments, a finding since extended to broader treatments for BED (Lydecker et al., 2019), although race predicted some outcomes (Black patients had higher dropout rates but greater improvements

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in eating-disorder psychopathology than White patients). Shingleton et al. (2015) found sex did not predict outcomes, although analyses revealed men with low shape/weight concerns were more likely to remit with shorter treatments whereas men with high shape/weight concerns and women (regardless of shape/weight concerns) were more likely to remit with longer treatments. The present study examined patient demographic/clinical variables as predictors/moderators of outcomes for participants who received either CBTth or CBTgsh.

METHODS

Participants

Participants were 457 patients with BED from aggregated CT-BED (Franko et al., 2012) who received either CBTgsh (n=164; four sites) or CBTth (n=293; six sites); other treatments were excluded. Table 1 summarizes demographic/clinical characteristics. Methods have been previously described for recruitment/assessment (Franko et al., 2012) and analytic modeling (Thompson et al., 2013); only a brief overview follows. Institutional Review Boards for each site approved studies.

Measures

Eating Disorder Examination (EDE; Fairburn & Cooper, 1993), semi-structured investigator-based interview, was administered to assess binge-eating frequency ("objective binge episode" (OBE) variable; eating unusually large quantity of food while feeling loss-of-control) and eating-disorder psychopathology reflected in four subscales (Restraint, Eating Concern, Weight Concern, Shape Concern). EDE has good psychometric properties (Berg et al., 2012). *Beck Depression Inventory* (BDI; Beck, 1961) and *Hamilton Depression Rating Scale* (HAM-D; Hamilton, 1960) assessed depression levels. BDI and HAM-D have good psychometric properties, high concordance (correlations>0.9; Reynolds & Koback, 1995), and have established cut-points (see Table 1). *Body Mass Index (*BMI; kg/m^2*)* was calculated from measured weights and heights.

Statistical analysis

Analyses (Table 2) tested for patient variables that predicted (main effect) and moderated (interaction effect) associations between treatment-type (CBTth, CBTgsh) and treatment-outcomes (dropout, binge-eating remission [defined as zero binge-eating (OBE) episodes/past month]). Covariates were baseline variables: age, sex, race/ethnicity, education, BMI, EDE subscales, binge-eating frequency, depression level (none, mild, moderate, severe). CBTgsh and CBTth varied in length across sites (Franko et al., 2012) and therefore adjusted statistically (number-of-weeks) per Shingleton et al. (2018) and Thompson et al. (2013). Interactions between treatment-type and covariates were of primary interest. Due to large number of potential interactions, final models included only interaction terms significant in initial exploratory analyses using stepwise regression (baseline covariates were forced into models and interactions allowed to enter/remain based on stepwise selection). Treatment-length (weeks) was added as predictor because exploratory analyses indicated significant interaction with treatment-type. Effect-sizes (odds ratios) were calculated. Odds ratio estimates and slope estimates were used to explain significant effects.

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Since participants could be viewed as non-independent (some participant subgroups were treated at same sites), confidence intervals were adjusted (Wolter, 1985) and mixed models were used with dataset treated as multi-site trial (Brown & Prescott, 1999) with random intercept for site. Site and baseline binge-eating frequency were adjustment variables in analyses. Multiple imputation was used for missing data (Allison, 2001). Mixed models, not meta-analysis, was used given several advantages (application of consistent techniques across sites, increased power; Cooper & Patall, 2009; Curran & Hussong, 2009).

RESULTS

Table 1 summarizes demographic/clinical variables, shown separately by CBT-type, tested as predictors/moderators of two main outcomes (dropout, binge-eating remission). CBTgsh had significantly younger age and lower Weight Concern and Shape Concern than CBTth; these variables were included as predictors/covariates in multivariate models (Table 2). Initial exploratory analyses revealed significant interactions between CBT-type and two variables [Weight Concern and treatment-length (CBTth was longer)]; these interactions were included in multivariate models. Table 2 summarizes logistic regression model parameter estimates for the outcomes.

For dropout, analyses revealed significant main effects of CBT-type, treatment-length, and Weight Concern, and significant 2-way interactions between CBT-type with Weight Concern and treatment-length. Multivariate models (adjusting for all demographic and baseline clinical variables) indicated greater Weight Concern predicted more dropout (medium effect-size, OR=1.8, p=.04) and CBTgsh had more dropout (large effect-size, OR=20.0, p< .01). Thus, when adjusting for other variables, participants in CBTgsh were 20 times more likely to drop out than those in CBTth. Association of CBTgsh with dropout depended on baseline Weight Concern (large effect-size, OR=2.9, p<.01) and treatment-length (medium effect-size, OR=1.8, p<.002). Significant interaction with treatment-length indicated CBTgsh with longer treatment had less dropout, while CBTth with longer treatment had greater dropout. Weight Concern moderated treatment dropout: CBTgsh participants with low versus high Weight Concern (below/above 3.4 on EDE scale) had comparable dropout rates (31.2% and 26.5%, respectively) as did CBTth participants with high Weight Concern (28.6%), whereas those with low Weight Concern had substantially lower dropout (17.8%).

