

Title: Group therapy for binge eating in type 2 diabetes: A randomized trial.

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Running title: TREATMENT OF BINGE EATING IN TYPE 2 DIABETES

Abstract

Aims: This preliminary study addresses three related issues. Firstly, there is a need to test the effectiveness of CBT (Cognitive Behavioural Therapy) for binge eating in populations with type 2 diabetes. Secondly, the impact of a treatment for binge eating on diabetes management is unknown. Finally, whilst a number of treatment modalities have been shown to improve binge eating there has not been a comparison between CBT and a non-specific therapy for binge eating.

Methods: Group CBT for binge eating was compared to a Group Non-Prescriptive Therapy (NPT), a therapy for which there is no theoretical or empirical support in eating disorders, in a randomised trial which included a post-treatment assessment and a three-month follow-up.

Results: There were no differences between CBT and NPT at post-treatment with both treatments being associated with significant changes in binge eating, mood and BMI. However there was a significant relapse in binge eating at the three-month follow-up in the NPT condition. This was in contrast to the CBT condition where treatment gains were maintained. Finally, across treatments, reduction in binge eating from pre- to post-treatment was associated with reduction in HbA1c.

Conclusions: Binge eating in type 2 diabetes is responsive to psychosocial treatment, and reduction in binge eating appears to improve glycaemic control. However this is a small study with a short follow-up period. Future studies will need to extend the follow-up period to assess for long-term maintenance of the effects of CBT on binge eating and diabetic control in this population.

Key words: Type 2 Diabetes, Psychology, Eating Disorder, Clinical Trial.

Abbreviations used: CBT (cognitive behavioural therapy), NPT (non prescriptive therapy), HbA1c (glycosylated haemoglobin A1c), BED (binge eating disorder), BN (bulimia nervosa), EDNOS (eating disorder not otherwise specified), IPT (interpersonal psychotherapy), DEC (diabetes education centre), OBE (objective bingeing), SBE (subjective bingeing), OOE (objective over eating), EDE (Eating Disorder Examination), EDI (Eating Disorders Inventory), WBQ (Well Being Questionnaire), BMI (body mass index).

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Introduction

Binge eating is a serious and largely overlooked problem in the study of weight management and eating disorders in diabetes. Examining the literature Herpertz and colleagues conclude that studies examining binge eating have rarely involved persons with type 2 diabetes [1]. Those that have done so find that binge eating is much more common in type 2 diabetes than in the general population. Wing and colleagues examined binge eating in females with NIDDM, and found 21% of the sample had elevated scores on a self-report measure of binge eating [2]. Kenardy, et al [3] found 14% of newly diagnosed with type 2 diabetes reported binge eating at least twice a week compared to 4% of BMI- and age-matched controls. We also found evidence of higher rates of binge eating amongst females. More recently Kenardy, et al [4] confirmed this finding in a different sample of 215 women with type 2 diabetes, with 21% binge eating at least once a week. Crow, et al [5] found that in their sample of 43 Type 2 diabetics, 35% of women and 15% of the men were diagnosed with binge eating disorder.

Binge eating has been found to interfere significantly with weight management [6]. Furthermore weight management is likely to exacerbate existing binge eating [7]. Therefore weight management with patients with type 2 diabetes who binge eat should proceed with care. Alternatively, when present, the binge eating should be treated prior to embarking on weight management. Whilst there is an association between overweight and binge eating which may link binge eating and diabetes, there may be a more direct relationship between binge eating and glycemic control in type 2 diabetes. Kenardy et al [4] have found a significant relationship between glycemic control (as measured by HbA1c) and binge eating independent of weight. In contrast Crow et al, [5] did not, however their sample size was smaller and they employed a single self-report Likert scale, whereas Kenardy et al [4] used a compound interview-based measure of binge frequency and a large single gender sample. Any relationship between binge eating and glycemic control may become more apparent following change in binge eating in response to treatment.

Cognitive Behavioral Therapy

Diabetes

Cognitive behavioural therapy (CBT) has been shown in a number of studies to be an effective and acceptable intervention with patients who have medical conditions including obesity [8] and cardiovascular disease [9]. With type 2 diabetes patients CBT has been shown to be effective in the treatment of depression [10] and stress [11].

