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Original Article

Nurse-led group cognitive behavioral therapy for major depressive disorder among adults in Japan: A preliminary single-group study

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ABSTRACT

Objectives: The prevalence and burden of disease of depression necessitates effective and accessible treatment options worldwide. Since April 2016, Japanese national health insurance has covered nurse-administered cognitive behavioral therapy (CBT) for mood disorders. However, empirical support for nurse-led CBT for depression in Asian countries, especially in Japan, is still lacking. This preliminary study aimed to examine the feasibility and acceptability of nurse-led group CBT for Japanese patients with depression.

Methods: In this single-arm study, we evaluated the effects of a 6-week group CBT, led by trained nurses, on patients with major depression. The primary outcome was the Beck Depression Inventory-II (BDI-II). Assessments were conducted at the beginning and end of the intervention.

Results: Of 25 participants screened, 23 were eligible for the study (of these, three dropped out during the trial but were included in the analysis). Nurse-led group CBT led to significant improvements in the severity of depression (BDI-II, $P < 0.001$). The mean total BDI-II score improved from 23.1 ($SD = 7.56$) to 12.4 ($SD = 8.57$), and the pre-to post-effect size was large (Cohen's $d = 1.33$). After CBT, 45% of the participants were judged to be treatment responders, and 34% met the remission criteria.

Conclusions: Our preliminary findings indicate that 6 weeks of nurse-led group CBT produced a favorable treatment outcome for individuals with major depression in a Japanese clinical setting. The results of this study might encourage more Asian nurses to provide CBT as a part of their nursing practice. Further controlled trials that address the limitations of this study are required.

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1. Introduction

Depression is a serious global social problem. According to the World Health Organization survey of the global burden of diseases, depression was ranked as the third most serious problem worldwide in 2004, and by 2030, depression is projected to become the leading burden of disease [1]. In Japan, the Japanese Ministry of Health, Labor, and Welfare estimated the number of individuals

with depression to be greater than one million in 2009. Thus, effective and accessible treatment options for depression are greatly needed.

Cognitive behavioral therapy (CBT) has consistently been shown to be effective for depression in a large database of clinical trials [2–4], and patients often prefer psychological treatment to pharmacotherapy [5]. In Japan, CBT was introduced in the late 1980s. Since then, awareness of CBT has gradually spread, not only among health care professionals but also the general public. In April 2010, the inclusion of CBT for mood disorders in the national health insurance scheme marked a milestone in Japanese mental health services, where pharmacotherapy has historically been much more common. However, patient access to CBT services is extremely limited owing to an insufficient number of CBT providers in the

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current health insurance system, which requires CBT to be conducted only by skilled psychiatrists [6]. To solve this problem, the subsequent medical fee revision in FY 2016 expanded the range of eligible CBT providers to include nurses.

In several countries, especially in the United Kingdom, nurses have played a significant role in disseminating CBT. In the 1970s, registered mental health nurses became the first group to receive a three-year systematic CBT training primarily for selected adult neurotics at the Maudsley Hospital in London. Marks et al. [7] reported that these early behavioral nurse therapists were as effective at delivering CBT as psychiatrists and psychologists. Further, a 25-year follow-up of nurses administering CBT found a considerable contribution to mental health service provision, specifically in primary care settings [8]. Other studies have also demonstrated the efficacy of nurse-led CBT for a wide range of mental disorders [9–14]. According to a document from Horatio (European Psychiatric Nurses), currently in the UK 90% of all CBT therapists have a psychiatric nursing background [15].

