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Research Article

Keywords: Eating disorders, Cognitive behavioral therapy, Self-help, Internet

Posted Date: May 26th, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1541574/v1>

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Development and pilot trial of online Guided Self-Help Cognitive Behavioral Therapy
program for Bulimia Nervosa and Binge Eating Disorder in Japanese patients

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ABSTRACT

Objectives:

The purpose of this study was to develop an internet-based Guided Self-Help(iGSH) cognitive behavioral therapy (CBT) for Bulimia Nervosa (BN) / Binge Eating Disorder (BED) for Japanese patients and to test its feasibility with a single-arm study. After baseline assessment, patients underwent a 16-week iGSH-CBT program, our Japanese adaption of the European-based Salut BN program. Evaluations were performed at baseline, after 8 weeks, at the end of the 16-week intervention, and at 2 months after treatment had ended. The primary outcome measure was the change in the weekly frequency of objective bingeing.

Results:

Participants were 9 female outpatients with BN (n=5) or BED (n=4), of whom 8 (88.9%) attended the assessment at the end of the 16-week intervention. Percent change of the weekly frequencies of objective bingeing was -4.40%. Although no significant

change was observed in the weekly frequencies of objective bingeing, the abstinence rate from bulimic behaviours of those who completed the assessments was 25.0% at the end of treatment, and the drop-out rate was 11.1%. iGSH-CBT may be an acceptable and possibly even a preferred method of CBT delivery for Japanese patients with BN or BED, and our Japanese adaptation of Salut BN seems feasible.

Keywords: Eating disorders, Cognitive behavioral therapy, Self-help, Internet

Introduction

Eating disorders are now frequent mental disorders, not only in western countries, where they first became commonplace, but also in Asian countries including Japan. Indeed, their pervasiveness in Japan is increasing and is associated with rapid cultural changes in relation to body image over the last three decades¹⁻⁴.

BN is an eating disorder (ED) that crucially impairs the mental and physical health as well as the social function of affected individuals⁵. A recent study indicated that the lifetime prevalence of DSM-5-defined BN in a general female population aged 18 years and older in the United States is 0.46%, and BED 1.25%⁶. Patients with BN or BED often present with suicide ideation and attempts^{7,8}. A meta-analysis by Preti et al., based on 16 studies published between 1988 and 2009, demonstrated that BN patients in

western countries are approximately seven times more likely to die by suicide compared to the general population⁷. However, 80% of individuals with EDs do not receive treatment⁹. Considering that many individuals with BN and BED do not have access to specialized treatment, multiple evidence-based treatment options need to be made available.

In Japan, BN has become an important public health concern, and is typically found among young women. A questionnaire survey for Japanese female students in 2002 (N=3031, average age \pm SD =17.2 \pm 1.7) that attempted to assess their eating-related psychopathology and behaviors resulted in a point prevalence rate for BN in Japan of 2.32% (95% confidence interval, 1.79-2.86), a definite increase from that in 1982¹⁰.

CBT for patients with BN and BED has been shown to be effective and durable. Controlled studies of CBT have shown benefit not only for binge or purge frequencies but also for cognitive symptoms^{11,12,13,14,15}. Clinical practice guidelines for EDs therefore generally recommend the use of CBT for patients with BN¹⁶⁻¹⁸.

Unfortunately, there is a shortage of therapists appropriately trained in CBT in Japan to treat all patients who would benefit from this therapy. Furthermore, it is difficult for young people who have school activities or active social lives to make regular visits to a hospital or clinic, leading to a pattern of dropping out from continuing

care. These issues make CBT relatively unavailable to many of those in need. Improved access to psychological care, including CBT, is very much needed in Japan.

On the other hand, the effectiveness of low-intensity CBT such as CBT-based self-help has been well documented^{19,20}. A meta-regression analysis has revealed that guided self-help (GSH) intervention is more effective in terms of adherence and treatment outcomes than “pure” self-help for BN²⁰. Indeed, the National Institute for Health and Care Excellence (NICE) guideline recommended GSH with cognitive behavioral self-help materials for EDs as a first-line treatment for BN and CBT-ED as the next-line therapy¹⁶.

Internet-based psychotherapy can overcome various barriers of face-to-face interventions because of its ease of accessibility, particularly for those with time limitations²¹. A controlled study by Fernández-Aranda et al. demonstrated that internet-based GSH with CBT concepts significantly improved the psychopathology and bulimic behavior compared to those on a waiting list²². However, there is as yet no available evidence-based iGSH-CBT in Japanese clinical settings.

This is the first study in Asia to examine adaption of the European-based Salut BN program. The main aim of this study was to demonstrate the feasibility and efficacy of iGSH-CBT for BN in Japan by assessing the change in binge eating frequency as a

primary endpoint.

