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Feasibility and Acceptability of Chromium Supplementation for Binge-Eating Disorder

Lauren Breithaupt[1,2]*, Margarita Sala[1,3], Robert M Hamer[1], Maria La Via[1], Cynthia M. Bulik[1,4,5] and Kimberly A. Brownley[1]

[1]*Department of Psychiatry, University of North Carolina, Chapel Hill, NC, USA*

[2]*Department of Psychology, George Mason University, Fairfax, VA, USA*

[3]*Department of Psychology, Southern Methodist University, Dallas, TX, USA*

[4]*Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden*

[5]*Department of Nutrition, University of North Carolina, Chapel Hill, NC, USA*

***Corresponding author:** *Lauren Breithaupt, Department of Psychology, George Mason University, 4400 University Drive, Farifax, VA22030; Department of Psychiatry, University of North Carolina, Chapel Hill, NC, USA, E-mail: lbreitha@gmu.edu*

Abstract

Chromium is an essential element involved in the regulation of blood glucose levels. We recently conducted the first pilot trial of chromium supplementation in the new binge-eating disorder (BED). Given the novelty of both BED and chromium supplementation, feasibility studies are essential to address questions regarding the interest in and acceptability of chromium supplementation in this patient population. The current study aimed to understand the overall acceptability of a chromium picolinate (CrPic) intervention for BED, general interest in alternative therapies, barriers to participation, and feasibility of study adaptation. Twenty-one overweight adults with BED completed a 6-month placebo controlled study of CrPic and a 3-month follow-up visit. Participants thought the study was helpful in terms of symptom improvement and reported no barriers to treatment. The results indicate that chromium supplementation for the treatment of BED appears to be feasible and acceptable to participants and that individuals with BED appear generally interested in the use of alternative therapies.

Keywords

Binge eating disorder, Alternative medicine, Chromium supplementation, Feasibility and acceptability

Introduction

Binge-eating disorder (BED) is a new disorder in the Diagnostic and Statistical Manual for Mental Disorders, fifth edition (DSM-V) and most prevalent eating disorder. BED is characterized by repetitive episodes of uncontrollable consumption of food, which are associated with distress but not with inappropriate compensatory behaviors [1]. BED is highly comorbid with obesity and depression [2,3]. Treatments for BED include psychological, pharmacological, and behavioral approaches that aim to reduce binge eating and the related psychological distress associated with binge eating (e.g., shame, guilt, depression, anxiety). Generally, evidence supports both cognitive behavioral therapy and interpersonal psychotherapyand selective serotonin reuptake inhibitors (SSRIs) as effective treatments for BED, however, many patients do not respond adequately to these traditional approaches, and there is considerable uncertaintyabout the long-term efficacy of pharmacological approaches, in particular [4-9]. Overall, BED treatment trials have suffered from high attrition rates, especially in the case of pharmacological interventions mainly due to adverse medication side effects [4,7,10]. Therefore, there is a need to develop novel, acceptable interventions with less severe side effects that are effective in reducing binge eating and improving psychological functioning in patients with BED.

Chromium (Cr) is an essential element with insulin-sensitizing properties [11,12] and is combined with picolinate acid (Pic) as supplement to enhance gut absorption. Cr directly effects three neurotransmitters – insulin, serotonergic (5HT), and dopaminergic (DA) systems [11,12], which all share a common protein kinase pathway involved in the central control of food intake and homeostasis, making it a plausible candidate for the treatment of BED. In placebo-controlled trials, CrPic for glucose regulation has been studied in patients with type-2 diabetes mellitus (T2DM) and related metabolic conditions [13-16] and in patients with atypical depression [17]. Results have been promising in terms of improved glucose regulation in insulin-resistant individuals and improved mood and appetite regulation in depressed individuals. In addition, in one study of non-depressed overweight women with carbohydrate cravings, CrPic was shown to reduce food intake and hunger levels [18]. We recently conducted the first pilot trial of CrPic in BED. Based on results from the 6-month trial, chromium supplementation appears to lower binge eating in overweight adults with BED, although this decrease in binge eating is not statistically significant [19]. However, conclusions cannot be drawn as large-scale randomized trials have yet to be conducted. In preparation for a larger-scale confirmatory trial, there is a need for feasibility studies to address a number of questions regarding the interest, acceptability, potential barriers and feasibility of the use of CrPic for BED treatment.

