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Treatment of binge eating disorder in racially and ethnically diverse obese patients in primary care: Randomized placebo-controlled clinical trial of self-help and medication

Carlos M. Grilo [a,*], Robin M. Masheb [a], Marney A. White [a], Ralitza Gueorguieva [b], Rachel D. Barnes [a], B. Timothy Walsh [c], Katherine C. McKenzie [d], Inginia Genao [d], Rina Garcia [d]

[a] Department of Psychiatry, Yale University School of Medicine, United States
[b] Department of Biostatistics, Yale University School of Public Health, United States
[c] Department of Psychiatry, Columbia University School of Medicine, United States
[d] Department of General Internal Medicine, Yale University School of Medicine, United States

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ABSTRACT

The objective was to determine whether treatments with demonstrated efficacy for binge eating disorder (BED) in specialist treatment centers can be delivered effectively in primary care settings to racially/ethnically diverse obese patients with BED. This study compared the effectiveness of self-help cognitive-behavioral therapy (shCBT) and an anti-obesity medication (sibutramine), alone and in combination, and it is only the second placebo-controlled trial of any medication for BED to evaluate longer-term effects after treatment discontinuation. 104 obese patients with BED (73% female, 55% non-white) were randomly assigned to one of four 16-week treatments (balanced 2-by-2 factorial design): sibutramine ($N = 26$), placebo ($N = 27$), shCBT + sibutramine ($N = 26$), or shCBT + placebo ($N = 25$). Medications were administered in double-blind fashion. Independent assessments were performed monthly throughout treatment, post-treatment, and at 6- and 12-month follow-ups (16 months after randomization). Mixed-models analyses revealed significant time and medication-by-time interaction effects for percent weight loss, with sibutramine but not placebo associated with significant change over time. Percent weight loss differed significantly between sibutramine and placebo by the third month of treatment and at post-treatment. After the medication was discontinued at post-treatment, weight re-gain occurred in sibutramine groups and percent weight loss no longer differed among the four treatments at 6- and 12-month follow-ups. For binge-eating, mixed-models revealed significant time and shCBT-by-time interaction effects: shCBT had significantly lower binge-eating frequency at 6-month follow-up but the treatments did not differ significantly at any other time point. Demographic factors did not significantly predict or moderate clinical outcomes. Our findings suggest that pure self-help CBT and sibutramine did not show long-term effectiveness relative to placebo for treating BED in racially/ethnically diverse obese patients in primary care. Overall, the treatments differed little with respect to binge-eating and associated outcomes. Sibutramine was associated with significantly greater acute weight loss than placebo and the observed weight-regain following discontinuation of medication suggests that anti-obesity medications need to be continued for weight loss maintenance. Demographic factors did not predict/moderate clinical outcomes in this diverse patient group.

Binge-eating disorder (BED), a formal diagnosis in the *DSM-5* (APA, 2013), is defined by recurrent binge eating (i.e., eating unusually large quantities of food accompanied by subjective feelings of loss of control), marked distress about the binge eating, and the absence of extreme weight compensatory behaviors (e.g., purging) that characterize bulimia nervosa. BED is a prevalent clinical problem that is associated strongly with obesity (Hudson, Hiripi, Pope, & Kessler, 2007) and with high rates of bio-psychosocial problems (Grilo, White, & Masheb, 2009; Hudson

* Corresponding author. Yale University School of Medicine, 301 Cedar Street (2nd Floor), New Haven, CT 06519, United States.
E-mail address: carlos.grilo@yale.edu (C.M. Grilo).

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et al., 2007). BED shares features with, but is distinct from other eating disorders and obesity (Grilo, Crosby, et al., 2009; Grilo et al., 2008) and thus represents a clinical challenge (Wlison, Grilo, & Vitousek, 2007).

Cognitive-behavioral therapy (CBT) is the best-established treatment for BED (NICE, 2004; Wilson et al., 2007). CBT has demonstrated "treatment specificity" (Grilo, Masheb, & Wilson, 2005) and produces robust improvements in binge eating, eating disorder psychopathology, and psychosocial functioning that are durable for 12-months (Grilo, Crosby, Wilson, & Masheb, 2012) to 48-months (Hilbert, Bishop, Stein, & Wilfley, 2012) following treatment. Although CBT generally produces remission rates of roughly 50%, weight loss tends to be minimal (Grilo et al., 2011; Wilfley et al., 2002). Several medications have short-term efficacy relative to placebo (Reas & Grilo, 2008, 2014), with specific anti-epileptic agents such topiramate (McElroy et al., 2007) and anti-obesity agents such as sibutramine (Appolinario et al., 2003; Wilfley et al. 2008) producing acute reductions in *both* binge eating and weight. Although BED is associated strongly with obesity (Hudson et al., 2007), and despite the well-known failure of CBT to reduce weight in obese persons with BED, only two studies to date have tested the additive strategy of combining medication known to produce weight loss with CBT methods (Claudino et al., 2007; Grilo, Masheb, & Salant, 2005). Both of those studies reported significant short-term benefits of combining specific medications and CBT to enhance weight losses in obese patients with BED suggesting the need for further research testing combined treatments and with expanded follow-up periods to determine the durability of outcomes (Reas & Grilo, 2008, 2014).

