

A Brief DBT Skills Group for Bulimia Nervosa: A Feasibility Study

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

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Overview

The focus of this thesis is eating disorders, specifically treatment outcomes for individuals with eating disorders. This thesis consists of three parts.

The first part of the thesis is a systematic literature review on the treatment outcomes and dropout rates for men with eating disorders. Men with eating disorders are often excluded from research because of the low prevalence rates of eating disorders in men. The consequence of this is that treatment guidelines are developed based on research that has few, if any, male participants. This review aimed to review the currently available evidence on men's treatment outcomes and dropout rates, and consider whether these are similar to women's treatment outcomes and dropout rates. The clinical and research implications of the findings of the review are discussed.

The second part of the thesis is an empirical paper on the feasibility of a 12-week Dialectical Behaviour Therapy (DBT) skills group for women with bulimia nervosa. The results showed significant improvements in the participant's eating disorder symptoms and functional impairment following the intervention. Feedback from participants also suggested that the intervention was acceptable to clients. Limitations, clinical implications, and research implications of the study are discussed. The data collection for this study was conducted jointly with another trainee investigating the change in acceptance and mindfulness following a DBT skills group.

The third part of this thesis is a critical appraisal that reflects on some of the issues that arose during the research process. This critical appraisal focuses on three topics, the practical problems that arose in the research, the group processes that were observed in the DBT skills groups, and the relationship between sexuality and eating disorders in men.

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List of Abbreviations

AN = anorexia nervosa

BDD = body dysmorphic disorder

BED = binge eating disorder

BEST = borderline evaluation of severity over time

BMI = body mass index

BN = bulimia nervosa

BPD = borderline personality disorder

BWLT = behavioural weight loss therapy

CBT = cognitive behavioural therapy

DBT = dialectical behaviour therapy

ED = eating disorder

EDE-Q = eating disorder examination questionnaire

EDNOS = eating disorder not otherwise specified

EES = emotional eating scale

ITT = intent-to-treat analysis

MDT = multi-disciplinary team

PD = personality disorder

RCT = randomised controlled trial

SAPAS = standardised assessment of personality scale

WSAS= work and social adjustment scale

Part One: Literature Review

Treatment Outcomes for Men with Eating Disorders: A Systematic Review

Abstract

Aim: To assess the evidence for the effectiveness of psychological therapies for men with eating disorders.

Method: A systematic review was conducted. Four databases were searched with terms related to eating disorders, treatment outcome and gender to retrieve relevant studies for the review. The relevant studies were quality assessed and a sub-sample of studies were also rated by an independent, blind assessor.

Results: Sixteen studies met inclusion criteria, seven of which reported dropout data and twelve of which reported treatment outcomes for men. All seven of the studies that reported dropouts found men were no more likely to drop out of interventions than women. The majority of the studies reporting treatment outcomes found that men's ED symptoms significantly improved following psychological interventions. One study found men with anorexia nervosa had higher remission rates than women and another study found that men with binge eating disorder were more likely to relapse than women.

Conclusions: Currently available studies suggest that men are no more likely to drop out of eating disorder interventions than women and men experience significant improvements in their ED symptoms following psychological interventions, which are comparable to women's treatment outcomes. However, more research is needed, particularly including larger samples of men.

Introduction

Eating disorders (EDs) are a significant mental health problem that can have devastating effects on people's lives. EDs can be described as a combination of abnormal eating behaviours alongside abnormal beliefs about shape and weight. The *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*; American Psychiatric Association, 2013) identifies three main types of ED. These are bulimia nervosa, anorexia nervosa and binge eating disorder. The DSM-5 criteria for anorexia nervosa (AN), bulimia nervosa (BN) and binge eating disorder (BED) can be seen in Table 1.

Table 1

DSM Diagnostic Criteria for EDs

Diagnosis	DSM criteria
AN	a) persistent restriction of energy intake leading to a significantly low body weight b) an intense fear of gaining weight or becoming fat c) self-evaluation being unduly influenced by shape or weight
BN	a) recurrent episodes of binge eating including a sense of lack of control b) recurrent inappropriate compensatory behaviour to try to prevent weight gain c) self-evaluation being unduly influenced by shape or weight
BED	a) recurrent episodes of binge eating including a sense of lack of control, including three or more of the following: - eating more quickly than normal - eating until uncomfortably full - eating when not hungry - eating alone due to embarrassment - feeling disgusted, depressed or guilty after binge eating

Another ED diagnosis that is commonly referred to in research is Eating Disorder Not Otherwise Specified (EDNOS). EDNOS was a diagnostic category in the DSM-IV (4th ed.; American Psychiatric Association, 1994) that included individuals who did not meet all of the criteria for a diagnosis of AN or BN, for example purging less frequently than required for a diagnosis. The DSM-5 has changed the diagnostic criteria for EDs so that fewer people should fall into the EDNOS category, and EDNOS has now been reclassified as Other Specified Feeding or Eating Disorder (OSFED). However, this is a term not yet commonly seen in published studies.

All EDs can have a significant impact on an individual's psychological wellbeing, physical health, social functioning, and educational and occupational engagement (NICE, 2004). People with EDs report feeling alone, misunderstood, worthless, and hopeless about the future (Federici & Kaplan, 2008). They also talk about the frustration associated with their symptoms, such as having a negative self-image and becoming obsessed with appearance and weight (Serpell, Treasure, Teasdale & Sullivan, 1999; Serpell & Treasure, 2002). The difficulties of living with, and trying to recover from, EDs highlight the need for research to better understand EDs and develop effective interventions.

Eating Disorders as 'Female Disorders'

EDs have historically been viewed as 'female disorders'. This is reflected in the diagnostic criteria for AN, which included amenorrhoea until the most recent update of the DSM-5 in 2013. EDs in men have often been neglected, overlooked and trivialised despite being serious problems that require detailed consideration (Andersen, 2014).

One reason why men with EDs are often overlooked may be that the prevalence of EDs in men is lower than in women. The National Co-morbidity

Replication Survey in the United States (Hudson, Hiripi, Pope, & Kessler, 2007) conducted a survey of 9,282 adults who were representative of households in the US (results in Table 2). A large community-based sample, such as the one used in this study, allows for individuals with ED symptoms to be identified, even if they have never sought treatment. Clinic samples may not represent the prevalence of men with EDs if there are barriers to men entering treatment. Although estimates vary, it is clear that EDs are more common in women and this is likely to contribute to the view, amongst the general public and health care professionals, that they are 'female disorders'.

Table 2

Lifetime Prevalence of EDs in Men and Women from the National Co-morbidity Replication Survey in the United States

Eating disorder diagnosis	Gender	
	Men	Women
Anorexia Nervosa	0.3%	0.9%
Bulimia Nervosa	0.5%	1.5%
Binge Eating Disorder	2%	3.5%

Another approach to understanding how EDs have become viewed as 'female disorders' are the feminist and sociocultural theories of EDs. Feminist and sociocultural theories have added an essential perspective to our understanding of the causes of EDs in women. But historically, there has been little space to understand and conceptualise men's experience of EDs within these theories. Feminist theories state that the fashion industry and the media have gradually narrowed the range of acceptable sizes for women's bodies. They highlight the way in which thinness has become associated with beauty, success, and happiness,

adding increasing pressure on women to be thin (Fallon, Katzman, & Wooley, 1994). Feminist theories also highlight the role of patriarchal societies, which view women's bodies as objects to be dominated by and used as a reward for men. They suggest that EDs may sometimes provide a way for women to communicate the violence and abuse that has been perpetrated against them in a physical manifestation of their pain and shame (Fallon et al.). These theories prompt an essential discussion about how women are viewed and treated in our society, and how inequalities are still having a lasting impact on women's psychological wellbeing. However, men's experiences of EDs are often not considered within these frameworks of thinking, despite the fact that men can also be influenced by narrow appearance standards and can also be victims of abuse and power imbalances (Strother, Lemberg, Stanford, & Turberville, 2012).

The view of EDs as 'female disorders' means that the focus of research has concentrated on women. This leads to the development of clinical interventions that are effective for women, but have not been systematically researched in male populations. This review aims to assess the effectiveness of interventions for men to further our understanding of how to best support men with EDs.

Eating Disorders in Men

Overall EDs in men appear to present very similarly to EDs in women but some important differences have been identified. Men are more likely to report using weight control measures to help them do a job or play a sport, in which weight control is important (Braun, Sunday, Huang & Halmi, 1999; Jones & Morgan, 2010). Men are also more likely to report using weight control measures to avoid weight-related teasing and weight-related health problems (Jones & Morgan). These reasons for weight control are different to many women's reasons for weight control,

such as body dissatisfaction and trying to achieve an idealised body shape or weight.

Another difference seen in some men with EDs is a focus on muscularity rather than thinness. Over the last 30 years the fashion industry has increased its focus on men's bodies, leading to increased pressures for men to meet a particular physical ideal (Strother et al., 2012). The ideal male body is presented as muscular, with very little body fat, with a large chest, large biceps and a relatively slim waist. This has led to men being concerned about their body shape from the waist upwards whereas women's concerns tend to be focused between the waist and knees (Andersen, 2014). This focus on muscularity can, at an extreme, be understood as muscle dysmorphia, also referred to as 'reverse anorexia'. The main belief for people with muscle dysmorphia is that their body is too small or slim and not muscular enough. Muscle dysmorphia is becoming increasingly recognised as a problem that appears to be significantly more common in men than in women and may be related to ED symptomology (Nieuwoudt, Zhou, Coutts, & Booker, 2012).

Because there are differences in the presentation of EDs in men and women, it is possible that men would benefit from a different treatment approach that focuses on the issues that are most relevant for men, for example muscularity, weight related teasing and excessive exercise.

Treatment for Men with Eating Disorders

The current NICE guidelines for EDs (2004) recommend Cognitive Behaviour Therapy (CBT) adapted for BN, CBT adapted for BED and a range of therapies to be considered alongside physical monitoring for AN (the range of therapies include Cognitive Analytic Therapy, CBT, Interpersonal Psychotherapy, family interventions and focal psychodynamic therapy). These recommendations are for both men and women with EDs despite the fact that much of the research on

which the guidelines are based has been conducted with female samples. Even when research does include men, the number of men in the study is often too small for any valid conclusions to be drawn about treatment outcomes. The same treatments that are effective for women may well be effective for men, but it is possible that there are important differences, which is why it is important to review this evidence.

Interest and research into men with EDs has been increasing in recent years. Cohn & Lemberg (2014) have recently published a book documenting current findings on men with EDs that gives an up-to-date summary of some of the issues in assessment, treatment and recovery. However, there are still mixed results in terms of treatment outcomes for men. This unclear picture provides the rationale for this systematic review.

When evaluating the evidence for the treatment effectiveness of interventions for men with EDs, it is important to consider the use of ED rating scales. The majority of ED diagnostic tools and rating scales have been developed for women and validated on female samples (Jones & Morgan, 2010). The questions tend to focus more on the common concerns of women (e.g. thinness) than the common concerns of men (e.g. fitness and muscularity), and the body parts that may be of more concern to women (e.g. thighs) than the body parts that are of concern to men. Rating scales also focus more on the methods of weight control commonly used by women (e.g. purging, laxative use, diet pills) than the weight control methods more commonly used by men (e.g. excessive exercise). A study by Mond and colleagues (2014) compared scores on the EDE-Q for 531 adolescent boys and 1,135 adolescent girls. They concluded that the EDE-Q could be used to assess ED symptoms in males but it did not adequately assess weight and shape control behaviours that may be more common in males than in females, for example behaviours to increase muscularity. Mond et al. concluded that the EDE-Q should

be supplemented with additional measures such as the Drive for Muscularity scale (McCreary & Sasse, 2000) when used to assess men. Very few research studies use additional, male-specific measures to measure the severity of ED symptoms or the change in symptoms over time so it is possible that they do not provide an accurate assessment of EDs in men, or of the effectiveness of treatments for males.

When assessing the evidence for any clinical intervention it is important to review the dropout rates from the intervention as well as the treatment outcomes. A treatment needs to be both acceptable to clients and clinically effective. Dropout rates can be accounted for by a number of factors, such as the acceptability of the intervention, client factors (e.g. age of client), therapist factors (e.g. level of experience), and the perceived effectiveness of the intervention (Swift & Greenberg, 2012). It is therefore important to review whether men drop out of interventions at a similar rate to women. If men dropout more often than women, this could be an indication that the intervention is less acceptable to men.

This systematic review aims to answer three questions:

1. What are the dropout rates from psychological interventions for men with EDs?
2. What are the treatment outcomes for men with EDs following psychological interventions?
3. Are treatment outcomes and dropout rates for ED interventions similar for men and women in studies that compare the two?

Method

The search strategy and reporting for this systematic review was based on the guidelines from the PRISMA statement (Liberati et al., 2009). Study

characteristics required to be included in this review were specified before the search was conducted. The eligibility criteria were as follows:

Participants: Male participants diagnosed with AN, BN, BED, or EDNOS. Studies which included both male and female participants were also included.

Interventions: Any psychological intervention treating EDs. A psychological intervention was defined as any form of psychological therapy (e.g. CBT, psychodynamic psychotherapy, family therapy) or multi-disciplinary interventions including psychological therapy.

Comparators: No comparators were specified.

Outcomes: Outcomes needed to be related to ED symptoms (e.g. ED questionnaires, ED diagnostic criteria).

Study design: Quantitative research designs including randomised controlled trials (RCTs), non-randomised controlled trials, pretest-posttest designs and case series.

Additionally the study needed to be available in English and needed to be published in a peer-reviewed journal. No limitations on the year of publication were applied. Exclusion criteria were (a) studies that only included adolescent participants (under 16s) and (b) studies that included less than five men. It was decided that the inclusion of fewer than five male participants made it difficult for valid conclusions to be drawn about treatment outcomes or dropout rates for men, hence these studies were excluded.

Search Strategy

A systematic search was conducted utilising both database searches and hand-searches to identify relevant studies (see Appendix A for details). The databases searched were Medline, PsychINFO, Web of Science and the Cochrane Library. The search terms used were variations of three terms; eating disorders, treatment outcomes, and male gender. For EDs the search terms were 'eating

disorder', 'anorexia nervosa', 'bulimia nervosa', binge eating disorder', and 'EDNOS'. For treatment outcomes the search terms were 'effectiveness', 'efficacy', 'outcome', and 'treatment outcome'. The terms used for men were 'male' and 'men'. Additionally subject headings were used for searches where possible. The subject headings used were 'treatment outcome', 'eating disorder', and 'adult men'. Searches were conducted so that there had to be at least one search term from each category for a study to be included in the results of the search. Where databases allowed limits to be set, limits were set to English language and human subjects. Reference lists of key studies were hand-searched to identify additional potentially relevant studies. Reviews were also screened, and relevant studies were identified.

The titles and/or abstracts of studies identified through database searching and hand-searching were screened first. If the study clearly did not meet the inclusion criteria (e.g. the title or abstract stated that the study included women only) then it was excluded. If the study appeared to meet inclusion criteria or if it was unclear whether it would meet inclusion criteria, then the full paper was screened. Exclusion reasons were documented throughout the screening process (see Figure 1).

Quality Assessment

In line with the PRISMA guidelines for systematic reviews (Liberati et al., 2009), a quality assessment of each study was conducted to identify areas of potential bias in each study. As expected, a range of study methodologies were found in the papers identified for this review, including RCTs, non-randomised controlled trials, pretest-posttest designs, and case series'. Two quality assessment scales were used to manage the diverse methods used in these studies. Both scales assessed the overall quality of the study and provided a score for internal validity, external validity, quality of reporting, and the power of the study. The overall

score and sub-scores for each study were used to determine if any studies should be excluded due to poor quality. The quality scores were also used to consider the methodological weaknesses of the studies and how the results of each study should be interpreted. Downs & Black's (1998) scale was designed for randomised and non-randomised designs and was therefore used to rate all the RCTs and non-randomised controlled trials. An adaptation of Downs & Black's scale was developed by Cahill, Barkham & Stiles (2010) for use with practice-based research. Cahill et al.'s scale was used to rate all pretest-posttest designs and case series'. Although the two rating scales are not directly comparable, using rating scales that are appropriate to the type of research being conducted was deemed more suitable than using an inappropriate rating scale for some studies.

The rating scale developed by Downs and Black (1998) consists of 26 yes/no questions and one question regarding the power of the study that can be rated from zero to five. Downs and Black found their checklist to have good inter-rater reliability ($r=0.75$). Cahill et al.'s (2010) adaptation of their rating scale scores the same categories as Downs and Black and had moderate agreement between raters ($k=0.59$). Cahill et al. highlighted that practice-based research makes a significant contribution to our understanding of interventions' effectiveness, however many quality-rating scales penalise these studies for lack of internal validity without acknowledging the importance of their external validity. Rating pretest-posttest designs and case series' using the rating scale by Cahill et al. allows for their external validity to be acknowledged, alongside their limitations.

The first author rated each study independently. A Senior Lecturer at UCL in the Department of Clinical, Educational and Health Psychology, blindly rated a sub-sample of three studies using the Downs and Black's (1998) rating scale and three studies using Cahill et al.'s (2010) rating scale. The percentage agreement between

raters for Downs and Black's scale was 85.2% and the percentage agreement between raters for Cahill et al.'s scale was 71.9%.

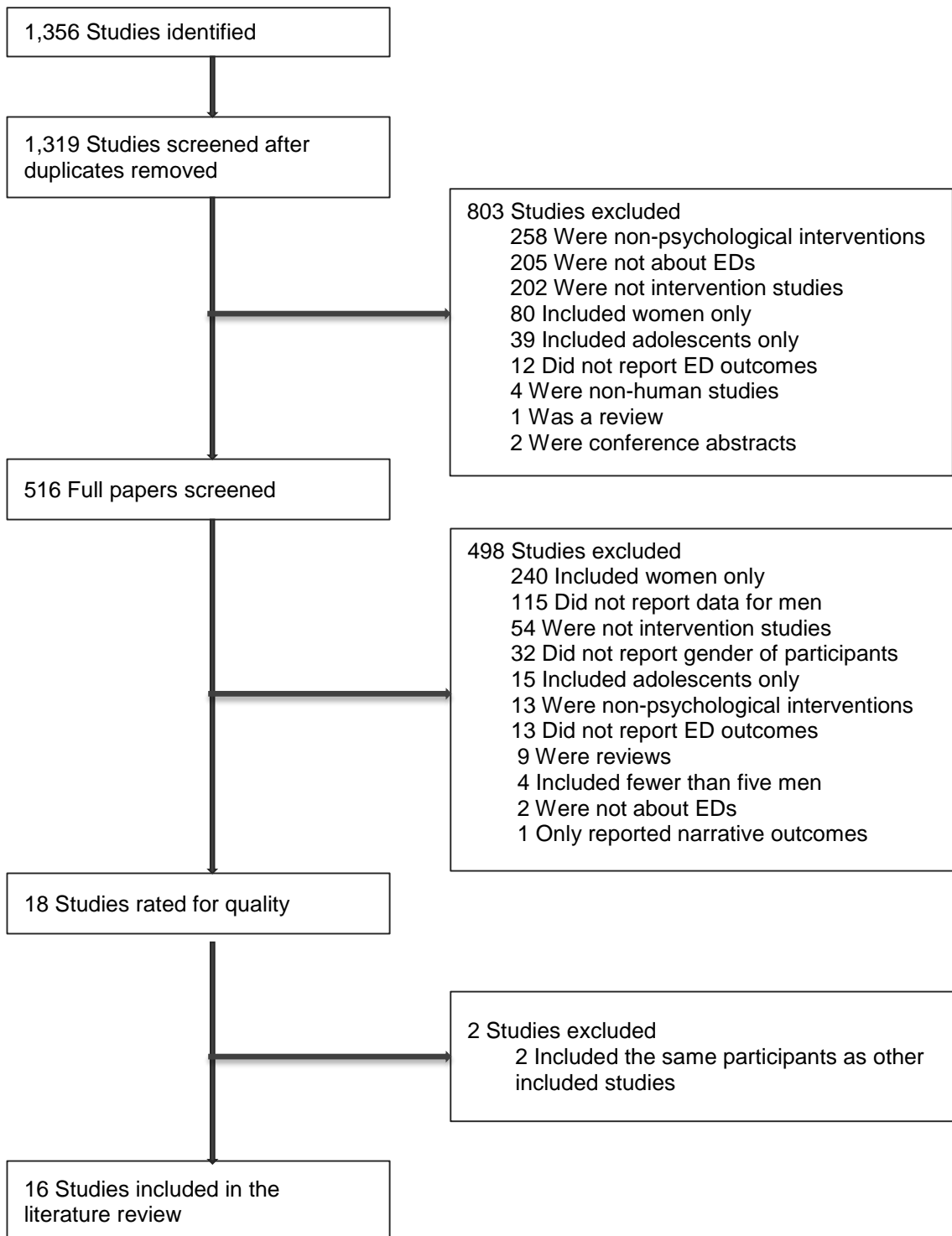
Synthesis of Results

It was decided that a systematic review would be most appropriate for the current review because a meta-analysis was not possible due to the range of ED diagnoses, the range of outcomes measured, and the range of interventions included in the review.