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Following published guidelines [20,21] this paper sought to determine the feasibility and acceptability of CrPic for BED treatment in a randomized placebo-controlled pilot trial [for study details, see Brownley et al. [19]]. Specifically, we aimed to understand the overall acceptability of the intervention, general interest in alternative therapies for BED, potential barriers and general feasibility of study adaption including recruitment, retention, and placebo response rates.

Methods

Participants

Participants responded to advertisements seeking overweight individuals struggling with symptoms of BED. All individuals provided written and informed consent. Eligible study participants currently met the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) criteria for BED and reported no suicidal or homicidal intent or other psychiatric condition requiring acute intervention. Individuals were excluded if their body mass index (BMI) was < 25 kg/m^2 (i.e., normal or under-weight) or > 45 (severely obese). Current use of psychotropic medication was prohibited with the exception of stable monotherapy involving citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, or sertraline.

Of the 220 potential participants self-referred to the study, 43 screened into the study and 41 met eligibility criteria. Of the 41 patients assessed, 3 declined to participate and 10 met exclusion criteria. The most common reason for exclusion was current BMI outside the 25 to 45 range. Twenty-eight participants completed a 1-month placebo run-in phase prior to randomization and 4 individuals were identified as "placebo -responders" [22] and were withdrawn from the study. Thus, a total of 24 participants randomized into the treatment phase of the study. The mean age of the sample was 36.6 (SD 10.6) years and their mean BMI was 34.2 (SD 5.4). Most of the sample was white (87.5%) and female (83.8%). For further details on participant characteristics, please see Table 1.

Table 1: Participant characteristics.

Variable	High (M, SD)	Moderate (M, SD)	Placebo (M, SD)
N	8	9	7
Age (yrs)	41.4 (8.5)	37.3 (13.6)	35.6 (11.8)
BMI (kg/m^2)	34.8 (4.0)	34.9 (7.0)	33.6 (5.4)
Gender	75% = F	80% = F	100% = F
Race	100% = White	78% = White 11% = Black 11% = Other	86% = White 14% = Black

Table 2: Median and interquartile range for overall study acceptability by group (n = 21).

	Placebo (Med, IQR)	High Dose (Med, IQR)	Low Dose (Med, IQR)
1) How helpful was this study for reducing you binge eating?	7 (3-8)	6 (5-8)	7 (3-8)
2) How helpful was this study for improving your mood?	6 (5-7)	6 (2-8)	8 (5-7)
3) How comfortable would you be recommending this study to a friend who has binge eating disorder?	9 (7-10)	9 (7-10)	9 (7-10)
4) How likely would you be to participate in another study involving chromium?	9 (6-10)	7 (5-10)	9 (6-9)
5) Overall, how satisfied are you with your experience in this study?	9 (8-10)	7 (5-9)	8 (8-10)
6) How much did you enjoy participating in this study?	9 (5-9)	7 (5-9)	8 (5-9)

Note: Values range from 1 (not at all helpful) to 10 (extremely helpful).There were no group differences across measures of acceptability.

Study design

Individuals enrolled in a 6-month double-blind placebo-controlled trial and were randomly assigned to receive either 1000 mcg CrPic/day ("high dose", n = 8), 600 mcg CrPic/day ("moderate dose", n = 9), or placebo (n = 7), followed by a 3-month follow-up visit. Questionnaires were distributed at the 3-month follow-up visit. Details of the study were previously published in Brownley et al. (2013). The study was approved by the Biomedical Institutional Review Boardat the University of North Carolina at Chapel Hill.

Measures

Feasibility: Feasibility was assessed by tracking attendance and dropout. Potential study barriers were assessed using a 10-item dichotomous (yes/no) questionnaire, with additional space for participants to explain responses. The questionnaire addressed barriers related to travel, participation time, and concerns with participation and taking CrPic.

Acceptability: Acceptability was assessed with a 5-item questionnaire and 4 open-ended questions. Participants used a Likert scale from 1 (not at all) to 10 (extremely) (see Table 1 for specific items) to report their perception of overall intervention helpfulness, comfort in recommending the study to a friend, satisfaction and enjoyment with participation, and likelihood of continued participation. The open-item response questions were as follows: (1) What aspects of this study were the most useful? (2) What aspects of this study were not useful or were in any way annoying? (3) What would you like to have added to this study? (4) Please give any other comments, suggestions, or criticisms that you feel would improve the quality of the study?

