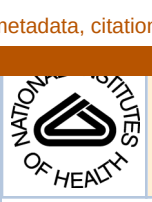

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CBT4BN versus CBTF2F: Comparison of Online versus Face-To-FaceTreatment for Bulimia Nervosa

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Abstract

Cognitive-behavioral therapy (CBT) is currently the "gold standard" for treatment of bulimia nervosa (BN), and is effective for approximately 40–60% of individuals receiving treatment; however, the majority of individuals in need of care do not have access to CBT. New strategies for service delivery of CBT and for maximizing maintenance of treatment benefits are critical for improving our ability to treat BN. This clinical trial is comparing an Internet-based version of CBT (CBT4BN) in which group intervention is conducted via therapeutic chat group with traditional group CBT (CBTF2F) for BN conducted via face-to-face therapy group. The purpose of the trial is to determine whether manualized CBT delivered via the Internet is not inferior to the gold standard of manualized group CBT. In this two-site randomized controlled trial, powered for non-inferiority analyses, 180 individuals with BN are being randomized to either CBT4BN or CBTF2F. We hypothesize that CBT4BN will not be inferior to CBTF2F and that participants will value the convenience of an online intervention. If not inferior, CBT4BN may be a cost-effective approach to service delivery for individuals requiring treatment for BN.

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1. Introduction

BN is a serious psychiatric disorder that occurs in approximately 1.5% of women and 0.5% of men and typically onsets in adolescence or early adulthood [1]. Cognitive-behavioral therapy (CBT) is the evidence-based treatment of choice for bulimia nervosa (BN), yet a considerable porportion of patients with BN do not have access to this approach. By leveraging technology and Internet-based delivery, we are exploring whether an Internet-based version of CBT (CBT4BN) in which group intervention is conducted via moderated therapeutic chat group is not inferior to the gold standard of face-to-face group CBT for BN (CBTF2F). This trial represents a shift in emphasis from improving efficacy of treatments to improvement of service delivery. Existing services are sub-optimal because: (1) even the best available treatment (CBT) does not help all patients, and (2) not all patients have access to CBT. Therefore, extending the reach of treatment to a greater number of individuals with a treatment that is not inferior to the gold standard is a reasonable strategy to address patient access—especially, if achievable in a cost-efficient manner.

1.1 Significance of Bulimia Nervosa

The core features of BN include repeated episodes of binge eating followed by inappropriate use of compensatory behaviors such as self-induced vomiting or misuse of laxatives. Individuals with BN place undue emphasis on body weight and shape on their self-evaluation [2]. BN is associated with significant medical and psychiatric morbidity [3]. Specifically, individuals with BN frequently present with major depression and anxiety disorders, display problems with impulse control, and are at increased risk for substance use disorders and Axis II pathology [4–11].

Physical complications of BN include fatigue, gastrointestinal problems, reflux, esophageal tears, electrolyte imbalances, and cardiac irregularities [12–14]. Mortality from BN is elevated [15]. Although one-half to two-thirds of individuals with BN eventually achieve full or partial remission [12, 16, 17], 23% of cases have a protracted course [18]. In addition, crossover to eating disorder not otherwise specified (EDNOS) and binge eating disorder (BED) occurs in nearly 20% of cases [18]. Thus, BN is frequently associated with significant long-term medical and psychological impairment.

1.2 Treatment for Bulimia Nervosa: Examining the Evidence Base

CBT is a multi-modal intervention that includes psychoeducation, self-monitoring, recognizing and modifying responses to antecedent cues, challenging automatic thoughts, thought restructuring, problem solving, exposure with response prevention, and relapse prevention [19–21]. CBT is currently considered the “gold standard” for treatment of BN in adults [22–24]. Approximately 40–60% of patients who complete CBT treatment demonstrate significant improvement [21, 25–30].

Notably, group and individual CBT for BN are effective [31–33]. Individuals in both treatments demonstrate decreases in objective and subjective binge episodes, vomiting, laxative use, and and cognitive and behavioral features of the eating disorder [31, 33]. Given the similarity of outcomes, group CBT is more economical from a cost-effectiveness perspective and represents a more parsimonious use of the therapist’s time [34].

There are two significant issues limiting the effectiveness of CBT in the treatment of BN. A significant minority of individuals do not respond to intervention and rates of attrition are high [24]. Moreover, relapse following treatment remains a substantial concern. Outcome studies suggest one third of women relapse [16] and that six months post treatment represents the highest risk period for relapse [35] with risk declining four years after treatment [16].

