



## Profiles of sociodemographic, behavioral, clinical and psychosocial characteristics among primary care patients with comorbid obesity and depression

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### ABSTRACT

The objective of this study is to characterize profiles of obese depressed participants using baseline data collected from October 2014 through December 2016 for an ongoing randomized controlled trial ( $n = 409$ ) in Bay Area, California, USA. Four comorbidity severity categories were defined by interaction of the binary levels of body mass index (BMI) and depression Symptom Checklist 20 (SCL20) scores. Sociodemographic, behavioral, clinical and psychosocial characteristics were measured. Mean (SD) age was 51 (12.1) years, BMI 36.7 (6.4) kg/m<sup>2</sup>, and SCL20 1.5 (0.5). Participants in the 4 comorbidity severity categories had similar sociodemographic characteristics, but differed significantly in the other characteristics. Two statistically significant canonical dimensions were identified. Participants with BMI  $\geq 35$  and SCL20  $\geq 1.5$  differed significantly from those with BMI  $< 35$  and SCL20  $< 1.5$  on dimension 1, which primarily featured high physical health (e.g., central obesity, high blood pressure and impaired sleep) and mental health comorbidities (e.g., post-traumatic stress and anxiety), poor health-related quality of life (in general and problems specifically with obesity, anxiety, depression, and usual daily activities), and an avoidance problem-solving style. Participants with BMI  $< 35$  and SCL20  $\geq 1.5$  differed significantly from those with BMI  $\geq 35$  and SCL20  $< 1.5$  on dimension 2, which primarily included fewer Hispanics, less central obesity, and more leisure-time physical activity, but greater anxiety and post-traumatic stress and poorer obesity- or mental health-related quality of life. In conclusion, patients with comorbid obesity and depression of varying severity have different profiles of behavioral, clinical and psychosocial characteristics. This insight may inform analysis of treatment heterogeneity and development of targeted intervention strategies.

**Trial registration:** [ClinicalTrials.gov #NCT02246413](https://clinicaltrials.gov/ct2/show/study/NCT02246413)

### 1. Introduction

Obesity and depression are serious health concerns in the United States (U.S.), both showing steadily increasing prevalence in the past

decade (Flegal et al., 2016; Pratt and Brody, 2014). More than two-thirds of U.S. adults have obesity based on a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> (Flegal et al., 2016). Over 15.7 million (6.6%) have experienced at least 1 major depressive episode in a 12-month period

**Abbreviations:** SCL20, Depression Symptom Checklist 20; EHR, Electronic health record; PCPs, Primary care providers; MET, Metabolic equivalent of task; SPSI-R:S, Social Problem-Solving Inventory—Revised: Short Form; PHQ, Patient Health Questionnaire; GAD7, Generalized Anxiety Disorder Scale; MINI, Mini-International Neuropsychiatric Interview; PTSD, Posttraumatic stress disorder; EQ-5D-5 L, European Quality of Life-5 Dimension-5 Levels; SF-8, Short Form-8 Health Survey

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(SAMHSA, 2015), with a life time prevalence of 18.6% (Gonzalez et al., 2010). Additionally, mounting epidemiologic evidence has shown a temporally reciprocal, positive relationship between these 2 conditions; namely, people with obesity are more likely to develop new-onset depression, and vice versa (Blaine, 2008; Luppino et al., 2010; Markowitz et al., 2008; Wiltink et al., 2013). Comorbid obesity and depression exact even greater morbidity and disability than either condition alone. They share major health sequelae, such as diabetes and cardiovascular disease, and have synergistic adverse effects on treatment adherence and response and quality of life (Katon, 2011; Ladwig et al., 2006; Werrij et al., 2006). Evidence-based behavioral therapies are recommended treatment options for obesity and depression based on studies that focused on each condition separately (American Psychiatric Association, 2010; Jensen et al., 2014). However, randomized controlled trials (RCTs) of similar approaches have shown mixed results when applied to treat comorbid depression and obesity (Linde et al., 2011; Ludman et al., 2010; Pagoto et al., 2013).

Obesity and depression are complex disorders, with heterogeneous etiology and clinical manifestations. So far, effects observed in RCTs of behavioral treatments for each condition have been modest and variable. Expected heterogeneity among individuals with both conditions is poorly understood, but likely important for population characterization and for treatment development. Yet, few studies to date have exclusively focused on patients with comorbid obesity and depression. Evidence is lacking on individual characteristics, or their combinations (profiles), that may differentiate patients with varying severity levels of the comorbidity. Addressing this gap will provide insights into the nature and extent of heterogeneity within a growing population afflicted with 2 major public health problems. The knowledge gained would improve the understanding of treatment heterogeneity, and inform the development and testing of targeted treatments.