Main text

Material and methods

This was an open-label feasibility study of patients with BN or BED; there was no control group. This study was first posted on April 1, 2018 on a clinical trial registry site (UMIN Clinical trials Registry Number: UMIN000031962). The study was approved by the Institutional Review Board of Chiba University Hospital on March 7, 2018 (G29054, No. 331) and the ethics committees of Sodegaura Satsukidai Hospital on April 6, 2019. The first patient was recruited on July 13, 2019.

We recruited participants from July 2019 to April 2020. Nine female outpatients with BN (n=5) or BED (n=4), who were recruited from the outpatient unit of Chiba University Hospital and Sodegaura Satsukidai Hospital participated in this study. The participants met the current diagnosis of BN and BED according to the Diagnostic and DSM-5 criteria²³ and had to be within the age range of 16-40 years.

The exclusion criteria included organic brain complications/disorders, substance use disorders, patients who were highly likely to attempt suicide, severe mental disorders requiring hospitalization, severe medical illness, severe social or

occupational dysfunction or severe dysfunction in school associated with psychiatric symptoms, currently receiving CBT, and patients for whom the program was considered unsafe for any other reason.

For the iGSH-CBT program, the authors (N.O., H.K., Y.H. and M.N.) adapted the Salut BN program for a Japanese audience, and subsequently gained approval of the adaptations from the original author (Tony Lam, director of Net Union, a provider of health management software). The coaches in the program (N.O. and M.N.) received a three-hour lecture on coaching that was in compliance with the principles of Salut BN as laid out by the original author. Coaches provided weekly guidance to participants by email. In addition, participants received regular psychiatric care during their 16-week iGSH-CBT program.

The patients were evaluated at pre-treatment, at the end of the 16-week treatment, and at 24 weeks as follow-up after the treatment. The primary outcome evaluated was the average change in weekly frequency of objective bingeing between pre and post-16-week treatment.

Secondary outcomes were changes in the weekly frequencies of objective purge episodes and monthly objective bingeing, dropout rates, self-report questionnaires of the frequencies of bingeing and purging, psychopathological characteristics of EDs

according to: Bulimia Investigatory Test, Edinburgh (BITE)²⁴, Eating Disorder Examination Questionnaire (EDE-Q)²⁵, Eating Disorder Inventory-2 (EDI-2)²⁶, Hospital Anxiety and Depression Scale (HADS)²⁷, and the 5-level Euro Qol 5 dimension (EQ-5D)^{28,29}, measurements of motivation, and completion rates of intervention vs. dropout rates.

The patients were evaluated at baseline, after 8 weeks, at the end of 16-week intervention, and at 24 weeks (follow-up). To reliably perform these evaluations, physicians participating in the study underwent several rounds of assessment training.

Statistical analysis

This was a single-center study, and considering the number of BN and BED patients per year at the hospital, a sample size of 20 was considered appropriate in terms of feasibility.

The primary and secondary analyses were based on the full analysis set, which was defined as all participants with efficacy data who were enrolled in the clinical study, and who experienced the iGSH-CBT program at least once. A per-protocol analysis, which included all patients in the full analysis set but excluded those who met any of the significant deviations from the study procedure, such as inclusion/ exclusion criteria not met, receiving prohibited concomitant drugs or therapies, or non-complying with the

study program, was not conducted because the subject group was the same as the full analysis set. Paired-t test was used for comparison between changes within each subject. Data were analyzed with SAS statistical software (version 9.4, SAS Institute, Cary, NC, USA) and R version 4.0.5 (R Foundation for Statistical Computing, Vienna, Austria.).

Results

Eight females received baseline assessment and were confirmed to have never previously received CBT or GSH. Figure 1 shows that one participant (11.1%) was unreachable after the initial assessment while all the other participants (n=8, 88.9%) underwent all assessments: baseline, midterm, post-treatment and follow-up assessment. No adverse events occurred.

All participants were female, and their mean age was 28.0 years (range 16-38, SD = 8.0). Equal numbers of participants were diagnosed with BN and BED. Fifty percent were diagnosed with mood (affective) disorders as comorbid psychiatric diagnoses, and 37.5% (n = 3) had ADHD tendencies. Mean body mass index was 22.2 (range 19.7–27.7; SD = 2.8) (Table 1).

There was no significant difference in the frequency of overeating pre- and post-treatment, and the mean rate of change was -4.40% (p = 0.914). At the end of the

treatment, 25% (n = 2) had no bulimic symptoms and 75% (n = 6) had decreased their frequency of bingeing by 25% or more (Table 2).

Table 2 shows various values at pre- and post-treatment and follow-up. In the comparison between pre- and post-treatment, HADS total scores were significantly improved (p = 0.026). In the comparison between pre-treatment and follow-up, the EDE-Q measure of binge eating frequency in the past 4 weeks (p = 0.011), EDE-Q weight concern (p = 0.004), EDE-Q shape concern (p = 0.011), EDE-Q global score (p = 0.016) and EDI-2 score (p = 0.038) were all significantly improved. There were no improvements in BITE or EQ-5D-5L. At the end of the 16-week intervention, the drop-out rate was 11.1%.