Second, although CBT is effective for a substantial portion of individuals seeking treatment, it is unavailable to many [36]. Well-trained CBT therapists are not available in many locations in the United States and throughout the world and telemedicine options are just emerging [37–39]. Thus many individuals requiring care are unable to access CBT, or accessing treatment is burdensome secondary to time or financial commitments. Group formats for CBT can also deter those with considerable social anxiety. To address this problem, the creation of new service delivery approaches are important [40, 41].

1.3 Incorporating Technology is Essential

Incorporating technology into CBT represents an attractive option to enhance mental health care for patients with BN. The Internet is rapidly becoming the primary source of healthcare information [42] and consumers are increasingly also turning to the Internet and other forms of technology for treatment, coaching, and support [43–45]. Modern Internet-based interventions are enhanced by interactive websites, self-monitoring and feedback tools and communication platforms [46].

Successful computer-based programs and the use of online anonymous environments have been reported for a number of problems including obsessive compulsive disorder, sexual abuse, anxiety, depression, obesity, smoking, and eating disorders [47–55]. One variable feature of computer-aided psychotherapy is the extent to which, and frequency with which, interaction with a human being occurs [56]. It seems to be important that at least short and regular therapeutic contact is provided, otherwise high drop-out rates and reduced effectiveness are likely to occur [57]. To integrate a group therapy setting in a web application, text-based chat-groups have been shown to be an appropriate tool [58]. For example Golkaramnay [59] investigated the effectiveness of group therapy delivered via Internet chat following inpatient treatment in 114 patients with various psychiatric diagnoses versus a matched control (no chat) group. Chat groups met weekly for 12–15 weeks for 90 minutes. Results showed that chat was well accepted as evidenced by a low dropout rate (9.4%), high session attendance (85%), and positive evaluation of sessions (90% were satisfied). Twelve months after discharge, chat participants showed a substantially lower risk for negative outcome relative to controls (24.7% versus 38.5%) and significantly fewer chat participants (22.2%) than control participants (46.5%) experienced a relapse [60]. Thus, chat-based therapy is an attractive platform for disseminating evidence-based treatment for psychiatric disorders.

2. Objectives of the Clinical Trial

The overall objective of this trial is to determine whether CBT4BN yields outcomes that are not inferior to those obtained with CBTF2F as a crtical first step in informing enhancements to health service delivery for patients with BN. In this manuscript, we detail the design and methods of the clinical trial and introduce the nature of the chat therapy delivery method. The study has four *specific aims*: To (1) compare the relative efficacy of CBT4BN versus CBTF2F; (2) determine the relative attrition, adherence, and acceptability of CBT4BN versus CBTF2F; (3) compare maintenance of treatment gains between CBT4BN versus CBTF2F; and (4) determine the relative cost-effectiveness of CBT4BN versus CBTF2F.

3. Study Design

3.1 Overview

The study is being conducted at University of North Carolina at Chapel Hill and at Western Psychiatric Institute and Clinic (WPIC) of the University of Pittsburgh Medical Center. Participants are being recruited from the greater Raleigh-Durham and Pittsburgh metropolitan areas. Participants are randomly assigned (using a permuted block algorithm

stratified by center) to 16 sessions over 20 weeks of either CBT4BN or CBTF2F (12 weekly sessions followed by 4 fortnightly sessions). Follow-up evaluations are scheduled at three, six, and 12 months post-treatment. The governing Institutional Review Board (IRB) at the University of North Carolina at Chapel Hill and the University of Pittsburgh Medical Center approved the protocol for this study.

3.4 Inclusion/Exclusion Criteria

Inclusion—To be eligible for participation, individuals must: (1) meet criteria for DSM-IV BN; (2) be age 18 or older; (3) speak English; and (4) have reliable, private Internet access. Participants in this study are permitted to take medications including psychotropic medications but are asked to not modify medications or dosages during the duration of the clinical trial.

Exclusion—Participants are excluded from the study if they report any of the following: (1) any major medical condition that would interfere with treatment or require alternative treatment (e.g., type 1 diabetes mellitus); (2) alcohol or drug dependence in the last three months; (3) current significant suicidal ideation reported during the clinical assessment or on the Beck Depression Inventory-II (BDI–II) [61] at baseline; (4) developmental disability that would impair the ability of the participant to benefit from psychotherapy or to use the Internet program effectively; (5) psychosis, including schizophrenia, and (6) bipolar I disorder.