Results

Following the literature search 1,356 studies were identified. These were reviewed and 18 studies meeting the inclusion criteria were found. Two studies were excluded because they reported the same participants as another included study (see Appendix B for a summary of excluded studies). The 16 remaining studies were published between 1984 and 2013.

Figure 1: Flow chart depicting the process of identifying studies



Participant Characteristics

As shown in Tables 5-7, four of the studies included participants with AN, two included those with BN, five included those with BED, and five included participants with a range of ED diagnoses. Five of the studies included men exclusively whereas the other studies included both men and women but reported outcomes for men separately or a comparison between genders. The number of men in each study ranged from seven to 111.

The age of participants was reported in all but one of the studies. The mean age for participants in AN, BN, and mixed diagnosis studies ranged from 18 to 42, with the majority of means falling between 21 and 26. The mean age for BED studies was notably older with mean ages ranging from 44 to 50.8. The ethnicity of participants was only reported in five of the studies. The vast majority of participants were reported to be White (between 89% and 100% of participants). The sexual orientation of the participants was reported in two of the studies. Weltzin et al. (2012) found that 5% of their male participants identified as homosexual and Harvey, Rawson, Alexander, and Bachar (1994) found that 18% of their male participants identified as either homosexual or bisexual.

Study Designs and Quality

The studies included four RCTs, one non-randomised controlled trial, and 11 pretest-posttest designs (as outlined in Tables 5-7). The quality of the RCTs ranged from 59.4% to 87.5% on Downs and Black's (1998) quality assessment scale. As seen in Table 3, the external validity for three of the RCTs was very poor but internal reliability and selection bias was generally high for each of the RCTs.

Table 3

Summary of Quality Ratings for RCTs and Non-Randomised Controlled Trials

Study	Percentage of quality criteria met						Overall %
	Study Design	Reporting %	External validity %	Internal reliability %	Selection bias %	Power	
Ricca et al. (2010)	RCT	81.8%	66.7%	85.7%	100%	5/5	87.5%
Peterson et al. (2009)	RCT	45.5%	0%	71.4%	100%	5/5	65.6%
Munsch et al. (2007)	RCT	81.8%	0%	57.1%	83.3%	3/5	65.6%
Compare et al. (2013)	Non-randomised controlled trial	45.5%	66.7%	71.4%	50%	5/5	62.5%
Grilo et al. (2012)	RCT	72.7%	0%	71.4%	83.3%	1/5	59.4%

Note. Quality ratings based on Downs and Black's (1998) quality assessment tool.

The 11 pretest-posttest design's quality ratings ranged from 50% to 78.1%. Their external validity scores were generally high but they often had poor selection bias scores and low power.

Table 4

Summary of Quality Ratings for Pretest-Posttest Studies

Study	Percentage of quality criteria met						
	Study design	Reporting %	External validity %	Internal reliability %	Selection bias %	Power	Overall %
Fernandez-Aranda et al. (2009)	Pretest-posttest design	81.8%	72.7%	100%	60%	1/5	78.1%
Stoving et al. (2011)	Pretest-posttest design	100%	81.8%	60%	20%	1/5	75%
Weltzin et al. (2012)	Pretest-posttest design	72.7%	81.8%	80%	40%	1/5	71.9%
Weltzin et al. (2007)	Pretest-posttest design	54.6%	90.9%	80%	40%	1/5	68.8%
Woodside & Kaplan (1994)	Pretest-posttest design	63.4%	90.9%	80%	20%	0/5	68.8%
Burns & Crisp (1984)	Pretest-posttest design	63.6%	81.8%	80%	20%	0/5	65.6%
Castellini et al. (2011)	Pretest-posttest design	72.7%	72.7%	80%	20%	1/5	65.6%
Gueguen et al. (2012)	Pretest-posttest design	54.6%	90.9%	60%	40%	1/5	65.6%
Bean et al. (2004)	Pretest-posttest design	54.6%	72.7%	60%	40%	1/5	59.4%
Rigaud et al. (2011)	Pretest-posttest design	54.6%	81.8%	60%	20%	1/5	59.4%
Harvey et al. (1994)	Pretest-posttest design	45.5%	72.7%	40%	20%	1/5	50%

Note. Quality ratings based on Cahill et al.'s (2010) quality assessment tool.

Of the 16 studies included in this review, 12 compared men and women in terms of either dropout or treatment outcomes. Participants were matched in terms of diagnosis but were not matched on any other variables.

Interventions

The studies investigated a range of interventions. The most common intervention was multi-disciplinary (MDT) inpatient programmes. The eight MDT inpatient programmes included in this review (Bean et al., 2004; Burns & Crisp, 1984; Gueguen et al., 2012; Harvey, Rawson, Alexander & Bachar, 1994; Rigaud, Pennacchio, Bizeul, Reveillard & Verges, 2011; Stoving, Andries, Brixen, Bilenberg, & Horder, 2011; Weltzin, Weisensel, Cornella-Carlson & Bean, 2007; Weltzin et al., 2012) differed from one study to another but had common themes, including a nutritional intervention (e.g. nutritional counselling), a psychological intervention (e.g. CBT, family therapy) and psychiatric monitoring. The next most common psychological intervention was CBT in either a group format (Fernandez-Aranda et al., 2009; Munsch et al., 2007; Peterson et al., 2009; Ricca et al., 2010) or individual format (Castellini et al., 2011; Grilo et al., 2012; Ricca et al., 2010). Additional interventions specifically for BED were researched, including Behaviour Weight Loss Therapy (BWLT; Munsch et al., 2007), Emotionally Focused Group Therapy (Compare et al., 2013) and Dietary Counselling (Compare et al., 2013). Finally, one study reported an outpatient MDT programme that consisted of multiple group therapies and nutritional stabilisation (Woodside & Kaplan, 1994).

Outcomes

The outcomes recorded were varied. Weight and/or BMI were used as an outcome measure in the majority of studies (12 out of 16). Validated measures of ED symptoms such as the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn & Beglin, 1994) and the Eating Disorder Inventory (EDI; Garner, Olmstead, & Polivy, 1983) were also used in the majority of studies (11 out of 16) and some

studies used more specific measures of eating behaviours, such as the Emotional Eating Scale (Arnow, Kenardy, & Agras, 1995) alongside global measures of EDs. Recovery was used as an outcome measure in five studies and was consistently defined as a participant no longer meeting diagnostic criteria for an ED. Another outcome measure used in two studies was the Morgan-Russell outcome score (Morgan & Russell, 1975) which classifies ED patients as either having a 'good outcome', an 'intermediate outcome', or a 'poor outcome'. The measure uses weight, nutritional status, socio-economic adjustment, mental state, and sexual activity as indicators of recovery. Two studies used un-validated structured interviews to assess treatment outcome and one study used mortality as a measure of outcome. Secondary outcomes were recorded in many studies and included validated measures of anxiety, depression, self-esteem, and quality of life.

Dropout Results

Seven studies were identified that reported dropout rates for men. Each of the studies also included women and calculated whether or not there was a statistically significant difference between the proportions of men and women who dropped out of treatment. There were two RCTs, one non-randomised controlled trial, and four pretest-posttest studies.

Table 5

Summary of Studies Reporting Dropout Data

Study and country	Population & number of participants	Participant characteristics	Setting	Design	Intervention/s	Outcome measures	Length of follow-up	Main findings
Peterson et al. (2009); USA	Community sample with BED 227 women 32 men	Age: Range from 19-65, <i>M</i> = 47.1 Ethnicity: 96.1% Caucasian Diagnosis: BED	Community sites	RCT	Therapist-led group CBT Therapist-assisted group CBT Self-help group CBT Waiting list control	Objective binge episodes EDE-Q IDS TFEQ RSES IWQOL BMI	6 months and 12 months	Number of dropouts per gender was not reported. No significant gender differences between dropouts and completers.
Munsch et al. (2007); Switzerland	Community sample with BED 71 women 9 men	Age: <i>M</i> = 46.1 Ethnicity: Not stated Diagnosis: BED	University setting	RCT	Group CBT Group Behavioural Weight Loss	Objective binge episodes BMI Recovery from ED EDE-Q BDI BAI Self-efficacy scale Life satisfaction questionnaire	1 year	Number of dropouts per gender was not reported. No significant gender differences between dropouts and completers.

Compare et al. (2013); Italy	Referrals to an ED clinic 94 women 95 men	Age: $M = 50.8$ Ethnicity: Not stated Diagnosis: BED	Eating Disorder Clinic	Non-randomised controlled trial	Emotionally Focused Group Therapy Dietary Counselling Combined Treatment	BES BUT EI ORWELL-97 BMI	6 months	Number of dropouts per gender was not reported. No significant gender differences between dropouts and completers.
Castellini et al. (2011); Italy	Patients attending an ED clinic 740 women 53 men	Age: $M = 31.2$ Ethnicity: Not stated Diagnosis: 165 AN 137 BN 262 BED 137 EDNOS	Eating Disorder Clinic	One group pretest-posttest design	Individual CBT	Recovery from ED Change in ED diagnosis	3 years and 6 years	Number of dropouts per gender was not reported. No significant gender differences between dropouts and completers.
Fernandez-Aranda et al. (2009); Spain	Male referrals to an ED clinic 150 women 19 men	Age: $M = 26.7$ for women, $M = 22.4$ for men Ethnicity: Not stated Diagnosis: BN	Eating Disorder Clinic	One group pretest-posttest design	Group CBT– male only groups	EDI EAT-40 BITE Weekly binge and purge frequency BMI	1 year	26.3% of men and 30% of women dropped out. No significant gender differences between dropouts and completers.

Gueguen et al. (2012); France	Admissions to an inpatient ED unit 601 women 23 men	Age: $M = 26.4$ for women, $M = 26.6$ for men Ethnicity: Not stated Diagnosis: AN	Eating Disorder Inpatient Unit	Pretest-posttest design	Inpatient programme including weight stabilisation, individual psychotherapy and body oriented therapy	BDI EAT-40 EDI SCL-90R BMI Length of hospitalisation	4 – 20 years	16.8% of men and 16.3% of women dropped out. No significant gender differences in dropouts.
Stoving et al. (2011); Denmark	Referrals to an ED unit 977 women 38 men	Age: $M = 21$ for women, $M = 18.9$ for men Ethnicity: Not stated Diagnosis: 356 AN 361 BN 298 EDNOS	Eating Disorder Inpatient Unit	Retro-spective cohort study	Inpatient programme including family therapy, individual psychotherapy and nutritional treatment	Remission (defined as weight restoration and no reported bingeing or purging behavior in the last 6 months)	1 – 11 years	Overall 28.9% of men and 18.7% of women dropped out. More men with AN dropped out (41.2%) than woman with AN (17.7%) but this difference did not meet statistical significance.

Note. BMI= body mass index

Measures: EDI= Eating Disorder Inventory (Garner, Olmstead & Polivy, 1983), EDE-Q= Eating Disorder Examination Questionnaire (Fairburn & Beglin, 1994), BDI= Beck Depression Inventory (Beck & Steer, 1996), BAI= Beck Anxiety Inventory (Beck, Epstein, Brown, & Steer, 1988), EAT-40= Eating Attitudes Test 40 (Garner & Garfinkel, 1979), SCL-90R= Symptom Checklist-90 Revised (Derogatis, 1977), BITE= Bulimia Investigatory Test Edinburgh (Henderson & Freeman, 1987), RSES= Rosenberg Self-Esteem Scale (Rosenberg, 1979), BES= Binge Eating Scale (Gormally, Black, Daston, & Rardin, 1982), EI= Eating Inventory (Stunkard & Messick, 1988), IDS= Inventory of Depressive Symptomology (Rush et al., 1986), IWQOL= Impact of Weight on Quality of Life (Kolotkin, Crosby, Kosloski, & Williams, 2001), BUT= Body Uneasiness Test (Cuzzolaro, Vetrone, Marano, & Garfinkel, 2006), TFEQ= Three Factor Eating Questionnaire (Stunkard & Messick, 1985).

RCTs. Both of the RCTs reporting dropouts for men were studies investigating BED (Peterson et al., 2009; Munsch et al., 2007). Both of the RCTs used ITT and both had a follow-up period of 12 months. Only Peterson et al. reported using blind assessors to measure the main outcomes of the intervention. Overall, the two RCTs had the same quality rating (65.6%).

Peterson et al. (2009) found that their therapist-led CBT group achieved lower dropout rates than both the therapist-assisted CBT group and the self-help group. There were no differences between genders on dropout rates. Munsch et al. (2007) found that both group CBT and behavioural weight loss therapy (BWLTL) led to significant improvements in binge eating and BMI, but CBT was superior at improving binge-eating symptoms while BWLTL was superior at reducing BMI. They found no significant difference in number of dropouts between treatment conditions and found no significant gender difference between completers and dropouts.

Non-randomised controlled trials. One non-randomised clinical trial was identified that reported dropouts for men (Compare et al., 2013). Participants were not randomised to treatment conditions but a clinician decided which treatment would be most appropriate, based on the participant's presentation, their preference, and their questionnaire scores. Raters were not reported to be blind to treatment allocation and data was analysed for completers rather than using an ITT analysis. There was more evidence of selection bias and poorer internal validity in this study than in the RCTs described above, but its external validity was higher resulting in only a slightly lower overall quality rating (62.5%). After a six-month follow-up period Compare et al. found that ED symptomology improved in both the EFT and combined treatment conditions but not in the Dietary Counselling condition. They also found a higher dropout rate in the Dietary Counselling condition (27% dropout) compared to EFT (12.7% dropout) and combined treatment (0% dropout).

They found no significant gender differences between dropouts and treatment completers.

Pretest-posttest designs. Four pretest-posttest studies were found that reported dropout rates for men, all of which compared men's and women's dropout rates (Castellini et al., 2011, Fernandez-Aranda et al., 2009; Gueguen et al., 2012; Stoving et al., 2011). All of the studies were conducted in ED services and received high external validity scores using Cahill et al.'s (2010) rating scale. Fernandez-Aranda et al.'s study had the highest quality rating (78.1%), closely followed by Stoving et al. (75%). Castellini et al. and Gueguen et al.'s studies both received lower overall ratings of 65.6%, largely due to poorer reporting. The treatment outcome data for both studies will be discussed in the next section.

Castellini et al. (2011) found no significant gender differences between dropouts and completers for participants who received individual CBT. Fernandez-Aranda et al. (2009) also found no significant difference in dropouts between men and women receiving group CBT; 26.3% of men dropped out compared to 30% of women.

Gueguen et al. (2012) and Stoving et al. (2011) reported outcomes for participants who attended multi-disciplinary treatment programmes including individual psychological therapy. Gueguen et al. found the dropout rates were comparable between men and women; 16.8% of men dropped out and 16.3% of women dropped out. Stoving et al. found that dropout rates were similar for men and women with BN (24.2% of women and 20% of men dropped out) and EDNOS (13.1% of women and 18.8% of men dropped out). Considerably more men with AN dropped out (41.2%) than women with AN (17.7%), but this difference did not reach statistical significance following a Bonferroni correction. Stoving and colleagues suggested that men might drop out of ED interventions because they do not feel comfortable in a treatment that they perceive is designed for women. Although this

may be true, there was not enough evidence from this study to conclude that men dropout of ED interventions significantly more frequently than women.

The seven studies described above have varying methodologies and methodological quality but their findings were consistent in failing to find significant differences in dropout between men and women.

Treatment Outcome Results

Twelve studies were identified that reported treatment outcomes for men with EDs. Two of these were RCTs (see Table 6) and ten were pretest-posttest designs (see Table 7).

Table 6

Summary of RCTs Reporting Outcome Data

Study and country	Population & number of men	Participant characteristics	Setting	Design	Intervention/s	Outcome measures	Length of follow-up	Main findings
Grilo, Masheb & Crosby (2012); USA	Community sample with BED 84 women 24 men	Age: Range from 21 to 59, <i>M</i> = 44	University setting	RCT	Individual CBT & Placebo	EDE-Q BDI RSES BMI	End of treatment	Outcomes for men and women were not reported separately.
		Ethnicity: 89% Caucasian, 8% African American, 3% Hispanic American.			Individual CBT & Fluoxetine 60mg daily			Predictor and moderator analyses found that male gender predicted decreases in BMI.
		Diagnosis: BED			Placebo			
					Fluoxetine 60mg daily			
Ricca et al. (2010); Italy	Referrals to an ED clinic 127 women 17 men	Age: <i>M</i> = 46.9 Ethnicity: All Caucasian Diagnosis: BED	Eating Disorder Clinic	RCT	Individual CBT Group CBT	Recovery from ED SCL-90 BDI EDE-Q EES STAI BMI	Three years	Outcomes for men and women were not reported separately. There were no significant differences between men and women on the main outcome measures.

Note. Measures: EDE-Q= Eating Disorder Examination Questionnaire (Fairburn & Beglin, 1994), BDI= Beck Depression Inventory (Beck & Steer, 1996), SCL-90R= Symptom Checklist-90 Revised (Derogatis, 1977), RSES= Rosenberg Self-Esteem Scale (Rosenberg, 1979), STAI= State Trait Anxiety Inventory (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), EES= Emotional Eating Scale (Arnow, Kenardy, & Agras, 1995)

RCTs. The two RCTs reporting treatment outcomes for men were researching BED (Grilo et al., 2012; Ricca et al., 2010). Both RCTs had blind assessors of the main outcome measures and Grilo et al. used a double-blind placebo-controlled procedure to ensure that participants and assessors were blind as to whether they were receiving Fluoxetine or placebo. Ricca et al. used ITT, whereas Grilo et al. only reported a completer analysis. Ricca et al. had an acceptable follow-up period of three years whereas Grilo et al. only reported outcomes at the end of treatment. The quality rating of Grilo et al.'s study was 59.4% whereas Ricca et al.'s study was 87.5%. Grilo et al.'s overall quality rating was lower due to a poor external validity rating.

Grilo et al. (2012) were investigating predictors and moderators of response to CBT and Fluoxetine. They found that several demographic characteristics predicted treatment outcomes such as older age at BED onset predicting higher remission rates and younger age at treatment presentation predicting improvements in binge-eating frequency. They found that male gender predicted significantly greater decreases in BMI, meaning that men lost more weight than women following the intervention. Ricca et al. (2010) randomly assigned participants to receive either group or individual CBT. At the end of treatment they found that there was a significantly higher recovery rate in individual CBT than group CBT, however this difference had disappeared at their 3-year follow-up. They compared men and women on the main outcome measures and found no significant differences in treatment outcomes.

Pretest-posttest designs. Of the ten pretest-posttest studies identified, three investigated treatment outcomes in AN, two investigated treatment outcomes in BN and five included participants with varying diagnoses (see Table 7).

