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Orlistat with behavioral weight loss for obesity with versus without binge eating disorder: Randomized placebo-controlled trial at a community mental health center serving educationally and economically disadvantaged Latino/as

Carlos M. Grilo[*] and **Marney A. White**
Department of Psychiatry, Yale University School of Medicine, New Haven, CT, USA

Abstract

Objective—This study was a randomized placebo-controlled trial testing the addition of orlistat to behavioral weight loss for obesity in Spanish-speaking-only Latino/as with versus without binge eating disorder (BED) performed at a community mental health center serving educationally- and economically-disadvantaged patients. Latino/as have high rates of obesity but are under-represented in obesity treatment studies and despite comparable-to-or-higher rates of BED than Whites, Latino/as are under-represented in BED treatment studies. BED is associated with obesity but whether it predicts/moderates treatment outcomes remains uncertain. Thus, this study also tested whether BED prospectively predicts/moderates outcomes.

Methods—Seventy-nine obese Spanish-speaking-only Latino/as with BED ($N = 40$) versus without BED ($N = 39$) at a community mental health center were randomly assigned to four-months of orlistat-plus-BWL or placebo-plus-BWL. BWL was culturally-enhanced modification of Diabetes-Prevention-Program delivered in weekly sessions in Spanish. Orlistat (120 mg tid) and matching-placebo delivered with standard clinical-management. Participants were assessed independently throughout treatment, post-treatment, and six-month follow-up.

Results—78% completed treatments; completion rates did not differ significantly by medication or BED. Intent-to-treat mixed-models analyses revealed significant improvements in binge eating, eating-psychopathology, and depression, and significant – albeit modest – weight-loss. Overall, the addition of orlistat to BWL was not associated with greater improvements; however, BED moderated weight-loss: orlistat-plus-BWL produced significantly greater weight-loss in non-BED group but not in BED. Improvements were maintained through 6-month follow-up; BED significantly predicted/moderated increases in eating concerns and depression following treatment. Within BED-group, binge-eating remission rates were 65% (post-treatment) and 50% (follow-up).

Conclusions—In this controlled trial performed at community mental health center serving educationally- and economically-disadvantaged Spanish-speaking-only Latino/as with co-morbid psychiatric needs, we observed outcomes for the BWL plus orlistat/placebo medication that approximate or are slightly dampened relative to the literature for efficacy trials with much more restrictive obese and BED samples. In this complex patient group, adding orlistat to BWL produced greater weight-loss than adding placebo among obese patients without BED but not among those with BED. Although 50% of BED patients maintained abstinence from binge-eating

[*]Corresponding author. Yale University School of Medicine, 301 Cedar Street (2nd Floor), New Haven, CT 06519, USA. carlos.grilo@yale.edu. .

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following these specific obesity treatments (BWL plus orlistat/placebo), BED was a negative prognostic indicator for some outcome variables.

Keywords

Binge eating disorder; Obesity; Behavioral weight loss; Medication; Latino; Hispanic

Obesity is considered one of the most prevalent (Flegal, Carroll, Ogden, & Curtin, 2010) and serious public health problems in the United States, with associated annual medical costs recently estimated at $147 billion (Finkelstein, Trogdon, Cohen, & Dietz, 2009). Latino/as face well-documented health disparities in obesity (Flegal et al., 2010), eating behaviors (Perez-Escamilla, 2011), and obesity-related medical co-morbidities (Smith et al., 2005). Latino/as have a higher and faster growing prevalence of obesity than whites; based on 2008 national data, 43% of Latinas versus 33% of white women are obese (Flegal et al., 2010). Latina/os, however, are less likely to use existing effective weight-loss methods (Tsai et al., 2009) and are under-represented in obesity treatment studies. A review of the limited obesity treatment literature with Latino/as concluded that traditional weight-loss interventions developed for Anglo-Americans demonstrate less effectiveness with Latino/as and highlighted the need for developing more effective interventions for this ethnic group (Lindberg & Stevens, 2007). A notable exception, the Diabetes Prevention Program (DPP, 2002; West, Prewitt, Bursac, & Felix, 2008), which enrolled a large number of Hispanics (mostly Mexican–American), found support for the effectiveness of lifestyle behavioral weight loss (BWL) for reducing weight and health risks in pre-diabetic Hispanics. However, the Look-AHEAD Study, another methodologically-rigorous effort, reported that Latino/as lost less weight than non-Hispanics (Wadden, West, Neiberg, & Look AHEAD Research Group, 2009).

Obesity is a heterogeneous problem and research has highlighted the significance of a specific subgroup with binge eating disorder (BED). BED is characterized by recurrent binge-eating (eating unusually large quantities of food accompanied by loss of control) and marked distress in the absence of inappropriate weight-compensatory behaviors. BED is prevalent (Hudson, Hiripi, Pope, & Kessler, 2007), differs from other eating disorders (Allison, Grilo, Masheb, & Stunkard, 2005), has demonstrated validity (Striegel-Moore & Franko, 2008), and is strongly associated with obesity and elevated risk for medical/psychiatric comorbidity (Hudson et al., 2007). For example, in the National Comorbidity Survey Replication study, Hudson et al. (2007) found that 79% of those with BED had at least one other lifetime DSM-IV psychiatric disorder, with 65% meeting criteria for an anxiety disorder, 46% for a mood disorder, and 23% for substance use disorders. Similarly, Grilo, White, and Masheb (2009), in a consecutive series of 404 treatment-seeking patients with BED, found that 74% had at least one additional lifetime psychiatric disorder, with 54% meeting criteria for a mood disorder, 37% for an anxiety disorder, and 25% for substance use disorders. Thus, obese patients with BED have complex behavioral and psychosocial needs relative to their obese non-binge-eating peers (Hudson et al., 2007).