3.3 Recruitment, Retention, and Incentives

Participants are recruited from the Eating Disorders Program at the University of North Carolina and the Center for Overcoming Problem Eating at the University of Pittsburgh to achieve a final sample size of 180. In addition, we send regular letters to local university counseling centers, physicians, and mental health organizations, particularly those that serve minority groups. Advertisements are also placed in local media through university Listservs, and radio advertisements and in social media through Facebook and Twitter.

We implement several strategies to minimize attrition, including the use of incentives. Participants are given $20 for completing the end of treatment assessment and $20 for completing the 12 month post-treatment assessment. Additional measures used to minimize attrition include asking participants to provide at least two phone numbers or email addresses where they can be reached and asking for an alternative or emergency contact who would know their contact information. Reminder calls and/or emails are made for all assessment appointments. At least six attempts are made (at several times of day and night) to reschedule missed assessment appointments. The number of sessions attended by participants are also being recorded and will be considered in the analyses.

3.4 Assessment Schedule

Table 1 presents the assessment schedule for the clinical trial. Individuals in CBT4BN complete the weekly assessments online and those in CBTF2F complete the assessments via paper and pencil.

3.5 Assessment Instruments

Eating Disorder Symptoms

Eating Disorders Examination (EDE; [62]): The EDE is a valid and reliable investigator-administered interview used to assess current eating disorder symptoms and is used as the primary measure of treatment outcome.

Eating Disorders Examination—Questionnaire Version (EDE-Q; [63]): The EDE-Q is a 38-item self-report measure based on the EDE. It requires about 15 minutes to complete. Research suggests good agreement between the EDE and EDE-Q on objective bulimic episodes, dietary restraint, and the attitudinal features of shape and weight concerns [64, 65]. The EDE-Q assesses interim changes in eating disorders symptoms during the acute and follow-up periods.

The Short Evaluation of Eating Disorders (SEED; [66]) is a brief instrument designed to assess eating disorder symptoms on a weekly basis during treatment participation.

ADQ: The ADQ is a follow-up to the SEED which asks participants to record the exact number of times and days per week they engaged in eating disorder behaviors [66].

Height and Weight: We weigh patients according to protocol at baseline using a regularly calibrated digital scale. Self-reported weights are acceptable if participants are unable or unwilling to return for face-to-face follow-up assessments. We measure height at baseline using a stadiometer.

Pregnancy Questionnaire: Because weight changes are an outcome variable, we include a 7-item self-report questionnaire assessing current pregnancy, any previous post-treatment pregnancies, birth and lactation status, and pre-pregnancy weight.

McKnight Follow-up of Eating Disorders (MFED): The MFED, developed for the McKnight Foundation studies [40, 67–71] provides interim measures of eating disorder status, status of comorbid psychopathology, and additional treatment received including other medical utilization. The instrument was developed from the Longitudinal Interval Follow-Up Evaluation (LIFE) [72] with additional questions adapted from the Structured Clinical Interview for DSM-IV (SCID), and specific questions developed for measuring medical and mental health utilization. In this trial, we employ only the utilization portion (as eating disorder outcome is being measured in other ways).

Comorbid Psychopathology

Structured Clinical Interview for DSM-IV Axis I Disorders - Patient Edition (SCID-I/P; [73]): The SCID-I/P, a well-studied and widely used semi-structured interview, assesses comorbid Axis I disorders.

Beck Depression Inventory-II (BDI–II; [61]): The BDI, a 21-item self-report questionnaire assesses the severity of current depressive symptoms; the revised version extends the reporting time frame to two weeks.

Beck Anxiety Inventory (BAI; [74]): The BAI is a 21-item self-report measure of anxiety that focuses on somatic symptoms converges with other measures of anxiety and has good reliability and validity.

Clinical and Research Inventory for Eating Disorders (CREAT; [75]: The emotion dysregulation subscale (8 items) of the CREAT assesses participant's awareness of his or her own emotional state. It serves as a supplement to the BDI.