Interest in alternative therapies: Interest in the use of alternative therapies (e.g., nutritional, dietary, or herbal supplements)was assessed with a 6-item questionnaire on a Likert scale from 1 (completely disagree) to 5 (completely agree) (see Table 2 for specific questions). The questions addressed the cost, side effects, and safety of alternative therapy compared to both traditional drug treatments and traditional behavioral/psychological treatments.

Eating disorder symptoms: Eating disorder symptoms were assessed using the 36-item Eating Disorder Examination Questionnaire (EDE-Q) [23]. The EDE-Q yields a comprehensive assessment of specific eating-related psychopathology as derived from four subscales (restraint, eating concerns, and shape concerns), with a range of 0 to 6, and a global score. Frequencies of behaviors focus on the number of episodes of each behavior occurring over the past 28 days.

Statistical analysis

Descriptive statistics included means and standard deviations for continuous variables and count and percent frequencies for categorical variables. Measures of centrality were used to characterize responses. Parametric group differences were analyzed using analysis of variance (ANOVA) and nonparametric group differences were analyzed using Kruskal-Wallis H test. Because estimating sample size is important for future adequately-powered studies, and the present study may serve as one source of data that can contribute to this process, we calculated change in binge frequency, change in weight (kg), and change in overall eating disorder symptoms from baseline to end of treatment in the high dose and placebo groups, and then computed the mean difference in these outcomes between groups. All statistical analysis were computed using R [24].

The open-ended questions were analyzed via thematic content analysis [25,26]. Content analysis focuses on grouping together similar patterns within the text and is often used to analyze open-ended survey questions [25]. This qualitative approach uses a procedural method in order to develop themes that reflect the data in a meaningful way [27]. Data were entered and coded in ATLAS. ti qualitative software [28]. Given the small number of participants, themes with at least two participant comments were included.

Results

Feasibility

There was no difference in proportion of dropouts across the

Table 3: Count and percentages for overall study acceptability (n = 21).

	Less than Somewhat (n, %)	Somewhat (n, %)	Very or Extremely (n, %)
1) How helpful was this study for reducing you binge eating?	2 (9.5%)	4 (19.0%)	15 (71.4%)
2) How helpful was this study for improving your mood?	4 (19.0%)	6 (28.6%)	11 (52.4%)
3) How comfortable would you be recommending this study to a friend who has binge eating disorder?	2 (9.5%)	0 (0.0%)	19 (90.5%)
4) How likely would you be to participate in another study involving chromium?	2 (9.5%)	2 (9.5%)	17 (81.0%)
5) Overall, how satisfied are you with your experience in this study?	1 (4.8%)	4 (21.1%)	16 (76.2%)
6) How much did you enjoy participating in this study?	1 (4.8%)	4 (19.0%)	16 (76.2%)

Note: Values range from 1 (not at all helpful) to 10 (extremely helpful). Rows ≠ 100% due to rounding.

Table 4: Participant Comment Themes (n = 21).

Topic	Theme	N	%
Most helpful part of the study	Self-awareness	11	52.4
	Monitoring eating behaviors/health	5	23.8
	Confirmation of BED	2	9.5
	Change in health behavior	2	9.5
	No comment	1	4.8
Non-useful or annoying aspects of study	Procedural challenges	7	33.3
	No aspects	6	29.0
	Other	2	9.5
Additions to the study	No comment	6	29.0
	More psychoeducation/tx info	6	29.0
	Procedural changes	2	9.5
	No additions	4	19.0
	Other	1	4.8
	No comment	8	38.1
Additional comments	Satisfied	6	29.0
	Other	3	14.3
	No comment	12	57.1

Note: Columns ≠ 100% due to rounding.

groups; one person dropped out of each group (placebo, high dose, low dose). Of the 24 participants that were randomized into the treatment, 21 (87.5%) completed the four major study visits (pre-treatment, 3-month/mid-treatment, 6-month/post-treatment, and 3-month follow-up). Participants who withdrew from the study did so for personal reasons and one withdrew due to pregnancy.