The treatment literature for obese patients with BED indicates that some medications have short-term efficacy relative to placebo but very little is presently known regarding maintenance (Reas & Grilo, 2008). The few available data from trials reporting longer-term effects of various medications for BED, either on maintenance doses (McElroy et al., 2004) or following discontinuation of medications (Grilo, Crosby, Wilson, & Masheb, 2012; Ricca et al., 2001) are negative. The psychological treatment literature for BED indicates that certain psychological and behavioral interventions are effective and have durable binge-eating outcomes but generally fail to produce meaningful weight losses (Wilson, Grilo, & Vitousek, 2007; Wilson, Wilfley, Agras, & Bryson, 2010).

BED is more prevalent among Latino/as than other ethnic/racial groups (Alegria et al., 2007) and strongly associated with obesity in this ethnic group (Alegria et al., 2007; Marques et al., 2011). Latino/as with eating-disorder psychopathology have lower mental health utilization rates than Anglos (Marques et al., 2011) but – in contrast to both population rates of Latino/as and to prevalence rates of BED in Latino/as – have been vastly under-represented in BED treatment studies (Franko et al., 2012). The generalizability of the BED treatment literature to obese Latino/as with BED is uncertain given both the small numbers of Latino/as in any of the published trials and recent findings that ethnic differences in BED psychopathology exist (Franko et al., 2012).

Since BED is strongly associated with obesity, it is important to find methods to reduce weight – in addition to eliminating binge-eating – in obese persons with BED. Obesity treatment studies that included self-report measures of binge-eating have produced mixed findings regarding whether obese binge-eaters required different treatments (Wilson et al., 2007). Significant methodological limitations of this literature, particularly retrospective non-randomized designs testing the predictive significance of binge-eating, reliance on self-report questionnaires for assessing binge-eating, inclusion of varying sub-threshold levels of binge eating, and the lack of follow-up data preclude any conclusions (Wilson et al., 2007). A matched-study meta-analysis of weight control trials reported that average weight losses for obese binge eaters were negligible (1.3 kg) and substantially less than for obese non-binge-eaters (10.5 kg) (Blaine & Rodman, 2007); this unusual comparison-strategy and the marked methodological variability, particularly measurement weaknesses of binge-eating in obesity trials, preclude firm conclusions. Within the BED literature, controlled studies of BWL have produced mixed findings; however, recent methodologically rigorous trials have reported BWL is more effective than CBT for producing weight-loss, although the amounts of weight-loss tend to be modest (Grilo, Masheb, Wilson, Gueorguieva, & White, 2011; Wilson et al., 2010). Therefore, the identification of effective supplemental treatments, such as medications, that can potentially enhance weight-loss is a research priority (Gray et al., 2012; Vetter, Faulconbridge, Webb, & Wadden, 2010).

The withdrawal of sibutramine from the market in 2010 due to cardiovascular-related concerns, left orlistat as the only anti-obesity medication approved by the FDA for longer-term use (Vetter et al., 2010) until the approval of two new medications (phentermine/topiramate and locaserin) in 2012. Two controlled studies with obese BED patients reported that adding orlistat to behavioral (Golay et al., 2005) or cognitive-behavioral (Grilo, Masheb, & Salant, 2005) treatments enhanced short-term weight losses. Among obese patients without BED, the Latin American Orlistat Trial reported that adding orlistat to diet produced greater weight loss than adding placebo (Halpern et al., 2003).

Thus, the current randomized placebo-controlled treatment study was designed to test the acute effects of adding orlistat to BWL for obese Latino/a patients with BED versus obese patients without BED, to test the durability of outcomes through 6-month follow-up after discontinuing treatments, and represents the first controlled prospective study testing the predictor/moderator effects of BED on obesity treatment outcomes. In addition to addressing health-disparities issues in Latino/as pertaining to obesity and BED, this trial was intended to contribute empirical findings relevant for the addressing the “gap” between the evidence-based treatment literature and dissemination, particularly the issue of whether or how treatment trials can produce findings for broader patient groups with few exclusionary criteria (Shafran et al., 2009). Despite BED being associated with high rates of psychiatric co-morbidity (Grilo et al., 2009; Hudson et al., 2007), the co-occurrence of additional psychiatric problems and/or the use of psychiatric medications are frequent exclusionary criteria in the pharmacotherapy literature for BED (Guerdjikova & McElroy, 2009). Similarly, psychiatric problems such as mood disorders are frequently exclusionary criteria

in the treatment literature for obesity (Schneider et al., 2008). Thus, we chose to perform this study in obese Spanish-speaking-only Latino/a patients at a community based mental health clinic serving economically-disadvantaged persons with mental health needs using minimal exclusionary criteria.