Temperament and Character Inventory (TCI: [76]) The TCI is a 240-item self-report measure that provides assessments of 4 temperament and 3 character dimensions. We are particularly interested in the assessment of harm avoidance and novelty seeking—temperamental traits that have been documented as significant in patients with BN and self-

directedness, a character scale that has been associated with rapid and positive treatment response in BN—and major depression [77, 78], and shown to improve with successful treatment of BN [79]. Self-directedness is assessed at mid-treatment and in post-treatment.

Suicidal Behavior Interview: This is a brief interview (11 items) assessing lifetime self-harm, suicide attempts, and suicidal ideation. All interviewers follow safety assessment protocols in the event that a participant endorses suicidal or self-harm thoughts or behaviors.

Quality of Life

Short-Form Health State Classification (SF-6D; [80]): This is a brief self-report form designed to measure quality of life in six dimensions: physical functioning, role limitation, social functioning, bodily pain, mental health, and vitality. Derived from the commonly used SF-36, it is briefer and has preference weightings for calculation of health utilities in cost effectiveness analysis.

Eating Disorders Quality of Life Questionnaire (EDQOL; [81]): The EDQOL is a health-related quality of life questionnaire that was designed specifically for use with disordered eating patients. The 26-item instrument has excellent test-retest reliability and convergent validity.

Web Self-Efficacy—We use a 16-item questionnaire [82], in which users evaluate their experience with, training in, and expectations for using the Internet.

Treatment Evaluation

Treatment Acceptability: This 9-item self-report measure designed for this study assesses participants' preferences, expectations, and concerns about each treatment condition. It is administered prior to beginning the active treatment phase of the study. Participants answer questions about their expectations for both study conditions.

Post-Treatment Evaluation: This is a 24-item self-report measure designed for this study of participants' experiences in their assigned study treatment condition. Following active treatment participants answer questions based on the condition that they participated in with all questions specific to elements of either the chat or face-to-face group.

Post-Group Evaluation: This is a 15-item self-report measure designed for this study that assesses participants' level of comfort, whether the participants feel supported by the other group members and therapist, and participant emotions following group. The measure also assesses self-reported participant safety at the end of group. Patients complete this weekly at the end of group for all participants. Group therapists are blind to all post-group ratings with the exception of the participant safety question.

Reasons for Drop-Out: This self-report questionnaire was designed for this study and is provided to participants who drop out of the active treatment phase. The questionnaire queries why the group may not have been a good fit for the participant and provides space for specific reasons for drop-out. The questionnaire is presented in a checklist format where participants can indicate any reasons for drop out that may have applied to them.

4.0 Interventions

Individuals are randomized to receive either CBT4BN or CBTF2F. During acute treatment (20 weeks) all individuals are asked to self-monitor in the manner consistent with CBT (e.g., food consumption, binge/purge episodes, situation, thoughts, feelings, intensity). Individuals

in the CBTF2F condition complete their monitoring in self-monitoring booklets by hand and those in CBT4BN complete their monitoring via the CBT4BN website.

4.1 Development of Treatment Manuals for CBTF2F and Internet Modules for CBT4BN

The treatment manual used in CBTF2F and from which the CBT4BN modules were built was initially developed for use in a randomized trial designed to dismantle CBT for the treatment of BN [83]. The basic modules of the CBT intervention include: psychoeducation, self-monitoring, normalization of meals (especially breakfast), cue identification, challenging automatic thoughts, thought restructuring, chaining, and relapse prevention—with special sections on body image, assertiveness, and cultural messages regarding thinness and appearance. Specific goals for each session are outlined clearly in the manuals and modules and homework is assigned after each session. The treatment has been modified both for group format delivery (CBTF2F) over 12–16 sessions and for Internet delivery via CBT4BN and now includes two nutrition modules that focus on the exchange system and are designed to be delivered by a registered dietitian.

Both treatments consists of sixteen, 1.5-hour long sessions delivered over a total of 20 weeks (12 weekly and 4 fortnightly sessions). Groups include 3–5 participants, one therapist, and two sessions with a registered dietitian. The progression of topics is presented in Table 2. Two flex sessions are included in the schedule to be used at the therapist's discretion. If a group struggles with a particular topic or needs additional work, the therapist can invoke a flex session.

