

**Feasibility and Acceptability of Cognitive-Behavioral Therapy in Older Japanese
People with Cognitive Decline: A Single-Arm Intervention**

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RUNNING HEAD: CBT for Cognitive Decline

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Abstract

Studies have shown that cognitive behavioural therapy (CBT) for older people with cognitive decline and depression/anxiety improves negative moods. However, CBT research focusing on this population in Japan is limited. This study aimed to evaluate the feasibility of a cognitive behavioural program for people with cognitive decline. Sixteen Japanese patients with mild dementia (n = 3) and mild cognitive impairment (MCI, n = 13) participated in the study. A single-arm, pre–post study was implemented in two hospitals in Japan. The CBT program included eight bi-weekly sessions. The feasibility outcomes (satisfaction, understanding and usefulness) were measured immediately after completing the sessions, and depression, anxiety, quality of life (QOL), neuropsychiatric symptoms, and caregiver burden were measured at three time points (i.e. before, immediately after, and 3-month follow-up). Ten MCI participants attended all sessions and the mean patient satisfaction scores using the Client Satisfaction Questionnaire were 31.0 ± 10.05 out of 32. Linear mixed model analyses demonstrated that the time effect was significant for depression (d = 1.62), anxiety (d = 1.39), and QOL (d = 1.00) for the patients, and significant for anxiety (d = 1.08) for their caregivers. The study found that this CBT program is feasible and acceptable for older Japanese people with cognitive decline. The program also improved patients' QOL, anxiety and depressive symptoms, and decreased caregivers' anxiety.

Keywords: cognitive decline, cognitive-behavioral therapy, mild cognitive impairment, depression, anxiety

Key Learning Aims

- (1) Recently, studies have shown that CBT for older people living with dementia has been effective in treating their depression and anxiety. However, evidence for the efficacy of CBT and other curative or care options for people living with dementia is limited in Japan.
- (2) We studied a short-period CBT program and found that it was likely to be feasible and acceptable for use among older Japanese people with mild cognitive impairment, that it may improve negative mood among this group, and that it may lessen the care burden for caregivers.
- (3) Furthermore, we found that caregiver involvement in the implementation of CBT for older people may be effective in improving the mood of family members.

Introduction

In 2020, almost 28.8% of the Japanese population was aged 65 years and older (Cabinet Office, 2021). Japan has emerged as a super-aged society and faces an increase in the prevalence of dementia in its population. In 2012, one in four Japanese people aged 65 years and older had dementia or suspected dementia, and 4 million people aged 65 years and older may have mild cognitive impairment (MCI), a transitional state of cognition between normal ageing and dementia which may eventually progress to dementia (Asada, 2013). Notably, MCI is characterized by preserved functional abilities (Hugo and Ganguli, 2014) and clinically significant memory impairment (classified as amnesic or non-amnesic) that does not meet the criteria for dementia; alternatively, it can also be characterized by a subtle decline in functions not related to memory (Petersen, 2011).

Depression and anxiety, which are associated with deterioration in social functioning, decreased independence, cognitive decline and an increased risk of institutionalization, are common in older people with dementia and MCI (Ballard et al., 2000; Enache et al., 2011; Gulpers et al., 2016; Monastero et al., 2009; Okura et al., 2011; Porter et al., 2003; Solfrizzi et al., 2007). The early detection and prevention of MCI can help in the prevention of dementia in older people (Petersen et al., 2001). Previous studies have suggested that depression and anxiety can be risk factors for cognitive decline and dementia, and can result in progression to dementia (Gulpers et al., 2016; Hesser et al., 2013; Rodríguez-Sánchez et al., 2011; Singh-Manoux et al., 2017). Similarly, in Japan, several relationships between cognitive decline and depressive symptoms in older adults have been reported (e.g. Hidaka et al., 2012; Kume et al., 2019); however, the relationship between cognitive decline and anxiety is still not clear. Notably, such psychological symptoms can increase the burden on caregivers (Shin et al., 2005). As mentioned earlier, scholars have emphasized the

importance of early detection and early treatment of dementia and MCI; however, in clinical practice in Japan, we often hear sarcastic comments – even from medical professionals, patients, and their families – about ‘early detection and early hopelessness’; that is, comments that suggest that even if the disease is detected early, there is nothing to be done but hopelessly despair. It is easy to imagine the anxiety that people living with dementia and their caregivers must be feeling about what will happen to them in the future as their cognitive decline progresses.