Methods

Participants

Participants were a consecutive series of 79 monolingual (Spanish-speaking-only) obese Latino/as (65 females, 14 males) recruited from clinical teams and referrals at a community mental health center serving economically disadvantaged persons with mental health needs. This study enrolled participants from August 2007 through October 2009. This RCT was designed with the goal of obtaining a broadly clinically-relevant obese patient group (aged 21–65 years of age with body mass index (BMI) of 30 or greater) with versus without BED, and therefore few exclusionary criteria were applied. Exclusionary criteria included serious mental illnesses (e.g., psychotic disorders, such as schizophrenia, or current severe bipolar illness, uncontrolled current substance dependence, or suicidality) but did not exclude most forms of psychiatric co-morbidity found to be associated with BED (Grilo et al., 2009) as is common for most efficacy trials for obesity and BED (Allison et al., 2009; Guerdjikova & McElroy, 2009; Schneider et al., 2008). Exclusionary criteria also included unstable/ changing medication regimens and current antipsychotic medications as well as cardiac and neurologic diseases. The study was approved by the Institutional Review Board (Yale School of Medicine). All participants provided written voluntary informed consent after receiving a complete description of all procedures.

Fig. 1 summarizes the flow of participants throughout the study. One hundred thirty-nine individuals were screened, 90 passed screening and were scheduled for in-person assessments to determine eligibility, and of these, 79 individuals were interested in participating, met eligibility requirements, completed baseline assessments, and were enrolled. Participants had a mean age of 46.32 years (SD = 9.68) and a mean BMI of 37.57 (SD = 6.62). Overall, education attainment was modest; 50% of participants reported a grammar or middle-school education. Participants were diverse in their country of origin, representing Puerto Rico and several countries from Central and South America.

Diagnostic assessments and outcome measures

Assessments were administered in Spanish by bi-lingual masters- and doctoral-level research-clinicians who were trained in the study's assessment procedures. The assessment battery comprised Spanish-language versions of the interview and self-report measures (described below). Whenever reading ability was a potential concern, research clinicians read the self-report questionnaires verbatim to participants. In such cases, participants' responses to self-report questions were coded "as is" – i.e., without further clarifications. Participants were provided subject payments ($75) for completing the major independent assessment evaluations (baseline, post-treatment, and 6-month follow-up) commensurate with time burden and IRB-approval.

Participants were categorized as either with or without BED (per *DSM5* criteria). BED status was based on findings from the Structured Clinical Interview for DSM-IV Axis I Psychiatric Disorders (SCID-I/P) (First, Spitzer, Gibbon, & Williams, 1996), the Eating Disorder Examination interview (EDE) (Fairburn & Cooper, 1993), and any additional relevant data from the clinical intake evaluation and medical record, following the "best-estimate" LEAD (i.e., longitudinal expert all data) standard (Pilkonis, Heape, Ruddy, & Serrao, 1991) used previously in diagnostic studies with complex Hispanic patient groups

(Grilo, Becker, Anez, & McGlashan, 2004). Forty participants met criteria for BED and 39 without BED.

Weight, height, and BMI—Actual measurements of weight and height were obtained during the initial assessment meeting using a calibrated medical balance beam scale and were used to calculate BMI. Actual weight measurements were obtained throughout treatment and at post-treatment and 6-month follow-up assessments.

Spanish language version of the Eating Disorders Examination—(S-EDE) (Grilo, Lozano, & Elder, 2005), like the EDE (Fairburn & Cooper, 1993), is a semi-structured investigator-based interview with good psychometric characteristics (Grilo, Masheb, & Wilson, 2001) and test–retest reliability (Grilo, Masheb, Lozano-Blanco, & Barry, 2004) in studies of obese patients. The S-EDE assesses the frequency of different forms of overeating, including objective bulimic episodes (OBEs; i.e., binge-eating defined as unusually large quantities of food with a subjective sense of loss of control). The S-EDE comprises four subscale scores (Restraint, Eating Concern, Shape Concern, and Weight Concern) and a global total score. Items are rated on 7-point forced-choice scales (0–6), with higher scores reflecting greater frequency or severity. The S-EDE has demonstrated good inter-rater and test–retest reliability (Grilo, Lozano, et al., 2005). In the present study, inter-rater reliability (rho) coefficients, based on $N = 20$ independently rated cases, were .85 for frequency of binge-eating (OBE) episodes and ranged .82–.99 for the EDE subscales and global score. The S-EDE was administered monthly during treatment and at post-treatment and 6-month follow-ups assessments.

Spanish-language version Beck Depression Inventory—(S-BDI) (Penley, Wiebe, & Nwosu, 2003) is a 21-item self-report instrument developed to measure the depression levels and features. Like the BDI (Beck, Steer, & Brown, 1996), the S-BDI has good reliability and validity (Penley et al., 2003). The alpha reliability of this measure in the present sample was .91. The S-BDI was administered monthly, post-treatment, and at 6-month follow-up.

Randomization to treatments

Treatment assignment occurred in exact order following completion of all assessments and was performed (and maintained) independently from the investigators by a research-pharmacist at a separate Yale facility. Subjects were randomly assigned with stratification by BED (present/absent) to one of two treatments: orlistat plus BWL or placebo plus BWL (Fig. 1). To ensure concealment of the randomization, medication (orlistat, placebo) was prepared in identical-appearing capsules. The double-blind medication status was broken after all participants completed all assessments including all of the 6-month follow-up visits. Study treatments were provided at no cost and no participation incentives were offered.

Medication treatment

Orlistat, a lipase inhibitor, is a non-centrally-acting medication that produces a dose-dependent reduction in dietary-fat absorption, with a maximum 30% reduction accomplished with dosing of 120 mg three times daily which demonstrates efficacy for weight-loss in obese patients (Davidson et al., 1999; Halpern et al., 2003). Medication treatments were administered in double-blind placebo-controlled fashion. Participants received either orlistat (120 mg 3 times daily) or pill placebo (3 times daily) fixed-dose throughout the four-month treatment.