4.2 CBTF2F Procedures

Each week, individuals in CBTF2F complete the pre-group assessments (SEED, ADQ, CREAT-ED) via paper and pencil. Self-monitoring is also done via pencil and paper and is collected weekly at each session by the therapist. Each week the therapist returns previous self-monitoring booklets with feedback to the participants and provides new blank self-monitoring booklets. Each group begins with a review of self-monitoring and progresses through the target topic of the week. Participants are given a copy of the module for the following session at the end of each group. At the end of each group meeting, participants complete post-group questionnaires via pencil and paper and turn them in to the therapist who looks only at the safety question. If a participant indicates not feeling safe, the therapist remains with them following group to further assess safety.

4.3 CBT4BN Procedures

The CBT4BN website was built using php, javascript and css and included separate pages for chat group log in, questionnaire assessment (via Web-Akquasi [84, 85]), self-monitoring, study modules and study worksheets. Participants create anonymous usernames and passwords to ensure privacy and confidentiality.

CBT4BN is divided into independent modules for the purpose of this study. Accordingly, individuals are only able to access the current week's module and modules from previous weeks. This allows investigators to equate the pattern of timing of delivery of topics across conditions so that we can more accurately assess the impact of mode of delivery on efficacy of CBT. The modules are released according to the same schedule as CBTF2F outlined in Table 2. Participants are able to access the site at any time. A technical support email address is provided so that participants can contact study coordinators for technical problems. Self-monitoring is conducted through the website. Therapists are able to check in on patients' progress and provide online feedback to self-monitoring and homework exercises at on regularly determined days throughout the week.

Each week, participants in CBT4BN log in 10 minutes prior to chat and complete the pre-chat assessments (SEED, ADQ, CREAT-ED). Participants are required to enter their current phone number and their current physical address as a safety measure and are then permitted to enter the chat room. Participants who miss a chat session receive a phone call from the therapist. Individuals with specific or personal concerns are able to send a request for a 10-minute private chat session with the therapist. These can be conducted after the scheduled chat session. Chats are hosted on the website via the secure UNC Eating Disorders server and participants all use appropriate chat pseudonyms. The chat is text-based, neither video nor audio is included. Post-group questionnaires are completed online at the end of the chat. If a CBT4BN participant indicates feeling unsafe on the post-group questionnaire, the therapist and study coordinators are immediately alerted by email and the therapist follows up with the participant by phone.

Given the novelty of the chat-based delivery format, we include a deidenfitied excerpt from a CBT chat session in the Appendix. This excerpt is from a group session attended by the therapist and 4 patients and occurs near the end of a course of CBT4BN. Comment boxes to the right of the chat alert the reader to unique features of the chat such as direct participant to participant communication, the use of emoticons to convey emotion, and the challenges of monitoring parallel conversations. A color version of the Appendix is available at http://insertwebsitehere.

5. Therapists, Training, and Supervision

Therapists for both conditions are Ph.D. level clinical psychologists or highly experienced master's level clinicians with experience in the provision of psychotherapy for eating or weight disorders.

Training

All therapists (CBTF2F and CBT4BN) familiarize themselves with the treatment manual and read specified preparatory material prior to initiating treatment. An initial two-day workshop was conducted at the beginning of the study for all therapists involved. Drs. Bulik and Marcus provided training in CBT.

Supervision

Dr. Bulik serves as the overall, study-wide supervisor for group and chat therapy as well as the on-site supervisor in Chapel Hill. Dr. Marcus serves as the on-site supervisor in Pittsburgh. Each supervisor meets weekly with study therapists to review patient progress as well as therapist adherence to treatment protocols. Cross-site supervision occurs via telephone as needed to ensure adequate supervision coverage as well as supervision consistency. Group sessions are audiotaped and chat transcripts are electronically saved and reviewed by Drs. Bulik and Marcus. Detailed feedback on each tape and transcript are provided to the therapists by one or both of the study supervisors. Audiotapes for CBT groups and chat transcripts are rated for fidelity to the treatment manual using an adaptation of a fidelity rating scale developed to assess adherence to treatment protocol in a large behavioral therapy outcome study [86]. Three tapes and three chat transcripts, representing early, middle and late therapy sessions, are rated for each group. Ratings are completed by individuals trained to criterion on each rating instrument.