Discussion

This pilot intervention study was conducted to examine the feasibility of iGSH-CBT for BN or BED in a Japanese clinical setting as a prelude to a randomized controlled trial (RCT), and to evaluate its feasibility and acceptability to an Asian audience. Although the intervention was estimated to have a statistically insignificant effect on weekly frequency of objective binge eating at the end of the 16-week period, a significant decline in binge-eating frequency was observed during the last 4 weeks of the 8-week post treatment follow-up period (P<0.05, CI 3.8–20.7). Furthermore, at the

end of the 16-week intervention, 25% of the participants had achieved abstinence, and no severe adverse events were observed over the course of treatment. As shown in Table 3, previous studies on Salut BN among patients of similar age and clinical background achieved abstinence from 23.0 to 48.6%^{22,30,31}; our result fell within that range.

A meta-analysis of ninety-nine RCTs by Linardon et al. demonstrated that the overall drop-out rate from CBT was 24% (95% CI =22-27%), whereas the drop-out rate from internet-based CBT was 33 % (95% CI =25-34%)³². At the end of the 16-week intervention in this study, the drop-out rate was 11.1%, which was less than those of previous studies with the Salut-BN programs for BN participants (Table 3).

This online CBT self-help manual is distinctive in two respects. First, it consists of 7 modules with concepts, examples and exercises: motivation, self-observation, modification of behavior, observation and modification of automatic thoughts, problem solving, self-affirmation, conclusion and relapse prevention^{22,33}. One of these exercises is a “daily food diary”, which takes approximately 5 to 10 minutes per day to fill in. Patients manage the time that they can and want to spend using the program, and they can work through the program at their own speed. Second, patients are required to maintain a weekly email support program with their trained counselors during the whole intervention. Thus, patients can receive treatment without being restricted to regular

visits to a hospital or clinic, which may increase the accessibility and the availability of CBT.

Although we modified food guides according to food availability, culinary cultures and eating habits in Japan, we found that no culture-related modifications of the treatment based on a CBT self-help manual were required for Japanese patients.

(<https://www.fao.org/nutrition/education/food-dietary-guidelines/home/en/>).

This study provided preliminary evidence that iGSH-CBT is feasible among Japanese patients who have BN or BED. The dropout rate was low, and no severe adverse events were observed over the course of the treatment.

Conclusions

Overall, our study findings revealed that iGSH-CBT may be an acceptable and possibly even a preferred method of CBT delivery for Japanese patients with BN or BED, and also that our Japanese adaptation of Salut BN is feasible. Further study using an RCT is warranted.

Limitations

There are several methodological limitations, primarily because this was a small-

scale open-label, single-arm feasibility study. Strong inferences cannot be made about the efficacy of iGSH-CBT due to the small sample size. Second, although this program Salut BN was developed for patients with BN, we assessed patients with BN and BED in this study. A previous systematic review demonstrated moderate support for the efficacy of CBT and GSH for BED¹³. However, our data suggest that further research such as an RCT is warranted to investigate the applicability of this therapeutical tool to patients with BN and BED in Japan.

List of abbreviations

iGSH internet-based Guided Self-Help

CBT cognitive behavioral therapy

BN bulimia nervosa

BED binge Eating Disorder

ED eating disorder

DSM-IV Diagnostic and Statistical Manual of Mental Disorders, 4th Edition

BITE Bulimic Investigatory Test, Edinburgh

EDE-Q Eating Disorders Examination Questionnaire

EDI-2 Eating Disorder Inventory-2

HADS Hospital Anxiety and Depression Scale

EQ-5D 5-level Euro Qol 5 dimension

RCT randomized controlled trial

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of Chiba University Hospital and the ethics committees of Sodegaura Satsukidai Hospital and performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to participation and, if the participant is under 20 year-old, additional informed consent was obtained from the legal guardian.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available from the Chiba University Clinical Research Center but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the Chiba University Clinical Research Center.

Competing interests

The authors declare that they have no competing interests.

Funding

This study has been supported in part by the Japan Agency for Medical Research and Development (AMED) under Grant Number JP17dk0307067.

Authors' contributions

H.K., M.I. and M.N. conceived and designed this study. N.O., H.K. and M.N. wrote the main manuscript text and N.O. prepared Table 1-3. N.O., H.K., H.T. and H.Y. collected and collated the data. Y.I. analyzed the data. All authors read and approved the final manuscript.

Acknowledgements

The authors thank Tony Lam and Netunion, Switzerland, who provided access to the Salut-BN program for their support.

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Figures

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Figure 1

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