For binge-eating remission, analyses revealed significant main effects of CBT-type, treatment-length, and age, and significant 2-way interactions between CBT-type with Weight Concern and treatment-length. Multivariate models (adjusting for demographic and baseline clinical variables) indicated significantly greater likelihood of remission predicted by older age (small effect-size, OR=1.18; p=.002) and longer treatment-length (small effect-size, OR=1.22; p<.006) and CBTgsh had significantly less remission than CBTth (large effect-size, OR=14.6, p=.001). Thus, when adjusting for other variables, participants in CBTgsh were 14.6 times less likely than those in CBTth to remit; moreover, for each 1-unit increase in age (years) and length of treatment (weeks), odds of remission increased by 18% and 22% respectively. Association of CBTgsh with remission depended on baseline Weight Concern (large effect-size, OR=5.13, p=.016) and treatment-length (medium effect-size, OR=2.66, p=0.008). Significant interaction with treatment-length indicated longer CBTgsh had less

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remission, while longer CBTth had greater remission. Weight Concern moderated treatment remission rates: among participants receiving CBTgsh, 44.1% of those with low Weight Concern (below 3.4 on EDE scale) compared to 56.3% with high Weight Concern remitted, whereas among participants receiving CBTth, 43.5% with high Weight Concern and 61.0% with low Weight Concern remitted.

DISCUSSION

Our multivariate analysis of aggregated data, compiled from RCTs testing psychosocial treatments for BED (Franko et al., 2012), revealed (after adjusting for demographic and baseline clinical characteristics) CBTth is associated with significantly lower dropout rates (OR=14.6) and higher rates of binge-eating remission (OR=20.0) than CBTgsh. These findings, reflecting large effect-sizes, should be considered alongside NICE (2017) guidelines that patients with BED start with CBTgsh, and if they do not benefit after one month, to switch to CBTth. Our findings suggest a more nuanced view in that CBTth appears to hold a substantial advantage relative to CBTgsh for achieving binge-eating remission after adjusting for patient characteristics. Our findings arguably could suggest that CBTth might be the most appropriate first treatment for adults with BED who have access and the ability to obtain such specialist care. Nonetheless, many patients benefit from CBTgsh and it is more readily available and less costly than CBTth (Wilson & Zandberg, 2012). Further research investigating cost-effectiveness (Lynch et al., 2010) and stepped care designs (Grilo et al., 2020) are needed to more fully support the NICE (2017) recommendations given the findings of the current study.

Our primary goal was to identify patient variables that predict/moderate outcomes of CBTgsh and CBTth. Identifying reliable predictors has been difficult and this is especially so for moderators (Linardon et al., 2017; Vall & Wade, 2015). Depression level did not emerge as a significant predictor/moderator of outcome, which adds to the mixed (Grilo et al., 2012; Lydecker & Grilo, 2021), albeit mostly non-significant literature (Grilo, Gueorguieva, & Pittman, 2021; Masheb & Grilo, 2008). Treatment-length interacted with CBT-type: in CBTgsh, longer duration was associated with higher dropout and lower remission, whereas in CBTth, longer duration had lower dropout and higher remission. This suggests that if CBTgsh does not produce rapid response, extending length will not benefit further, and switching to CBTth is prudent (NICE, 2017).

Analyses revealed Weight Concern significantly predicted and moderated CBTgsh and CBTth outcomes (multivariate analyses adjusted for baseline covariates including BMI). This finding adds to literature regarding prognostic significance of body-image concerns in BED (Anderson et al., 2020; Grilo et al., 2012; Sysko et al., 2010) and provides further evidence that body-image warrants consideration as severity specifier for BED because it provides more meaningful information than *DSM-5* specifier of binge-eating frequency (Forrest, Jacobucci, & Grilo, 2020). *Specifics* of the body-image findings, however, are complex and we cautiously offer comments to place them in the literature and stimulate research. First, significant findings were observed for Weight Concern but not Shape Concern and reasons for this are uncertain. One speculation is because BED is associated strongly with obesity, this distinction might be a salient one for treatment-seeking

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patients with BED. Further BED research should consider concerns about weight and shape separately. Second, Weight Concern moderated CBT's outcomes: among participants receiving CBTgsh, 44.1% with low Weight-concern compared to 56.3% with high Weight-concern achieved remission, whereas among participants receiving CBTth, 43.5% with high Weight Concern and 61.0% with low Weight Concern achieved remission. Finding higher Weight Concern associated with higher remission in CBTgsh is perhaps counter-intuitive based on CBT-E models (Fairburn et al., 2009) but echoes findings from one RCT for bulimia nervosa where CBTgsh had advantage over CBTth in patients with higher eating-disorder psychopathology (Mitchell et al., 2011).