Participants traveled an average of 31.74 (*SD* = 34.66) miles to the research center for their study-related visits. Only one participant reported the distance traveled as a barrier to treatment. The majority of participants (85.7%) felt that the participation involvement required the amount of time they expected and 90% of participants did not view the number of study visits or time spent during study visits as a barrier to their participation.

One participant expressed concern about taking CrPic, reporting that she was "slightly concerned about the long term effects", she was in the low dose group. No other concerns or barriers were reported in the open-response section.

Acceptability of the intervention

Overall, responses were positive (Table 3). Acceptability of the intervention was divided into three categories: less than somewhat, somewhat, and very acceptable (Table 3). To assess for a main effect of treatment, we first compared measures of acceptability by treatment group. A Kruskal-Wallis H test showered that there were no group differences across measures of acceptability for the different groups (reducing BE $\chi^2(2) = 0.61$, $p = 0.74$, *n.s*; improving mood $\chi^2(2) = 1.55$, $p = 0.46$, *n.s*; referring a friend $\chi^2(2) = 0.12$, $p = 0.95$, *n.s*; participation in another chromium study $\chi^2(2) = 0.91$, $p = 0.63$, *n.s*; overall satisfaction $\chi^2(2) = 2.28$, $p = 0.66$, *n.s*; overall enjoyment $\chi^2(2) = 0.83$, $p = 0.66$, *n.s*) (See Table 2 for medians). Likewise, all other responses regarding the acceptability of the treatment did not differ significantly by treatment group, patient age, and other demographics. Thus, we collapsed across groups to look at overall feasibility of the intervention. More than half of the participants felt that the study was very helpful in reducing their binge eating (71.4%) and improving their mood (52.4%). Ninety percent of participants reported that they would be very comfortable recommending this study to a friend with binge-eating disorder. Only one (4.8%) participant reported that she was less than satisfied with the overall study or that she did not enjoy participating in the study. The participant did not provide a rationale for her response in the section provided. Participants did not express concern about randomization and no participants dropped out because of randomization. As noted in Brownley et al. (2013), reported side effects were low: headache, tiredness, and sleep disturbance were the most commonly reported. Notably, in the placebo group, participants did report an increase in frequency of headaches from baseline to end of treatment and sleep disturbance.

Results from the open-ended survey questions indicated general acceptance of the study (Table 4). Themes and examples are presented in table 5. Four themes emerged as the most helpful aspects of the study. Two themes emerged from the assessment of the non-useful or annoying aspects of the study. Two other comments were made in the non-useful or annoying aspects of the study, one related to a lack of clear directions and the other related to a lack of educational information. Six (29.5%) participants did not comment. Three themes emerged regarding suggested changes or additions to the study.Eight (38.1%) of the participants did not suggest changes to the study. One theme emerged from the additional comment section (Table 5).

Interest in alternative medicine

Acceptability of the intervention was divided into three categories: strongly disagree, agree, and strongly agree (Table 6). When we asked participants to compare alternative medicine to behavioral/psychological treatment, more than half of the participants agreed with the statement that alternative medicine costs less than traditional behavioral/psychological treatments (52.4%). Less than half of the participants felt that alternative therapies have fewer side effects than traditional (behavioral/psychological) treatments (47.6%) or that alternative therapies are safer for long-term use than traditional (behavioral/psychological) treatments (42.9%). When participants were asked to compare alternative medicine to traditional drug treatments, a greater percentage (66.7%) agreed with the statement that alternative medicine has fewer side effects than traditional (drug) treatments (66.7%). Slightly less than half (47.6%) of participants agreed with the statement that alternative therapies cost less than traditional drug treatments. Treatment group, patient age, and other demographics did not influence responses to the interest questionnaire, either significantly or by trend (Table 7). In addition, median differences between alternative therapy and drug treatment and alternative therapies and behavioral and/or psychological treatment in terms of cost, side effects, or safety were all non-significant.

Understanding sample size in bed trials

The mean difference in binge frequency was 0.65 (SD = 0.77), the mean difference in weight (kg) was 2.15 (SD = 4.35), and the mean difference in overall eating disorder symptoms was 3.83 (SD = 14.79). If these differences were the true population differences, future studies would have 80% power to detect significant differences in change in binge frequency with 25 participants per group, in change in weight with 66 participants per group, and in change in eating disorder symptoms with 236 participants per group. However, if the observed

Table 5: Themes from open ended questions.