Medication clinical management procedures for Orlistat (Davidson et al., 1999) were delivered in brief individual meetings by a bi-lingual psychiatrist at the community center

who was trained by the investigators. Patients were educated about orlistat and how it works, instructed to take the medication three times each day (with breakfast, lunch, and dinner), and were encouraged to follow the BWL program closely – particularly the reduced fat-intake recommendations. Brief meetings with the study physician during the course of treatment were held as needed to review adherence, problem-solve issues of non-compliance, assess side effects, and if present, methods for coping with side effects. Patients were given a once-daily multivitamin containing fat-soluble vitamins and instructed to take it two hours prior to the study medication at dinner.

Behavioral weight loss treatment

BWL consisted of a culturally-enhanced adaptation of the Diabetes-Prevention-Program delivered in Spanish by fully-bilingual masters' and doctoral-level clinicians at the community center. The DPP (DPP, 2002; West et al., 2008) federally-funded protocol and materials, found to be effective for producing weight-loss in adults with impaired glucose tolerance, are available on a public domain website. The DPP focuses on goal-setting including reasonable weight loss, healthy eating behaviors and nutritional practices, lifestyle physical activity, and problem-solving to overcome barriers to achieve these lifestyle changes. Our adaptations included the use of handouts and examples geared to the Latino/a population of Connecticut (largely Puerto Rican and mixture of South American countries), and culture-specific food props to teach healthy portion size and combinations. Following initial training in BWL and DPP methods by the investigators, the clinicians participated in the cultural adaptation process jointly with the investigators, and subsequently received weekly supervision in BWL delivery by one of the investigators (MAW). The delivery of BWL occurred within a framework of treatment informed by Latino/a cultural constructs (Añez, Paris, Bedregal, Davidson, & Grilo, 2005). In instances where reading ability was a potential concern (e.g., for patient handouts, monitoring and food records, etc), the clinicians took a flexible approach and would read (and re-read) the materials to participants and collaboratively developed strategies to carry out and keep track of the weekly tasks.

Six-month follow-up period

The double-blind medication status was broken after all participants completed all assessments including the 6-month follow-up visits. None of the participants received study treatments (BWL or orlistat) during the 6-month follow-up period after completing the 4-month treatments, although they continued with their naturalistically-delivered treatment-as-usual mental-health services.

Statistical analysis

Sample size calculation for this study was based on findings from controlled trials of orlistat (Davidson et al., 1999) and orlistat-plus-CBT/BWL (Golay et al., 2005; Grilo, Lozano, et al., 2005; Grilo, Masheb, et al., 2005). Our sample size provided 80% power with two-tailed significance .05 levels for detecting roughly 20% difference in rates of clinically-meaningful weight-loss overall (orlistat versus placebo and BED versus NBO). The primary outcome variable was BMI loss and secondary outcomes were eating-disorder psychopathology (EDE scales and, in the BED subgroup, binge-eating frequency) and depression (BDI) scores.

Analyses were intent-to-treat (ITT) performed for all randomized patients and were performed separately for treatment and follow-up periods. Baseline characteristics between treatments were compared using chi-square analyses for categorical variables and ANOVAs for continuous measures. For the treatment period, ITT analyses involved mixed models (SPSS) using all available data throughout the study; to make use of individual trajectories for post-treatment analyses, analyses included data for baseline, monthly during treatment, and post-treatment assessments in the equations.

In each model, fixed effects of treatment condition (orlistat versus placebo) and BED (present versus absent) were considered as between-subject factors, time as a within-subject factor (levels representing the repeated assessment time-points at baseline, monthly during treatment, and post-treatment for BMI, EDE scales and binge-eating, and BDI), and relevant interaction effects. Distributions of data were examined and transformations applied if necessary to satisfy model assumptions. Different variance–covariance structures were evaluated and best-fitting structures selected based on Schwarz's Bayesian Criterion (BIC).

To evaluate maintenance effects, analyses tested changes from post-treatment to 6-month follow-up. Analyses of covariance were employed testing the same independent variables as for the treatment period at 6-month follow-up using post-treatment values as covariates. In instances of missing data, baseline values were carried forward.

Results

Randomization and progression through the study

Fig. 1 summarizes the progression of participants through the study treatments and assessments. Of the 79 randomized patients, 40 (n = 20 with BED, n = 20 without-BED) received orlistat-plus-BWL and 39 (n = 20 with BED, n = 19 without BED) received placebo-plus-BWL. Treatment completion rates by medication status did not differ significantly: 75% (n = 30 of 40) for orlistat-plus-BWL and 82% (n = 32 of 39) for placebo-plus-BWL ($\chi^2(1) = .58$, $p = .45$). Treatment completion rates by BED status did not differ significantly: 73% (n = 29 of 40) for BED and 85% (n = 33 of 39) for without-BED ($\chi^2(1) = 1.72$, $p = .19$). Independent assessments were successfully performed on 95% (n = 74 of 79) of participants at post-treatment and 91% (n = 72 of 79) at 6-month follow-up.