Table 7

Summary of Pretest-Posttest Designs Reporting Outcome Data

Study and country	Population & number of participants	Participant characteristics	Setting	Design	Intervention/s	Outcome measures	Follow-up length	Main findings
Bean et al. (2004); USA	Referrals to an ED unit 26 women 7 men	Age: Range from 13 to 29, $M = 18$ Ethnicity: Not stated Diagnosis: AN	Inpatient Eating Disorder Unit	One group pretest-posttest design	Residential programme including CBT, family therapy, interpersonal therapy, nutritionist sessions and art therapy	Weight 23-item phone survey designed by medical staff to assess ED symptoms	12-21 months after discharge	On average men had a net gain of two BMI points; women had a net gain of one. Both men and women significantly increased in weight from admission to FU and from discharge to FU.
Rigaud et al. (2011); France	Referrals to an ED unit 462 women 22 men	Age: Range from 16-43, $M = 22.8$ Ethnicity: Not stated Diagnosis: AN	Inpatient Eating Disorder Unit	One group pretest-posttest design	Inpatient programme including dietary counselling, interpersonal psychotherapy and CBT.	Mortality rate Recovery from ED EDI EDE-Q BDI HAS Morgan-Russell outcome score	10 – 21 years	63.6% of men recovered, 27% had a 'relatively good' outcome and 9% had a severe outcome. Recovery rates for men were comparable to those for women. The 2-year relapse rate was not explained by gender.

Burns & Crisp (1984); UK	Consecutive male referrals to second author 27 men	Age: $M = 21.6$ Ethnicity: Not stated Diagnosis: AN	Psychiatry clinic	Pretest-posttest design	Inpatient setting that offered re-feeding combined with individual and family psychotherapy. Outpatient psychotherapy	Weight Morgan-Russell outcome score	2-20 years after discharge	44% had a 'good' outcome, 26% had an 'intermediate' outcome and 30% had a 'poor' outcome.
Fernandez-Aranda et al. (2009); Spain	Referrals to an ED clinic 150 women 19 men	Age: $M = 26.7$ for women, $M = 22.4$ for men Ethnicity: Not stated Diagnosis: BN	Eating Disorder Clinic	One group pretest-posttest design	Group CBT–gender specific groups	EDI EAT-40 BITE Weekly binge and purge frequency BMI	1 year	66.7% of men and 51% of women no longer met BN diagnostic criteria at end of treatment. At the 1-year FU men had a 28.6% probability of suffering from BN or EDNOS (women had a 25.7% probability).
Harvey et al. (1994); USA	Male treatment completers from an ED programme 50 men	Age: $M = 42$ Ethnicity: 98% Caucasian, 2% African American Diagnosis: BN	Inpatient Eating Disorder Unit	Pretest-posttest design	Six-week inpatient programme including group therapy, family therapy and behavioural training.	Structured interview asking about eating related behaviours and self-ratings of mental health.	6 - 27 months	Men showed significant decreases in the frequency of binge eating and 'ED related behaviours' at FU. 60% had a 'good' outcome and 40% had a 'poor' outcome.

Weltzin et al. (2007); USA	Male referrals to an ED clinic 104 men	Age: $M = 23$ Ethnicity: Not stated. Diagnosis: 58 AN, 30 BN, 16 EDNOS.	Inpatient Eating Disorder Unit	One group pretest-posttest design	Inpatient programme including CBT, interpersonal psychotherapy, family therapy, psychodynamic therapy and nutritional therapy	Weight EDI	6 - 15 months	Men's scores on ED measures significantly improved by the end of treatment and these improvements were maintained at FU.
Woodside & Kaplan (1994); Canada	Referrals to an ED clinic 334 women 15 men	Age: Not stated Ethnicity: Not stated Diagnosis: 126 AN 223 BN	Eating Disorder Service	One group pretest-posttest design	Day hospital programme including multiple group therapies (psycho-educational, CBT & interpersonal), family therapy and nutritional stabilisation.	Binge and purge frequency EDI EAT-40 BDI HAS RSES Family Assessment Measure Weight	End of treatment	28.6% of men and 39.9% of women had a 'good' outcome. Treatment outcomes were not significantly different for men and women.
Weltzin et al. (2012); USA	Male referrals to an ED unit 111 men	Age: Range from 12-60, $M = 24$ Ethnicity: 89% White, 1% Hispanic, 1% Black, 2% Asian, 7% Other Diagnosis: 64 AN 24 BN	Inpatient Eating Disorder Unit	One group pretest-posttest design	Inpatient programme including male only group therapy, CBT, and nutritional therapy as appropriate.	EDI EDE-Q BDI STAI CAC BMI	End of treatment	Men had significantly improved scores on ED measures at end of treatment.

23 EDNOS

Stoving et al. (2011); Denmark	Referrals to an ED unit 977 women 38 men	Age: <i>M</i> = 21 for women, <i>M</i> = 18.9 for men Ethnicity: Not stated Diagnosis: 356 AN 361 BN 298 EDNOS	Inpatient Eating Disorder Unit	Retrospective cohort study	Inpatient programme including family therapy, individual psychotherapy and nutritional treatment	Remission (defined as weight restoration and no reported bingeing or purging behavior in the last 6 months)	1 – 11 years	The median remission times: AN – 7 years in women, 3 years in men EDNOS – 6 years in women, 3 years in men Remission rates: AN – 39% for women, 59% for men EDNOS – 45% for women, 77% for men.
Castellini et al. (2011); Italy	Referrals to an ED clinic 740 women 53 men	Age: <i>M</i> = 31.2 Ethnicity: Not stated Diagnosis: 165 AN 137 BN 262 BED 137 EDNOS	Eating Disorder Clinic	One group pretest-posttest design	Individual CBT	Recovery from ED Change in ED diagnosis	3 years and 6 years	Outcomes for men and women were not reported separately. Relapse in BED was associated with male gender.

Note. FU= follow-up. Measures: EDI= Eating Disorder Inventory (Garner, Olmstead & Polivy, 1983), EDE-Q= Eating Disorder Examination Questionnaire (Fairburn & Beglin, 1994), BDI= Beck Depression Inventory (Beck & Steer, 1996), HAS= Hamilton Anxiety Scale (Hamilton, 1959), EAT-40= Eating Attitudes Test 40 (Garner & Garfinkel, 1979), SCL-90R= Symptom Checklist-90 Revised (Derogatis, 1977), BITE= Bulimia Investigatory Test Edinburgh (Henderson & Freeman, 1987), RSES= Rosenberg Self-Esteem Scale (Rosenberg, 1979), STAI= State Trait Anxiety Inventory (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), CAC= Compulsive Activity Checklist (Freund, Skeketee & Foa, 1987).

Anorexia nervosa. All three of the studies investigating interventions for AN reported outcomes from multi-disciplinary inpatient treatment programmes. The quality ratings for these studies ranged from 59.4% (Bean et al., 2004 & Rigaud et al., 2011) to 65.6% (Burns & Crisp, 1984). All had poor selection bias ratings and low power ratings.

Bean et al. (2004) completed a phone survey with each participant between 12 and 21 months after discharge from a residential MDT treatment programme and asked them about their ED symptoms, their current weight, their work and social adjustment, and any depressive symptoms. This questionnaire was designed by the research team and was not a validated measure, so the validity and reliability of the data from the questionnaires is not known. They found that both men and women showed significant weight gain from discharge to follow-up. They also found that women were more likely than men to have been hospitalised since discharge.

Rigaud et al. (2011) reported the long-term prognosis of 484 participants who were admitted to an inpatient ED unit. They defined recovery as having a healthy body weight and normal eating behaviour including eating regular meals, no excessive fear of fatty foods, and no obsession with weight or food. At a 13-year follow-up they found that 60.3% of the participants were recovered, 25.8% had a 'relatively good' outcome, and 12.8% had either a 'poor' or 'severe' outcome. Rigaud and colleagues reported the recovery rates for men but they did not report the recovery rates for women separately. This limits a direct comparison between men and women and only allows men's recovery rates to be compared with those of the whole sample (63.6% of men were recovered, 27% had a relatively good outcome, and 9% had a severe outcome). The men's recovery rates were very similar to the whole sample's recovery rates, suggesting that men's recovery rates did not differ substantially from women's. Rigaud et al. investigated predictors of the 2-year

relapse rate and predictors of recovery and found gender did not predict either recovery or relapse.

Burns and Crisp (1984) reported the treatment outcomes for 20 participants who received a multi-disciplinary inpatient programme and two participants who received outpatient psychotherapy. The remaining five participants were not seen again following their assessment. Because of the differing levels of treatment the clients received it is unclear how much the outcomes reported are dependent on the treatment. Burns and Crisp assessed outcome using the Morgan-Russell outcome score to classify participants as having a 'good outcome', an 'intermediate outcome', or a 'poor outcome'. They compared these results to two case series of female patients reported by Hsu, Crisp and Harding (1979) and Morgan and Russell (1975) and concluded that the treatment outcomes for men were comparable to those reported for women, however no statistical comparison was made. The Morgan-Russell outcome score uses menstrual function as an outcome category so Burns and Crisp substituted this with sexual activity for men. Regular sexual activity was coded as an indicator of a 'good outcome'. However irregular or absent sexual activity could be dependent on many factors, such as the individual's relationship status and their pre-morbid sex drive and is therefore not a good measure of ED outcomes in men. This study is the oldest included in this review and it could be argued that its design and outcome measures are out-dated. The results from this study should therefore be interpreted cautiously.

Bulimia nervosa. Of the two studies reporting treatment outcomes for men with BN, Harvey et al.'s (1994) study had the lowest quality rating of the studies included in this review (50% quality rating). Harvey and colleagues used a structured interview rating ED symptoms and self-ratings of mental health to follow-up men who had completed an inpatient treatment programme. They gathered baseline data on ED symptoms such as bingeing, purging, and laxative abuse from

medical records but asked participants to rate retrospectively their baseline measures of restricting, fasting, and sneak eating at follow up. This may have introduced bias into the reporting of these symptoms. They classified the participants as either having a good outcome (defined as binge eating, grazing, or vomiting less than once a week) or a poor outcome (defined as binge eating, grazing, or vomiting at least once a week). Harvey and colleagues did not use any validated measures to report treatment outcomes and their classification of good and poor outcomes is limited in its scope because it only includes behaviours. Harvey et al. concluded that men responded well to treatment but because of the poor quality rating of this study and its methodological weaknesses, the results should be interpreted cautiously.

Fernandez-Aranda et al. (2009) had a quality rating of 78.1%. They compared men and women receiving group CBT for BN in gender specific treatment groups. Although all groups followed the same protocol, Fernandez-Aranda and colleagues reported that different topics were highlighted more in the men's group than the women's groups and vice versa. For example, they reported that dealing with stress, over-evaluation of muscularity, and homosexuality were issues emphasised in male treatment groups in order to meet the clients' needs. They found that both men and women showed significant improvements on various ED symptom measures and there was no significant difference in the probability of men and women suffering from either BN or EDNOS at the one-year follow-up. They concluded that group CBT treatment is similarly effective for men as it is for women.

Mixed diagnosis studies. Four of the five mixed diagnosis studies investigated MDT treatment programmes (Stoving et al., 2011; Weltzin et al., 2007; Weltzin et al., 2012; Woodside & Kaplan, 1994). All of them found that men had significant improvements in their ED symptoms. Woodside and Kaplan's study had a quality rating of 68.8%. They found that men and women had comparable scores on

various psychometric measures, including measures of ED symptoms, depression, anxiety, and self-esteem, at both admission and discharge. They concluded that men can be successfully treated in a predominantly female environment. Stoving and colleagues also compared men and women and found that men with AN and men with EDNOS had shorter remission times than women, and men with AN and men with EDNOS had higher remission rates than women. Hence, they found that men with AN and EDNOS recover more quickly than women and are more likely to remain in remission than women. Stoving et al.'s study had a quality rating of 75% and was one of the highest quality pretest-posttest designs.

Weltzin et al.'s (2007) study had a quality rating of 68.8%, with high scores on external validity and internal reliability, but a lower score on selection bias. They compared weight and ED symptoms at admission and discharge for 104 men with AN, BN, or EDNOS. They found that there was a significant reduction in ED symptom severity (as measured by the EDI) from admission to discharge. They compared these treatment outcomes to 35 women with AN, BN, or EDNOS who were residents at the same hospital. They found that females had significantly higher scores on the EDI than males at admission, discharge, and follow-up, but both males and females made significant and comparable improvements. Weltzin et al. (2007) obtained follow-up information from 23 of the 104 male participants and found that improvements in the severity of the men's ED symptoms were maintained at follow-up. However, because they only followed up a small sample of the participants, this finding may not be representative of the other participants in the study. Weltzin et al. (2012) had a quality rating of 71.9% and had a large sample size (111 men), but they only reported end of treatment outcomes. They found that men's scores on measures of ED symptoms, depression, and anxiety had significantly improved at the end of the intervention. Weltzin and colleagues (2012) emphasised the importance of the male treatment environment that they provided, in

which group programmes and eating times were separate from women. They suggested that a male treatment setting allowed men's experience of EDs to be normalised and challenged the perception of EDs as 'female disorders'. However they did not report any comparisons to women on the treatment programme.

Castellini et al. (2011) conducted a large follow-up study of participants who had received individual CBT. They found the overall recovery rates for AN, BN, BED, EDNOS-A, and EDNOS-B were 52.1%, 49.6%, 59.2%, 56.5%, and 63.5%, respectively. They did not report separate recovery rates for men and women but did find that male gender was a predictor of relapse for BED, but not any other ED diagnosis.

Discussion

This systematic review is a broad review encompassing different ED diagnoses and different psychological interventions. This was necessary due to the paucity of research in the ED field including men and reporting outcomes for men. This review provides an overview of the current research including men. It also starts to answer the questions of what the treatment outcomes and dropout rates are for men with EDs following psychological interventions, and additionally whether these outcomes are similar to those for women with EDs.

The seven studies reporting dropout data found no significant differences between men and women in the likelihood of dropping out of an intervention. Three of those studies were investigating psychological interventions for BED (Peterson et al., 2009; Munsch et al., 2007; Compare et al., 2013), one was investigating BN (Fernandez-Aranda et al., 2009), one was studying AN (Gueguen et al., 2012), and two included multiple diagnoses (Castellini et al., 2011; Stoving et al., 2011). Drawing firm conclusions from a small number of studies is difficult, however the studies included in this review suggest that men do not have significantly higher rates of drop out from treatment than women. This is reassuring given suggestions

that treatments may be unsuitable for men or biased against them because of the preponderance of women in most programmes.

Swift and Greenberg (2012) conducted a meta-analysis investigating the rates of dropouts from adult psychotherapy. They reviewed 669 studies and found the highest dropout rates were from studies with participants with personality disorders and from studies with participants with EDs. They found the average dropout rate for ED studies was 23.9%. The dropout rates for men reported in the studies in this review ranged from 16.8% to 28.9% (Fernandez-Aranda et al., 2009; Gueguen et al., 2012; Stoving et al., 2011), suggesting that men's dropout rates are not dissimilar to those found in other ED research studies.

There were 12 studies reporting treatment outcomes for men with EDs. Two of those studies were RCTs researching interventions for BED (Grilo et al., 2012; Ricca et al., 2010). Ricca and colleagues found no significant differences in treatment outcomes between men and women, and Grilo et al. found that male gender predicted decreases in BMI at the end of treatment. These two studies suggest that men with BED have comparable treatment outcomes to women with BED, however the low number of studies reporting outcomes for men with BED mean this result should be interpreted cautiously.

There were three pretest-posttest studies researching AN, all of which evaluated outcomes following inpatient MDT programmes (Bean et al., 2004; Burns & Crisp, 1984; Rigaud et al., 2011). These studies found that men with AN make similar progress to women in inpatient treatment programmes. One of the studies (Bean et al.) concluded that men could be successfully treated in an inpatient environment alongside women.

Two pretest-posttest studies investigated treatment outcomes for men with BN (Fernandez-Aranda et al., 2009; Harvey et al., 1994). Both studies found that men made significant improvements following treatment and Fernandez-Aranda et al. found that men's outcomes were comparable to women's outcomes. These two studies suggest that men have similar treatment outcomes to women, but because there were only two studies, further research is required to draw firmer conclusions.

There were five pretest-posttest studies that included multiple ED diagnoses (Weltzin et al., 2007; Castellini et al., 2011; Weltzin et al., 2012; Stoving et al., 2011; Woodside & Kaplan, 1994). These studies also provided some evidence that men and women have similar treatment outcomes, but also suggested that long term remission rates for AN and EDNOS may be better in men whereas long term outcomes for men with BED may be worse.

Overall, the studies included in this review suggest that men are no more likely to drop out of psychological interventions than women. They also suggest that men's ED symptoms significantly improve following psychological interventions and men's treatment outcomes are comparable to those achieved by women with EDs.

Limitations

There are a number of limitations to this review. Because of the lack of research in this field the review took a broad focus and encompassed research investigating different ED diagnoses. The consequence of this was that there was a reasonable number of studies in total but only a few studies representing each ED diagnosis. It is therefore difficult to draw conclusions about specific ED diagnoses and it is only possible to summarise the evidence for EDs as a whole.

Another limitation of this review is that a number of the studies included had small sample sizes of men. The small sample sizes limit the generalisability of the results to the population of men with EDs. Small sample sizes also mean that there

is less power to find a significant difference, if one exists. It is therefore possible that there were differences between men and women's treatment outcomes, in the studies that compared genders, but these were not found due to lack of power.

Although studies did not need to compare genders to be included in this review, 12 out of the 16 studies did compare men and women. For the four studies that did not compare genders it was only possible to comment on whether the intervention was effective for men; it was not possible to conclude whether this was comparable to its effectiveness for women. Of the 12 studies that did compare men and women, none of them matched participants on variables such as severity of ED, age at onset of ED, or duration of ED. Men with EDs have been found to have a later onset of their ED, present to services after a shorter duration of illness, have significantly more psychiatric co-morbidities, and to have significantly worse social functioning (Bramon-Bosch, Troop, & Treasure, 2000). Matching men and women on variables such as these ensures that any differences identified are due to gender, rather than due to other factors, such as duration of illness. The lack of matching used in the studies reviewed is therefore a limitation of their designs.

Another limitation of this review is the quality of studies included. The majority of the studies in this review were pretest-posttest designs. Non-randomised controlled trials and pretest-posttest designs have poorer internal validity than RCTs because they cannot control selection bias through randomisation. A further limitation of the one-group pretest-posttest design is that there is no control group so it is harder to know whether any changes observed are the result of the intervention or whether they are due to factors independent of the intervention (e.g. spontaneous remission). RCTs, however, are able to control for selection bias and have greater internal validity and can therefore be used to make inferences about causality (Barker, Pistrang, & Elliott, 2002). Effectiveness studies, like many of the pretest-posttest studies included in this review, have the advantage of being conducted in

naturalistic clinical settings, using clinicians without additional training and supervision. The pretest-posttest studies included in this review generally had higher external validity scores on the quality rating tools than the RCTs. Three out of the five RCTs met 0% of the criteria evaluating external validity and two of the RCTs met 66.7% of the criteria. This is compared to the pretest-posttest designs that met between 72.7% and 90.9% of the criteria evaluating external validity. It should be noted that different quality rating tools were used to evaluate RCTs and pretest-posttest designs so they may not be directly comparable. However, Cahill et al.'s (2010) rating tool is an adaptation of Downs and Black's (1998) rating tool so the criteria evaluating external validity are broadly similar in both.

A potential limitation of the studies included in this review is that none of them used male-specific ED measures. As discussed above, men with EDs present as broadly similar to women with EDs but some important differences exist. Men are typically more driven to achieve a muscular physique than a thin physique (Bean et al., 2004) and are usually less concerned by fatness. Using male-specific ED measures could help to capture issues to be addressed in therapy and may better evaluate areas of therapeutic change. Greenberg and Schoen (2008) recommend a number of male-specific ED measures such as the Drive for Muscularity scale (McCreary & Sasse, 2000) and the Male Body Attitudes scale (Tylka, Bergeron, & Schwartz, 2005). As previously noted, many widely used ED measures were developed using female participants. It is therefore possible that the studies included in this review were unable to fully capture men's experiences of EDs and their treatment outcomes because there were limitations to the measures used.

Finally, because of the broad focus of this review and the lack of research including men with EDs, this review is unable to answer specific questions such as whether some psychological interventions are more effective with men than others. This is an important question requiring further study.

Clinical Implications

The results of this review suggest that men engage in therapy for EDs and experience significant improvements in their ED symptoms, which appear to be comparable to the improvements women experience. It is therefore important that men are offered equivalent interventions to women so they can access the support they need in a timely manner. To ensure that EDs in men are recognised, clinicians should be aware of the differences in presentation for some men with EDs, such as a focus on muscularity and using excessive exercise more than other methods of weight control. Using male specific ED measures in clinical practice may help identify EDs in men and may be more appropriate tools for measuring therapeutic change. Stanford and Lemberg (2014) developed the Eating Disorder Assessment for Men (EDAM) which is a 50-item questionnaire designed to identify EDs in men. The EDAM correctly identified 82.1% of EDs in their sample and was found to have good reliability. This may be an appropriate measure to use when assessing EDs in men.