Incorporating CBT (effective psychotherapeutic approach) into nursing practice is the ideal vehicle for the nurse to use to guide counseling and education interactions with individuals. CBT gives nurses another method to use in addition to existing nursing practice. One of the earliest papers [16] described how psychological technologies and nursing fit together well, and how nurses could use additional skills to develop better relationships with their patients. Some of the fundamentals of CBT are the same as those of nursing: empathy, building relationships with patients, and engaging with them. The 2012 document from the Health Service Executives (the Irish public health provider) [17] – in an effort to change the orientation of the mental health services to a recovery approach – lists the skills and competencies required by mental health nurses to improve patient experiences and outcomes: Assessment skills, Risk Assessment skills, Psychosocial interventions, Interpersonal and communication skills, and Teamwork skills. Most of these are incorporated in CBT training. Basic CBT approaches can be used by nurses in many different settings, and indeed by nurses who want to bridge the mental/physical services gap in areas such as pain management, post-natal depression, gynecological disorders etc. One of the benefits of having nurses trained in CBT approaches is the implementation of CBT for depression in behavioral activation. Socratic questioning is also an useful technique which helps patients figure out their own problems and empowers them. Our previous study also supports the idea that there is a positive association between high-involvement in CBT (e.g. experience of receiving CBT training and providing CBT) and high levels of professional autonomy among Japanese psychiatric nurses [18]. Today, effective psychotherapeutic approaches (i.e. CBT) provided by nurses are viewed as being linked to a holistic nursing framework [19], and it has become clear that nurses providing psychotherapy for mental disorders are associated with being clinical nurse specialists as well as advanced nurse practitioners.

However, in Japan, there are some comparative studies of CBT in the field of psychiatric nursing, but CBT therapists are not only nurses in most studies [20]; thus, empirical support for the clinical effectiveness of nurse-led CBT is still lacking. Therefore, the purpose of the present study is to report the preliminary outcomes of a nurse-led group CBT program in a sample of Japanese patients with depression. The study had a single-arm, uncontrolled trial design. We employed CBT in a group format because it has several advantages over an individual format: higher cost- and time-efficiency, beneficial effects of group cohesion and normalization, provision of additional opportunities to engage in behavioral experiments, learning from others, and functioning as a co-therapist [11,21–23].

2. Material and methods

2.1. Participants

This study was carried out from April 2014 to December 2015, and the participants were recruited at one psychiatric hospital and one general hospital in Miyazaki Prefecture, Japan. The criteria for study inclusion were: a primary diagnosis of major depressive disorder (MDD) according to the Diagnostic and Statistical Manual of Mental Disorders-4th Edition (DSM-IV), assessed by their primary psychiatrist; having depressive symptoms (Beck Depression Inventory-II [BDI-II] score > 10) [24]; and being aged 18–65 years. The exclusion criteria were: organic brain disorders, alcohol dependency/abuse, dementia, active suicidality, and primary personality disorder.

The participants were required to gain the permission of their primary psychiatrist to participate in the study, and written informed consent was obtained from all participants after the study procedures had been fully explained. This study has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki). The study protocol was approved by the Ethics Committee of University of Miyazaki (reference number: 995), and was registered at the UMIN Clinical Trials Registry (ID: UMIN000032393).

2.2. Intervention

We used the CBT protocol for depression introduced by the Association of Cognitive Behavioral Group Therapy (2011), as a reference for generating our group CBT program [25–27]. The program had six 90-min weekly sessions, as shown in Table 1. Across the six sessions, the following elements were included: motivation and psychoeducation, cognitive techniques, behavioral techniques, and problem-solving techniques. Homework was assigned after every session. Each group contained 3–4 participants.

The program sessions were conducted by one leading nurse and one or two facilitators. The leading nurse especially contributed to set and follow a main agenda, presenting information as an educator (e.g. introducing CBT techniques), inviting and seeking feedback, summarizing the discussion and key leanings, and managing time. The facilitator (s) especially contributed to provide more detailed support for members' work and discussion during the program (e.g. individual support such as identifying key cognition and behavior, assigning and reviewing homework, and group facilitation). The leading nurses were two of the authors (HT and YS), who both had previously led more than three other group CBT programs. Facilitators were nurses working in outpatient departments and/or clinical psychologists. All leading nurses and facilitators had more than 5 years of clinical experience and 2 years of CBT training experience.

The participants were permitted to continue concomitant medication regimens provided by their primary psychiatrists (e.g. antidepressant and anxiolytic medications). All medication changes on patients' electronic medical records were monitored throughout the study.

2.3. Outcomes

All outcome measures were administered pre- and post-treatment. The primary outcome measure was the most widely used self-report measure of depression, as measured on the BDI-II [24,28]. The severity of depression is categorized based on the following BDI-II scores: a score of 10 or less is classified as normal (minimal); 11 to 18 as mild; 19 to 29 as moderate; and 30 or greater

Table 1
Overview of the program.