Implementation of treatments

Overall *mean* of BWL sessions received by participants was 13.2 (SD = 4.7) of 16 possible total. Mean number of BWL sessions completed did not differ by either BED status (12.2 (SD = 5.3) for BED versus 14.1 (SD = 3.9) for non-BED; $F(1,79) = 2.87$, $p = .094$) or by medication (12.8(SD = 5.1) for orlistat versus 13.5 (SD = 4.2) for placebo; $F(1,79) = 1.13$, $p = .29$). Orlistat was generally well tolerated by participants. Overall frequency of reported side effects was only slightly higher for orlistat than for placebo, although reports of minor gastrointestinal events known to be due to orlistat's mechanism of action (e.g., flatus with discharge, fatty or oily stools) were higher for the orlistat condition. Nearly all events occurred early in treatment, were generally mild, and resolved spontaneously. Medication compliance (defined as 75% or greater of pill dosages provided that were taken) did not differ by either BED status (68% (n = 27/40) for BED versus 74% (n = 29/39) for non-BED; ($\chi^2(1) = .45$, $p = .50$)) or by medication (70% (n = 28/40) for orlistat versus 72% (n = 28/39) for placebo; ($\chi^2(1) = .03$, $p = .86$)).

Treatment outcome

Treatment groups did not differ significantly in demographic or psychiatric variables (Table 1) or pretreatment levels of outcome variables (Table 2). Table 2 summarizes outcomes for orlistat-plus-BWL versus placebo-plus-BWL across major time-points presented separately for BED and non-BED groups. Mixed-models analyses (testing data from baseline, monthly during treatment, and post-treatment time-points) revealed significant improvements and time effects in BMI, eating-disorder psychopathology, and depression levels (Table 3). Overall, adding orlistat to BWL was not associated significantly with any greater improvements than adding placebo.

Within BED, remission rates for the BED participants (defined as zero OBE binge-eating episodes for past 28 days) using ITT analyses (missing values replaced with "failure to remit") did not differ significantly for orlistat-plus-BWL (60% (n = 12/20)) versus placebo-plus-BWL (70% (n = 14/20) ($\chi^2(1) = .44$, $p = .51$)). Mixed-analyses restricted to *within* BED revealed similar findings to those above for the overall sample: significant time effects indicating improvements for BMI, eating-disorder psychopathology, and depression levels; adding orlistat to BWL did not produce greater improvements than adding placebo.

Mixed-models analyses revealed that BED predicted significantly worse eating-disorder and depression post-treatment outcomes and moderated significantly the effects of medication on BMI and some eating-disorder features (Table 2). Fig. 2 graphically shows the significant moderating influence of BED on medication effects on BMI: among obese non-BED patients (but not for BED), adding orlistat to BWL produced greater BMI loss than adding placebo.

Maintenance and follow-up

Overall, treatment effects were well maintained through 6-month follow-up (Table 2). At 6-month follow-up, remission rates for the BED participants were 50% (n = 10/20) in both treatment conditions. ANCOVAs revealed no significant main effects for medication status, significant effects for BED predicting increases in EDE eating concerns (F = .039, p = .004) and BDI depression levels (F = 4.790, p = .03), and significant moderator effects of BED on medication (greater BDI depression level increases in BWL + placebo) (F = 7.018, p = .01). Additionally, *within* the BED group, patients who achieved remission from binge-eating at post-treatment (N = 26/40) had significantly lower BMI than patients without a remission (N = 14/40) at post-treatment (M = 35.8 (SD = 5.4) versus M = 40.1 (SD = 6.6); $F(1, N = 40)$ = 5.01, p = .03). At 6-month follow-up, patients who maintained remission (N = 20/40) had lower BMI than patients without a remission (N = 20/40) at non-significant trend-level (M = 35.9 (SD = 3.8) versus M = 39.1 (SD = 6.5); $F(1, N = 40) = 3.77$, p = .059).

Discussion

This study was a randomized double-blind placebo-controlled treatment study performed with Spanish-speaking-only obese Latino/as with versus without BED at a community mental health center serving educationally- and economically-disadvantaged patients with mental health needs. This study tested the acute effects of adding orlistat to BWL, tested the durability of outcomes through 6-month follow-up after completing treatments, and represents the first controlled prospective study of prediction/moderation effects of BED on obesity treatment outcomes. Overall, in this trial with a complex patient group, we observed outcomes for the BWL plus orlistat/placebo medication that approximate or are slightly dampened relative to the literature for efficacy trials with much more restrictive obese and BED samples. In this complex patient group, BWL plus orlistat/placebo resulted in significant overall improvements in binge-eating, eating-disorder psychopathology, and depression, and significant – albeit modest – weight-loss. Overall, the addition of orlistat to BWL was not associated with greater improvements; however, BED significantly moderated weight-loss findings: the addition of orlistat to BWL resulted in significantly greater weight-loss in the obese group without BED but not within the BED group. Improvements were well maintained through 6-month follow-up although BED status significantly predicted/moderated subsequent increases in eating concerns and depression levels. *Within* the BED group, binge remission rates were 65% at post-treatment and 50% at follow-up; patients who stopped binge-eating had greater weight-losses than those who did not.

This study, conducted with Spanish-speaking-only, educationally- and economically-disadvantaged, obese persons in a community-based mental health center, addressed several

major obesity-related health disparities (Perez-Escamilla, 2011). Despite higher rates of obesity and comparable rates of binge-eating, Latino/as are greatly under-represented in treatment studies in both fields. Franko et al. (2012), in a multi-site effort pooling data from 11 RCTs testing psychological treatments for BED, were able to accrue only 64 Latino/a participants representing only 4.6% of the total subject group. Latino/as with eating-related disorders have lower mental-health treatment utilization rates than Anglos (Marques et al., 2011) and non-English-speaking, poorly assimilated, and educationally- and economically-disadvantaged Latino/as face greater barriers to health-care services (Añez et al., 2005; Perez-Escamilla, 2011). Finally, although persons with psychiatric disorders have heightened rates of obesity (Allison et al., 2009), they are routinely excluded from most obesity trials (Schneider et al., 2008) and BED trials testing medications (Guerdjikova & McElroy, 2009).

