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A randomized controlled trial for obesity and binge eating disorder: Low-energy-density dietary counseling and cognitive-behavioral therapy

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ABSTRACT

The present study examined a dietary approach – lowering energy density – for producing weight loss in obese patients with binge eating disorder (BED) who also received cognitive-behavioral therapy (CBT) to address binge eating. Fifty consecutive participants were randomly assigned to either a six-month individual treatment of CBT plus a low-energy-density diet (CBT + ED) or CBT plus General Nutrition counseling not related to weight loss (CBT + GN). Assessments occurred at six- and twelve-months. Eighty-six percent of participants completed treatment, and of these, 30% achieved at least a 5% weight loss with rates of binge remission ranging from 55% to 75%. The two treatments did not differ significantly in weight loss or binge remission outcomes. Significant improvements were found for key dietary and metabolic outcomes, with CBT + ED producing significantly better dietary outcomes on energy density, and fruit and vegetable consumption, than CBT + GN. Reductions in energy density and weight loss were significantly associated providing evidence for the specificity of the treatment effect. These favorable outcomes, and that CBT + ED was significantly better at reducing energy density and increasing fruit and vegetable consumption compared to CBT + GN, suggest that low-energy-density dietary counseling has promise as an effective method for enhancing CBT for obese individuals with BED.
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Introduction

Various health organizations now recommend a reduction in dietary energy density (kcal/g) for weight management (Centers for Disease Control and Prevention, 2008a, 2008b; World Cancer Fund, 2007; World Health Organization, 2003). The main strategies for decreasing dietary energy density are to consume more water- and fiber-rich foods such as fruits and vegetables, and to decrease the proportion of fat (Duncan, Bacon, & Weinsier, 1983). Strategies for lowering dietary energy density allow for consumption of greater quantities of food while reducing energy intake and the associated reduction in hunger may for some individuals improve compliance with dietary recommendations. The purpose of the present research is to investigate the effects of a low-energy-density dietary approach in a population known to have difficulty with weight loss.

Binge eating disorder (BED) comprises a subset of overweight and obese individuals for whom weight loss in clinical trials has been an elusive goal. BED is characterized by recurrent binge eating, defined as eating an unusually large amount of food while experiencing a subjective sense of loss of control at least two days per week for at least a six-month duration, and not engaging in compensatory behaviors characteristic of bulimia nervosa (American Psychiatric Association, 2000). While obesity is not a diagnostic criterion for BED the two are strongly associated such that most persons with BED who present for treatment are obese and at increased risk for medical and psychiatric morbidity (Hudson, Hiripi, Pope, & Kessler, 2007). A number of psychotherapies (Wilson, Grilo, & Vitousek, 2007) and pharmacotherapies (Reas & Grilo, 2008) have been shown to produce significant and substantial reductions in binge eating and BED-related outcomes, but treatments tested to date have failed to produce significant or meaningful weight loss (Wilson et al., 2007). Cognitive behavior therapy (CBT) has emerged as the treatment of choice for BED, particularly because of its robust effects on reducing binge eating and improving the behavioral and psychological aspects of the disorder, despite its minimal effect on weight loss (Wilson et al., 2007).

A number of studies have directly compared CBT to behavioral weight loss treatments (BWLs) such as the *LEARN Program for Weight Management* (Brownell, 2000) and the National Institutes of Diabetes and Digestive and Kidney Diseases's Diabetes Prevention

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Program (Grilo, Masheb, & Wilson, 2005; Grilo, Masheb, Wilson, Gueorguieva, & White, 2011; Munsch et al., 2007; Wilson, Wilfley, Agras, & Bryson, 2010). Collectively these studies have shown that CBT is superior to BWL in reducing and eliminating binge eating in BED. However, these studies have also reported minimal weight loss with BWL (Grilo & Masheb, 2005; Grilo et al., 2011; Munsch et al., 2007) and any short-term weight loss advantage for BWL over CBT appears to be lost at two-year follow-up (Wilson et al., 2010).

Studies have shown the effectiveness of lowering energy density for reducing energy intake in short-term laboratory studies (Bell, Castellanos, Pelkman, Thorwart, & Rolls, 1998; Bell & Rolls, 2001; Duncan et al., 1983; Rolls, Bell, Castellanos, et al., 1999; Rolls, Bell, & Thorwart, 1999; Rolls, Hetherington, Stoner, & Andersen, 1997; Rolls, Roe, & Meengs, 2004), and more recently, for producing weight loss in longer-term efficacy (Ello-Martin, Roe, Ledikwe, Beach, & Rolls, 2007; Rolls, Roe, Beach, & Kris-Etherton, 2005) and effectiveness (Lowe et al., 2008) trials. Treatment with strategies to lower-energy density, such as increased intake of fruits and vegetables, in combination with decreased fat intake, was shown to result in lower-energy intake and less hunger than a diet which emphasized decreased fat intake only (Ello-Martin et al., 2007).