Binge Eating

Binge eating is defined as episodic consumption of objectively large amounts of food with an associated loss of control within that consumption. Binge eating is a core feature in two eating disorders under DSM-IV [12], Bulimia Nervosa (BN), and the research diagnosis Binge Eating Disorder (BED) which nominally falls under the diagnosis of Eating Disorder Not Otherwise Specified (EDNOS). In BN episodes of binge eating are associated with compensatory behaviours such as vomiting and use of laxatives. In contrast no such compensation occurs within BED. Instead DSM-IV places emphasis on the severity criterion for the core behavioural symptom of BED, binge eating, by specifying a minimum of two binges a week over a six-month duration. As an alternative to DSM-IV Fairburn and colleagues have proposed the "Oxford" criteria [13] which requires a minimum of one episode per week over a three-month period. There is an ongoing debate in the literature about the DSM-IV criteria [14] and many researchers believe that they are too strict and arbitrary. It has been argued that the Oxford criteria provide a more empirically-supported diagnostic approach.

CBT applied in both an individual and group basis has been extensively studied as a treatment for BN [15]. The CBT approach to treatment is based upon the cognitive view of BN, which proposes dysfunctional attitudes towards shape and weight to be of primary importance in the maintenance of the disorder [16]. In particular, societal pressures for a thin body shape are hypothesised to lead to

dietary restraint and subsequently binge eating accompanied by compensatory purging [17]. A meta-analysis identified CBT as the treatment of choice for bulimia nervosa. CBT has been shown to be as effective, if not more effective in reducing bingeing and purging, than all other treatments with which it has been compared [18]. These have included supportive psychotherapy [19], and non-directive therapy [20].

The clinical similarities between BN and BED have resulted in the suggestion that the cognitive view of BN, and therefore CBT, may be appropriately applied to BED. The application of CBT to BED has been the subject of much recent study yielding encouraging results [21]. A number of studies have shown that group CBT applied to BED is effective in reducing the frequency of binge eating [22,23,24,25].

Smith et al [23] conducted a controlled study administering CBT to obese binge eaters. Following treatment subjects experienced an 81% combined reduction in objective and subjective bulimic episodes, with an abstinence from binge eating of 50%. Improvements in shape and weight concerns were also evidenced. Wilfley, and colleagues [25] compared CBT and interpersonal psychotherapy (IPT) for binge eaters. In this study CBT performed as well as IPT. Thus “a wide range of treatments are effective in reducing binge eating in BED patients” [26]. However to date there have been no studies that have compared an active but non-specific psychotherapy to CBT in BED. This is important since treatments for BED may be effective because of non-specific factors.

Non-Prescriptive Therapy (NPT) [27] is derived from Rogerian principles of self-awareness and self-acceptance. There is no evidence of its efficacy with binge eating, or disordered eating broadly. There is no theoretical or empirical support for links between the constructs addressed in NPT and binge eating although it is possible to administer NPT in a systematic fashion based on prescribed procedures [28], even to the extent of incorporating self-monitoring without linking this to cognitive-behavioural analysis. Given these factors the choice of NPT as a control provides an opportunity to

evaluate CBT against an intervention that contains many of the non-specific elements of CBT without the specific CBT principles and techniques that should produce long-term change. Thus in this study Cognitive Behaviour Therapy is compared to Non-Prescriptive Therapy as a treatment for binge eating in women with type 2 diabetes. It is expected that both treatments will be effective due to commonality of non-specific factors, however only CBT should produce sustained change in binge eating.

Patients and Methods

Participants

Participants were recruited from the Diabetes Education Centre (DEC), Royal Newcastle Hospital, Australia as part of an ongoing study of eating behaviours in type 2 diabetes [4]. All participants had been diagnosed with type 2 diabetes prior to referral to the DEC. Of 215 women who consented to being assessed with a modified Eating Disorders Examination, 45 were identified as engaging in binge eating at least weekly [13] and were therefore eligible to participate in the study. Participants who met diagnostic criteria for bulimia nervosa or anorexia nervosa, major depressive episode, any psychotic or organic mental disorder, or alcohol dependence were not eligible for inclusion in the study. Thirty-four of the 45 women identified as eligible agreed to participate. Participants and non-participants in the treatment study were compared on age, body mass index and glycemic control and binge eating severity. No significant difference was found between participants and non-participants.

Study Design

Participants were randomly assigned to a 10-week group cognitive behavioral therapy (CBT) or 10-week group non-prescriptive therapy (NPT) and assessed pre-treatment, post-treatment and at a 12-week follow-up.

Treatments

Both treatments were group-based, administered over ten weekly sessions with each group session lasting 1.5 hours. Both treatments protocols were prescribed in a manual (both manuals are available

from Justin Kenardy by request). Two experienced clinical psychologists conducted the group therapy, one administered CBT the other NPT, and overall supervision was given by Justin Kenardy.