6. Statistical Analyses

For the first specific aim, to compare the relative efficacy of CBT4BN versus CBTF2F, the analysis will be a logistic regression where the predictor variable is treatment assignment, and the response for each participant is abstinence, defined as the completion of 16 sessions

(20 weeks) of treatment and evaluation and being abstinent at the 20-week visit. Conservatively, we will define all participants who fail to meet criteria for abstinence as non-abstinent, under the assumption that if a participant is not able to complete 16 sessions of the treatment, then the treatment has failed to help the participant to achieve abstinence. Thus, for the primary efficacy outcome, we will have no missing data. We have defined the non-inferiority margin as 0.06, justified below under Statistical Power. We will conduct two sensitivity analyses: 1) we will repeat the analysis on completers only, thus making dropouts missing data; and 2) if possible, we will classify dropouts as abstainers or non-abstainers, and then repeat the analysis for all subjects (dropouts plus completers) for whom we are able to make this classification. For the additional primary outcome variables of binge and purge frequency, we will use Poisson regression as these are count variables. We will perform the same sensitivity analyses, consider possibility of a site effect, and assess potential mediators and moderators.

For the second aim, to determine the relative attrition, adherence, and acceptability of CBT4BN versus CBTF2F, we will focus on all-cause treatment discontinuation (dropout) at the end of treatment. Aside from the difference in outcome variable, this hypothesis differs from the primary outcome in that a participant who remains in the study for 20 weeks, but fails to be abstinent would meet this hypothesis's criterion for completion, even though she/he would fail to meet criteria for abstinence in Aim 1. The primary analysis will be a logistic regression, with provision for a site effect with site included as a covariate.

For the third aim, to compare maintenance of treatment gains between CBT4BN versus CBTF2F, the analysis for these outcomes will parallel the analyses for Aim 1, namely a non-inferiority analysis using logistic regression.

Finally, for the fourth aim, to determine the relative cost-effectiveness of CBT4BN versus CBTF2F, we propose a cost minimization analysis based on our primary non-inferiority hypothesis. The cost minimization or cost effectiveness (CE) will be calculated from the third party payer perspective. In addition, a second set of CE analyses from a societal perspective will be completed, using time associated with traveling to and from treatment, as well as the time treatment takes up. Analyses will be conducted based on end of treatment status.

7. Data Management and Safety Monitoring Plan

All participants have a full physical examination at the time of assessment to include height, weight, pulse, and blood pressure. In addition, participants undergo a blood draw for laboratory assessment of Na, K, Cl, CO2, BUN, creatinine, glucose, Ca, Mg, AST, ALT, lipase, CBC, and a serum pregnancy test. A 12 lead EKG is also performed on each participant at the time of baseline assessment. Laboratory assessments are repeated as often as deemed appropriate by the physician based on clinical history.

Participants are referred to their primary care physician if necessary for ongoing medical care during the course of the study. Weekly administration of the SEED, ADQ, and CREAT allow for careful tracking of any deterioration in symptoms and monitoring of harms associated with either CBTF2F or CBT4BN. CBT4BN participants have a monthly scheduled check-in call with the study physician at their site. At follow-ups, all patients are queried regarding any non-study interventions (psychotherapy or medications) that they have received for the treatment of BN.

Data are double-entered by the research assistants with extensive experience in database management. Participants are assigned a code number, which is used, instead of names, to maintain confidentiality. Only study staff have access to identifiable information, and they

are required to complete Health Insurance Portability and Accountability Act (HIPAA) training. In addition, all study staff are required to complete comprehensive research ethics training and to provide documentation prior to funding. All data are collected and maintained in accordance with these legal and ethical standards. All data are transmitted encrypted, the database is password-protected, regularly backed up, and maintained on a secure server behind a firewall.

An independent Data and Safety Monitoring Board (DSMB) is responsible for monitoring the safety of the data obtained in the proposed investigation. The DSMB meets bi-annually, has access to all protocol data, and has the authority to inquire into protocol process and to suspend or terminate the protocol. The board also ensures that the study is being conducted according to protocol specifications. The DSMB receives copies of all reportable adverse events. Any adverse events are reported to the IRB, as well as to the National Institute of Mental Health. In accordance with the Office of Research Subjects Protection reporting requirements, any serious, unexpected, related, or possibly related adverse events is reported to the IRB in writing within two business days of occurrence. The DSMB also prepares yearly reports on the study, which is included in yearly continuation applications.