We note limitations. Most participants were female and White and generalizability of findings to patients with different characteristics is uncertain. CBT across sites used different manuals, self-care materials, and treatment-lengths; although analyses adjusted for treatment-length, potential effects of such factors are uncertain. Analyses were limited to the RCTs' variables and tests of different variables (e.g., psychiatric comorbidity; Lydecker & Grilo, 2021) might yield other findings. Analyses were limited to EDE scales and we could not test specific body-image constructs (e.g., overvaluation of shape/weight; Grilo et al., 2012). Strengths include aggregated RCT data across sites yielding findings with implications for delivering CBT for BED across settings.

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Data availability statement:

The data that support the findings of this study are available from the senior author in response to a reasonable written request to achieve goals in an approved written proposal.

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Table 1.

Baseline characteristics and logistic regression model parameter estimates for dropout and remission for cognitive-behavioral therapy guided-self-help (CBTgsh) and therapist-led (CBTth).

Baseline characteristic	CBTgsh (N=164)		CBTth (N=293)		
	Mean/%	SD	Mean/%	SD	Test
Age (years)	48.5	11.2	45.3	9.6	t(446)=3.06, p=0.002*
Female	82.3%		85.3%		t(9)=−1.95, p=0.083
Education					
HS or less	10.4%		14.7%		t(9)=−1.15, p=0.281
>HS	84.8%		83.6%		t(9)=0.21, p=0.836
Missing	4.9%		1.7%		t(9)=0.52, p=0.613
Ethnicity/Race					
White	87.8%		89.4%		t(9)=−0.24, p=0.815
African American	5.5%		5.5%		t(9)=−0.26, p=0.802
Hispanic American	4.9%		3.4%		t(9)=0.43, p=0.680
Other	1.8%		1.7%		t(9)=−0.07, p=0.942
Body mass index	37.3	7.3	38.1	6.8	t(445)=−0.11, p=0.911
EDE Psychopathology					
Restraint	1.7	1.4	1.9	1.4	t(446)=−0.97, p=0.334
Shape Concern	3.6	1.0	4.0	1.0	t(446)=−2.77, p=0.006*
Weight Concern	3.3	1.1	3.5	1.1	t(446)=−2.86, p=0.004*
Eating Concern	1.9	1.3	2.4	1.3	t(445)=−1.89, p=0.059
EDE Binge-eating frequency	20.2	13.7	19.2	13.4	t(442)=−0.15, p=0.877
Depression category					
None	25.3%		26.5%		t(8)=0.55, p=0.598
Mild	41.4%		37.9%		t(8)=1.7, p=0.128
Moderate	27.2%		25.6%		t(8)=0.17, p=0.872
Severe	6.2%		10.0%		t(8)=−0.86, p=0.412

Note: SD = standard deviation; EDE = Eating Disorder Examination interview; Depression category operationalized as follows: None (0–7 on the HAM-D and 0–13 on the BDI), mild (8–13 on the HAM-D and 14–19 on the BDI), moderate (14–18 on the HAM-D and 20–28 on the BDI), or severe (>19 on the HAM-D and ≥29 on the BDI).

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Table 2.

Logistic regression model parameter estimates for dropout and remission for cognitive-behavioral therapy guided-self-help (CBTgsh) and therapist-led (CBTth).

Outcome	Model Parameter	Estimate	SE	p-value	Effect size
Dropout	Intercept	−2.41	1.31	0.0656	n/a
	EDE Weight Concern	0.42	0.21	0.0439	1.78
	Treatment length	−0.15	0.06	0.0072	1.16
	CBTgsh treatment	3.00	0.92	0.0011	19.99
	EDE Weight Concern*CBTgsh	−0.63	0.24	0.0095	2.91
	Treatment length*CBTgsh	0.26	0.08	0.0016	1.79
Binge-eating Remission	Intercept	−0.26	1.12	0.8184	n/a
	Age	0.03	0.01	0.0020	1.18
	Treatment length	0.20	0.07	0.0055	1.22
	CBTgsh treatment	−2.68	0.82	0.0011	14.63
	EDE Weight Concern*CBTgsh	0.58	0.22	0.0083	2.66
	Treatment length*CBTgsh	−0.24	0.10	0.0159	5.13

Notes: Only the significant variables are included in the logistic regression model summaries of the parameter estimates. EDE = Eating Disorder Examination interview; Binge-eating remission defined as zero binge-eating (OBE) episodes during past month assessed with EDE; SE = standard error. Effect sizes were as follows: odds ratio (OR), interpreted as the group difference in odds of being in one treatment outcome category vs. the other (holding constant the other covariates), was used to estimate effect sizes (odds ratios around 1.3 are considered “small,” 1.5 are “medium” and 2.0 are “large”). For BMI, age, and length of treatment, which were modeled as continuous, groups for effect size purposes were defined by first identifying participants who were above vs. below the covariate median, then using the covariate mean within each category to define the distance between groups.

All data presented above are for intent-to-treat analyses with all randomized participants. Parallel exploratory analyses performed with treatment completers produced essential similar model parameters suggesting absence of biases due to differential dropout and are therefore not presented.