Categories	Theme	Example
Most helpful aspect of the study	Increases in self-awareness	"The fact that I was more aware of the behavior seemed to help reduce it."
	Monitoring of eating patterns and/or health	"Test results and checkup results were helpful in monitoring my health."
	Confirmation of BED diagnosis	"Confirming my disordered eating."
	Changes in health behaviors	"Reducing binges."
Non-useful or annoying aspects of the study	Procedural challenges	"Long blood draws"
	No aspects	"Nothing"
Suggested changes or additions to the study	More psychoeducation/treatment information	"…interesting information on binge eating and chromium"
	Procedural changes	"More recalls or journal"
	No additions	"Nothing"
Additional comment	Satisfied	"Satisfied with the outcome, glad I chose to be a part of the trial."

Table 6: Count and percentages for interest in alternative medicine (n = 21).

	Strongly Disagree (n, %)	**Agree (n, %)**	**Strongly Agree (n, %)**
1) Alternative therapies (for example, nutritional, dietary, or herbal supplements) **cost less than traditional** (drug) treatments.	7 (33.3%)	10 (47.6%)	4 (19.0%)
2) Alternative therapies (for example, nutritional, dietary, or herbal supplements) have **fewer side effects** than traditional (drug) treatments.	4 (19.0%)	14 (66.7%)	3 (14.2%)
3) Alternative therapies (for example, nutritional, dietary, or herbal supplements) are **safer** for long term use than traditional (drug) treatments.	7 (33.3%)	7 (33.3%)	7 (33.3%)
4) Alternative therapies (for example, nutritional, dietary, or herbal supplements) **cost less than traditional** (behavioral/psychological) treatments.	2 (9.5%)	11 (52.4%)	8 (38.1%)
5) Alternative therapies (for example, nutritional, dietary, or herbal supplements) have **fewer side effects** than traditional (behavioral/psychological) treatments.	6 (28.6%)	10 (47.6%)	5 (23.8%)
6) Alternative therapies (for example, nutritional, dietary, or herbal supplements) are **safer** for long term use than traditional (behavioral/psychological) treatments.	7 (33.3%)	9 (42.9%)	5 (23.8%)

Note: Values range from 1 (completely disagree) to 5 (completely agree), with 3 indicating agree.Rows ≠ 100% due to rounding.

Table 7: Medians and interquartile range for interest in alternative medicine (n = 21).

	Placebo (Med, IQR)	**High Dose (Med, IQR)**	**Low Dose (Med, IQR)**
1) Alternative therapies (for example, nutritional, dietary, or herbal supplements) **cost less than traditional** (drug) treatments.	3.00 (1.75-3.25)	2.50 (1.75-3.50)	3.00 (2.00-4.00)
2) Alternative therapies (for example, nutritional, dietary, or herbal supplements) have **fewer side effects** than traditional (drug) treatments.	3.50 (2.75-4.00)	3.00 (2.00-3.00)	3.00 (3.00-3.00)
3) Alternative therapies (for example, nutritional, dietary, or herbal supplements) are **safer** for long term use than traditional (drug) treatments.	3.00 (2.00-4.25)	3.00 (2.00-3.25)	3.00 (3.00-4.00)
4) Alternative therapies (for example, nutritional, dietary, or herbal supplements) **cost less than traditional** (behavioral/psychological) treatments.	3.50 (2.50-4.25)	3.00 (3.00-3.50)	3.00 (3.00-4.00)
5) Alternative therapies (for example, nutritional, dietary, or herbal supplements) have **fewer side effects** than traditional (behavioral/psychological) treatments.	3.00 (3.00-4.00)	2.50 (2.00-3.50)	3.00 (2.00-3.00)
6) Alternative therapies (for example, nutritional, dietary, or herbal supplements) are **safer** for long term use than traditional (behavioral/psychological) treatments.	3.00 (2.75-4.00)	3.00 (2.00-3.50)	3.00 (2.00-4.00)

Note: Values range from 1 (completely disagree) to 5 (completely agree), with 3 indicating agree.

mean or standard deviation varied from the true mean or standard deviation the necessary number of participants needed to conduct the trial would change considerably. For example, by doubling the observed mean or standard deviation or splitting the observed mean or stand deviation in half, power analysis indicates that a trial of CrPic for BED should have between 7-90 participants in each arm to have a power of 80% to evaluate changes in binge frequency, 18-259 participants to have 80% power detect a difference in weight, and 60-938 participants to detect a difference in overall eating disorder symptoms.