In this treatment study, with a goal of obtaining a broadly clinically-relevant obese Latino/a patient group in a community mental health center setting, we recruited obese Latino/as with and without BED. Our participants were disadvantaged (50% reported a grammar or junior high school education). Lifetime psychiatric and/or substance use disorders were nearly universal and 75% met criteria for a current psychiatric disorder; 81% were currently taking at least one psychotropic medication and 53% were currently taking at least two psychotropic medications. Serious psychiatric conditions, such as mood disorders, and psychotropic medication regimens are thought to represent negative prognostic indicators for obesity treatments (Allison et al., 2009; Schneider et al., 2008). Despite this challenging patient profile that would have resulted in exclusion from any obesity or BED trial performed to date, treatment completion rates by medication (75% for BWL plus orlistat and 82% for BWL plus placebo) and by BED status (73% for BED and 85% for non-BED) and assessment completion rates (95% at post-treatment and 91% at 6-month follow-up)[1] compare favorably with rigorous published obesity and BED trials comparing similar treatments in more restrictive designs (Davidson et al., 1999; Golay et al., 2005; Grilo, Masheb, et al., 2005; Grilo et al., 2011; Wilson et al., 2010). These findings contribute to the literature regarding the generalizability of RCTs to “routine” or “real-world” clinical settings (Shafran et al., 2009). Our findings also provide further support for leading experts’ views that RCTs can successfully enroll and treat complex and highly co-morbid patients typically seen in clinical practice (Crits-Christoph, Wilson, & Hollon, 2005).

Participation in this RCT resulted in significant overall improvements in eating psychopathology, depression, and significant – albeit modest – weight-loss; these broad improvements were well-maintained through 6-months follow-up after discontinuing the BWL and study medication. The addition of orlistat to BWL resulted in significantly greater weight-loss among those without BED but not those with BED. The non-BED obese group receiving orlistat-plus-BWL had a mean BMI loss of 4.9% (versus roughly 1.9% for placebo-plus-BWL) which closely approximates the mean 4.7% weight-loss reported by a Latin-American trial of orlistat (Halpern et al., 2003) and systematic reviews of orlistat for obesity (Gray et al., 2012; Vetter et al., 2010). It is noteworthy, however, that the BWL plus placebo condition achieved less weight loss in our Latino/a participants than is customarily observed in BWL treatment studies, although even in the intensive Look-AHEAD Study,

[1]The high success rates in obtaining post-treatment and follow-up assessments could reflect several factors. We provided participants with $75 subject payments for completing those major assessments. Although subject payments are generally helpful for enhancing follow-up assessment rates, they are unlikely to suffice. The research team made very aggressive efforts to contact (and re-contact) participants to schedule post- and follow-up assessments and minimized lag times when recontacting participants whenever there were cancellations or requests for different appointment times. The team exercised much flexibility to accommodate the participants’ schedules. Many of the participants came to the community center for other meetings and appointments and therefore our team made every effort to schedule assessments for those opportunities in order to reduce barriers. Lastly, research staff attempted to build positive relations with participants being mindful of important interpersonal cultural constructs important to the Latino/a community.

Latino/as lost less weight than non-Hispanics (Wadden et al., 2009). Weight-loss within the BED group (3.9% for orlistat-plus-BWL versus 2.1% for placebo-plus-BWL), however, also fell short of statistical significance. These weight-loss findings within BED were similar to those reported by Grilo, Lozano, et al. (2005) and Grilo, Masheb, and Salant (2005) for orlistat plus cognitive-behavioral therapy for BED but failed to replicate the findings reported by Golay et al. (2005) for orlistat-plus-BWL for BED. The Golay et al. (2005) trial, however, was an "efficacy" study performed in Switzerland with many exclusionary criteria including psychiatric conditions and use of anti-depressant (and other psychotropic) medications.

Within the BED group, 65% achieved remission from binge-eating at post-treatment and 50% maintained binge-eating remission at 6-month follow-up. These remission rates at post- and 6-month follow-up are slightly higher than those reported by Grilo et al. (2011) at the same assessment time-points in a study comparing BWL and cognitive-behavioral treatments and nearly identical to those Grilo, Masheb, and Salant (2005) and Grilo, Masheb, et al. (2005) at post- and 3-month follow-up in a study testing cognitive-behavioral therapy for BED. Although BED appeared to respond well overall to BWL, our report includes the first prospective findings using a randomized design indicating that BED represents a negative prognostic indicator for some outcomes. The presence of BED prospectively moderated less weight loss at post-treatment, predicted/moderated some poorer associated clinical outcomes (depression and ED psychopathology levels), and predicted/moderated greater increases in eating concerns and depression levels following treatment to the 6-month follow-up. Our weight-loss findings, while modest overall and particularly within the BED group, converge with previous reports that abstinence from binge eating is associated with weight loss (Devlin et al., 2005; Grilo, Lozano, et al., 2005; Grilo, Masheb, et al., 2005; Grilo et al., 2011; Wilson et al., 2010). These findings suggest that stopping binge-eating may play a role in subsequent successful weight-control. As further context for interpreting these modest weight losses, we note that many patients with BED experience substantial weight gains prior to seeking treatment (Blomquist et al., 2011). Blomquist et al. (2011), for example, found that obese patients with BED reported a mean gain of 15.1 pounds during the year prior to seeking treatment.