Some of the studies in this review, such as Woodside and Kaplan (1994) and Bean et al. (2004), concluded that men could be successfully treated in majority-female environments without specific amendments to therapeutic interventions. Whereas others, such as Fernandez-Aranda et al. (2009) and Weltzin et al. (2012) concluded that treating men in all-male treatment groups and adapting the treatment to meet the needs of men was important to the success of the intervention. To our knowledge, there have been no studies directly comparing gender-specific and gender-neutral ED interventions for men. The results of many of the studies in this review concluded that men's treatment outcomes are comparable to women's treatment outcomes, even when the treatment is not adapted. However it should be noted that because many of the studies included in this review are pretest-posttest designs, they do not monitor treatment adherence. It is therefore possible that men

were receiving slightly different treatment to women because therapists often make ad hoc adaptations to their therapy based on the needs of the client. Because this was not systematically recorded in the studies reviewed, it is not possible to claim that men and women received indistinguishable interventions. It is not therefore possible to conclude whether gender specific interventions are superior to gender neutral interventions. However, acknowledging and discussing male-specific issues in therapy should be part of good clinical practice. It should also be noted that running male-only interventions, such as groups, might not always be practical in ED services because of the lower numbers of male referrals.

Research Implications

Further research in this field would be valuable, particularly more research including men. Many studies still exclude men from ED research, whereas including men and reporting any differences in presentation and outcomes could improve our understanding of men's experience of EDs and the most effective interventions.

Larger scale studies would also benefit this research field because many of the studies in this review had small numbers of men. It was also notable that the only RCTs meeting inclusion criteria for this review were investigating interventions for BED. RCTs investigating other EDs that report men's outcomes would allow for stronger conclusions to be drawn because of the more stringent methodology used in RCTs. A design such as an RCT could match participants on variables such as duration of illness, and severity of ED symptoms to ensure that any differences between men and women that are found are due to gender, not other variables.

This review only included studies with adult participants. Further research could investigate whether treatment outcomes and dropout rates for adolescent males is similar to adolescent females. Further research could also compare

gender-specific and gender-neutral interventions for men to investigate whether male-specific content in therapy improves treatment outcomes and dropout rates.

Conclusions

This review found that psychological interventions have a significant impact on men's ED symptoms and men achieve similar treatment outcomes to women when offered therapy. It also suggests that men are no more likely to drop out of psychological interventions than women. This review had a number of limitations and further research is required to support or challenge its conclusions. However, it can be safely concluded that male EDs are an important clinical phenomena that must be identified and treated with the same consideration as female EDs.

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Part Two: Empirical Paper

A Brief DBT Skills Group for Bulimia Nervosa: A Feasibility Study

Abstract

Aims: To assess the feasibility of a 12-week Dialectical Behaviour Therapy (DBT) skills group for women with bulimia nervosa (BN), with or without a co-morbid personality disorder (PD).

Method: Women meeting diagnostic criteria for BN were recruited from an NHS Trust and from a University. The DBT skills covered in the group were mindfulness, emotional regulation, and distress tolerance, all of which were adapted for BN. Retention, appropriateness of measures, and the acceptability of the intervention were recorded to assess feasibility. Eating disorder symptoms, PD symptoms, and functional impairment were measured throughout the intervention and at a one-month follow-up to assess clinical effectiveness.

Results: Twenty-nine participants started the intervention and seven dropped out before the end of the group. At the end of the intervention there were significant reductions in weekly binge-purge frequency. There were also significant improvements in general eating disorder symptoms, emotional eating, and functional impairment; and these differences were maintained at follow-up. Participants reported that the intervention was acceptable and effective.

Conclusions: A brief DBT skills group is a promising intervention for BN that requires further study.

Introduction

Bulimia nervosa (BN) is an eating disorder (ED) characterised by episodes of binge eating followed by compensatory behaviours such as purging. The *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*; American Psychiatric Association, 2013) defines binge eating as consuming, in a discrete period, more food than most people would consume in a similar time period, with a sense of loss of control over eating. Compensatory behaviours are understood to be any behaviour performed to try and prevent weight gain following a binge, such as vomiting, excessive exercise, and laxative use. To be diagnosed with BN an individual's self-evaluation must be highly influenced by their shape and/or weight. This includes excessive concern about one's weight and/or shape, and weight and/or shape having a strong influence on an individual's mood and perceived self-worth (Fairburn, Cooper, & Shafran, 2003).

The lifetime prevalence of BN in Western countries has been estimated to be between 0.9% and 4.6% (Wade, Keski-Rahkonen & Hudson, 2011). The relatively high prevalence of BN means that effective and accessible interventions are essential. The most recent NICE guidelines for EDs (NICE, 2004), which are currently under revision, highlight the importance of psychological interventions. The guidelines for BN recommend that the first step in treatment is inviting the client to engage in an evidence-based self-help programme but if this is not sufficient, then to offer 16-20 sessions of Cognitive Behavioural Therapy-BN (CBT-BN; Fairburn, Marcus, & Wilson, 1993). CBT-BN is an adapted version of CBT developed by Fairburn and colleagues that focuses on the beliefs, thoughts, and behaviours underlying EDs. Fairburn and colleagues developed a cognitive-behavioural model of the maintenance of BN that proposed that over-evaluation of shape, weight, and eating leads to strict dieting and weight-control behaviours. When an individual is restricting their diet they are more likely to binge eat because they are hungry and feel dissatisfied. Individuals usually feel guilty after binge eating, and because they

overvalue shape and weight they are more likely to engage in compensatory behaviours to try to counteract the effect of bingeing. However compensatory behaviours reinforce binge eating because individuals view the compensatory behaviors as effective strategies for avoiding weight gain, which reduces the perceived negative consequences of bingeing.

The cognitive behavioural theory of BN has been updated by Fairburn, Cooper, and Shafran (2003) who proposed a 'trans-diagnostic' model of EDs. They added a number of factors to the formulation of EDs, one of which was 'mood intolerance'. Fairburn and colleagues suggested that some individuals find it difficult to tolerate and modulate their emotional states and 'mood intolerance' could be a triggering and maintaining factor for their ED. The affect regulation model of BN expands on the concept of mood intolerance and proposes that individuals with BN experience more negative emotions and find them more difficult to manage than people without a history of an ED (Safer, Telch & Chen, 2009). The model suggests that when an individual experiences a strong emotion, that they feel unable to cope with, they binge eat to try and avoid or suppress that emotion. The individual then feels guilt and shame, which is similarly intolerable, and uses compensatory strategies to reduce those emotions. Bingeing and purging therefore become strategies for controlling negative emotional states because they provide short-term relief from those emotions, thus reinforcing bingeing and purging.

Consistent with the view that at least some binges are triggered by negative emotional states, a number of studies have found that people with EDs experience more negative affect, more mood fluctuations, and find it more difficult to tolerate distress than those without EDs (Corstorphine, Mountford, Tomlinson, Waller, & Meyer, 2007; Lingswiler, Crowther, & Stephens, 1989). Further evidence to support the affect regulation model comes from studies investigating the subjective experience of bingeing and purging for those with BN. Smyth et al. (2007) conducted a naturalistic study with 131 women with BN in which they rated their

mood and binge-purge episodes six times a day on a hand-held computer. They found higher ratings of anger/hostility, negative affect, and stress on the days the women had a binge-purge episode and found that high negative affect and anger/hostility reliably preceded binge-purge episodes. They also found that there was an increase in positive affect and a decrease in negative affect following a binge-purge episode. Similar findings have been reported by Abraham and Beumont (1982), Crosby et al. (2009), and Powell and Thelen (1996). These studies have been able to study the impact of emotional dysregulation on eating behaviours but have not investigated the emotional changes between a binge episode and a purge episode. The affect regulation model would predict that although a binge episode may temporarily increase positive affect (due to relief from negative emotions), this is quickly followed by feelings of guilt or shame about the binge and the loss of control over eating. The purging episode that follows leads to a reduction in guilt and shame and a temporary increase in positive affect because the individual feels a return of control.

The affect regulation model of BN therefore suggests that a treatment that focuses on emotions and addresses difficulties with emotion management may be an effective treatment for BN. Dialectical Behaviour Therapy (DBT; Linehan, 1993a; 1993b; 2014) is an evidence-based intervention that addresses difficulties in affect regulation and aims to teach clients strategies to manage their emotions and tolerate distress. DBT was initially developed as a treatment for individuals with Borderline Personality Disorder (BPD) and self-harm or suicidal behaviours. The DBT model understands the behaviours commonly seen in people with BPD, such as self-harming and drug and alcohol use, as maladaptive coping strategies to manage intense emotional states. Similarly the DBT model for BN (Safer, Telch, & Chen, 2009) identifies bingeing and purging as the maladaptive coping strategies used by individuals with an ED when they are struggling to tolerate high emotional affect. DBT was designed to help clients understand their emotional experiences by

labelling, monitoring, modifying, and accepting their emotions. DBT balances acceptance, through validation of the client's difficulties regulating emotions, with emphasising the importance of change and the ability of the client to develop healthier coping strategies. The four skills modules taught in standard DBT for BPD are mindfulness, emotional regulation, distress tolerance, and interpersonal effectiveness.

DBT adapted for BN has been studied using a number of different research designs including case reports, case series, pretest-posttest studies, and two randomised controlled trials (RCT). Initially a single case report by Safer, Telch, and Agras (2001a) reported that a 36 year-old woman with BN abstained from bingeing and purging after five sessions of individual DBT. This outcome was maintained throughout 20 sessions of treatment and at six-month follow-up. Safer, Telch, and Agras (2001b) then conducted a RCT comparing DBT to a wait-list control group. They randomly assigned 31 women with BN to receive 20 individual sessions of adapted DBT or a 20-week wait-list control group. They found that participants who received DBT reported significantly fewer binge-purge episodes than the control group (Cohen's $d = 1.15$ for binge eating, and $d = 0.61$ for purging). They also found improvements in their measures of negative mood regulation, as measured by the Negative Mood Regulation Scale ($p < 0.03$), depression, as measured by the Beck Depression Inventory ($p < 0.04$), and emotional eating, as measured by the Emotional Eating Scale ($p < 0.008$) in the DBT group compared to the control group. However the differences in their secondary measures did not meet statistical significance following a conservative Bonferroni correction ($p < 0.0045$). They concluded that DBT is a promising treatment for BN but a larger sample size may have been required to detect differences between the groups on the secondary outcome measures.

DBT for BN has also been adapted to include appetite awareness training (DBT-AF; Hill, Craighead, & Safer, 2011). The authors added appetite awareness

training to the DBT programme because they proposed that binge eating was a result of both emotional dysregulation and a failure to respond to internal hunger and fullness cues. They suggested that helping clients become aware of their bodies' signals would help prevent binge eating and purging. Hill et al. (2011) randomly assigned 32 women with BN to either 12 individual sessions of DBT-AF or a delayed treatment control. They compared the two groups six weeks into the intervention and found that participants in the DBT-AF group had significantly fewer binge and purge episodes and significantly lower scores on the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn & Beglin, 1994) than the control group. They found that 61.5% of their participants no longer met diagnostic criteria for BN and 26.9% of participants were abstinent from binge eating episodes at post-treatment. Unfortunately follow-up data was not collected because the control group started DBT-AF after a six-week wait. These studies provide preliminary evidence that DBT for BN is an effective intervention that reduces bingeing and purging.

Additional research has evaluated DBT as an intervention for co-morbid BN and PDs (Ben-Porath, Wisniewski, & Warren, 2009; Chen, Matthews, Allen, Kuo, & Linehan, 2008; Fischer & Peterson, 2015; Kröger et al., 2010; Palmer et al., 2003). Sansone, Levitt, and Sansone (2004) reviewed previous research and concluded that approximately 28% of individuals with BN also meet criteria for a diagnosis of BPD, thus suggesting that PDs are relatively common in ED populations. From a DBT perspective, this co-morbidity is unsurprising given the similarities in emotional dysregulation and maladaptive coping strategies that are hypothesised to be an important part of both disorders (Safer et al., 2009). Rossiter, Agras, Telch and Schneider (1993) found that high scores on a measure of Cluster B PDs (Antisocial, Histrionic, Narcissistic, and Borderline) predicted poor outcomes following a CBT and medication intervention for BN. However, a number of other studies have found that although individuals with co-morbid PDs tend to have worse general psychopathology and worse social functioning, they do not differ on ED treatment

outcomes and make similar progress to those without a PD following CBT-BN (Rowe et al., 2008; Rowe et al., 2010), general outpatient therapy (Wonderlich, Fullerton, Swift & Klein, 1994) and a specialist multi-modal ED treatment programme (Zeeck et al., 2007).

Because DBT already has a strong evidence base for the treatment of BPD (Stoffers et al., 2012), DBT may be an effective intervention for co-morbid BN and PD. Chen et al. (2008) conducted a case series with eight women with a diagnosis of BPD and either BN or BED. Participants received a six-month standard DBT programme that included individual sessions, a weekly skills group, a therapist consultation team, and 24-hour telephone coaching as needed. They found that half of the participants were abstinent from bingeing at the six-month follow-up and all of the participants with BN were abstinent from vomiting and/or diuretic abuse at follow-up. They also found improvements in social functioning at follow-up and concluded that DBT was a promising treatment for those with co-morbid BPD and BN/BED.

Four pretest-posttest studies have investigated DBT for BN and PD in different formats (Ben-Porath et al., 2009; Fischer & Peterson, 2015; Kröger et al., 2010; Palmer et al., 2003). Palmer et al. (2003) offered between 6 and 18 months of a standard outpatient DBT programme, with an additional skills module they devised that focused on problems with weight, shape, and eating. They found that three of their seven participants no longer met criteria for an ED and three moved from a diagnosis of BN to EDNOS (indicating reduced frequency of bingeing and purging). Ben-Porath et al. (2009) offered twice-weekly DBT skills groups, a therapist consultation team, and 24-hour telephone coaching in a partial hospitalization programme that adapted DBT for EDs (e.g. including a nutrition module and adapting skills cards to focus on ED behaviours). They analysed data for the 40 participants who completed treatment and found significantly lower scores on the EDE-Q and the Negative Mood Regulation scale at post-treatment. Kröger et al.

(2010) offered a three-month inpatient DBT programme including individual therapy, three times weekly skills groups, and an added skills module focusing on weight and eating. They found that seven of the 15 participants with BN no longer met criteria for BN at post-treatment and there were significantly fewer binge eating episodes at post-treatment compared to pre-treatment. Fischer and Peterson (2015) investigated a full outpatient DBT programme that included psycho-education about EDs and parental involvement where possible, for adolescents with BN, suicidal behavior and self-harming behavior. They found significant improvements on the EDE-Q, number of binge episodes, and the frequency of self-harm after six months of treatment.

Although these studies provide some support for DBT for BN and PD, they have a number of limitations. Ben-Porath et al. (2009) only analysed data for the 40 participants who completed treatment (15 participants dropped out and 16 participants' data was lost due to an administrative error) so it is possible that their analysis overstated the benefits of the intervention. Both Palmer et al.'s (2003) and Fischer and Peterson's (2015) studies only included small numbers of participants making it more difficult to generalise their results. None of the studies included a comparison group so it is not possible to know how much of the improvement noted was due to the intervention. More high-quality studies are needed to demonstrate the effect of DBT for those with BN and those with BN and a PD.

The studies discussed above offered very intensive interventions; between three months and 18 months of DBT treatment ranging from individual sessions alone to full standard DBT programmes (individual therapy, weekly skills group, therapist consultation team, and 24-hour telephone coaching). In the current climate of spending cuts on public services in the UK, it is increasingly important for the NHS to offer treatments that are both clinically effective and cost-effective. The NHS Institute for Innovation and Improvement state on their website that "the NHS faces an unprecedented challenge ahead to improve quality and reduce cost at scale and

pace” (“Measurement for quality and cost” n.d., para. 1). Research to determine the minimum length of treatment that is needed for therapeutic change is therefore very important.

Feasibility studies are the first step proposed by the Medical Research Council’s (MRC) guidance on developing and evaluating complex interventions (Craig et al., 2008). In preparation for the development of a full scale randomised controlled trial, this study investigated the feasibility and effectiveness of a 12-week DBT skills group (consisting of weekly, two-hour sessions) for individuals with BN and for individuals with BN and a PD. A 12-week group offers considerably less therapist time per participant than the other studies reported, making it more cost-effective in terms of therapeutic time. The therapeutic time required for a 12-week group with two facilitators is 48 hours, which split between eight clients in each group is six hours per client. This is considerably lower than the number of hours of intervention per client in the other studies discussed which ranged from 15 hours to 144 hours.

The primary aims of the study were to assess the feasibility of a 12-week DBT intervention. Feasibility includes the perceived acceptability of the intervention, the effectiveness of the intervention, the retention rates and the suitability of measures used (MRC guidelines; Craig et al., 2008). Because of the prevalence of PDs in the population of women with BN, it was expected that some of the participants in this study would also have a PD. The secondary aim of the study was to compare participants with and without a PD to assess whether the presence of a co-morbid PD affected ED outcomes.

Hypotheses

1. Weekly binge-purge frequency will be significantly reduced at post-treatment and this change will be maintained at follow-up.

2. Participants with a co-morbid PD will have significantly poorer outcomes (as measured by weekly binge-purge frequency) than those without a co-morbid PD.
3. The participants will view the intervention as acceptable.

Method

Participants

Clinical participants were recruited from a large NHS Foundation Trust in Greater London and student participants were recruited from a London University between July 2014 and January 2015. To be included in the study participants had to: (a) be female, (b) be aged 18 and older, (c) meet DSM-5 criteria for current BN, (d) have a BMI of 18 or more, and (e) be registered with a GP.

Participants were excluded if they: (a) were experiencing current psychosis, (b) were unable to communicate in conversational English, (c) had a learning disability, or (d) had a known organic cause of their ED.

Procedure

All GPs and psychology services in the relevant NHS Trust were sent information about the study along with posters to display in waiting rooms. Anyone registered with a GP could contact the research team to express an interest in the study. Participants were also identified, by the research team, from the waiting lists of the ED service and the PD service as being potentially eligible for the study. Clinicians in both services reviewed their caseloads to identify clients who may be eligible. Potentially eligible participants who provided contact details were phoned and asked if they were interested in the study. If the clients were interested in taking part they were sent the Participant Information Sheet (Appendix C) and were invited to a face-to-face assessment.

At the University, posters (Appendix D) were displayed across campus inviting students to contact the research team if they were interested in the study.

Posters were also displayed at Student Psychological Services and clinicians there were informed about the study. Students contacted the research team via phone and email and were sent the Participant Information Sheet and invited to a face-to-face assessment.

Before the assessment commenced the study was explained in full and participants signed a consent form before proceeding (Appendix E). A clinical interview was then conducted to determine whether potential participants met DSM-5 criteria for BN. Participants who met inclusion criteria and wanted to be included in the study then completed the assessment questionnaires. If participants did not meet inclusion criteria for the study they were given information on local and national support services for EDs (e.g. Beat) and, if they were recruited from the NHS, directed back to their treating team.

Eligible participants were invited to a 12-week DBT skills group. For University participants a group was run at the University. For NHS participants groups were run in an NHS setting. One month after the end of the group participants were invited to a follow-up appointment. The one-month follow-up was used to review participant's symptoms and complete a questionnaire to ascertain the participant's views of the intervention.

Recruitment was carried out jointly with another doctoral trainee researching the change in mindfulness and acceptance following DBT for BN (see Appendix F for details of joint working).

Measures

At the assessment, participants completed the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn & Beglin, 1994), the Emotional Eating Scale (EES; Arnow, Kenardy, & Agras, 1995), the Standardised Assessment of Personality – Abbreviated Scale (SAPAS; Mann, Jenkins, Cutting, & Cowen, 1981), the Borderline Evaluation of Severity over Time (BEST; Blum, Pfohl, St John, Monahan, & Black, 2002), and the Work and Social Adjustment Scale (WSAS; Marks, 1986). These

questionnaires were repeated at the follow-up appointment. At the follow-up appointment participants also completed a questionnaire regarding the acceptability of the intervention.