Session	Purpose	Agenda/content	Homework/tool
1	<ul style="list-style-type: none"> • Building alliance to the group • Psychoeducation • Motivate the patient • Socializing the patient 	<ul style="list-style-type: none"> • Perception of illness • Psychoeducation on depression, cognitive models, structure of the therapy 	<ul style="list-style-type: none"> • "What is depression?" • "What is group CBT?"
2	<ul style="list-style-type: none"> • Goal setting • Activating the patient 	<ul style="list-style-type: none"> • Collaboratively setting treatment goals • The features of the concept 	<ul style="list-style-type: none"> • Problem list • "The events that recently felt the stress"
3	<ul style="list-style-type: none"> • Identifying mood and automatic thoughts 	<ul style="list-style-type: none"> • Dysfunctional thought record (three columns) 	<ul style="list-style-type: none"> • "How to identify your moods and thoughts"
4	<ul style="list-style-type: none"> • Testing automatic thoughts 	<ul style="list-style-type: none"> • Dysfunctional thought record (seven columns) 	<ul style="list-style-type: none"> • "How to balance your thoughts"
5	<ul style="list-style-type: none"> • To enhance the ability to solve problems 	<ul style="list-style-type: none"> • It leads to the solution by using a problem-solving technique. 	<ul style="list-style-type: none"> • Try the solutions to problems.
6	<ul style="list-style-type: none"> • Set up an action plan towards the goal 	<ul style="list-style-type: none"> • Create an action plan to achieve the goal. 	<ul style="list-style-type: none"> • The execution of the action plan

as severe [29–31]. The Japanese version of BDI-II has been shown to have good reliability with Cronbach's $\alpha = 0.87$, and adequate correlation ($r = 0.69$, $P = 0.001$) between the total score of the BDI-II and that of the Center for Epidemiological Studies Depression Scale (CES-D) [24].

Secondary outcomes were measured using the Quick Inventory of Depressive Symptomatology-Self Rated (QIDS-SR) [32,33] which is also the commonly used self-reporting measure for assessing depression, the Medical Outcomes Study 36-Item Short-Form Health Survey version 2 (SF-36v2) [34,35] for measuring self-reported generic health-related quality-of-life, and the Rosenberg Self-Esteem Scale (RSES) [36,37] for assessing global self-esteem. Good reliability and the validity of the Japanese versions have also been reported for all secondary outcome measures (Fujisawa et al., 2010; Fukuhara, Bito, Green, Hsiao, & Kurokawa, 1998; Mimura & Griffiths, 2007) [33,34,37].

2.4. Statistical analysis

The analyses for all outcomes were conducted twice; once based on the intention-to-treat (ITT) principle, whereby all the dropouts were considered to be non-responders and their last obtained data points were carried forward, and once among the treatment completers (defined as attendance of at least 4 out of 6 sessions).

We compared the baseline and endpoint scores (BDI-II, QIDS-SR, RSES, and a three component summary of the SF-36v2) using paired t-tests. The cutoff point for remission according to the BDI-II was defined as an endpoint score of 10 or less, and treatment response was defined as a reduction in BDI-II score of at least 50% [29–31,38]. Treatment effect sizes were calculated as Cohen's d . According to Cohen [39], we categorized effect sizes as follows: small (0.20–0.49), medium (0.50–0.79), and large (≥ 0.80). Daily doses of medication were calculated based on the imipramine-equivalent for antidepressants and diazepam-equivalent for anxiolytics.

All statistical tests were two-tailed, and $\alpha = 0.05$ was employed. Statistical analyses were performed using IBM SPSS Statistics, version 24.0 (IBM, Armonk, New York, USA).

3. Results

3.1. Baseline data

The selection process and flow are shown in Fig. 1. Twenty-five patients were recruited for the study, of which two patients were excluded (not clinically depressed: $BDI-II \leq 10$). The remaining patients ($n = 23$) met the eligibility criteria. Six of the patients (25%) were diagnosed with recurrent episode MDD and the others (75%) were diagnosed with single episode MDD. The average age was 36.1

(standard deviation, $SD = 11.4$) years. Table 2 shows more details about the clinical characteristics of the patients.