In this study, we leveraged rigorously assessed baseline data from a large ongoing RCT of an integrated behavior therapy for obese depressed adult patients in primary care (Ma et al., 2015). The main objective was to examine whether patients with obesity and depression had different profiles of sociodemographic, behavioral, clinical, and psychosocial characteristics according to the severity levels of their comorbidity.

## 2. Methods

### 2.1. Study design

This cross-sectional study used baseline data collected from October 2014 through December 2016 for a 2-arm RCT, titled “Research Aimed at Improving Both Mood and Weight (RAINBOW).” The RAINBOW trial aims to compare an integrated behavioral intervention with usual care for adult patients with comorbid obesity and depression seen in primary care. The Institutional Review Board for the health system where recruitment occurred approved the trial; all enrolled participants provided written informed consent. The full RAINBOW trial protocol was previously published (Ma et al., 2015). The current study examined only baseline data.

### 2.2. Participants

Participant recruitment occurred in the family and internal medicine departments of multiple medical centers within a large community-based multispecialty group practice in the Silicon Valley, California. English-speaking patients  $\geq 18$  years of age who did not have exclusionary medical (e.g., diabetes or cardiovascular disease) or psychiatric comorbidities (e.g., psychotic or bipolar disorders) completed a multistep screening process. First, patients whose electronic health record (EHR) documented BMI  $\geq 30$  kg/m<sup>2</sup> ( $\geq 27$  if Asian), with or without indications of depression (e.g., prior diagnosis or antidepressant prescriptions), were pre-identified for approval of study

contact by their primary care providers (PCPs). All PCP-approved patients received recruitment invitations by email or mail (if no email address in EHR). A bifurcated screening strategy was then used for efficiency. Study staff proactively called to screen patients with prior depression based on EHR. Because of their expected lower eligibility rates, patients *without* prior depression were incentivized with raffles to self-screen using the 9-item Patient Health Questionnaire (PHQ9) (Kroenke et al., 2001), and study staff called only those who self-screened eligible. Finally, all participants must have completed an in-person baseline measurement visit and passed final EHR review and approval by the study physician to be randomized.

### 2.3. Dependent variables

BMI (kg/m<sup>2</sup>) was calculated based on height and weight measured by trained study coordinators at baseline. As per standardized protocol (Measures from the PhenX Toolkit, 2011), duplicate measurements were taken in light indoor clothes and no shoes using calibrated equipment, and rounded to the nearest 0.1 cm for height and the nearest 0.1 kg for weight. Depression severity was measured using the Symptom Checklist 20 items (SCL20) (Derogatis et al., 1974; Glass et al., 1978; Goldberg et al., 1976). To elucidate different profiles, we divided these 2 baseline measures according to commonly used cut-points, and then combined them to create 4 comorbidity severity categories. We used BMI  $\geq 35$  kg/m<sup>2</sup> (Class II obesity) as the cut-point for high severity obesity and SCL20  $\geq 1.5$  as the cut-point for high severity depressive symptoms. (Linde et al., 2011) These cut-points were appropriate also based on the study sample means. The 4 comorbidity severity categories included the lowest severity (BMI  $< 35$  and SCL20  $< 1.5$ ), depression-dominant intermediate severity (BMI  $< 35$  and SCL20  $\geq 1.5$ ), obesity-dominant intermediate severity (BMI  $\geq 35$  and SCL20  $< 1.5$ ), and the highest severity (BMI  $\geq 35$  and SCL20  $\geq 1.5$ ).

### 2.4. Independent variables

#### 2.4.1. Sociodemographic characteristics

Participants self-reported their age, sex, race, ethnicity, education, family annual income, marital status and household size.

#### 2.4.2. Behavioral characteristics

These included measures of diet, physical activity, sleep quality, and problem solving orientation and skills. Trained study coordinators administered a single 24-h diet recall to each participant by phone using the multiple pass method (Conway et al., 2004; Conway et al., 2003) through the Windows-based Nutrition Data System for Research (NDSR, Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN, USA). These data were used to compute each participant's Dietary Approaches to Stop Hypertension (DASH) concordance index as a measure of overall diet quality (Mellen et al., 2008). The study coordinators also administered in person the Stanford 7-day Physical Activity Recall, which provided data on leisure time physical activity in metabolic equivalent of task (MET) minutes per week (Blair et al., 1985). Participants self-administered the PROMIS sleep disturbance and sleep impairment scales, 8 items each (Yu et al., 2011), and the 25-item Social Problem-Solving Inventory—Revised: Short Form (SPSI-R:S). The latter includes 5 subscales for positive problem orientation (PPO), negative problem orientation (NPO), rational problem solving (RPS), impulsive/careless style (ICS), and avoidance style (AS) (D'Zurilla et al., 1998).

#### 2.4.3. Clinical characteristics

These included waist circumference, blood pressure (BP), binge eating disorder, anxiety, and posttraumatic stress disorder. The study coordinators obtained duplicate measurements of waist circumference using a nonstretchable tape placed in a horizontal plane around the

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