8. Discussion

BN is a serious mental illness and evidence-based treatment is challenging to access for many individuals. The results of this trial have potential to broaden our therapeutic reach and extend availability of CBT to individuals who fdo not have ready access to CBT. Initial anecdotal feedback indicates that patients value the convenience of being able to participate in group therapy without the inherent hassles of travel, parking, and transportation costs. Therapists also find the chat format engaging and value the flexibility in scheduling afforded by an online intervention (i.e., must not be confined to work hours or office availability).

In addition to these advantages, there are also challenges inherent in the implementation of this protocol. First, therapists are not equally comfortable with a chat-based delivery. Individuals who are more comfortable with the chat medium may be more effective at managing the therapeutic flow with several patients chatting simultaneously. This is not dissimilar to therapist experiences with telemedicine delivery of CBT [87], in which therapists conducting face-to-face treatment rated therapeutic bond more positively than therapists conducting telemedicine assisted CBT. Second, with the exception of the initial and post-treatment assessments and follow-ups, therapeutic or research staff has no face-to-face contact with participants randomized to CBT4BN. By including the monthly telephone check-ins with the study physician, we ensure some non-electronic contact with treatment personnel; however, we monitor carefully whether any differences emerge in harms or adverse events when face-to-face contact does not occur. Third, Internet access can be unreliable. Patients experience outages, spotty wireless or slow connections, malfunctioning computer hardware or are occasionally unable to find a private location to participate in the chat therapy. These can all limit feasibility and acceptability of CBT4BN and are monitored closely. Finally, participants also vary in how computer-savvy they are. More adept participants find navigating the CBT4BN site and the chat room simple, whereas others are challenged by the technology. Careful tracking of participant choice (i.e., which therapy they hoped to be randomized to) as well as Internet efficacy will help inform for whom chat-based therapy is most effective.

8. Conclusion

Results of this investigation may have public health significance and implications for adaptation of evidence-based treatments for Internet delivery. First, by testing a novel internet-based program, we will be able to determine the impact of Internet-based delivery

on CBT specifically for BN and potentially open new avenues for broader and cost-effective evidence-based mental health services for eating disorders. If non-inferiority is demonstrated, there will be clear directions for additional research. For example, the Internet-based program could be tested in a primary care setting in an effectiveness trial. Finally, our research collaborative group will be interested in examining whether Internet-based materials can augment clinic-based specialty care for the full range of eating disorders.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix: Excerpt for Chat Therapy Session

Table 1

Clinical Trial Assessment Schedule by Reporter

	Notes	Baseline	Weekly	10 Weeks	20 Weeks	3 Months	6 Months	12 Months
Self-Report								
Bio datasheet		X						
Contact Info		X						
Pre-Treatment Acceptability		X						
Web Self-Efficacy		X						
TCI		X						
SF-36		X			X	X	X	X
BAI		X			X	X	X	X
BDI		X			X	X	X	X
EDE-QOL		X			X	X	X	X
SEED		X	X	X	X	X	X	X
ADQ		X	X	X	X	X	X	X
CREAT-ED		X	X	X	X	X	X	X
TCI-SD				X	X	X	X	X
EDE-Q				X		X	X	
Pregnancy Questionnaire					X	X	X	X
Self-Monitoring	F2F		X					
	Online		**daily**					
Post-Group			X	X				
Evaluation								
Post-Treatment Evaluation					X			
Completed by Assessor								
SCID		X			X			X
EDE		X			X			X
Treatment History	Modified M-FED	X						
M-FED					X	X	X	X
Suicide Interview		X			X			X

	Notes	Baseline	Weekly	10 Weeks	20 Weeks	3 Months	6 Months	12 Months
Completed by Therapist								
AE Form			X					
SAE Form								
Completed by Physician								
Vitals, Height		X						
Weight					X	X	X	X
Labs		X						
EKG		X						
Physical Form		X						
Medical Approval Sheet		X						

Table 2

Schedule of Topics for CBT4BN and CBTF2F

Week	Topic
1	Introduction to CBT
2	The Language of CBT
3	Nutrition—The Basics
4	Challenging Automatic Thoughts
5	Alternatives to Binge Eating and Purging
6	Thought Restructuring
7	Techniques for Avoiding Bulimic Behaviors and Body Image
8	Chaining
9	Advanced Nutrition
10	Problem Solving
11	Relapse Prevention I
12	Relapse Prevention II
13	Complete Material—Flex Week
14	Complete Material—Flex Week
15	Review and Consolidate I
16	Review and Consolidate II