During the course of the intervention participants completed the EES, the WSAS, and number of weekly binges and purges, every week. The primary outcome measure was the frequency of weekly binge-purge episodes. The secondary outcomes were scores on the EES, WSAS, BEST, and EDEQ.

Eating Disorder Examination-Questionnaire. The EDE-Q was developed by Fairburn and Beglin (1994) as a self-report questionnaire that could be used as an alternative to the Eating Disorder Examination, which is a 30 to 60 minute structured clinical interview. The EDE-Q is a 28-item measure, based directly on the EDE, which assesses eating disorder pathology over the last 28 days. It includes four subscales: restraint, weight concern, shape concern, and eating concern and a global scale that is the average of the four subscales. Some items of the questionnaire ask individuals to rate how often in the last 28 days they have engaged in certain behaviours and other items ask individuals to rate how much their thoughts and feelings, related to their shape and weight, have affected them.

Peterson et al. (2007) evaluated the internal consistency of the EDE-Q with a sample of women with BN. They found high internal consistency for the EDE-Q total score ($\alpha = 0.9$) and acceptable internal consistency for each subscale (α was between 0.7 and 0.83 for each of the four subscales). In the current study the EDE-Q was used to measure the severity of ED symptoms and change in ED symptoms using the EDE-Q total score.

Emotional Eating Scale. The EES is a 25-item questionnaire developed by Arnow et al. (1995) to measure the extent to which the negative emotional states of anger, depression, and anxiety lead to an urge to eat. Individuals rate how much 25 different emotions led to an urge to eat that week from 'no desire to eat' to 'an overwhelming urge to eat'.

Arnouk et al. (1995) investigated the validity and reliability of the EES and found that the sub-scales were confirmed in a factor analysis, it had good internal consistency (coefficient alpha for the total scale was 0.81) and good test-retest reliability ($r = 0.79$). They also investigated the construct, criterion and discriminant validity of the EES and found that the EES was unrelated to measures of general psychopathology and changes in the EES correlated with changes in other measures of binge eating. The EES is directly related to the affect regulation model of BN and was used to measure changes in emotional eating throughout the intervention.

Standardised Assessment of Personality-Abbreviated Scale. The SAPAS was developed by Mann et al. (1981) as an abbreviated form of the Standardised Assessment of Personality (SAP) to diagnose ICD-10 or DSM-IV PDs. The SAPAS contains eight yes or no questions drawn from the opening section of the SAP (for example 'In general, do you have difficulty making and keeping friends?'). Individuals answer yes if the statement in the question is true of them most of the time and in most situations.

Moran et al. (2003) tested the validity and reliability of the SAPAS and found moderate internal consistency (alpha coefficient was 0.68) and moderate test-retest reliability ($r = 0.61-0.83$, for each question). They compared SAPAS scores to the Structured Clinical Interview for DSM-IV Personality Disorders (SCID-II) and found that a cut-off score of three or four correctly identified over 80% of the patients with a PD (identified by the SCID-II). The sensitivity of a score of three was 0.94 and its specificity was 0.85, so three was deemed an appropriate cut-off score for identifying a probable PD. They concluded that although the SAPAS should not be used to make a diagnosis of PD it could be used to identify those at high risk of having a PD, which is how it was used in this study.

Borderline Evaluation of Severity over Time. The BEST is a 15-item self-report questionnaire designed to measure severity and change in the thoughts,

emotions, and behaviours commonly found in individuals with BPD. The BEST was developed as part of the Systems Training for Emotional Predictability and Problem Solving (STEPPS) treatment program (Blum et al., 2002). In the first part of the questionnaire individuals rate how much the issues stated in each item (e.g. 'feelings of emptiness') caused them distress, relationship problems or difficulty getting things done from 'none/slight' to 'extreme'. In the second part of the questionnaire individuals rate how much they used positive or helpful behaviours during the week from 'almost always' to 'almost never'. In this study the BEST was used to measure the severity of BPD symptoms and any change in BPD symptoms following the intervention.

Pfohl et al. (2009) investigated the validity and reliability of the BEST and found good internal consistency (Cronbach's alpha was 0.86) and moderate test-retest reliability ($r = 0.62$). They found that the BEST was strongly correlated with other measures of BPD severity and social functioning. They also found that the BEST was sensitive to clinical change.

Work and Social Adjustment Scale. The WSAS (Appendix K) is a five-item self-report scale developed by Marks (1986) to measure how much functional impairment individuals experience as a result of an identified problem, such as depression or an ED. The questionnaire asks how much the individual's problem affects their ability to work, their home management, their social leisure activities, their private leisure activities, and their close relationships. Individuals can rate the affect their problem has on each of these areas from 'not at all' to 'very severely'. The WSAS was used in this study to measure severity of functional impairment related to BN and any changes in functional impairment throughout the intervention.

Mundt et al. (2002) evaluated the reliability and validity of the WSAS using data from two previous studies. They found good internal consistency (Cronbach's alphas ranged from 0.79 to 0.94) and good test-retest reliability ($r = 0.73$). They also found that the WSAS was positively correlated to other measures of disorder

severity and changes in perceived clinical improvement were associated with changes in the WSAS. They concluded that the WSAS is a simple and reliable measure of functional impairment.

Follow-up Questionnaire. This questionnaire) was developed for this study. It asked participants five questions about the change in their symptoms of BN, the usefulness of the group, the usefulness of homework, the number of sessions offered, and whether they would recommend the group to someone else with BN. The first three questions were answered on a 5-point Likert scale and the last two questions had three options to choose from (e.g. yes, not sure, no).

Intervention

The group content was based on the 20-session DBT protocol developed by Telch, Agras and Linehan (2000) for treating BED. The protocol was adapted for BN using principles from Safer et al.'s (2009) book about DBT for BED and BN. Interpersonal effectiveness skills, which are found in standard DBT, were not included in the protocol. Neither Telch et al. or Safer et al. include interpersonal effectiveness skills in their protocols in order to reduce the theoretical overlap with Interpersonal Psychotherapy. The handouts for each topic were taken from the revised DBT skills manual (Linehan, 2014).

The protocol was condensed into 12 two-hour sessions:

- Session 1 – introduction to DBT and chain analysis
- Session 2-4 – mindfulness skills
- Session 5-7 – emotion regulation skills
- Session 8-10 – distress tolerance skills
- Session 11 – living a life according to your values
- Session 12 – review and planning for the future

In the first session group guidelines, such as confidentiality, were discussed and agreed upon to facilitate a safe and contained environment. The diagnosis of

BN was considered and the affect regulation model of BN was introduced. It was explained that the aim of the group was to teach participants the skills to recognise, describe, and manage emotions in order to reduce dependence on bingeing and purging as a way of managing or escaping from painful emotions. The participants were shown how to use a chain analysis to notice the links between their emotions, thoughts, physical sensations, and behaviours that led up to bingeing and purging. For example, restricting food intake, feeling hungry, feeling angry, and thinking 'I can't cope' may all be part of an individual's chain analysis. It was explained that being aware of and being able to identify and label these links in the chain was the first step in breaking that chain.

Mindfulness skills were taught using experiential exercises. Mindfulness was the main focus of sessions two to four but a short mindfulness exercise was completed at the beginning of each session to maintain practice. Mindfulness was taught as a way that participants could become aware of their experiences, particularly their thoughts and emotions, without becoming overwhelmed by them. Participants were encouraged to notice their thoughts and feelings without judging them. The mindfulness teaching covered what mindfulness is, how to practice mindfulness, and wise mind. The short mindfulness exercises at the beginning of each session were used to practice mindful eating. The exercises started with what participants deemed to be 'safe' foods (e.g. lemons and satsumas) and progressed to more challenging foods (e.g. a biscuit and crisps).

Emotion regulation skills were taught to help participants understand the function of emotions, to name emotions appropriately, and to reduce their vulnerability to emotions. Sessions five to seven involved teaching participants a model to understand their emotions and to assess whether the emotions they were experiencing fit the facts of the situation as well as whether the intensity of the emotion was effective in the situation. Reducing emotional vulnerability included discussing how to balance sleep, take care of one's health, resist unhelpful

behaviours, and gain mastery.

Distress tolerance skills were introduced as a way of enduring distress and emotional pain, either through techniques to improve the moment (e.g. distraction and self-soothing) or through acceptance. Radical acceptance and willingness were explored as ways of accepting reality for what it is and doing what is needed in a given situation rather than running away from or fighting reality.

As in standard DBT, each session built on the skills taught in the previous session. The first half of each session was focused on reviewing the homework from the previous week to see how participants had practiced the skills between sessions, to give corrective feedback on skills use, and to discuss any obstacles that arose. The second half of each session focused on teaching new skills. In terms of attendance, the group followed the 'four miss' rule in DBT (Linehan, 1993a; Linehan, 1993b), which defines treatment dropout as missing four consecutive sessions.

Each group was led by one of the developers of this research study (JF, AH, or SA) and was co-facilitated by a mental health professional. One group was co-facilitated by an ED therapist, two groups were co-facilitated by a Trainee Clinical Psychologist, and one group was co-facilitated by an Assistant Psychologist, all of whom had experience with either ED clients or with facilitating DBT interventions.

Risk of self-harm and suicide was monitored every session throughout the group. All risk issues were discussed with the client and reported to the participant's GP, when necessary. Risk management plans were agreed with participants who reported risk (e.g. what skills to use, where to gain support, crisis services). For NHS participants under the care of an NHS team (ED service or PD service), risk issues were also reported to the clinician monitoring the participant's care.

Statistical analysis

Power analysis for this study was informed by previous studies that measured the number of binges and purges as an outcome (Chen et al., 2008; Hill et al., 2011; Kröger et al., 2010; Safer et al., 2001b). A weighted average of effect sizes was

calculated, according to Hunter and Schmidt's (2004) recommendation, to ensure that the sample size of each study was taken into account. The weighted average of effect sizes was 1.2. The power calculation was carried out using the "G*Power3" computer program (Faul, Erdfelder, Lang, & Buchner, 2007) using the matched pairs sample calculator, specifying $\alpha = 0.01$ and desired power = 0.8. Alpha was set at 1% to account for the multiple comparisons that were to be carried out in the analysis (comparisons were planned for each of the five outcome measures; weekly binge-purge frequency, EDE-Q, EES, WSAS, and BEST). The required sample size to find a significant difference in the number of binges and purges, if one exists, was 12.

Each variable to be analysed was checked for normality by calculating the z-score for skewness and kurtosis and by using the Kolmogorov-Smirnov test. One variable (EDE-Q at assessment) was slightly negatively skewed and one variable (binge-purge frequency at session 12) was slightly positively skewed due to outliers. There was no justification for removing these outliers so they were included in the analysis. The skewness was not significant enough (according to the Kolmogorov-Smirnov test at $p < 0.01$) to necessitate the use of non-parametric tests.

Analysis was conducted in three stages. The first stage compared pre-treatment, post-treatment, and follow-up scores to ascertain whether there were any significant changes. Scores on weekly binge-purge frequency, the EES, and the WSAS were compared using repeated measures ANOVAs. The pre-treatment measures were obtained from the start of the first session of the intervention because the assessment did not collect a weekly binges and purges measure and because each participant's assessment was conducted at differing time intervals before the intervention started. The post-treatment measures were obtained from session 12. If a participant completed the intervention (attended at least eight sessions) but was unable to attend session 12 their scores from session 11 were carried forward. The EDE-Q and BEST were only collected at assessment and

follow-up so two-tailed, paired samples t-tests were used to compare the scores on these measures. Because there were five pre and post-treatment measures a Bonferroni correction was used to account for the multiple comparisons ($0.05/5 = 0.01$), to reduce the risk of making a Type 1 error.

Both a completer analysis and an intent-to-treat (ITT) analysis were completed in order to assess DBT's overall effectiveness for individuals with BN, but also to answer the research question of whether those completing a 12-week intervention have significant treatment outcomes. In the completer analysis, only participants who attended at least eight sessions and the follow-up were included. In the ITT analysis the last available weekly measures were carried forward and used as the post-treatment data points for participants who dropped out.

The second stage of the analysis planned to investigate whether having a probable PD diagnosis had a moderating effect on the treatment outcomes. The analysis planned to split participants into two groups based on their SAPAS score. It was planned that those scoring three or above on the SAPAS would be compared to those scoring less than three. A 2x3 ANOVA (two levels of the independent variable; PD and no PD and three levels of the dependent variable; weekly binge-purge frequency at pre-treatment, post-treatment, and follow-up) was planned to test if there were any differences between the participants with probable PD and those without.

The final stage of analysis evaluated the frequency of answers to each of the questions in the follow-up questionnaire, to summarise the participants' views of the group.

Ethics

Ethical approval for this study was granted by the National Research Ethics Service (Appendix H) and by University College London.

Because some participants were recruited from the waiting lists of the ED service and the PD service, participants were informed that their participation in the

study would not affect their place on the waiting list and they would still be eligible to receive support from the service they were recruited from after the study finished. All participants recruited from NHS services received ongoing monitoring from a mental health professional in the service they were recruited from whilst attending the group.

Because some participants were University students who were not under the care of a mental health service, at the end of the intervention all participants recruited from the University were given information on local and national organisations from which they could gain further support. A letter was sent to each of the participants' GPs to inform them of their participation in the study (Appendix I) and to let them know when their participation was complete (Appendix J).

Another ethical consideration was the burden to participants of filling out large numbers of questionnaires. Some of the questionnaires that were used would be completed as part of standard care in psychology services e.g. the EDE-Q and the WSAS, but other questionnaires were beyond what is used in standard practice. Because of this, and in order to encourage completion, participants were offered a £5 voucher for completing the questionnaires at the assessment and a £10 voucher for completing the questionnaires at the follow-up appointment. Both vouchers were given at the follow-up session, or posted to those who did not attend the follow-up.

Results

Thirty-seven participants were assessed for the study, three participants were excluded and five were booked to start the intervention but did not attend (see Figure 1 for flow chart of participants and reasons for dropout). Twenty-nine participants started a DBT for BN group and seven dropped out. Four DBT for BN groups were run with between six and eight participants in each group. Three of the groups consisted of NHS participants and one group consisted of University participants. There were 21 NHS participants and eight University participants. On

average participants attended eight out of the 12 sessions ($SD = 3.45$).

Participant Characteristics

The participants who attended the intervention were aged between 18 and 56 ($M = 25.93$, $SD = 8.34$). The majority of the participants were White British (65.5%); 13.8% were White Other, 13.8% were Asian British, 3.4% were from a mixed background, and 3.4% were Black British. The mean number of years the participants had been in education was 15.75 years.

Almost half of the women (41.4%) self-reported having a diagnosis of BPD, and 27.5% described themselves as having depression. The mean duration of BN before the start of the group was 7.38 years. The majority of the participants (89.7%) were receiving no other treatment. Three participants were also attending a DBT programme at the PD service that involved a weekly DBT skills group and weekly individual sessions. However these sessions were not tailored to address ED symptoms.

Figure 1: Flow chart depicting participant flow through the study



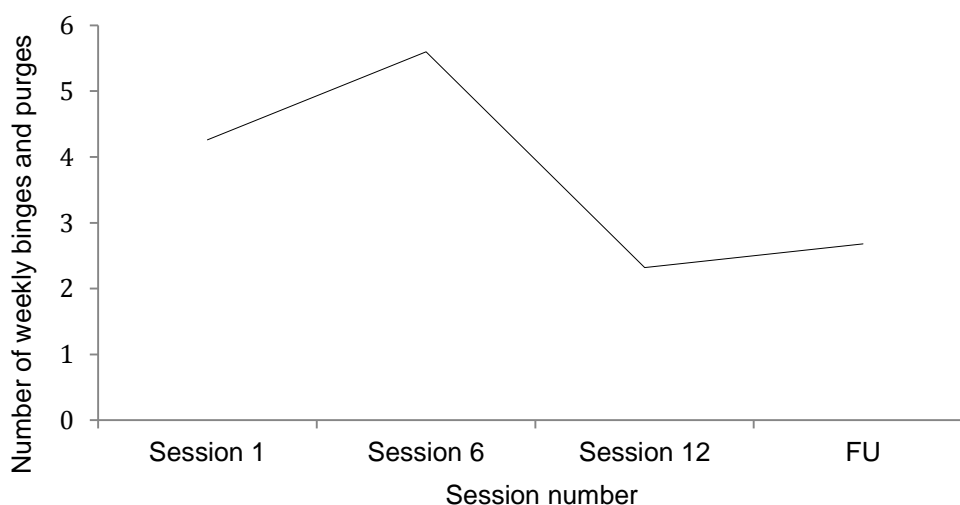
Dropouts

Of the 29 participants who started the intervention, seven dropped out. This is a dropout rate of 24.14%. Dropout reasons are documented in Figure 1. Dropouts' and completers' ages and symptom measures were compared to discover if there were any notable differences. Independent, two-tailed t-tests were used to compare participant's ages, and assessment scores on the SAPAS, weekly binge-purge frequency, EDE-Q, BEST, EES, and WSAS. There were no significant differences on any of the variables apart from SAPAS scores which were significantly higher for dropouts ($M = 5.71$, $SD = 1.11$) than for completers ($M = 4.09$, $SD = 1.97$), $t(27) = 2.06$, $p = .049$. However, this significance level would not pass a Bonferroni correction for multiple comparisons ($p < .007$).

Primary Outcomes Measure

For completers the mean weekly binge-purge frequency increased from session one to session six then reduced from session six to the end of the intervention. Binge-purge frequency then increased slightly at follow-up.

Figure 2: The mean weekly binge-purge frequency for completers throughout the intervention



A repeated measures ANOVA was used to compare the pre-treatment, post-

treatment and follow-up scores of the primary outcomes measure; weekly binge-purge frequency.

Table 1

Weekly Binge-Purge Frequency Repeated Measures ANOVA

Measure	Analysis type	Pre-treatment Mean (SD)	Post-treatment Mean (SD)	Follow-up Mean (SD)	<i>F</i>	<i>p</i>	Effect size (h_p^2)
B/P	Completer	4.26 (3.59)	2.32 (3.28)	2.68 (4.22)	7.68	.002*	.3
	ITT	6.38 (6.76)	5.59 (8.59)	5.83 (8.76)	0.27	.63	.009

Note. B/P = weekly binge-purge frequency

* denotes the differences that remain significant following a Bonferroni correction ($p < 0.01$)

For completers ($n = 19$), mean weekly binge-purge frequency reduced from 4.26 a week at pre-treatment to 2.32 a week at post-treatment, but then increased slightly to 2.68 at follow-up. In the completer analysis the repeated measures ANOVA was significant, $F(2, 36) = 7.68$, $p = .002$, with a large effect size (partial $h^2 = 0.3$). Planned comparisons, using a Bonferroni correction, found a significant reduction in binge-purge frequency from pre-treatment to post-treatment, but a non-significant difference between pre-treatment and follow-up, and between post-treatment and follow-up. When looking at all participants (ITT analysis; $n = 29$) mean weekly binge-purge frequency decreased from 6.38 at pre-treatment to 5.59 at post-treatment, then increased slightly at follow-up to 5.83. In the ITT analysis the repeated measures ANOVA found no significant difference between the three time points, $F(1.08, 30.34) = 0.27$, $p = 0.63$.

Table 2

Planned Comparisons for Weekly Binge-Purge Frequency

Analysis type	Planned comparison	Mean difference	<i>p</i>	95% confidence interval for difference
Completer	Pre and post	1.95	.002	.71 – 3.18
	Pre and FU	1.58	.06	-.05 – 3.21
	Post and FU	-.37	1.0	-1.65 - .91
ITT	Pre and post	.79	1.0	-2.62 – 4.2
	Pre and FU	.55	1.0	-2.9 – 4.0
	Post and FU	-.24	1.0	-1.05 - .56

Note. Pre = pre-treatment, Post = post-treatment, FU = follow-up

Secondary Outcome Measures

Repeated measures ANOVAs were used to compare the pre-treatment, post-treatment and follow-up scores of two of the secondary outcomes measures (the EES and the WSAS), and paired samples t-tests were used to compare the scores on the other two secondary outcomes measures (the EDE-Q and the BEST) from assessment to follow-up.