Discussion

BED treatment remains a challenge. Patients commonly present with complex co-occurring conditions, such as major depressive disorder, obesity, and metabolic syndrome [5,29-31] and many patients do not respond adequately to currently available therapeutic interventions [32-35]. Our current understanding of pharmacological interventions for BED, particularly, is limited due to high treatment dropout secondary to the negative side effects of medication [4,5,36,37].

The use of CrPic appears to be feasible to conduct. Individuals with BED appear to be interested in the use of alternative therapy. No study participants dropped out due to negative side effects and only one individual from the study raised concerns about taking CrPic.

Understanding the perception of alternative medicine is important for study development, as few studies have assessed the use of alternative medicine for the treatment of BED. According to our observations, individuals with BED appear open to alternative therapies. Study participants rated alternative therapy as having potential advantages compared to traditional treatments such as drugs, behavioral, and psychological treatment.

The current study also provides insight into the challenge of designing and implementing treatments for BED. There were no significant differences between groups in terms of participants' perception of binge reduction or mood improvement. In addition, 72% of the participants indicated that the most helpful part of participation was related to raising self-awareness. This finding may have relevance to understanding the high placebo response in BED treatment trials. That is, participation in the trial may provide an initial avenue for self-disclosure and sharing of one's feelings of shame and secrecy (e.g., binge eating in private, eating alone, avoiding social gatherings with food) that are associated with BED. By raising awareness of behaviors and associated negative feelings, participation in the trial may increase motivation to change. Previous

studies looking at the effects of behavior modeling often show that the simple act of tracking behavior changes the target behavior. Self-monitoring was once described as the most effective technique used in behavioral treatments of obesity [38-41]. The use of self-monitoring as a method to affect behavior change has been documented across a variety of health behaviors [42-44] and is recommended by the National Institute of Health (NIH) as a guideline to behavior change for weight loss [45]. As indicated in the qualitative responses, the dietary monitoring often used as a measurement tool in BED treatment studies may actually have a positive effect on treatment by raising ones awareness of the behavior. As such, one option to reduce the number of participants responding to placebo treatments may be to include a longer placebo run-in trial that incorporates both food recall diaries and/or educational material. Future studies should continue to assess participants' perceptions of helpful components of treatment studies in order to address the high rates of "placebo responders" in BED treatment trials.

We report data that allow for sample size calculations. Effect size estimates based on small sample sizes, such as the current study, are likely to be unreliable. Given the inherent instability in pilot data [46,47], these sample size estimates must be viewed with considerable caution. We advocate strong caution in using a pilot study, such as ours, to guide power calculations because of inherent instability in the pilot data. Nonetheless, our study was a randomized controlled trial with implementations for use in an understudied cohort in need of attention. When conducting future studies, we advise recruitment of a more robust sample size to allow for attrition, as attrition and insufficient sample sizes are frequent in the literature [4]. The present results suggest that larger samples are needed to detect differences in eating-related psychopathology than binge eating frequency. Therefore, future trials should clearly identify the primary outcome variable *a priori* to guide sample size determination and, subsequently, consider any observed treatment differences in other outcomes judiciously.

Clinical trial feasibility and acceptability are becoming more widely recognized and discussed as key components of study development that directly inform the development and implementation of efficacious treatments [48,49]. The current findings suggest that CrPic may be a feasible and acceptable intervention with potential health benefits for individuals with BED. Future adequately powered studies are warranted to determine the feasibility, acceptability, and efficacy of chromium supplementation treatment for BED.