Recent international studies have reported the efficacy of cognitive behavioural therapy (CBT) in alleviating depression and anxiety and improving quality of life (QOL) among older people with dementia and MCI (Orgeta et al., 2015; Spector et al., 2015; Stanley et al., 2013). The underlying concept of CBT is that thoughts and behaviours influence emotions. Therefore, CBT attempts to modify dysfunctional thoughts and behaviours, improve emotions experienced as challenging or negative, and boost feelings of well-being. However, there has been little research on CBT in the psychosocial treatment of depression or anxiety in older people with dementia or MCI in Japan.

Aims of this Study

This study examined the feasibility and acceptability of a newly developed CBT program among older Japanese patients with cognitive decline. The program was originally created for a study with older Japanese female adults diagnosed with MCI who reported anxious and depressive moods (Kashimura et al., 2019). To our knowledge, this is the first study investigating the feasibility of CBT treatment for people with decreased cognitive function in Japan. This study involved the following five principles:

- 1) >33% referrals were recruited for the study (invited to participate and consent)
- 2) An expected follow-up rate of >70%

- 3) Attendance of > six sessions adherence, as per a previous study (Spector et al., 2015; Stanley et al., 2013)
- 4) Intervention could be carried out with fidelity
- 5) Ability to collect outcome measures consistent with those which were used in a previous CBT for dementia randomized controlled trial (RCT) for mood and QOL.

Methods

Participants

Participants were recruited based on the inclusion criteria outlined below:

- 1) diagnosed with dementia or MCI, with a score of at least 20 points on the Mini-Mental State Examination (MMSE).
- 2) living within travelling distance of a hospital (i.e., within 60 minutes).
- 3) able to perform homework assignments for at least 15 minutes every day.
- 4) able to complete more than two-third of the program.

Individuals who met the following criteria were excluded:

- 1) concurrent psychiatric disorders (e.g., schizophrenia, bipolar disorder, substance-related disorders, and Cluster A personality disorders).
- 2) a history of epilepsy, with an electroencephalogram that has not been normalized.
- 3) cognitive dysfunction (e.g., severe language and executive function disorders) that precludes CBT.
- 4) physical health problems which made engagement in CBT difficult.
- 5) current engagement in another structured psychological intervention.
- 6) inability or unwillingness to participate in the study because of other commitments, lack of motivation, or difficulty in comprehending the program.
- 7) hospitalization due to severe depression or anxiety, self-injury, or suicide attempt.

These criteria were somewhat different from the CBT criteria adopted in previous dementia studies (Spector et al., 2015; Stanley et al., 2013). As this study was the first trial of the CBT program for patients with cognitive decline, setting more detailed criteria allowed us to conduct it with utmost caution. The presence or absence of a diagnosis of dementia or MCI was determined based on the results of diagnoses made by the participants' physicians and specialists, and those diagnoses were based on Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) or the National Institute on Aging and Alzheimer's Association (NIA-AA) diagnostic guidelines and various brain imaging findings. The MMSE is a brief measure of cognitive function used worldwide, with total scores ranging from 0 to 30 (Folstein et al., 1975; Mori et al., 1985). The MMSE is a valid test for cognitive function and has good test-retest reliability ($= .89$) (Folstein et al., 1975). This instrument evaluated participants who completed the MMSE for assessing their cognitive decline level relative to the exclusion criteria and assessed score changes across the three assessment periods. This test took approximately 10 minutes to complete.