Cognitive Behavioural Therapy

The CBT treatment was adapted from the approach evaluated by Telch et al [24] which involves 10 sessions of individual therapy. This approach is accepted as having demonstrated efficacy [29] with binge abstinence rates comparable to treatments of greater duration [23]. Our adaptation involved extension of session length to 90 minutes, group administration format, and acknowledgement of specific issues associated with diagnosis of type 2 diabetes. The approach focused on factors and processes involved in maintaining binge eating. These factors include absence of dietary regulation, body image disturbance and misconceptions about food and eating. Stage 1 of the CBT treatment approach involves presentation of the cognitive model of binge eating and the use of behavioral techniques to replace binge eating with regular eating. Stage 2 of the CBT treatment approach involves extensive use of cognitive procedures, particular attention being devoted to identifying binge eating antecedents, cognitive restructuring and teaching problem solving skills. Stage 3 of the CBT approach seeks to ensure progress maintenance through challenging unrealistic expectations and formulating plans for dealing with future high-risk situations. Participants were given a handout describing the CBT model and its application to binge eating. Participants also self-monitored eating, binge triggers, and used dysfunctional thoughts records.

Non-prescriptive Therapy

The non-prescriptive therapy (NPT) approach is based on Rogerian principles and consists of two components – non-directive counseling and “focused evocative unfolding” [27]. The aim of the focused reflective listening component of NPT is increasing both awareness and acceptance of negative affect. Acceptance of negative affect is hypothesized to reduce the shame, fear and guilt evoked by these feelings, thus resulting in reduced avoidance of negative affect which increases opportunities to develop more effective coping skills, diminishing the sense of uncontrollability and therefore reduced vulnerability to binge eating. This rationale was presented to participants along with a handout that included broad issues of the causes of binge eating including emotions and dieting. Participants also

self-monitored eating and emotions without explicit links between the two records being made. The intent was to control for self-monitoring without explicitly utilizing self-monitoring to analyze binge triggers.

Procedure

Participants who met the inclusion and exclusion criteria were allocated randomly to either treatment condition. Random allocation was done via random number tables in blocks without knowledge of pre-treatment status. Interview, self-report and blood measures were taken prior to randomization in order to assess for inclusion criteria. Participants attended the weekly group treatment and were re-assessed within two weeks of the completion of the group, and again 12-weeks following the completion of the group. Two experienced clinical psychologists administered the therapy, one was assigned to the NPT condition and the other to the CBT condition.

Measures

The Eating Disorders Examination (EDE) [13] is a standardized interview that is designed to measure the current level of specific psychopathology of eating disorders. It has been used in both clinical and community based settings, has good discriminant validity, and is reliable and sensitive to change [18]. During a pilot of this study it was determined necessary to modify the EDE to increase its suitability with persons with diabetes. Items related to restriction were scored accounting for the diabetic dietary constraints. Due to the removal and modification of non-diagnostic items in the original EDE, subscale scores could not be obtained. According to the EDE bingeing is the consumption of a large amount of food accompanied by a feeling of loss of control over eating. Objective bingeing (OBE) refers to consumption of an amount of food that most people would judge as large. Subjective bingeing (SBE) refers to the consumption of an amount of food personally perceived to be excessive but considered by others as normal. Subjective bingeing is salient for individuals with diabetes, where not only the quantity of food eaten, but also the content of the diet is significant. Objective overeating (OOE) refers to consumption of an amount of food that most people would judge as large but without

the associated feeling of loss of control over eating. Three additional measures were derived from the EDE to indicate overall frequency of types of overeating, that is, frequency of objective binge episodes, subjective binge episodes and objective overeating episodes. The frequency of objective and subjective binge episodes was combined to give an overall frequency of binge eating.

The Eating Disorders Inventory (EDI) [30] is a widely used self-report measure of symptoms commonly associated with eating disorders. Respondents are asked to answer each item concerning whether it applies 'always', 'usually', 'often', 'sometimes', 'rarely' or 'never'. Within this study, only three sub-scales of the EDI were used - bulimia, body dissatisfaction and drive for thinness as these sub-scales have been used within other studies of persons with diabetes to screen for eating disorders [31].

The Well Being Questionnaire (WBQ) [32] provides a measure of psychological well being designed for persons with diabetes. The 22-items on the WBQ are rated on a '0' to '3' likert scale, and the questionnaire is reliable and has demonstrated validity. It is also sensitive to treatment effects [30].

Data Analysis

We used t-test or chi-square to compare groups at baseline. We used 2-way Group X Time (CBT vs NPT X Pre-, Post-, Follow-up) repeated-measures ANOVA's to analyse the main outcome variables, and Bonferroni-adjusted multiple comparisons to test for difference post-hoc. We also use chi-square tests to compare categorical outcome variables at post-treatment and follow-up. In the main analyses where there were missing values at post-treatment or follow-up we carried forward the baseline data, thus we took an intention-to-treat analysis approach.