In closing, we note several potential limitations of the study. Participants were educationally- and economically-disadvantaged monolingual Latino/as and our findings may not generalize to broader samples of Latina/os who are more assimilated or have a more favorable education/economic profile. Moreover, this study was performed at a community mental health center serving persons with mental health needs and our findings may not generalize to obese persons who do not have co-morbid psychiatric disorders and are not taking psychotropic medications. Our follow-up extended only to 6-months after completing treatments (i.e., 10-months total) and longer-term studies are needed to determine the durability of outcomes.

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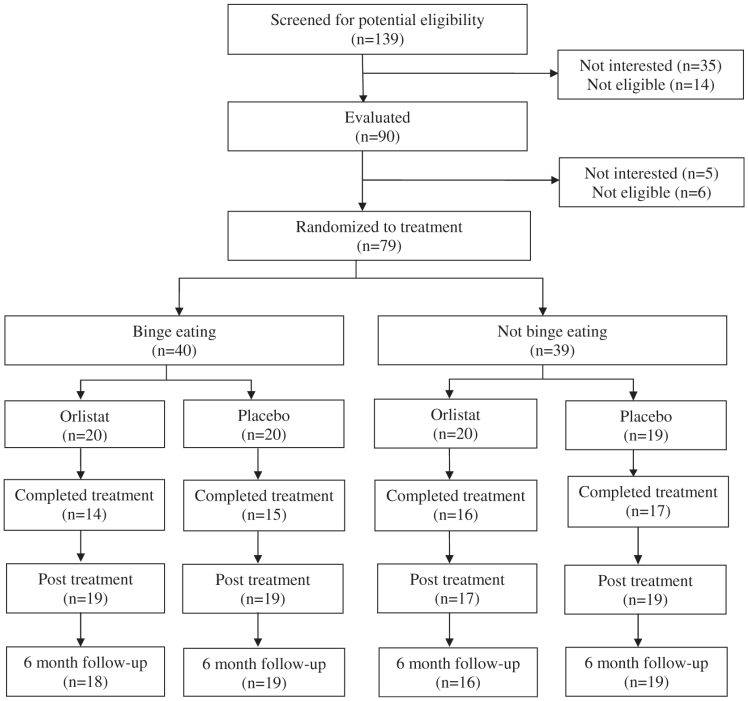
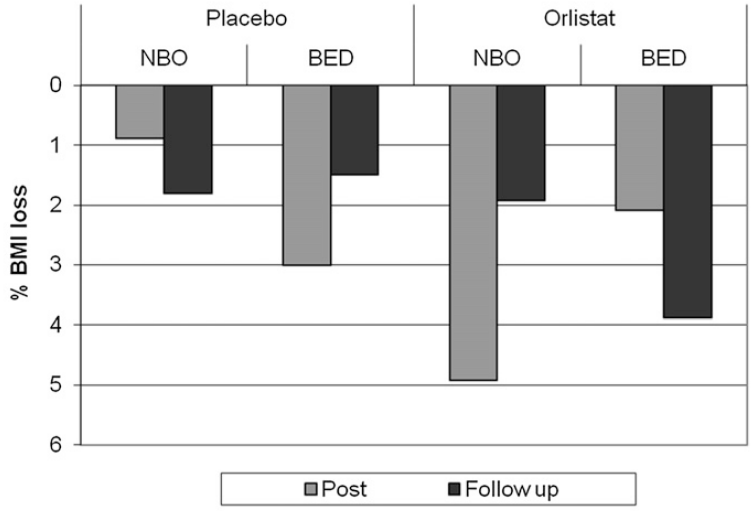


Fig. 1.
Participant flow throughout the study.



Percent body mass index (BMI) loss for placebo and orlistat treatment conditions shown separately for NBO (non-BED obese group) and BED obese group at post-treatment and at 6-month follow-up.

Fig. 2.
BED status moderates treatment effects on BMI loss.

Table 1

Demographic and psychiatric characteristics of participants.