3.2. Treatment acceptability

The mean number of CBT sessions attended was 5.67 ($SD = 0.56$) and 20 patients (87%) completed the program (three dropped out (Fig. 1). The following reasons were given for dropping out: the therapy was too difficult ($n = 1$), and absence due to other problems (e.g. schedule conflict because of family problems, a marked increase in the severity of secondary illness) ($n = 2$). We observed no serious adverse events during the study.

3.3. Outcomes

Table 3 presents the pre- and post-treatment scores with respect to the outcome measures. Significant improvements were observed in the primary outcome (BDI-II) between the baseline and week 6, not only for the ITT sample but also for the treatment completers ($P < 0.01$). The mean total BDI-II score for the ITT sample decreased from 23.1 ($SD = 7.56$) to 12.4 ($SD = 8.57$), which corresponds with clinical improvement from moderate to minimal depression. The pre-to post-effect size was large (Cohen's $d = 1.33$). Ten patients (45.4%) were judged to be treatment responders and eight patients (36.3%) were judged to be treatment remitters. As for secondary outcomes, significant changes were observed in QIDS-SR, RSES, and the role/social component summary of SF36v2 scores (but not for the physical and mental component summary of SF-36v2) (all $P < 0.05$).

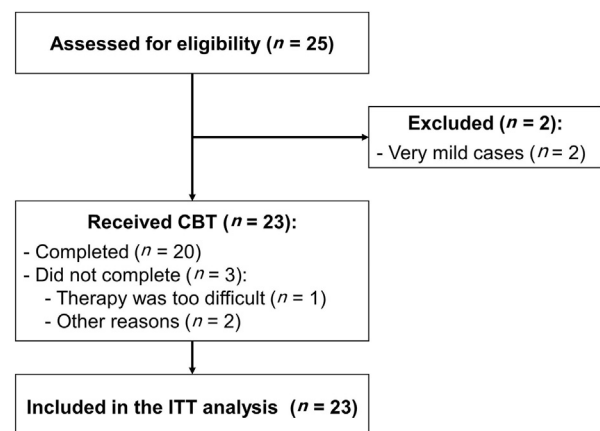


Fig. 1. Participants' flow.
CBT: cognitive behavioral therapy; ITT: intention-to-treat.

Table 2
Baseline characteristics ($n = 23$).

Characteristics	Value
Gender	
Female	11
Male	12
Age (years, Mean \pm SD)	36.1 \pm 11.4
Marital status	
Single	11
Married or cohabitant	11
Divorced	1
Employment	
Employed	10
Housewife	2
Unemployed	11
Depression episode	
Single episode	17
Recurrent episode	6
Duration of current depression episode (years, Mean \pm SD)	3.1 \pm 1.6
Comorbidity	
No comorbid condition	18
Concomitant antidepressants or anxiolytics use	
Yes	20

No significant differences were found between groups in terms of antidepressant (imipramine-equivalent) or anxiolytic (diazepam-equivalent) doses throughout the study. The mean imipramine-equivalent dose was 46.7 ($SD = 75.5$) at baseline and 46.25 ($SD = 81.1$) at week 6. The mean diazepam-equivalent dose was 7.83 ($SD = 10.7$) at baseline and 6.53 ($SD = 8.59$) at week 6.

4. Discussion

Our results indicate that 6 weeks of nurse-led group CBT led to a significant reduction in MDD severity among Japanese patients. The treatment also had excellent acceptability. Generally, around 25% of patients with MDD drop out from CBT programs: the dropout rate for individual CBT is 42%, and for group CBT about 17% [40]. The program investigated in the current study had a low dropout rate (13%).

Our CBT program was administered solely by nurses and was relatively short compared with those in previous studies, the treatment led to considerable improvements (effect size of 1.33 on BDI-II). Most previous studies comprised CBT programs with 8–12 sessions (with each session lasting 90–120 min) and had effect sizes in terms of BDI-II score (0.5–1.0) that were lower than those observed in this study [40]. There may be three reasons for this. First, our study therapists (both leading nurses and facilitators) received sufficient training and clinical experience before the trial. Second, our program was conducted in small groups (only 3–4

patients) to allow for maximal individual attention while retaining the advantages of a group format (e.g. group cohesion, role playing, and learning through peers). Therefore, our program can be thought to have a more individualized format compared with many other group format studies (5–7 patients per group, and fixed sessions) [40]. In addition, patients in this study may have had high expectations, preferences, motivations, and allegiances to CBT. As mentioned in the introduction, in Japan the effectiveness of CBT has recently become known, not only among professionals but also in the general public. However, there are few competent CBT therapists, and patients' access to CBT is severely limited in Japan. These factors might contribute to a larger treatment effect.