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References

1. American Psychiatric Association (2013) (DSM-V-TR) Diagnostic and statistical manual of mental disorders, 5th edition. Washington, D.C: American Psychiatric Association.
2. Javaras KN, Pope HG, Lalonde JK, Roberts JL, Nillni YI, et al. (2008) Co-occurrence of binge eating disorder with psychiatric and medical disorders. J Clin Psychiatry 69: 266-273.
3. Swinbourne J, Hunt C, Abbott M, Russell J, St Clare T, et al. (2012) The comorbidity between eating disorders and anxiety disorders: Prevalence in an eating disorder sample and anxiety disorder sample. Australian and New Zealand Journal of Psychiatry 46: 118-131.
4. Brownley KA, Berkman ND, Sedway JA, Lohr KN, Bulik CM (2007) Binge eating disorder treatment: a systematic review of randomized controlled trials. Int J Eat Disord 40: 337-348.
5. McElroy SL, Guerdjikova AI, Mori N, O'Melia AM (2012) Pharmacological management of binge eating disorder: current and emerging treatment options. Ther Clin Risk Manag 8: 219-241.
6. Grilo CM, White MA (2013) 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. Behav Res Ther 51: 167-175.
7. Reas DL, Grilo CM (2014) Current and emerging drug treatments for binge eating disorder. Expert Opin Emerg Drugs 19: 99-142.
8. White MA, Grilo CM (2013) Bupropion for overweight women with binge-eating disorder: a randomized, double-blind, placebo-controlled trial. J Clin Psychiatry 74: 400-406.
9. Brownley KA, Peat CM, La Via M, Bulik CM (2015) Pharmacological approaches to the management of binge eating disorder. Drugs 75: 9-32.
10. Berkman ND and Center RI-UoNCE-bP (2006) Management of eating disorders. Agency for Healthcare Research and Quality.
11. Komorowski JR, Tuzcu M, Sahin N, Juturu V, Orhan C, et al. (2012) Chromium picolinate modulates serotonergic properties and carbohydrate metabolism in a rat model of diabetes. Biol Trace Elem Res 149: 50-56.
12. Hua Y, Clark S, Ren J, Sreejayan N (2012) Molecular mechanisms of chromium in alleviating insulin resistance. J Nutr Biochem 23: 313-319.
13. Suksomboon N, Poolsup N, Yuwanakorn A (2014) Systematic review and meta-analysis of the efficacy and safety of chromium supplementation in diabetes. J Clin Pharm Ther 39: 292-306.
14. Abdollahi M, Farshchi A, Nikfar S, Seyedifar M (2013) Effect of chromium on glucose and lipid profiles in patients with type 2 diabetes; a meta-analysis review of randomized trials. J Pharm Pharm Sci 16: 99-114.
15. Cefalu WT, Rood J, Pinsonat P, Qin J, Sereda O, et al. (2010) Characterization of the metabolic and physiologic response to chromium supplementation in subjects with type 2 diabetes mellitus. Metabolism 59: 755-762.
16. Bailey CH (2014) Improved meta-analytic methods show no effect of chromium supplements on fasting glucose. Biol Trace Elem Res 157: 1-8.
17. Docherty JP, Sack DA, Roffman M, Finch M, Komorowski JR (2005) A double-blind, placebo-controlled, exploratory trial of chromium picolinate in atypical depression: effect on carbohydrate craving. J psychiatr pract 11: 302-314.
18. Anton SD, Morrison CD, Cefalu WT, Martin CK, Coulon S, et al. (2008) Effects of chromium picolinate on food intake and satiety. Diabetes Technol Ther 10: 405-412.
19. Brownley KA, Von Holle A, Hamer RM, La Via M, Bulik CM (2013) A double-blind, randomized pilot trial of chromium picolinate for binge eating disorder: Results of the Binge Eating and Chromium (BEACh) Study. J Psychosom Res 75: 36-42.
20. Lancaster GA, Dodd S, Williamson PR (2004) Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract 10: 307-312.
21. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, et al. (2009) How we design feasibility studies. Am J Prev Med 36: 452-457.
22. Appolinario JC, Bacaltchuk J, Sichieri R, Claudino AM, Godoy-Matos A, et al. (2003) A randomized, double-blind, placebo-controlled study of sibutramine in the treatment of binge-eating disorder. Arch Gen Psychiatry 60: 1109-1116.
23. Fairburn CG, Beglin SJ (1994) Assessment of eating disorders: interview or self-report questionnaire? Int J Eat Disord 16: 363-370.
24. Dean CB, Nielsen JD (2007) Generalized linear mixed models: a review and some extensions. Lifetime Data Anal 13: 497-512.
25. Braun V, Clarke V (2006) Using thematic analysis in psychology. Qual Research Psych 3: 77-101.
26. Boyatzis RE (1998) Transforming qualitative information: Thematic analysis and code development. Sage, New Delhi.
27. Dey I (2003) Qualitative data analysis: A user friendly guide for social scientists. Routledge, New York.
28. Hwang S (2008) Utilizing qualitative data analysis software: A review of Atlas. ti. Social Science Computer Review.
29. Wilson GT, Wilfley DE, Agras WS, Bryson SW (2010) Psychological treatments of binge eating disorder. Arch Gen Psychiatry 67: 94-101.
30. Hudson JI, Lalonde JK, Coit CE, Tsuang MT, McElroy SL, et al. (2010) Longitudinal study of the diagnosis of components of the metabolic syndrome in individuals with binge-eating disorder. Am J Clin Nutr 91: 1568-1573.
31. Brownley KA, Boettiger CA, Young L, Cefalu WT (2015) Dietary chromium supplementation for targeted treatment of diabetes patients with comorbid depression and binge eating. Medical hypotheses 85: 45-48.
32. Grilo CM, Masheb RM, Salant SL (2005) Cognitive behavioral therapy guided self-help and orlistat for the treatment of binge eating disorder: a randomized, double-blind, placebo-controlled trial. Biol Psychiatry 57: 1193-1201.