Table 3

Differences Between Pre-Treatment, Post-Treatment and Follow-Up for the EES and WSAS

Measure	Analysis type	Pre-treatment Mean (SD)	Post-treatment Mean (SD)	Follow-up Mean (SD)	<i>F</i>	<i>p</i>	Effect size (h_p^2)
EES	Completer	54.74 (14.54)	33.05 (23.18)	30 (20.92)	22.32	.0001*	.55
	ITT	52.52 (20.91)	37.66 (26.61)	35.66 (25.79)	16.59	.0001*	.37
WSAS	Completer	23.78 (9.22)	16 (12.51)	12.61 (11.99)	12.18	.0001*	.42
	ITT	24.69 (8.78)	20.9 (12.59)	18.79 (13.22)	5.63	.006*	.17

Note. EES = Emotional Eating Scale, WSAS = Work and Social Adjustment Scale

* denotes the differences that remain significant following Bonferroni correction ($p < 0.01$)

For completers ($n=19$), the mean of EES scores decreased from 54.74 at pre-treatment to 33.05 at post-treatment, and further reduced to 30 at follow-up. In the completer analysis, the repeated measures ANOVA found the change in the EES across the intervention was significant, $F(2, 36) = 22.32$, $p = .0001$, with a very large effect size (partial $h^2 = .55$). Planned comparisons, using a Bonferroni correction, found a significant reduction on the EES between pre-treatment and post-treatment scores, and between pre-treatment and follow-up scores, but a non-significant change between post-treatment and follow-up scores. In the ITT analysis ($n= 29$) mean scores on the EES also decreased from pre-treatment ($M= 52.52$) to post-treatment ($M= 37.66$) and were further decreased at follow-up ($M= 35.66$). In the ITT analysis, the repeated measures ANOVA found a significant difference between the three time points, $F(1.4, 39.17) = 16.59$, $p = .0001$, with a large effect size (partial $h^2 = .37$). As in the completer analysis, planned comparisons using a Bonferroni correction, found a significant reduction between pre-treatment and post-

treatment scores, and between pre-treatment and follow-up scores, but a non-significant change between post-treatment and follow-up scores.

Table 4

Planned Comparisons for the EES

Analysis type	Planned comparison	Mean difference	<i>p</i>	95% confidence interval for difference
Completer	Pre and post	21.68	.001	9.42 – 33.95
	Pre and FU	24.74	.0001	13.19 – 36.28
	Post and FU	3.05	.9	-4.5 – 10.61
ITT	Pre and post	14.86	.001	5.48 – 24.25
	Pre and FU	16.86	.0001	7.47 – 26.25
	Post and FU	2	.89	-2.78 – 6.78

Note. Pre = pre-treatment, Post = post-treatment, FU = follow-up

For completers ($n = 19$), the mean score on the WSAS decreased from 23.78 at pre-treatment to 16 at post-treatment, and was further reduced to 12.61 at follow-up. The repeated measures ANOVA found the change in the WSAS across the intervention was significant, $F(2, 34) = 12.18$, $p = .001$, with a large effect size (partial $h^2 = .42$). Planned comparisons, using a Bonferroni correction, found a significant reduction in scores from pre-treatment to post-treatment, and from pre-treatment to follow-up. There was no significant difference between post-treatment and follow-up scores. In the ITT analysis ($n = 29$) mean scores on the WSAS also decreased from pre-treatment ($M = 24.69$) to post-treatment ($M = 20.9$) and were further decreased at follow-up ($M = 18.79$). The repeated measures ANOVA in the ITT analysis found a significant difference across the three time points, $F(2, 56) = 5.63$, $p = .006$, with a medium-large effect size (partial $h^2 = .17$). The planned comparisons found a non-significant difference between pre-treatment and post-treatment but a significant difference between pre-treatment and follow-up. The difference between post-treatment and follow-up was not significant.

Table 5

Planned Comparisons for the WSAS

Analysis type	Planned comparison	Mean difference	<i>p</i>	95% confidence interval for difference
Completer	Pre and post	7.78	.008	1.89 – 13.66
	Pre and FU	11.17	.001	4.51 – 17.83
	Post and FU	3.39	.44	-2.51 – 9.29
ITT	Pre and post	3.79	.13	-.74 – 8.33
	Pre and FU	5.9	.03	.56 – 11.23
	Post and FU	2.1	.43	-1.46 – 5.67

Note. Pre = pre-treatment, Post = post-treatment, FU = follow-up

The change on the EDE-Q and BEST questionnaires, from assessment to follow-up, was assessed using two-tailed, paired samples t-tests. For completers ($n= 19$) the mean EDE-Q score at pre-treatment was 4.47 and this reduced to 3.22 at follow-up. In the ITT ($n= 29$) the mean EDE-Q score was 4.63, which reduced to 3.83 at follow-up. The paired samples t-test found the reduction in scores on the EDE-Q between pre-treatment and follow-up was statistically significant, using both the completer analysis, $t(17) = 4.17$, $p = .001$, and the ITT analysis, $t(27) = 3.61$, $p = .001$. Both analyses had large effect sizes.

For completers ($n= 19$) the mean BEST score at pre-treatment was 43.89 and this reduced to 30.74 at follow-up. In the ITT analysis ($n= 29$) the mean BEST score was 45.52, which reduced to 36.9 at follow-up. The paired samples t-test found the reduction in scores on the BEST from pre-treatment to follow-up was significant, using both the completer analysis, $t(18) = 3.64$, $p = .002$, and the ITT analysis, $t(28) = 3.28$, $p = .003$. Both analyses had large effect sizes.

Table 6

Differences Between Assessment and Follow-Up Measures

Measure	Analysis type	Pre-treatment Mean (SD)	Follow-up Mean (SD)	<i>t</i>	<i>p</i>	Effect size (Cohen's <i>d</i>)
EDE-Q	Completer	4.47 (1.01)	3.22 (1.44)	4.17	.001*	2.02
	ITT	4.63 (0.91)	3.83 (1.46)	3.61	.001*	1.39
BEST	Completer	43.89 (11.91)	30.74 (13.76)	3.64	.002*	1.72
	ITT	45.52 (11.38)	36.9 (15.15)	3.28	.003*	1.24

Note. EDE-Q= Eating Disorder Examination Questionnaire, BEST= Borderline Evaluation of Severity over Time

* denotes the differences that remain significant following a Bonferroni correction ($p < 0.01$)

The Effect of Personality Disorders

A score of three or more on the SAPAS identifies an individual as having a high risk of having a PD. The majority of the participants (89.7%) had a score of three or more on the SAPAS. The number of participants at high risk of having a PD was similar in the NHS participants (90.5%) and the University participants (87.5%). Due to the high levels of probable PD in the sample, it was not possible to compare those with and without PDs because the sample size of the non-PD group would be too small.

Acceptability of the Intervention

The acceptability of the intervention was measured using a questionnaire at the follow-up session (Appendix G). Table 6 shows the percentage of participants that gave each answer on the follow-up questionnaire. The majority of the participants (89.5%) said they would recommend the group to someone else struggling with symptoms of BN. None of the participants thought the group had too many sessions, but 42.1% thought there were 'not enough' sessions. All of the participants either 'agreed' or 'strongly agreed' that the group helped them to

understand and address their difficulties better, and the majority of the participants (73.68%) rated their BN symptoms as either ‘improved or ‘significantly improved’.

Table 7
Feedback Questionnaire Answers

Question	Percentage of participants giving each answer				
1	Significantly worsened 0%	Worsened 10.53%	The same 15.79%	Improved 36.84%	Significantly improved 36.84%
2	Strongly disagree 0%	Disagree 0%	Not sure 0%	Agree 31.58%	Strongly agree 68.42%
3	Strongly disagree 0%	Disagree 5.26%	Not sure 10.53%	Agree 42.11%	Strongly agree 42.11%
4	Too many 0%		Just right 57.89%		Not enough 42.11%
5	Yes 89.47%		Not sure 10.53%		No 0%

Note. Question 1 = How would you rate the change in your symptoms of BN?
Question 2 = The group has helped me to better understand and address my difficulties
Question 3 = The homework helped me put into practice the skills I learnt in the group
Question 4 = What do you think about the number of sessions offered?
Question 5 = Would you recommend this group to someone else struggling with symptoms of BN?

Discussion

This study aimed to assess the feasibility of a 12-week DBT skills group for women with BN. The first hypothesis was that the main outcome measure of weekly binge-purge frequency would be significantly reduced at post-treatment and this change would be maintained at follow-up. Figure 2 showed that weekly binge-purge frequency increased from session one to session six but then decreased by session 12 to lower than pre-treatment levels. For those who completed the intervention, the reduction in the weekly binge-purge frequency from pre-treatment to post-treatment was significant, and this difference had a large effect size. The increase in binge-

purge frequency from session one to session six is interesting and may be accounted for by various factors. A number of participants identified that they usually coped with their emotions and their bulimic symptoms by trying to suppress them and avoid thinking about them. It is possible that exploring their BN symptoms at the beginning of the intervention led to an increased awareness of emotions and an increased focus on bulimic symptoms, which could have had the effect of temporarily increasing bingeing and purging. At the beginning of the intervention participants had not yet learned all the skills necessary to manage their emotions and change unhelpful behaviours. The decrease in bingeing and purging from session six to session 12 may be accounted for by an increase in mindfulness, emotional regulation, and distress tolerance skills, which equipped participants to manage their emotions more effectively, and not binge and purge to manage their emotional states. The number of binges and purges increased slightly at the follow-up, but this difference was not significant, suggesting that treatment gains were generally maintained during the follow-up period. The change in binge-purge frequency was not significant in the ITT analysis.

Both of the other weekly measures (EES and WSAS) were found to have significantly improved by the end of treatment, for both completers and the ITT, and these improvements were maintained at follow-up. The EDE-Q and the BEST had also significantly improved at the follow-up, for both completers and the ITT, and these differences had large effect sizes. This shows that participants' overall level of ED symptoms had improved (as measured by the EDE-Q), the frequency with which participants' emotions triggered an urge to binge had reduced (as measured by the EES), the impact BN was having on their social and occupational functioning had reduced (as measured by the WSAS) and symptoms of BPD had reduced (as measured by the BEST).

There were no significant differences, on any measures, between the end of

the intervention and the one-month follow-up indicating that treatment gains remained static after the intervention had finished. However, it is possible for treatment outcomes to change over a longer follow-up period. Agras, Walsh, Fairburn, Wilson, and Kraemer (2000) compared treatment outcomes for CBT and IPT for individuals with BN. They found that participants who received CBT had significantly better treatment outcomes than those who received IPT at the end of treatment, but there was no significant difference between CBT and IPT at a 12-month follow-up. They concluded that treatment outcomes for the participants who received IPT had a tendency to improve throughout the follow-up period whereas treatment outcomes for those who received CBT tended to be maintained rather than improve. It would therefore be beneficial to follow-up participants after DBT for BN for a longer duration after the end of treatment to investigate whether treatment gains change over a longer period of time.

These encouraging results provide preliminary evidence that a 12-week DBT skills group can produce significant improvements in bulimic symptoms. The effect sizes found in this study are comparable to the effect sizes reported for CBT-BN (Hay, Bacaltchuk, & Kashyap, 2009). Hay et al. conducted a Cochrane review of psychological interventions for BN and binge eating. They calculated the average effect size for the change in bulimic symptom scores for nine studies that compared CBT-BN to a wait list control group. They found a Standardised Mean Difference of -1.01. This study found the mean difference for binge-purge frequency, between pre-treatment and post-treatment, was 1.95 for completers and 0.79 for the ITT. CBT-BN is the treatment of choice for BN so it is relevant that a short term DBT intervention achieved similar effect sizes.

Other studies investigating the effect of DBT for BN (Ben-Porath et al., 2009; Chen et al., 2008; Fischer & Peterson, 2015; Hill et al., 2011; Kröger et al., 2010; Palmer et al., 2003; Safer et al. 2001a; Safer et al., 2001b) all offered longer term

and more intensive interventions. Each of these studies offered either individual therapy or a combination of skills groups, individual therapy, and telephone support. Evidence that this intervention can lead to significant changes in symptoms of BN in just 12 group sessions suggests that this intervention is worthy of further investigation.

The second hypothesis was that participants with a co-morbid PD would have significantly poorer outcomes than those without a co-morbid PD. Although previous studies have found that participants with co-morbid BN and PD had good treatment outcomes following DBT (Ben-Porath et al., 2009; Chen et al., 2008), these studies offered longer and more intensive interventions than the intervention reported here. The NICE guidelines for BPD (NICE, 2009) recommend that brief psychological interventions, of less than three months duration, should be not offered to individuals with BPD because longer interventions are usually indicated. This is why it was hypothesised that a 12-week DBT skills group would be less effective for those with co-morbid PD than those with BN alone. Unfortunately, it was not possible to compare the outcomes of those with and without co-morbid PD because of the high proportion (89.7%) of participants who were identified as having a probable PD. This level of co-morbid PD is higher than the levels reported in previous studies. As noted above, Sansone et al. (2004) reviewed previous studies and reported that approximately 28% of participants with BN also had BPD. It is possible that the level of PD in this sample was inflated due to referrals from the PD service. It is also possible that the higher level of co-morbidity in this study was found because of the measure used. The SAPAS is designed to identify any of the 10 PDs outlined in the DSM-IV, not just BPD as in Sansone et al.'s study. It is also pertinent to note that the SAPAS is not used to diagnose PDs but to identify those at high risk of having a PD. Moran et al. (2003) found that the SAPAS has a 94% chance of correctly identifying an individual with a PD and has an 85% chance of

correctly excluding an individual who does not have a PD. These sensitivity and specificity scores are impressive, but it is possible that up to 15% of our participants were incorrectly identified as having a probable PD. Part of a feasibility study is to consider the appropriateness of the measures used. The use of the SAPAS may be reconsidered in future studies because of the risk of inflating the reported levels of PD. Even if the SAPAS incorrectly identified some of the participants as having probable PD, the level of co-morbidity in this study was still high.

This study found a very similar rate of probable PD in the participants recruited from the NHS (90.5%) and the participants recruited from the University (89.7%). Studies indicate that PDs are significantly more prevalent in psychiatric outpatient samples than in community samples. Zimmerman, Rothschild, and Chelminski (2005) found a prevalence rate of 31.4% in a large psychiatric outpatient sample in the US. Because the majority of the participants were recruited from outpatient mental health services, it would be expected that a relatively large proportion of them would have a co-morbid PD. However, this would not necessarily be expected in the University participants. The high rate of PD in both NHS and University participants suggests that PD may be more prevalent in ED populations than previously reported. Given that the majority of participants met criteria for probable PD, this provides tentative evidence that the intervention is effective for clients with co-morbid BN and PD.

The final hypothesis was that the participants would view the intervention as acceptable. All of the 19 participants who attended the follow-up completed the follow-up questionnaire. The vast majority of the participants (89.5%) answered that they would recommend the group to another person suffering from BN. All of the participants either 'agreed' or 'strongly agreed' that the group helped them to understand and address their difficulties better and 73.7% reported that their symptoms had either 'improved' or 'significantly improved'. Most of the participants

(84.2%) either 'agreed' or 'strongly agreed' that the homework helped them put into practice the skills they learnt. Finally, 57.9% of participants rated the number of sessions as 'just right' and 42.1% rated the number of sessions as 'not enough'. Overall the feedback from the participants was positive but two participants reported that their symptoms had 'worsened'. Both of these participants were University students and when this was explored in their follow-up appointment they both attributed their worsened symptoms to exam stress, rather than the intervention itself. This feedback suggests that overall the intervention was acceptable to clients. However, it is important to bear in mind that this feedback was collected at the follow-up session, which was only attended by participants who completed the intervention. It is possible that those who dropped out of the intervention would have given different feedback. Group facilitators also conducted the follow-up assessments so it is possible that participants may have felt inhibited from giving negative feedback.

It is interesting that 42.1% of the participants felt the intervention was not long enough. It is understandable that many clients do not want therapy to end and want to continue receiving weekly support. However, it is particularly pertinent to this study because this intervention was shorter and less intensive than DBT interventions in previous studies (Ben-Porath et al., 2009; Chen et al., 2008; Fischer & Peterson, 2015; Hill et al., 2011; Kröger et al., 2010; Palmer et al., 2003; Safer et al., 2001b) and it is shorter than the current NICE recommended treatment for BN (NICE, 2004), which is 16 to 20 sessions of CBT-BN. From the perspective of the group facilitators, there was a large amount of content to discuss each session and, at times, getting through this content felt rushed. Further research could investigate a 16-session protocol to match standard treatment lengths for BN and to give each DBT skill more time to be explained and explored in sessions.

When considering the acceptability of an intervention it is also important to

consider those who dropped out of the intervention. Seven participants dropped out of the group, all of whom gave reasons for dropping out which were unrelated to the treatment. However it is possible that those who dropped out did not want to report treatment-related reasons for not completing the intervention and gave more palatable reasons to the researchers. A dropout rate of 24.14% is similar to the dropout rates reported from other psychological interventions. A systematic review of RCTs investigating treatments for BN found that dropout rates from psychological interventions, including CBT-BN, ranged from 6% to 37%, with a typical dropout rate being 25% (Shapiro, Berkman, Brownley, Sedway, Lohr, & Bulik, 2007). The dropout rate in this study also appears to be similar to the dropout rates reported in previous studies investigating DBT for BN, which were between 0% and 30% (Ben-Porath et al., 2009; Chen et al., 2008; Fischer & Peterson, 2015; Hill et al., 2011; Kröger et al., 2010; Palmer et al., 2003; Safer et al., 2001b).

A comparison between the completers and the dropouts found no significant differences in age or severity of symptoms. It is therefore not possible to know if there were any client factors that increased the likelihood of dropping out of the intervention. Many of the dropout reasons cited were practical considerations (e.g. starting a new job, change in hours at work, and moving away) so the dropout rate may have been more determined by practical factors than client or treatment-specific factors.

Only three participants were lost to follow-up. Sadly one of those participants was a University student who was discovered to have completed suicide five weeks after the end of the group. This individual did not report risk throughout the group and fully participated in the sessions. At the end of the intervention she appeared to have benefited from the group and her ED symptoms had reduced. The exact reasons for her suicide are not known, but the report to the coroner from student health services, where she had previously been seen for anxiety and depression,

stated that she was having difficulty adjusting to University and was worried about exams. It is not possible to know whether this client's suicide was related to the DBT intervention, but nonetheless some changes to the intervention protocol are being proposed. As the co-morbidity of BN and PD was found to be high in this study and PDs are associated with high rates of suicide (Black, Blum, Pfohl, & Hale, 2004), a suicide risk protocol should be added to the intervention. Many of the previously evaluated DBT interventions for BN included telephone support, which may be an important modality of DBT treatment that could also be added to this intervention. This would provide participants with out of hours telephone support that could be utilised if they felt suicidal or unable to cope. Further studies should carefully consider the risk of suicide and self-harm following DBT for BN.

This study has found preliminary evidence that a short term DBT skills group for BN can lead to significant treatment outcomes. Dropout rates were similar to dropout rates for other BN interventions and the intervention was generally viewed as acceptable.

Limitations and Strengths

This study has a number of limitations that are important to consider. The one-group pretest-posttest design of this study, although appropriate for a feasibility study, has a number of limitations. One-group pretest-posttest designs do not have a control group so it is not known how much of the change observed is attributable to the intervention and how much is attributable to factors independent of the intervention (e.g. spontaneous remission). There were also three participants who were receiving a concurrent DBT programme at the PD service, so it is not possible to disentangle the treatment effects from the two interventions. However, two of these participants dropped out so only one completer was receiving two DBT interventions. Because this study was a one-group pretest-posttest design there was no control or comparison group so selection bias could not be controlled through

randomisation, reducing the internal validity of the study (Barker, Pistrang, & Elliott, 2002).