Given that obese individuals with BED have increased gastric capacity compared to obese individuals without binge eating (Geliebter & Hashim, 2001) it seems logical to test whether such a dietary approach focused on greater food volume and lower caloric density might facilitate weight loss in this patient group. Preliminary support for this comes from a laboratory study that found individuals with BED reduced their energy intake with lower-energy-dense meals (Latner, Rosewall, & Chisholm, 2008) but this has not yet been tested as a clinical intervention. Thus, we performed a randomized, controlled trial to investigate a dietary approach – lowering energy density – for producing weight loss in obese patients with BED who also received CBT to address binge eating and BED-related outcomes. We additionally aimed to determine whether improvements in binge eating and BED-related outcomes could be achieved and sustained with dieting added to CBT, and to be the first treatment study of obese individuals with BED to examine dietary and metabolic outcomes.

Methods and procedures

Participants

Participants were adult patients who met DSM-IV-TR (American Psychiatric Association, 2000) criteria for BED, were recruited via print advertisements for treatment studies for binge eating and weight loss at a medical school, and were required to be aged 21–60, obese (body mass index (BMI) of 30 or greater) and available for the length of the treatment and follow-up at twelve-months. The study received full human subjects and ethics review, and approval by the University Institutional Review Board. The 50 consecutively randomized participants were aged 29–60 years ($M = 45.8$, SD = 7.6), 76% ($n = 38$) were female, and 84% ($n = 42$) attended or finished college. The participant group was 80% ($n = 40$) Caucasian, 18% ($n = 9$) African American, and 2% ($n = 1$) Hispanic American. Mean BMI was 39.1 (SD = 6.6).

Procedures

Social, psychiatric and medical histories were obtained, and two semi-structured interviews were administered. The Structured Clinical Interview for DSM-IV (SCID-I/P) (First, Spitzer, Gibbon, & Williams, 1996) was used to assess for BED, and axis I psychiatric exclusions and co-morbidity. The BED diagnosis assessed with the SCID-I was confirmed on the semi-structured Eating Disorder Examination-Interview – 12th Edition version (EDE) (Fairburn & Cooper, 1993). Laboratory testing included blood chemistry, blood count, serum electrolytes, thyroid function tests, and lipid profile analysis. After review of all of the above, potential participants were excluded if they (1) had co-existing psychiatric conditions requiring alternative treatments or hospitalization; (2) met criteria for current substance dependence; (3) were currently receiving psychiatric, psychological, behavioral, or pharmacologic treatment known to affect eating or weight; (4) had any physical conditions, such as diabetes, known to affect eating or weight; (5) had serious cardiac disease; (6) had serious neurologic illness; (7) had cognitive impairments that would interfere with being able to complete assessments and understand treatments; or (8) were pregnant, lactating or planning to become pregnant during the treatment period.

Fig. 1 summarizes the recruitment and flow of participants throughout the study. Three hundred forty five individuals made telephone inquiries, 242 phone screens were completed, and 80 individuals were evaluated in person. Fifty individuals met all eligibility criteria, signed the informed consent, and were randomized to treatments from a computer-generated randomization schedule created by a data analyst and independent of the investigators, in the order they completed assessments. Treatments, delivered by doctoral-level research clinicians in psychology, included CBT plus a low-Energy-Density diet (CBT + ED) and CBT plus General Nutrition counseling not related to lowering energy density or weight loss (CBT + GN). Clinicians were experienced in treating patients with weight and eating problems and with CBT methods, and received specialized training and reading in the treatments used in this study. Clinicians attended weekly group supervision with one of the investigators (RMM) to discuss cases and review audio-tapes of sessions, and on-going consultation with the other investigators with regard to the dietary (BJR) and CBT (CMG) interventions was used.

Measures

In the present study, the primary outcomes were percentage of participants achieving at least a 5% weight loss (Rissanen, Lean, Rossner, Segal, & Sjostrom, 2003), binge remission, energy density, and servings of fruits and vegetables. Secondary outcomes included dimensional measures of weight, eating, diet and metabolism. Measures used to assess these outcomes are described below.

Weight outcome

Body mass index (BMI; weight [kg] divided by height squared [m^2]) weight and height were obtained using a medical balance beam scale. Participants were weighed without shoes or coats at each assessment point and treatment session.

BED-related outcomes

Eating Disorder Examination-Interview 12th Edition (EDE) (Fairburn & Cooper, 1993) is a standardized semi-structured investigator-based interview that assesses the diagnoses and features of eating disorders including objective bulimic episodes (OBEs; binge eating defined as an unusually large amount of food coupled with a subjective sense of loss of control) for both the number of days and episodes on which these occurred in the past 28 days. The EDE is also comprised of four subscales (dietary restraint, eating concern, weight concern and shape concern) that reflect the attitudinal features of eating disorders. The EDE is a well-established assessment method for eating disorder psychopathology (Grilo, Masheb, & Wilson, 2001a, 2001b) and has demonstrated good test-retest reliability (Grilo, Masheb, Lozano-Blanco, &

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