33. Grilo CM, Masheb RM (2005) A randomized controlled comparison of guided self-help cognitive behavioral therapy and behavioral weight loss for binge eating disorder. Behav Res Ther 43: 1509-1525.

34. Arnold LM, McElroy SL, Hudson JI, Welge JA, Bennett AJ, et al. (2002) A placebo-controlled, randomized trial of fluoxetine in the treatment of binge-eating disorder. J Clin Psychiatry 63: 1028-1033.

35. Safer DL, Jo B (2010) Outcome from a randomized controlled trial of group therapy for binge eating disorder: comparing dialectical behavior therapy adapted for binge eating to an active comparison group therapy. Behav Ther 41: 106-120.

36. Reas DL, Grilo CM (2008) Review and meta-analysis of pharmacotherapy for binge-eating disorder. Obesity (Silver Spring) 16: 2024-2038.

37. Jacobs-Pilipski MJ, Wilfley DE, Crow SJ, Walsh BT, Lilenfeld LR, et al. (2007) Placebo response in binge eating disorder. Int J Eat Disord 40: 204-211.

38. Kirschenbaum DS (1987) Self-regulatory failure: A review with clinical implications. Clinical Psychology Review 7: 77-104.

39. Perri MG, Nezu AM, Viegener BJ (1992) Improving the long-term management of obesity: Theory, research, and clinical guidelines. John Wiley & Sons 259-282.

40. Baker RC, Kirschenbaum DS (1993) Self-monitoring may be necessary for successful weight control. Behavior Therapy 24: 377-94.

41. Boutelle KN, Kirschenbaum DS (1998) Further support for consistent self-monitoring as a vital component of successful weight control. Obes Res 6: 219-224.

42. Guerci B, Drouin P, Grange V, Bougnères P, Fontaine P, et al. (2003) Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. Diabetes Metab 29: 587-594.

43. Breland JY, McAndrew LM, Burns E, Leventhal EA, Leventhal H (2013) Using the common sense model of self-regulation to review the effects of self-monitoring of blood glucose on glycemic control for non–insulin-treated adults with Type 2 Diabetes. Diabetes Educ 39: 541-559.

44. Lorig KR, Sobel DS, Stewart AL, Brown BW, Bandura A, et al. (1999) Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med care 37: 5-14.

45. Aim for a Health Weight. In: Health NIo, (ed.). NIH Publication No. 05-5213, 2005.

46. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA (2006) Caution regarding the use of pilot studies to guide power calculations for study proposals. Arch Gen Psychiatry 63: 484-489.

47. Bulik CM, Hamer RM, Crosby R, Root TL, Von Holle A, et al. (2009) International Journal of Eating Disorders: Statistical Guidelines. Int J Eat Disord 42: 193-194.

48. Loscalzo J (2009) Pilot trials in clinical research: of what value are they? Circulation 119: 1694-1696.

49. Taylor J (2007) In praise of the feasibility study. J Clin Nurs 16: 1789-1791.