Another pressing issue facing the eating disorder field concerns the need for research on disseminating effective treatment methods (Shafran et al., 2009; Wilson & Zandberg, 2012). Despite the existence of empirically-supported treatments (Wilson et al., 2007), few individuals with eating/weight concerns receive mental health services (Marques et al., 2011), and even fewer receive treatments that have demonstrated effectiveness (Hart, Granillo, Jorm, & Paxton, 2011; Wilson & Zandberg, 2012). There is a shortage of clinicians with specialized training in evidence-based methods such as CBT (Kazdin & Blase, 2011; Shafran et al., 2009) especially for eating disorders (Hart et al., 2011; Mussell et al., 2000).

One potential approach to broader dissemination of effective interventions involves the use of various forms of "guided" self-help and "pure" self-help CBT methods which have shown promise in emerging research (NICE, 2004; Sysko & Walsh, 2008; Wilson & Zandberg, 2012). "Guided" self-help CBT – i.e., with some guidance or facilitation by clinicians – has demonstrated efficacy for BED (Sysko & Walsh, 2008; Wilson & Zandberg, 2012), including "treatment-specificity" for guided self-help CBT compared to guided self-help behavioral weight loss (Grilo & Masheb, 2005). Much less is known, however, about the efficacy of "pure" self-help CBT – i.e., self-help purely self-directed and without guidance from clinicians. Across studies, findings generally indicate that pure self-help is less effective than guided-self-help CBT (Sysko & Walsh, 2008). Only three published studies, however, have directly tested pure self-help CBT for BED against no-self-help (i.e., wait-list) and these studies yielded mixed results. Carter and Fairburn (1998), in a community-based study in the UK, reported that self-help CBT was superior to a wait-list control. In two studies performed in specialist settings, one reported that pure self-help CBT was superior to a wait-list control (Peterson et al., 1998) whereas a recent and much larger study did not (Peterson, Mitchell, Crow, Crosby, & Wonderlich, 2009). Thus, further research is needed on the effectiveness of self-help CBT for BED particularly across different health-care settings (Wilson & Zandberg, 2012).

Nearly all of the treatment literature for BED is based on trials performed in specialist research clinics and comprised mostly of white participants (Franko et al., 2012) and may not generalize adequately to generalist clinical settings or to more ethnically and racially diverse patient groups. Franko et al. (2012), for example, using pooled data from 11 treatment trials of CBT for BED, found significant ethnic/racial differences in BED symptoms that existed even after adjusting for differences in BMI and education. The three RCTs that have tested pure self-help CBT for BED consisted of nearly all white patients – i.e. 96% in Peterson et al. (1998) and 97% in both of the other studies (Carter & Fairburn, 1998; Peterson et al., 2009) – which contrasts sharply with epidemiologic findings regarding the relatively comparable distribution of BED across ethnic/racial groups (Alegria et al., 2007; Marques et al., 2011). Thompson-Brenner et al. (2013) reported significant associations for race and education with some treatment outcomes in specialty clinic trials: lower level of education predicted greater frequency of binge eating at posttreatment and African Americans had greater reductions in eating disorder psychopathology than did Caucasians. Moreover, minority groups with eating disorders have lower utilization rates of mental health services than whites and tend to receive most of their health care from primary care settings (Marques et al., 2011). Thus, treatment research for BED needs to be performed in general clinic settings with more diverse patient groups and include analyses testing demographic features as predictors and moderators of outcomes (Grilo, Masheb, & Crosby, 2012).

Concerns about the generalization of findings from specialist to generalist settings are neither merely "academic" nor are they limited to CBT interventions. For example, in the treatment literature for bulimia nervosa, we note the striking discrepancy between findings from a RCT testing self-help CBT methods and fluoxetine performed in a specialty clinic (Mitchell et al., 2001) versus those performed in a primary care setting (Walsh, Fairburn, Mickley, Sysko, & Parides, 2004). Whereas Mitchell et al. (2001) found that both shCBT and fluoxetine were effective, Walsh et al. (2004) found that both guided-self-help CBT and fluoxetine had very high dropout rates and poor outcomes when delivered in primary care (i.e., only 30.8% completed treatment and only 12.2% and 15.9% achieved remission in the guided-self-help and fluoxetine conditions, respectively) when delivered in primary care.

BED is associated with heightened service utilization in primary care settings (Johnson, Spitzer, & Williams, 2001) but continues to be infrequently identified by general healthcare providers (Mond, Myers, Crosby, Hay, & Mitchell, 2010). Thus, this RCT was designed to determine whether treatments with demonstrated efficacy for binge eating disorder (BED) in specialist treatment centers can be delivered effectively by generalists in primary care settings to racially/ethnically diverse obese patients with BED. Specifically, this study compared the effectiveness of (pure) self-help CBT and an anti-obesity medication (sibutramine), alone and in combination, as initiated by generalist primary care physicians, as potential "first-step" interventions for BED. These two treatments were selected both for their demonstrated efficacy and for their potential ease of use in primary care. The medication, sibutramine, chosen for this study was FDA-approved for the treatment of obesity during the design and initiation of this trial. Two RCTs, specifically with obese patients with BED, reported significant reductions in *both* binge eating and weight for sibutramine relative to placebo (Appolinario et al., 2003; Wilfley et al., 2008). Based on emerging concerns and findings from the SCOUT study (James et al., 2010), the manufacturer withdrew sibutramine from the market in 2010 (Reas & Grilo, 2014), at which time enrollment in this RCT was stopped. However, the present study nonetheless provides important information about the effectiveness of sibutramine and the potential benefits of combining an anti-obesity agent with shCBT. This is only the second study to date testing the additive effects of combining an anti-obesity medication with