One strength of this study was that it had good external validity. The majority of groups were conducted in a naturalistic setting, as part of the ED service. The participants had suffered from BN for an average of 7.38 years, and the average score on the EDE-Q at assessment was 4.63 (over two standard deviations above the mean norm for young adult women; Mond, Hay, Rodgers, & Owen, 2006) indicating that their difficulties were significant and long-term. The participants also had a high level of co-morbidity, notably PD symptoms. This matches the complexity of clients often seen in ED services and therefore increases the external validity of this study. It is also notable that group facilitators did not receive extensive training prior to running the intervention. The first intervention was run by an expert DBT practitioner (JF), and co-facilitated by two Trainee Clinical Psychologists (AH & SA) who learnt the treatment protocol and the DBT skills through observation and supervision. The two Trainee Clinical Psychologists then ran the remaining three groups with co-facilitators with experience either in DBT and/or working with EDs. This study provides some evidence that it is possible to see significant treatment gains even when the therapists have not received extensive training in the treatment model. This is important to consider when funding in the NHS for extensive training is limited.

An additional limitation of this study was that the therapist who had run the intervention administered the questionnaires at follow-up. It is possible that participants, consciously or unconsciously, gave answers they thought would please the therapist or gave answers they thought the therapist was expecting (Podsakoff, MacKenzie, & Podsakoff, 2003). Future replications of this study would benefit from an independent researcher completing the assessment and follow-up questionnaires. Future replications of this study would also benefit from having a

longer follow-up period. Due to the time constraints it was not possible to complete a follow-up longer than one month, but it would be helpful to know whether treatment gains were maintained throughout a longer follow-up period.

A final limitation of this study is that it only included female participants. Men were excluded from this study because it was predicted that there would not be enough men recruited to offer a male-only group and including just one or two men in a majority-female group may be difficult for both the men and the women in that group. Some studies have highlighted the additional issues men with EDs face, and the need to adapt interventions to normalise the experience of EDs for men (Fernandez-Aranda et al., 2009; Weltzin et al., 2012). In a small-scale feasibility study we did not have the capacity to compare men's and women's treatment outcomes or to consider what adaptations, if any, would be necessary for men with BN.

Research Implications

Further research would be beneficial to replicate the findings of this study and to overcome some of its limitations by offering longer follow-up periods, using independent assessors, and including male participants. It would also be interesting to compare the effectiveness of the 12-week protocol reported in this study to a longer protocol (e.g. 16 weeks) following the feedback of many of the participants that the intervention was not long enough.

Future research is needed to test the effectiveness of DBT for BN in a more controlled research design, such as an RCT. RCTs have greater internal validity and can therefore be used to make inferences about causality (Barker, Pistrang & Elliott, 2002). In an RCT, DBT could be compared to other evidence-based treatments such as CBT-BN to assess whether they have similar treatment outcomes. This research may also be able to further investigate client-specific factors that may lead to DBT being more or less effective. The emotion regulation model of BN suggests

that it would be clients who have difficulties regulating their emotions that would most benefit from DBT (Safer et al., 2009). Further research could measure emotional regulation difficulties and compare participants with high emotional regulation difficulties to those with low emotional regulation difficulties to assess whether there are any differences in treatment outcomes following DBT for BN.

Future research could investigate the impact of a co-morbid PD diagnosis on the effectiveness of DBT for BN, particularly in a short-term intervention such as the one reported in this study. It would be important for a study to have a larger sample size than the one reported in this study to allow for comparison between participants with and without a PD. It is also worth considering other measures to identify those with a PD (other than the SAPAS). For example, the SCID-II is a semi-structured interview used to diagnose DSM-IV PDs (the SCID-5-PD to diagnose DSM-5 PDs is currently being developed) that could be used to diagnose PDs more accurately (First, Gibbon, Spitzer, Williams, & Benjamin, 1997).

One of the aims of a feasibility study is to discuss the appropriateness of measures for consideration in future research (Craig et al., 2008). As previously discussed, the SAPAS, although convenient, may not be the most appropriate measure of the prevalence of PDs in an ED sample. The other measures used (binge-purge frequency, EDE-Q, BEST, and WSAS) were well tolerated and the researchers concluded that they were appropriate measures of ED symptoms, PD symptoms and functional impairment. The BEST may not be necessary to use in future research unless the hypotheses relate to changes in PD symptoms alongside changes in ED symptoms.

Clinical Implications

The results of this study suggest that DBT skills groups could be an effective intervention for women with BN. The short-term nature of the intervention means it could be offered by primary care psychology services (e.g. IAPT), adult psychology services or specialist ED services. This study also suggests that clinicians who have

not received full DBT training, but who are trained to deliver the treatment protocol and who are supervised by an experienced DBT clinician could offer the intervention.

This study has shown that a DBT skills group can lead to significant treatment outcomes, even for those with co-morbid PD symptoms. Cluster B PDs, particularly BPD, have been found to predict poor outcomes following CBT and other psychological interventions for BN (Lilenfeld, Wonderlich, Riso, Crosby, & Mitchell, 2006; Rossiter, Agras, Telch & Schneider, 1993), so a treatment that is effective for those with both BN and PD is important for clinical services.

Conclusions

This study provides evidence for the feasibility of a 12-week DBT skills group for women with BN. Overall the intervention was viewed as acceptable, the drop-out rate was comparable to other studies of psychological therapies for EDs, the majority of the measures used were appropriate, and there is preliminary evidence for significant treatment gains. This study was in preparation for a larger research trial that could utilise the same procedures tested in this study, but using a more methodologically rigorous design such as an RCT.

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Part Three: Critical Appraisal

Introduction

This critical appraisal will discuss some of the practical problems encountered whilst conducting the research for the empirical paper, and will consider how these problems affected the methodology of the study. It will then discuss how group processes influenced engagement in the intervention. Finally, it will explain the link between the empirical paper and the systematic review and will explore in more depth one issue that arose whilst completing the literature review; the relationship between sexuality and eating disorders (EDs) in men.

Challenges of the Research

As many researchers do, I came into this project full of enthusiasm and with high expectations of what could be achieved. As the study progressed it became clear that there were a number of practical considerations that were going to limit the design and methodological quality of the study. In the initial proposal for this study it was planned that eight dialectical behavior therapy (DBT) for bulimia nervosa (BN) groups would be run with between 10 and 12 participants in each group, resulting in up to 96 participants in total. In retrospect this was a highly ambitious recruitment proposal that proved unmanageable. Recruitment was significantly slower than anticipated. Both the internal and external supervisor of this project worked in mental health settings (the eating disorder service and the personality disorder service) in the NHS Trust this study was recruiting from and it was anticipated that the majority of participants would come from these two services. Unfortunately we had no referrals from the other psychology services in the Trust that were contacted (e.g. IAPT, community mental health teams) or directly from GPs. Both supervisors were surprised at the slow rate of recruitment, despite concerted efforts by myself and the other trainee working on this project (see Appendix F for summary of joint working). By the end of the recruitment process we had recruited 34 participants, 29 of which started the intervention. This was

considerably less than originally planned.

Patel, Doku & Tennakoon (2003) consider the challenges researchers face when recruiting participants for psychiatric research. They highlight the importance of establishing a collaborative relationship with clinicians working in the recruitment sites. They suggest that researchers should quickly establish who is interested in the research and identify a member of the team who they can liaise with and have regular contact with. In terms of this study, we spent time at the ED service and established relationships with the staff there, but we did not have one nominated member of the team, who was interested in the research, with whom to liaise on recruitment issues. This may have been a significant help to our recruitment. In the personality disorder (PD) service the team is split over four sites and we were only present at one of those sites. It may have been beneficial to attend multiple sites of the PD service to meet more of the staff face-to-face to engage them in the recruitment process. It also may have helped to have a nominated clinician at each of the sites to liaise with. Patel and colleagues emphasised the importance of being clear with staff about what is expected of them, what the inclusion/exclusion criteria of the study are and what the research involves. Although we communicated with staff face-to-face and via email regarding the study, I think it might have helped to have a poster in each office detailing the study information and how to contact us. This would have helped to keep the study in clinicians' minds, amongst their busy caseloads, and would have kept the information easily accessible instead of clinicians having to search their emails for the details.

As well as considering how to engage clinicians, Patel et al. (2003) discuss how to engage participants. One suggestion they make, that is relevant for this study, is being as flexible as possible for participants in terms of appointment times, travel arrangements, and meeting in convenient locations. Although myself and the other trainee working on the project tried to be as flexible as possible we were restricted to recruiting and running the intervention on a specific day (to fit with our

University and clinical placement commitments). We were also limited in the locations we could meet participants because of the availability of rooms in busy clinical settings. This may have been a barrier to recruiting some of the individuals we contacted. Because many of the potential participants were working full or part-time we ran one group in an evening but there were still many people we contacted who couldn't attend due the timings and locations of the groups.

Because of the recruitment difficulties experienced, we decided to make two changes to the methods of the study. One was to include participants who were already in DBT treatment at the PD service and one was to expand recruitment to University students who met diagnostic criteria for BN and run a group at the University. The advantage of both of these changes was that they increased the number of participants in the study, increasing the power of the study. However, the disadvantage was that both changes reduced the methodological quality of the study. Including University participants meant that we had a mixed sample of NHS and University participants reducing the generalisability of the results to either population. Including participants who were already in DBT treatment meant that we were unable to determine whether the treatment outcomes observed were due to the DBT for BN group or the other DBT interventions. This reduces the certainty of the conclusions that can be drawn from the study. Because this was a feasibility study there can be some flexibility in the methodology as the study is in preparation for a larger, well-controlled study such as a RCT (Craig et al., 2008). However, it was disappointing to have to make changes that compromised the quality of the study, because of the recruitment problems experienced.

If I were repeating this study, I would have spent more time engaging clinicians from recruitment sites, I would have identified a clinician at each site who was interested in the study, I would have developed a poster for each office at recruitment sites, and I would have tried to make arrangements to be more flexible with participants. I would aim to make these changes to improve recruitment rather

than make post-hoc methodological changes. In terms of other methodological changes, I would not change the inclusion or exclusion criteria of the study or the assessment procedure. However, I would consider offering a 16-week intervention rather than a 12-week intervention. As noted in the empirical paper, 42.1% of the participants fed back that there were not enough sessions. I think it would have been valuable to have more time to introduce and explore the skills (e.g. introducing two new skills a week instead of three), and more time to review the skills that had already been learnt. In terms of the content of the intervention, Linehan's (2014) recently updated skills handouts were used. The participants did not give negative feedback about the handouts but it may have been helpful to use handouts that were tailored for individuals with BN. Safer, Telch and Chen's (2009) book includes some handouts for clients with BN and BED but does not include all of the up-to-date skills in Linehan's new skills manual. The time constraints of the research study made developing new handouts impossible, but with more time I think it would have been helpful to combine the ED specific content with Linehan's updated skills handouts.

Group Processes

Running a group intervention for my research project was a challenging but rewarding experience. I noticed a marked difference between the three groups I facilitated and have reflected upon some of the group processes that may have been occurring. Yalom has written extensively about group psychotherapy and the factors that influence treatment outcomes from group interventions (Yalom & Leszcz, 2005). Although Yalom often discusses issues arising in long-term psychodynamic group interventions, the group processes identified are likely to be relevant to other group interventions as well. Yalom and Leszcz (2005) identify 11 factors that they suggest are important for therapeutic change. I am going to discuss three of those factors that appeared to be relevant in the DBT for BN groups. The

first of those is the instillation of hope. Yalom and Leszcz explain that hope in clients can be increased through having faith in the treatment model, through the therapist's conviction in the usefulness of the treatment and through observing improvement in other group members. What I noticed in the groups was the powerful effects of observing improvement in others. In one of the groups there were two participants who had already attended a CBT group for BN and although they were still suffering with significant symptoms of BN they were further along in their recovery journey than the other participants in the group. Their testimony of making behavioural changes (e.g. restricting their food intake less) and attitudinal changes (e.g. not viewing food in a dichotomous good/bad manner) made a significant impact on other participants who, in their follow-up appointments, reported these group members as an important part of the group's usefulness. One example of this impact was from one participant who, after hearing that another group member had stopped taking laxatives a year beforehand and had maintained her abstinence, went home that evening, threw away her remaining laxatives and did not take laxatives again throughout the group or during the one month follow-up period. I think she experienced the installation of hope that Yalom and Leszcz describe.

The second of Yalom and Leszcz's (2005) group process factors that appeared to play an important role in the groups I facilitated was universality. Universality is the feeling that one is not alone in one's symptoms or in one's distress. It is the experience of seeing similarities in other group members to yourself and understanding that you are not disgusting and shameful but you are suffering from an illness that others are also experiencing. Yalom and Leszcz specifically mention BN in their discussion of universality because EDs are often secretive disorders in which sufferers try to hide their behaviours because of guilt and shame (Hayaki, Friedman, & Brownell, 2002). The experience of universality was one that many of the group members cited as an important factor in the acceptability of the group intervention and their engagement in the intervention. It

appears that universality is also linked with the installation of hope because if a client observes that they are similar to others in the group and others are able to make therapeutic changes then this gives hope to the client that they can also make changes.

The third factor that I observed to be important in the groups was group cohesiveness. Group cohesiveness has been described in many ways but Yalom and Leszcz (2005) described it as the sense of solidarity that develops when group members place a high value on the group and feel comfortable with one another. Yalom and Leszcz discuss the research that has demonstrated a link between group cohesiveness and attendance and engagement. When group cohesiveness is higher, dropout tends to be lower and group members engage more fully in the group. I observed both the positive and negative consequences of group cohesiveness. In one of the groups I facilitated group cohesiveness appeared to be low for the first half of the group. Group members were less inclined to share personal information, one client was openly ambivalent about the group and attendance was inconsistent indicating a lower level of commitment to the group. This group also had a two-week break after session four due to the Christmas holidays, which may have negatively impacted on group cohesiveness. This group had the highest rate of dropouts (50% dropout rate) and sessions felt more challenging, as the facilitator, than they had in other groups. It is possible that as well as lower group cohesiveness there was a 'domino' effect of dropouts in which each dropout normalises dropping out of therapy. Also the more clients that drop out of the group, the more others may doubt the group's effectiveness.

I had a very different experience of group cohesiveness in the final group I facilitated which had a high level of verbal commitment from participants in the first session (after my experience in the previous group, I may have made more effort to elicit this), a high level of personal disclosure, and a strong sense of solidarity. This group only had one dropout. Group cohesiveness is unlikely to be the only factor

determining the dropout rates in these groups but it appeared to play a significant role in the level of engagement from participants.

Reflecting on group processes is both an interesting and important exercise and I will take forward my learning from these groups to other group-based interventions in the future. I am incredibly grateful to all of the participants for their willingness to engage in a group process.

Sexuality and Men with Eating Disorders

The link between my empirical paper and my systematic review may not be immediately obvious. My research study excluded men whereas the systematic review focuses exclusively on men with EDs and their treatment outcomes. When we attended the Research Ethics Committee meeting to answer questions about the study and discuss ethical issues we were asked why men were being excluded from the study. The rationale was that there was unlikely to be enough men recruited to offer a male-only group and that men may have felt uncomfortable in a majority-female group, as well as the possibility that women may have felt less comfortable with a man in the group. Despite having this rationale I was challenged to think more about why men are often excluded from research into EDs, and what is known about men with EDs and their treatment outcomes. This is how the question for my literature review was developed.

I would like to expand on one issue that arose in my literature review but was beyond the scope of the review to explore further. This was the relationship between sexuality and EDs in men. Two of the studies in my literature review reported their participant's sexuality (Harvey, Rawson, Alexander & Bachar, 1994; Weltzin et al., 2012) and one of the studies highlighted sexuality as an issue that was discussed in their male-only treatment groups (Fernandez-Aranda et al., 2009). Psychodynamic theories of EDs often place sexuality and sexual development at the heart of their understanding of EDs. Psychodynamic theories have suggested that EDs in men,

particularly anorexia nervosa (AN), are a way of avoiding sexual development and sexual maturity due to unconscious fears about sexuality (Falstein, Feinstein, & Judas, 1956). Falstein and colleagues suggest that restricting food intake and the resulting weight loss allows adolescent males to remain under-developed, which results in a suppressed sex drive. This allows adolescent males to continue to be looked after by their mothers, who are commonly described as over-involved, and allows them to avoid facing their conflicts about their gender identity, sexuality and adult responsibilities. Herzog, Bradburn, and Newman (1990) discussed evidence available at the time on sexuality in males with EDs and concluded that sexual anxiety, gender identity issues, and homosexuality were significant risk factors for the development of EDs. Evidence to support the suggestion that some men with EDs experience fear and anxiety about their sexuality comes from a study by Fichter and Daser (1987) who interviewed 20 men with AN. They found that 95% of their participants reported attempting to suppress their sexual desires and 75% reported anxiety and disgust in relation to heterosexual relationships (this included both homosexual and heterosexual men). Although it is possible that emerging sexuality is a feared experience for some adolescent males, which leads to ED symptoms, it is not clear how psychodynamic theories can account for men developing EDs after the adolescent period when they are no longer experiencing the sexual developments of puberty.

Homosexuality has been viewed as a risk factor for EDs in men because many studies have found a higher prevalence of homosexuality in male ED populations than in the general population (Freeman, 2005; Russell & Keel, 2002). A number of explanations have been put forward to account for this difference. One explanation is that the male gay community tends to place a higher value on physical attractiveness than heterosexual men, leading to higher levels of body dissatisfaction among gay men, which is a risk factor for the development of EDs (Carlat, Camargo, & Herzog, 1997; Dakanalis et al., 2014; Freeman, 2005). There is

evidence to suggest that gay men have higher levels of appearance related anxiety, body shame, and disordered eating when compared to heterosexual men (Carper, Negy, & Tantleff-Dunn, 2010; Dakanalis et al., 2014). The objectification theory (Fredrickson & Roberts, 1997) suggests that the sexual objectification of men's and women's bodies in the media leads viewers of media to see their own bodies as objects, and base their value on their physical attractiveness. Dakanalis et al. wanted to test the objectification theory, which has previously been used to understand the risks associated with EDs in women, with homosexual men. They compared 125 homosexual men to 130 heterosexual men and found that gay men reported significantly more exposure to sexually objectifying media. Media exposure positively correlated with body surveillance and body shame in both homosexual and heterosexual men. However, for gay men body surveillance was positively correlated with disordered eating but this was not the case for heterosexual men. They concluded that gay men may have a higher prevalence of EDs because they are exposed to more sexually objectifying media and they are more affected by this media exposure because of the high value placed on physical attractiveness in the gay community.

An alternative explanation of the higher prevalence of EDs in homosexual men may be that the lesbian, gay, bisexual, and transgender (LGBT) community have been found to have a higher prevalence of general mental health problems than their heterosexual counterparts (Meyer, 2003). Meyer (2003) presents a minority stress model as a way of understanding the prevalence of mental health problems in the LGBT community. Meyer discusses the relationship between stressful life events and mental health outcomes and highlights the stressors unique to LGBT communities, such as homophobic prejudice, discrimination and violence. So it is possible that the higher prevalence of EDs in homosexual men reflect the higher prevalence of poor mental health outcomes in the LGBT community, which is closely related to experiences of stigma and discrimination.

Another explanation for the higher prevalence of EDs found in homosexual men is that this difference reflects a treatment seeking difference rather than a difference in prevalence (Freeman, 2005). Cochran and Mays (2000) used a national household survey in the US to compare the prevalence of mental health problems and treatment seeking behaviour in heterosexual and homosexual individuals. They found that homosexual men and women were more likely to have accessed mental health services in the last year than heterosexual participants. However, it is difficult to know whether this is because of increased treatment seeking behaviour or the increased prevalence of mental health problems found in homosexual participants. Meyer (2003) suggests that because homosexual individuals have gone through a 'coming out' period, they have usually experienced a period of reflection and introspection that may make them more aware of their own psychology and mental health difficulties, when they are present. They may therefore find it easier to disclose mental health problems in clinical settings and in research situations. The implication is that the higher prevalence of mental health problems in homosexual research participants may actually be a reflection of under-reporting by heterosexual participants.

It is unclear whether the higher prevalence of EDs in homosexual men is due to a high value being placed on physical attractiveness combined with a greater exposure to sexually objectifying media, leading to higher levels of body dissatisfaction, whether it is due to increased treatment-seeking behaviour, or whether it is related to the higher levels of mental health problems found in the LGBT community. It is likely that a combination of each of these factors plays a role. Nonetheless, the evidence seems to suggest that sexuality is important in the development of EDs and homosexuality may be a risk factor for EDs in men.