Results

Thirty-four participants (17 CBT, 17 NPT) completed baseline assessments. For all patients English was their first language, and only one patient was not born in Australia. There were no significant differences on any demographic or baseline measures between participants in the CBT or NPT groups (Table 1.) Two participants failed to complete the post-treatment interview only. Five participants failed to complete all post-treatment questionnaires, and five (different) participants failed to complete all follow-up questionnaires. Two participants, both in NPT, failed to complete any blood test throughout the course of the study and 13 participants (10 CBT, 3 NPT) failed to provide blood test results at follow-up. Thus it was decided to exclude all follow-up HbA1c data from analysis. Two participants in the NPT group attended only two sessions of the treatment, however both provided post- and follow-up data.

There were no significant main effects for group on any outcome variable (Table 2.) Main effects for Time were significant for Binge Frequency [$F(2,64) = 36.27, p < .001, \eta^2 = 0.53$], EDI-Bulimia [$F(2,64) = 14.80, p < .001, \eta^2 = 0.32$], EDI-Drive for Thinness [$F(2,64) = 13.52, p < .001, \eta^2 = 0.30$], EDI-Body Dissatisfaction [$F(2,64) = 12.38, p < .001, \eta^2 = 0.28$], WBQ-Total [$F(2,64) = 10.64, p < .001, \eta^2 = 0.25$], and BMI [$F(2,64) = 4.93, p < .05, \eta^2 = 0.13$]. In all cases the significant difference was from pre- to post-treatment and pre- to follow-up, with no difference found between post- and follow-up. There were no significant interaction effects. There was no significant effect for Time for HbA1c pre- (mean=7.45, SD=1.42) to post-treatment (mean=7.25, SD=1.48). At post-treatment there was no association between condition and abstaining from binge eating with 29.4% within NPT abstinent, and 47.1% within CBT. However at follow-up there was a significant relapse in the NPT condition (17.6% abstinent) compared to 58.8% following CBT [$\chi^2(1, N=34) = 6.10, p < .05$]. One patient in the CBT condition and one in the NPT condition increased the dose of their medication over the course of the treatment, one patient in the CBT condition added an additional medication (metformin) to their existing regimen (sulphonylurea), and one patient in the NPT condition stopped their medication. There was no

relationship found between change in medication regimen and HbA1c or binge eating at post-treatment.

A series of t-tests were conducted to attempt to find baseline differences between patients who were abstinent for binge eating at follow-up compared to those that were not. More frequent binge eating at baseline is significantly associated with binge eating (mean=4.19 SD=1.75) versus binge abstinence (mean=2.85 SD=1.52) at follow-up ($t(32)=-2.28, p<.05$).

In order to examine the mechanisms of change, difference scores (post-treatment – baseline) were calculated for each of the outcome measures that were then correlated with change in binge frequency (Table 3). Only improvement in HbA1c correlated significantly ($r=0.41, N=32, p<.05$) with reduction in binge frequency. To test the hypothesis that this relationship was confounded by reduction in BMI a partial correlation was conducted between change scores for binge frequency and HbA1c controlling for BMI. After controlling for change in BMI the partial correlation between reduction in binge frequency and improvement in HbA1c remained significant ($r=0.40, N=29, p<.05$).

Discussion

This study was designed to compare two psychological treatments for binge eating in women with type 2 diabetes. Results indicate that on measures of binge eating, eating-related beliefs, weight, mood and glycemic control both treatments are effective, but on abstinence from binge eating the NPT condition is associated with relapse in binge eating. However this relapse effect is not reflected in other outcome variables and hence must be treated with caution. This is the first study to evaluate a CBT treatment designed specifically for binge eating within a population with type 2 diabetes. It could be argued that cognitive-behavioral therapy appears to be providing a more sustained change in binge eating than the non-prescriptive therapy, however this must be demonstrated in a fully powered study. Nevertheless NPT appears to be an effective treatment. NPT contained components that include of self-monitoring, education, and development of a supportive therapeutic environment. All of these may have contributed to the positive outcome. It is also possible that NPT was effective because of its focus on self-awareness and acceptance of negative affect. There is evidence to indicate that emotional tolerance has a role in the maintenance of binge eating [33]. Across conditions analysis of prognostic indicators suggest that the interventions produce less change in individuals who have more frequent binge episodes suggesting that the more severe the presentation, the less effective the intervention. It may be that longer treatment is necessary for those who have not recovered at the end of 10 weeks.