	BED				NBO				BED versus NBO	Orlistat versus placebo
	Orlistat (n = 20)		Placebo (n = 20)		Orlistat (n = 20)		Placebo (n = 19)			
Age (M, SD)	45.9	(9.0)	45.6	(7.6)	47.8	(12.3)	46.7	(10.5)	$F(1,77) = .48$, $p = .49$	$F(1,77) = .10$, $p = .76$
BMI (M, SD)	39.0	(7.0)	37.2	(5.3)	35.2	(3.3)	37.4	(4.7)	$F(1,77) = 2.30$, $p = .13$	$F(1,77) = .02$, $p = .88$
Female (N,%)	17	85%	14	70%	17	85%	16	84%	$\chi^2(1) = .65$, $p = .42$	$\chi^2(1) = .84$, $p = .36$
Education (N, %)									$\chi^2(1) = 3.12$, $p = .08$	$\chi^2(1) = 1.03$, $p = .31$
Less than high school	12	60%	9	45%	15	75%	13	68%		
With high school or more	8	40%	11	55%	5	25%	6	32%		
Psychiatric comorbidity (N, %)										
Lifetime axis I disorder	16	80%	19	95%	18	90%	14	70%	$\chi^2(1) = .46$, $p = .50$	$\chi^2(1) = .002$, $p = .96$
Lifetime mood disorder	16	80%	17	85%	17	85%	13	68%	$\chi^2(1) = .38$, $p = .54$	$\chi^2(1) = .38$, $p = .54$
Lifetime anxiety disorder	10	50%	9	45%	9	45%	10	53%	$\chi^2(1) = .01$, $p = .91$	$\chi^2(1) = .01$, $p = .91$
Lifetime substance disorder	6	30%	6	30%	5	25%	3	16%	$\chi^2(1) = .94$, $p = .33$	$\chi^2(1) = .20$, $p = .65$
Current axis I disorder	14	70%	16	80%	16	80%	13	68%	$\chi^2(1) = .004$, $p = .95$	$\chi^2(1) = .004$, $p = .95$
% Taking at least 1 psych med	15	75%	18	90%	16	80%	15	79%	$\chi^2(1) = .12$, $p = .73$	$\chi^2(1) = .65$, $p = .42$
% Taking at least 2 psych meds	10	50%	16	80%	13	65%	13	68%	$\chi^2(1) = .02$, $p = .88$	$\chi^2(1) = 2.50$, $p = .11$
% Taking antidepressants	14	70%	15	75%	15	75%	15	79%	$\chi^2(1) = .20$, $p = .65$	$\chi^2(1) = .20$, $p = .65$

Within binge eating groups, no significant differences were observed between the medication and placebo groups.

Table 2

Clinical measures at the major time-points.

BED (*n* = 40)	**Orlistat**						**Placebo**					
	Pre (*n* = 20)		**Post (*n* = 19)**		**6 Month follow-up (*n* = 18)**		**Pre (*n* = 20)**		**Post (*n* = 19)**		**6 Month follow-up (*n* = 19)**	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
BMI	39.0	(7.0)	37.9	(6.9)	37.6	(5.7)	37.2	(5.3)	36.0	(5.0)	36.7	(5.3)
EDE restraint	1.2	(1.3)	1.8	(1.0)	1.1	(1.1)	1.4	(1.1)	2.1	(1.1)	1.2	(1.3)
EDE eating concern	1.8	(1.6)	.6	(1.0)	.6	(.6)	2.0	(1.5)	.6	(.6)	1.2	(1.4)
EDE shape concern	3.8	(1.3)	2.2	(1.5)	2.2	(1.4)	4.0	(1.5)	2.6	(1.4)	2.7	(1.6)
EDE weight concern	3.2	(1.0)	2.0	(1.3)	2.2	(1.0)	3.5	(1.0)	2.6	(1.0)	2.5	(1.0)
EDE total	2.5	(1.1)	1.6	(.9)	1.5	(.8)	2.7	(.9)	2.0	(.7)	1.9	(1.0)
BDI	22.9	(12.0)	11.4	(12.0)	10.3	(10.1)	25.7	(10.6)	17.7	(12.0)	20.9	(11.9)

NBO (*n* = 39)	**Orlistat**						**Placebo**					
	Pre (*n* = 20)		**Post (*n* = 17)**		**6 Month follow-up (*n* = 16)**		**Pre (*n* = 19)**		**Post (*n* = 19)**		**6 Month follow-up (*n* = 19)**	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
BMI	35.2	(3.3)	33.6	(3.4)	35.3	(3.1)	37.4	(4.7)	36.6	(4.5)	36.7	(4.0)
EDE restraint	1.2	(1.1)	1.0	(.7)	1.3	(1.1)	1.5	(1.2)	1.5	(1.3)	1.4	(1.1)
EDE eating concern	.7	(.7)	.4	(.8)	.3	(.4)	.5	(.6)	.2	(.7)	.2	(.6)
EDE shape concern	3.4	(1.4)	2.0	(1.3)	2.2	(1.6)	2.7	(1.6)	1.4	(1.3)	1.4	(1.5)
EDE weight concern	3.1	(1.0)	2.1	(1.3)	2.3	(1.0)	2.5	(1.0)	1.5	(1.0)	1.9	(1.3)
EDE total	2.1	(.8)	1.4	(.8)	1.5	(.8)	1.8	(.8)	1.2	(.8)	1.2	(.9)
BDI	20.2	(11.4)	11.0	(14.4)	10.9	(11.1)	17.4	(13.0)	8.6	(9.6)	6.6	(9.0)

Table 3

Mixed-models analyses through post-treatment.

	Post tx value different from zero		Time		Med		Binge status		Med*binge status	
	F	*p*	*F*	*p*	*F*	*p*	*F*	*p*	*F*	*p*
BMI	1022.139	.000	41.162	.000	3.544	.063	.109	.742	5.109	.027
EDE restraint	85.852	.000	1.896	.173	3.193	.078	1.072	.304	.957	.331
EDE eating concern	.040	.843	22.296	.000	1.546	.218	7.190	.009	.765	.385
EDE shape concern	21.783	.000	91.662	.000	3.275	.074	12.287	.001	4.382	.040
EDE weight concern	61.074	.000	53.352	.000	2.413	.124	10.444	.002	4.464	.038
EDE total	53.110	.000	46.799	.000	1.170	.283	13.412	.000	2.110	.151
BDI	6.310	.014	44.188	.000	1.206	.275	10.079	.002	3.465	.066