Conclusions

This critical appraisal has discussed the diverse topics of research challenges, group therapy processes, and sexuality in men with EDs. This research was challenging in a number of ways, firstly due to difficulties in recruitment and secondly due to challenges with group processes and group dynamics. The research study could have been improved by making some practical changes to improve the recruitment process. The research intervention itself may also have been improved by attending more closely to group processes and trying to support the installation of hope, universality and group cohesiveness in each of the therapy groups. Finally, this critical appraisal has considered the relationship between sexuality and EDs in men. The relationship between sexuality and EDs is a complex one that could benefit from further exploration to ensure that, where possible, risk factors for homosexual men are reduced. Further research could explore the lived experience of homosexual men with EDs to more fully understand the impact of sexuality on the development of their symptoms.

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Appendices

Appendix A

Table Documenting Details of the Literature Review

Details of Literature Search

Database	Date searched	Search terms used	Limits applied
Medline	15 th August 2014	Treatment outcome*, outcome*, effectiveness, efficacy, anorexia nervosa, bulimia nervosa, binge eating disorder, purging, eating disorder, EDNOS, male, men Subject Headings: Treatment Outcomes, Eating Disorders, Human Males	Humans English language
PsychINFO	20 th August 2014	Treatment outcome*, outcome*, effectiveness, efficacy, anorexia nervosa, bulimia nervosa, binge eating disorder, purging, eating disorders, EDNOS, male, men Subject Headings: Treatment Outcomes, Eating Disorders, Human Males	Humans English language
Web of Science	29 th August 2014	Treatment outcome*, outcome*, effectiveness, efficacy, anorexia nervosa, bulimia nervosa, binge eating disorder, purging, eating disorders, EDNOS, male, men	None
Cochrane Library (via Wiley Online Library)	29 th August 2014	Treatment outcome*, outcome*, effectiveness, efficacy, anorexia nervosa, bulimia nervosa, binge eating disorder, purging, eating disorder, EDNOS, male, men	None

Appendix B

Table Summarising Excluded Studies

Summary of Excluded Studies

Study and country	Population & number of men	Setting	Design	Quality rating	Intervention	Length of follow-up	Reason for exclusion
Crisp et al. (1986); UK	Referrals to an ED unit 27 men	Eating Disorder Clinic	Pretest-posttest design	Cahill quality rating = 15	Re-feeding alongside individual and family psychotherapy	2-20 years	Reporting outcomes for the same participants as Burns & Crisp (1984).
Fluckiger et al. (2011); Switzerland	Community sample with BED 8 men	University Clinical Psychology Department	RCT	Downs & Black rating = 17	Group CBT Group Behaviour Weight Loss Therapy (BWLT)	End of treatment	Reporting outcomes for the same participants as Munsch et al. (2007).

Appendix C
Participant Information Sheet

RESEARCH DEPARTMENT OF CLINICAL,
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Participant Information Sheet
Version 7 (21/05/2014)

Researchers: Anna Hall and Sharlene Akinyemi

Group DBT for bulimia nervosa: An effectiveness study

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 20-30 minutes. Please take some time to read this sheet, and to discuss it with other people if you wish. You are also very welcome to ask us any further questions about the study, or if you find anything on this sheet unclear.

Part 1 of the information sheet

What is the purpose of this study?

Previous research has shown an important link between the ability to manage emotions and the occurrence of bingeing and purging. There is a model of bulimia nervosa that suggests that bingeing and purging are a way of controlling negative emotions. Dialectical Behaviour Therapy (DBT) is a therapy that aims to help people understand their emotional experiences and learn to regulate their emotions in healthy ways. There have been a small number of studies that show DBT is an effective treatment for reducing bulimia nervosa symptoms. There are two parts to this study. Firstly, this study is investigating the feasibility of running 12-week DBT skills groups for individuals with a diagnosis of bulimia nervosa. We will be investigating whether a 12-week DBT skills group is an acceptable intervention and whether it is effective in reducing bulimic symptoms. Secondly, the study aims to investigate whether DBT groups increase mindfulness and acceptance skills in individuals with bulimia nervosa. If DBT is shown to be effective, the study will investigate whether increases in mindfulness and acceptance predict improvements in bulimic symptoms.

Why have I been invited to take part?

You have been invited to take part in this study because a healthcare professional has identified you as someone who has bulimia nervosa or difficulties with bingeing and purging. We aim to recruit approximately 96 people to take part in our study.

Do I have to take part?

No. Taking part in the study is entirely voluntary. It is your choice whether or not you would like to participate. Deciding not to take part in the study will not affect the care you receive from services either now or in the future.

If you do decide to participate, you will be given this information sheet to keep, and you will later be asked to sign a consent form stating that you wish to take part. If

you do give consent to take part in the study, you are still free to leave the study at any point, without giving a reason. This will not affect the care you are currently receiving, or will receive in the future. If you decide to withdraw from the study, you can request that all of the information that you have provided be removed by the researcher.

What will happen to me if I take part?

If you wish to take part in the study, then please ring us on 07798 585 147 and we will arrange a time to discuss the study in more detail and to complete the first assessment. Alternatively, if you prefer, you can ask the member of staff who gave you this information sheet to ring us and pass on your contact details. We can then contact you to arrange a convenient time to meet. At this meeting, you will meet with Anna Hall or Sharlene Akinyemi (primary researchers) or another member of the research team and you can ask any other questions you may have. You will then be asked to sign a consent form to say that you wish to take part in the study.

At the assessment appointment you will be asked to fill in eight questionnaires about your mood, your bulimic symptoms and your use of NHS services (the questionnaires will take approximately 50 minutes to complete). The assessment appointment will take approximately one and a half hours to complete. After this meeting, if you agree you would like to go ahead with the study, we will book you into a DBT group running in North East London. You will be asked to attend all 12 sessions of the group, which will run weekly. However we understand that people sometimes have to miss sessions, due to unforeseeable circumstances, and you will not be excluded from the study if this happens. Each group session will last for a duration of two hours. One month after the group has finished we will invite you back for a follow-up session in which we will ask for feedback about the group and ask you to fill in the same questionnaires you filled out in your first assessment. The main aim of the follow-up session is to find out how you experienced the group and what you found helpful. Your opinions and experiences will help inform the conclusions of our research. As a result we would like to record the follow-up sessions. However this is not compulsory, and if you do agree to your session being recorded, we will ask you to sign a consent form.

As an acknowledgement of your time, we will be offering you a £5 voucher for your participation in the assessment session and a £10 voucher for your participation in the follow-up session. You will receive both of the vouchers when you attend the follow-up session. If you do not attend the follow-up session your £5 voucher from the assessment session will be posted to you.

The meetings and the groups will take place at NHS settings across North East London.

From now until the follow-up session, the length of your involvement in our research study will be approximately four months. We will be conducting the research until October 2015.

No part of the study is compulsory, and it is not related to the care that you receive from your GP, hospital or other mental health professionals.

What will I have to do?

If you decide to take part in our research you will be expected to attend the assessment appointment, 12 weekly DBT group sessions and a follow-up appointment. Furthermore, you will be required to complete questionnaires about your mood and bulimic symptoms.

What are the possible disadvantages and risks of taking part?

Some people can find it upsetting to talk about their personal experiences. However, we will support you if you become upset because this is an important part

of the therapy. We will also signpost you to other support services if you need further support. You can get further support from your GP, Mental Health Direct and the Samaritans. We will also provide the contact details of the Chief Investigator, Janet Feigenbaum and the Research Supervisor, Lucy Serpell should you need additional support.

People may find filling out a number of questionnaires time consuming and inconvenient. We will ask you to complete eight questionnaires at the assessment and follow-up appointments, this will take approximately 30 minutes. We will ask you to complete four of those questionnaires on a weekly basis (approximately 15 minutes) and two of those questionnaires every three weeks (approximately 10 minutes). Some of these questionnaires are the same or similar to questionnaires that you would be asked to complete in routine practice but others will be beyond standard practice. To minimise the potential burden you will be given the option of completing the weekly questionnaires on an electronic system which can be accessed via the internet and therefore, enables you to complete the questionnaires on your home computers, smart phones or tablets.

What are the possible benefits of taking part?

You may find the therapy effective for learning how to manage your bulimia nervosa and the information gathered during this study will also help to inform our understanding of treatment for bulimia nervosa, which will hopefully be a step towards improving interventions in the future.

What happens when the research study stops?

The results of the research study will be written up as part of Anna Hall's and Sharlene Akinyemi's theses for the Clinical Psychology Doctorate at University College London (UCL). The report of the study could also be published in relevant journals outside UCL. As mentioned, you will not be identifiable from these results. At the end of data collection we will invite you to a meeting to review the results and help us make sense of what we found. In addition we will send you a copy of the report of the study.

What if there is a problem?

Every care will be taken in the course of this study to protect you. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

Part 2 of the information sheet

What if relevant new information becomes available?

If this happens, your research therapist might consider you should withdraw from the study. They will explain the reasons and arrange for your care to continue.

What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff, you should initially contact Dr Janet Feigenbaum, who is the Chief Investigator for the research, and is based both in NELFT and University College London. If she is not able to resolve the complaint or you are not satisfied with her actions then the normal National Health Service complaints mechanisms are available to you. Please ask your research therapist if you would like more information on this.

If you suspect that harm is the result of UCL or the hospital's negligence then you may be able to claim compensation. After discussing with your research therapist please make the claim in writing to the Dr Janet Feigenbaum, Chief Investigator at IMPART Goodmayes Hospital, Barley Lane, Ilford, IG3 8XP. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

In the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. If this is the case you may make the claim in writing to Dr Janet Feigenbaum, who is the Chief Investigator for the research. She will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Will my taking part in the study be kept confidential?

If you give us consent, we will inform your GP of your participation in this study. If you are currently on the waiting list for a psychological therapy service we will also inform them when you start and complete the study. However, information collected during all stages of the study will be kept strictly confidential. Any information that we collect can only be viewed by members of the research. However, if through the course of the study we became concerned about risk of harm to yourself or others, based on NHS policy, this information will be shared with clinicians involved in your care, if necessary.

Your consent form will be kept in a separate location from your questionnaires, ensuring that this remains anonymous. All data will be stored in secure locations and on computers or flash drives which are password protected. Any published data will also be entirely anonymous meaning individuals cannot be identified.

The data from this study will be stored in accordance with the UCL and NHS Data Protection and Records Management policies.

Who is organising and funding the research?

The research has been organised by Anna Hall and Sharlene Akinyemi, Trainee Clinical Psychologists. They are conducting this study as part of their Clinical Psychology Doctorates. The research will be funded by UCL.

Who has reviewed this study?

This study has been reviewed by the research committee in the clinical psychology department at UCL, by the NELFT Research and Development department and by Bloomsbury Research Ethics Committee.

Further information

Patient Advice and Liaison Service (PALS); they are an independent contact that you can address questions to about taking part in this research:

King Georges' Hospital

Barley Lane

Ilford

Essex

IG3 8YB

Telephone: 0800 389 8324

Contact Details of Researchers

If you wish to contact us to discuss any of the information further or any concerns you have about the study, then please do so by ringing 07798 585 147.

If you feel that we have not addressed your questions adequately or if you have any concerns about our conduct, then please contact our supervisor Dr. Janet Feigenbaum (Strategic and Clinical Lead for Personality Disorder Services, North East London NHS Foundation Trust and Senior Lecturer, Research Department of Clinical, Educational and Health Psychology, UCL) on 0300 555 1213 or by email at janet.feigenbaum@nhs.net.

Thank you very much for taking the time to read this information sheet.
Anna Hall and Sharlene Akinyemi
Trainee Clinical Psychologists

Appendix D
Study Poster

Do you have **bulimia**?

Do you **struggle** with bingeing and purging?



We are running a research study into the effectiveness of Dialectical Behaviour Therapy (DBT) for people with bulimia nervosa. We are running 12-week DBT groups for people who would like support to manage their bulimia.

If you are interested in participating in our study or would just like to find out more then contact us on the number or email below.

NUMBER
EMAIL

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Appendix E
Consent Form



RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY
UNIVERSITY COLLEGE LONDON
GOWER ST
LONDON
WC1E 6BT



Study Number: 14/0104
Patient Identification Number for this trial:

**Consent Form
Version 5 (02/07/2014)**

Researchers: Anna Hall and Sharlene Akinyemi

**Group DBT for bulimia nervosa: An effectiveness study
CONSENT FORM**

Before participating in this research study, please read the Participant Information Sheet Version 7 (21/05/2014) and then, if you are happy to participate, complete this form.

Please read the statements below. If you agree with a statement please initial the box next to it and then write your initials and the date, and sign the form in the spaces provided. Your consent form will be stored in a secure location separate from your questionnaires. This will ensure that your completed questionnaire pack remains anonymous. Thank you.

I confirm that I have read and understand the Participant Information Sheet Version 6 (26/03/2014) for the above study and have had the opportunity to consider this information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand that if I withdraw from the study, I can request that all of the information I have provided will be removed by the researchers.

I understand that my participation in the follow up session, and consent to be audio recorded is voluntary. I understand that my decision will not affect my care after the follow up session. I understand the recording will be used for the purpose of research only, and will be stored in keeping with the data protection act, 1998.

I understand and agree that my GP will be informed of my involvement in the study, as will any other mental health professionals involved in my care.

I understand that the information that I provide will be included in the researchers' doctoral thesis, will be published in a scientific journal, and may be presented at a national or international conference. I understand that all information included will be anonymised to protect my identity.

I give my consent to take part in the above study.

I understand that relevant sections of my medical notes and data, collected during the study may be looked at by individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

Please write your initials and the date, and sign below:

INITIALS	
DATE	
SIGNATURE	

Researchers details:

INITIALS	
DATE	
SIGNATURE	

Appendix F
Details of Joint Working

Outline of Joint Working

Data collection was carried out jointly with another Doctorate in Clinical Psychology Trainee, Sharlene Akinyemi, who was considering the change in mindfulness and acceptance following DBT for BN.

Recruitment, assessment, group facilitation, and data collection were conducted jointly for the first three groups that were run. Both trainees were equally involved in these stages of the research. Recruitment, assessment, group facilitation, and data collection for the fourth group was conducted by myself.

All theoretical conceptualisation, data analysis, and writing up were conducted independently. The focus of the two theses were different, with my write-up focusing on the feasibility and effectiveness of the intervention and Sharlene Akinyemi's write-up focusing on the mechanisms of change in the intervention.

Reference

Akinyemi, S. (2015). A multiple single case design study of a Dialectical Behaviour Therapy skills group for bulimia nervosa: does it lead to an increase in mindfulness and acceptance? *In preparation*.

Appendix G
Follow-up Questionnaire

Questionnaire for feedback session
Version 1 (09/04/2014)
Researchers: Anna Hall and Sharlene Akinyemi

Group DBT for bulimia nervosa: An effectiveness study

1. How would you rate the change in your symptoms of bulimia?

Significantly worsened Worsened Stayed the same Improved Significantly improved

2. Rate how much you agree or disagree with this statement:

The group has helped me to better understand and address my difficulties.

Strongly disagree Disagree Not sure Agree Strongly agree

3. Rate how much you agree or disagree with this statement:

The weekly homework helped me put into practice the skills I learnt in the group.

Strongly disagree Disagree Not sure Agree Strongly agree

4. What do you think about the number of sessions offered?

Too many Just right Not enough

5. Would you recommend this group to someone else struggling with symptoms of bulimia?

Yes Not sure No

Thank you for taking the time to complete this questionnaire!

Appendix H
Ethical Approval Letter



Health Research Authority

National Research Ethics Service

NRES Committee London - Bloomsbury

HRA NRES Centre Manchester
Barlow House 3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7815

Fax: 0161 625 7299

23 June 2014

Dr Janet Feigenbaum
Department of Clinical, Educational and Health
University College London
Gower Street
London
WC1E 6BT

Dear Dr Feigenbaum

Study title: Group Dialectical Behavioural Therapy (DBT) for bulimia
nervosa: An effectiveness study
REC reference: 14/LO/0672
IRAS project ID: 143574

Thank you for your email of 16 June 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Dr Ashley Totenhofer, nrescommittee.london-bloomsbury@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation

with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants	2	31 January 2014
Covering letter on headed paper		04 April 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	Arthur J Gallagher International	28 July 2013
GP/consultant information sheets or letters	7	11 June 2014
Interview schedules or topic guides for participants	2	28 March 2014
Non-validated questionnaire [BEST]	Validated	
Non-validated questionnaire [Standardised Assessment of Personality]	Validated	
Non-validated questionnaire [Questionnaire for Feedback Session]	1	09 April 2014
Other [Divisional Clinical Lead Approval email]		04 April 2014
Participant consent form	4	28 March 2014
Participant information sheet (PIS) [Participant]	7	21 May 2014
REC Application Form	3.5	16 June 2014
Research protocol or project proposal	5	14 February 2014
Response to Request for Further Information		16 June 2014
Summary CV for Chief Investigator (CI)	Mary Serpell	
Summary CV for Chief Investigator (CI)	Anna Hall	
Summary CV for Chief Investigator (CI)	Janet Feigenbaum	
Summary CV for Chief Investigator (CI)	Sharlene Akinyemi	
Summary, synopsis or diagram (flowchart) of protocol in non technical language	Flowchart - Version 4	28 March 2014
Validated questionnaire [WSAS]		
Validated questionnaire [AAQ-II]		
Validated questionnaire [Service Utilisation Questionnaire]		
Validated questionnaire [EDE-Q]		
Validated questionnaire [Five Facet Mindfulness Questionnaire]		
Validated questionnaire [Emotional Eating Scale]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *After ethical review – guidance for researchers* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/LO/0672	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



Signed on behalf of:
Reverend James Linthicum
Vice-Chair

Email: nrescommittee.london-bloomsbury@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Clara Kalu - University College London
Ms Fiona Horton - North East London NHS Foundation Trust
Mrs Anna Hall - University College London

Appendix I

GP Letter

RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY
UNIVERSITY COLLEGE LONDON
GOWER ST
LONDON
WC1E 6BT



GP Letter

Version 4 (26/03/2014)

Researchers: Anna Hall and Sharlene Akinyemi

Group DBT for bulimia nervosa: An effectiveness study

Dear GP NAME / PERSONAL THERAPIST,

Re: PARTICIPANT NAME, D.O.B.
ADDRESS, NHS number

I am writing to inform you that your patient, PARTICIPANT NAME, has agreed to participate in a study assessing the effectiveness of group based Dialectical Behaviour Therapy (DBT) for bulimia nervosa. The study involves attending an assessment session, completing a 12-week group DBT intervention and attending a follow-up session.

I have included a copy of the participant information sheet for further information.

If you have any questions at all please feel free to contact us on [REDACTED].

Yours sincerely,

Anna Hall / Sharlene Akinyemi
Trainee Clinical Psychologist

Cc. PARTICIPANT NAME

Appendix J
GP Closing Letter

RESEARCH DEPARTMENT OF CLINICAL,
EDUCATIONAL AND HEALTH PSYCHOLOGY
UNIVERSITY COLLEGE LONDON
GOWER ST
LONDON
WC1E 6BT



GP Letter

Researchers: Anna Hall and Sharlene Akinyemi

GP NAME
GP ADDRESS

DATE

Group DBT for bulimia nervosa: An effectiveness study

Dear Dr NAME,
Re: PARTICIPANT NAME D.O.B: NHS number:
Address:

Following my previous letter dated XXX we are writing to inform you that PARTICIPANT NAME has now completed the 12-week Dialectical Behavioural Therapy (DBT) group for bulimia nervosa. DBT understands binge eating and purging as a way of managing negative emotions. The purpose of the group was to teach individuals alternative and more helpful ways of managing negative thoughts and emotions, with the aim of reducing bulimic symptoms.

PARTICIPANT NAME attended X out of 12 group sessions. NOTE CLIENT'S ENGAGEMENT IN THE GROUP. I saw PARTICIPANT NAME for a follow up today, one month after the DBT group finished. SUMMARISE CLIENT'S CHANGE IN SYMPTOMS.

PARTICIPANT NAME remains under the care of the Eating Disorder Service/IMPART service (DELETE AS APPROPRIATE). If you have any questions at all please feel free to contact me on [REDACTED].

Yours sincerely,

Anna Hall/ Sharlene Akinyemi
Trainee Clinical Psychologist

Cc. PARTICIPANT