The following limitations should be considered with respect to the current findings. First, this study employed a single-group design without a control group (pre-post comparison); therefore, we cannot conclusively state that our group CBT was effective. The presence of the Hawthorne effect, which is typically observed in uncontrolled trials, cannot be denied in our study design; thus, future controlled studies are required. Second, our study had a limited number of participants. The distribution of the participating patients was somewhat skewed from the distribution of previous surveys in Japan [41–43]. This study had a relatively younger sample, a smaller proportion of patients who were married/cohabitant, a small number of patients who were either employed or housewives, and few patients with comorbid conditions. Third, although having a relatively small number of participants in each session/group (3–4 patients) allowed for a more individualized format, it was also a limitation (most programs include 5–7 patients). Future study should address the issue of adequate numbers, both in the entire study and in each group session. Fourth, both therapists were nurses who were acquainted with the participants. This may have contributed to the reduced dropout rate. Fifth, there is no long-term follow-up data, which limits the generalizability of the study's conclusions to longer-term outcomes. Sixth, the lack of patient commentaries limits our understanding of the effectiveness and acceptance of the program.

Several obstacles remain in the process of making CBT widely available to Japanese patients suffering from MDD. According to Yoshinaga et al. [20,44], the most important issue hindering the dissemination of CBT in Japan is the paucity of training opportunities for all health care professionals. Opportunities are limited because of the scarcity of CBT experts. Pre- and post-qualification training programs should be established across Japan so that more health professionals can receive adequate training. This will enable more patients to access such services in their local areas. In addition, research on efficient ways to disseminate treatment procedures, including the efficacy of CBT by trainees, would be useful in addressing empirical questions about how to best train

Table 3
Outcome measures at pre- and post-treatment.

	Intention-to-treat ($n = 23$)				Completers ($n = 20$)			
	Pre (Mean \pm SD)	Post (Mean \pm SD)	Improvement (%)	ES	Pre (Mean \pm SD)	Post (Mean \pm SD)	Improvement (%)	ES
BDI-II	23.14 \pm 7.56	12.36 \pm 8.57	47	1.33**	23.35 \pm 7.78	12.35 \pm 8.67	47	1.34**
QIDS-SR	11.91 \pm 3.98	6.95 \pm 5.04	42	1.09**	11.60 \pm 4.03	6.70 \pm 4.92	42	1.09**
RSES	25.80 \pm 9.06	31.36 \pm 10.20	22	0.58*	25.84 \pm 9.41	32.06 \pm 10.46	24	0.62*
SF-36v2								
PCS	50.41 \pm 10.77	48.15 \pm 10.80	–4	–0.21	49.4 \pm 10.77	46.90 \pm 10.80	–5	–0.23
MCS	38.74 \pm 9.38	42.60 \pm 12.30	10	0.35	38.74 \pm 9.72	42.60 \pm 12.62	10	0.34
RCS	26.25 \pm 14.97	34.79 \pm 12.51	33	0.60*	26.30 \pm 14.61	35.74 \pm 11.38	36	0.72*

Note: Higher scores on the BDI-II and QIDS-SR indicate greater pathology or severity of depression. ** $P < 0.01$. * $P < 0.05$.

BDI-II: Beck depression inventory-II score; ES: Effect size of Cohen's d ; QIDS-SR: Quick inventory of depressive symptomatology – self-rated; RSES: Rosenberg self-esteem scale; SF-36v2: MOS 36-item short-form health survey version 2; PCS: Physical component summary; MCS: Mental component summary; RCS: role/social component summary.

therapists.

5. Conclusions

In conclusion, this study shows that 6 weeks of nurse-led group CBT has excellent acceptability, and is associated with positive outcomes in Japanese patients with MDD in a clinical setting. The results of this study, demonstrating the feasibility and acceptability of nurse-led CBT for depression, might encourage more Asian nurses to provide CBT as a part of their nursing practice. Further controlled trials that address the limitations of this study are required.

Declarations

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.ijnss.2018.06.005>.

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