The effectiveness of the group treatments in changing binge eating, BMI and mood in the diabetic population demonstrates that psychotherapeutic groups have value and utility in type 2 diabetes. The effect size for change in BMI is small, but this may be a function of the brief follow-up, given that change in BMI is usually relatively slow. No effect of the intervention was found on HbA1c. Even so, baseline HbA1c was relatively low and the impact of any treatment is likely to be diminished by floor effects. Further research should select out binge eating patients with type 2 diabetes who also have elevated HbA1c, and evaluate their response to psychosocial treatment. Interestingly, an evaluation of process supports a direct relationship between reduction in binge frequency and improvement in

glycemic control after accounting for changes in BMI. The most likely link between binge eating and HbA1c is carbohydrate intake. There was no measurement of dietary intake in this study and this would be an important variable to include in future research.

The study has a number of limitations and these constrain any conclusions drawn from the results. The study has a relatively small sample size. This was compounded by the missing data. Thus the effects of low power may have diminished the likelihood of a significant difference being detected. Clearly the study should be repeated with a larger sample size. The methodology involved a relatively short follow-up of three-months. If patient follow-up was continued it is quite possible that the differences in binge eating may have emerged over time, as well as weight and glycemic control. Missing data for HbA1c at follow-up meant that it was not possible to identify any long-term influences of the therapy on actual diabetic control. Even so, baseline HbA1c was relatively low and the impact of any treatment would be diminished by floor effects. Further research should select out binge eating patients with type 2 diabetes who also have elevated HbA1c, and evaluate their response to psychosocial treatment. The sample itself is limited to women with type 2 diabetes, and whilst meeting the Oxford criteria for binge eating disorder, nevertheless do not all meet the DSM-IV [12] research criteria.

In conclusion this study provides preliminary evidence that binge eating in type 2 diabetes is responsive to a psychosocial treatment, and that intervention with binge eating appears to impact on glycemic control as well. Arguably cognitive-behavioral therapy provides sustainable effects of binge eating in women with co-morbid type 2 diabetes. The follow-up for this study was short, and it would be essential to determine long-term outcomes of psychosocial treatment for binge eating.

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Table 1 Means, standard deviations and frequency counts for sample characteristics compared across treatment condition

Variable	CBT	NPT	Significance
Age (yrs)	51.77 (9.59)	57.99 (11.35)	NS
Occupational Status (ASCO) (1=low, 8=high)	5.91 (1.51)	5.80 (2.04)	NS
Dieting Frequency in past year (1=none, 5=always)	2.41 (0.62)	2.17 (0.64)	NS
Glycolylated Haemoglobin A1c	7.38 (1.66)	7.53 (1.33)	NS
Time since diagnosis of diabetes (mo)	39.07 (48.48)	37.21 (84.00)	NS
<u>Treatment Regimen</u>			
Diet only	11 (64.7%)	8 (47.1%)	NS*
Oral Medication	6 (35.3%)	7 (41.2%)	
Insulin	0	2 (11.8%)	

*Chi-square

Table 2. Mean and standard deviations for outcome variable for each treatment group for three times.

Measure	Cognitive Behavior Therapy group (N=17)						Non-Prescriptive Therapy group (N=17)					
	Pre-intervention		Post-intervention		Follow-up		Pre-intervention		Post-Intervention		Follow-up	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Binge Frequency (0-12)	3.71	1.72	1.06	1.39	1.06	1.39	4.24	1.75	1.63	2.03	1.88	1.69
BMI (kg/m ²)	40.18	8.46	38.98	7.25	38.52	7.28	35.49	5.97	34.65	6.13	34.29	5.62
EDI-Bulimia	22.71	6.54	18.29	7.59	18.35	7.04	22.59	7.76	18.53	5.94	18.53	6.04
EDI-Drive for Thinness	10.71	6.22	6.14	5.24	6.35	4.99	8.53	5.22	6.94	3.88	5.56	4.96
EDI-Body Dissatisfaction	21.82	5.17	17.09	8.38	18.35	7.04	21.47	4.61	16.64	6.84	18.06	7.51
Wellbeing Questionnaire	31.59	12.15	42.00	12.80	39.65	12.99	35.35	10.61	42.02	13.24	41.82	12.30

Table 3 Correlations between pre- to post-change scores on outcome measures and binge frequency.

	Δ Binge Frequency
Δ HbA1c	.41*
Δ BMI	.25
Δ EDI- Body Dissatisfaction	.10
Δ EDI- Bulimia	-.17
Δ EDI- Drive for Thinness	-.28
Δ Wellbeing Questionnaire	-.03

* $p < .05$