Setting and Recruiting Procedure

This study was a single-arm, pre-post study (Figure 1) conducted from 2016–2018 (approximately two years) at the psychiatry outpatient department in Nippon Medical School Hospital (the monthly average number of outpatients was approximately 2,300; of these, the proportion of patients with dementia or MCI was 3.69%). Owing to the exploratory nature of the study, a convenience sampling approach was used. We conducted the program in an outpatient department. The participants were referred to doctors (i.e., psychiatrists and neurologists) in the research team. We also requested patients' caregivers to participate in this program. The study team approached the participants who showed initial interest in this study and provided them with relevant information (e.g., purpose, program content, potential

benefits of participating, duration, time commitment, rewards, and round-trip travel expenses) before agreeing to participate.

[Insert Fig. 1 about here]

Intervention

We developed the CBT program for people with cognitive decline with reference to previous studies (Spector et al., 2015; Stanley et al., 2013; Charlesworth et al., 2015; Kraus et al., 2008; Teri et al., 1997). We prepared case examples for inclusion in the manual based on our clinical experience with older Japanese people. The development of the program did not require further consideration of culturally relevant aspects, because CBT has been widely used in Japan, and CBT developed in foreign cultures can be implemented in Japan without accounting for cultural differences. Therefore, we conducted this study because we thought that its intervention could be implemented without considering cultural adaptations.

In developing the program, several pairs of older people with MCI and dementia and their caregivers were briefly interviewed and asked about the frequency and duration of their visits for counseling and required time for counseling, and whether they would feel less burdened. The reason for this was to consider the physical and mental burden of the participants in the study, since older people in Japan are known to routinely visit the hospital for other diseases. Therefore, the respondents expressed that they felt it would be burdensome to have to go to the hospital every week for counseling over six months, and that they would be willing to receive counseling if sessions were limited to approximately 30 minutes every other week and if the program comprised less than 10 sessions. After summarizing their opinions, we decided that sessions would be 30–40 minutes long and take place every two weeks, with the greatest possible consideration about the feasibility of CBT sessions for older adults with any vulnerabilities.

This program differed from that of Spector et al. (2015) in that it had two fewer sessions, which were not held every week. Furthermore, while their program was dedicated to the treatment of anxiety and structured around coping with anxiety, this program focused on improving overall deterioration in mood (psychological distress, in other words)—evidenced, for example, in worsening anxiety and depression—among the older adults. Charlesworth et al. (2015) suggested that “less is more” when working with people with dementia, and James (2010) recommended that the therapist “keep it slow and simple.” Accordingly, we determined that only two or three CBT skills should be included in the program. The program comprised eight sessions (Table 1) on topics such as psychoeducation, behavioral activation, relaxation training (e.g., deep breathing and progressive muscle relaxation), and cognitive restructuring. It also included two optional sessions (communication skills and problem-solving skills); however, none of the participants engaged in these during the trial. The two relaxation training sessions were developed with reference to a brief relaxation technique (McKay & DuFrene, 2011). Session 1 socialized to the CBT model, assessed participants’ pre-therapy skills (Charlesworth et al., 2015), and asked them to set goals. Based on Spector et al. (2015) and our own clinical experience to date, we decided that introducing behavioral rather than cognitive tasks in CBT sessions with older adults would facilitate their understanding of the CBT concept and reduce dropout. Therefore, we conducted behavioral activation at the beginning of the program, in Sessions 2 and 3, and reserved cognitive restructuring for later.

The program used in this study was implemented by adding considerations and modifications to standard CBT for older adults with cognitive decline. In preparing this study, the CBT Guidelines for Anxiety in Older Adults with Dementia by Charlesworth et al. (2015), which is based on a detailed review of previous CBT research and practice with older adults, was used as a reference. These guidelines suggest that strategies for accommodating

cognitive impairments include 1) taking full advantage of the scaffolding provided by CBT, including session structure, pacing, within-and between-session strategies used for retention of new learning, and conceptualization as a mnemonic; 2) incorporating cognitive rehabilitation strategies and techniques; 3) including a supportive other; and 4) supporting the learning of pre-therapy skills, including self-awareness. Since these details are described in Charlesworth et al. (2015), we do not repeat them here. Although their suggestions are based on special considerations for older adults, especially those with cognitive decline, many of the accommodations described are consistent with standard CBTs. A workbook discussing the topics of each session was provided to each participant at no charge. The workbook was A4 size and printed in color on both sides. We prepared the workbook using Microsoft PowerPoint. We tried to minimize the amount of information per sheet of paper, used a large font size, reduced the amount of text, and used figures and illustrations to make it easy for participants and their caregivers to read. We actively encouraged participants to take notes on their interactions with the therapist during the session that they found helpful, to aid their memory. When family caregivers were in attendance to sessions, we encouraged them to take notes as well. Reading about a topic for the next session as homework was optional.

To monitor mental health, a brief assessment of psychological distress was conducted for both the participants and their caregivers at the beginning of each session, using the Kessler Psychological Distress Scale (K6). The K6 is a brief, self-reported scale to assess psychological distress and has good internal consistency (Cronbach's alpha coefficient = .89) among adults (Kessler et al., 2002). It contains six items on a five-point scale ranging from 0 to 4. Additionally, they were encouraged to make notes in the workbook.

[Insert Table 1 about here]

Therapist

The program was delivered by a Japanese clinical psychologist (the therapist) who was familiar with CBT and had more than 10 years of training. Before this trial, we devised a fidelity checklist in Japanese containing the six most important components of each session: “all information covered,” “the participant successfully completed the task in the session,” “successfully encouraging the participant to think of the material,” “successfully teach the material,” “successfully introduced the homework,” and “keeping the participant focused on the session.” The therapists recorded each session with each participant, and research members (clinical psychologists, neurologists, and psychiatrists) who were not directly involved in the sessions rated them on the fidelity checklist referring to the manual. The study team evaluated the sessions on the aforementioned criteria with scores ranging from 1 (not at all) to 5 (very well), and overall fidelity scores ranged from 6 (the lowest) to 30 (the highest). The therapist and the research members engaged in over ten hours of peer-to-peer training on the program protocol and held regular peer supervision sessions for ongoing cases. If the fidelity scores were low, the members discussed the reason and solution for the next sessions during the peer supervision. Furthermore, the therapist received on-demand clinical supervision from a psychiatrist with over 30 years of clinical experience and over five years of CBT supervisory experience.

Measurements

Participants were interviewed three times at the hospital: before the commencement of the program (pre-intervention; week 0), immediately after the completion of the program (post-intervention; week 17), and three months thereafter. We collected sociodemographic details of the participants and their caregivers such as age, sex, their interpersonal relationship, the participant’s diagnosis, level of education, job history, and basic living conditions, only at week 0. A well-trained study member who was not involved in presenting the program assessed the participants, except in the self-reported scales below, which they

filled out individually. At each assessment period, participants completed the measures listed below in approximately 15 minutes, taking breaks as needed.

Pre-intervention assessment measure

For participants

The Mini-International Neuropsychiatric Interview (MINI).

The MINI (DSM-IV; ICD-10) (Sheehan et al., 1998) is a brief, structured interview that was used at the baseline assessment to evaluate the participants on the exclusion and inclusion criteria.

Geriatric Depression Scale-15 (GDS-15)

The GDS-15 is a 15-item, self-reported scale measuring depressive symptoms in older people (Sugishita et al., 2017; Sheikh & Yesavage, 1986), with the questions requiring yes (1) or no (0) answers. The GDS-15 has good internal consistency (Cronbach's alpha coefficient = .83) and clinical usefulness (Mitchell et al., 2010; Sugishita et al., 2017). This scale was administered to the participants only.

Hospital Anxiety and Depression Scale-Anxiety (HADS-A)

The HADS is a self-reported scale measuring anxiety and depression (Kitamura, 1993; Zigmond & Snaith, 1983) on a four-point scale ranging from 0 to 3. The scale has two subscales, anxiety (HADS-A) and depression (HADS-D), each containing seven items. HADS has good internal consistency (Cronbach's alpha coefficient = .60 to .93) and construct validity (Bjelland et al., 2002; Herrmann, 1997). We used HADS-A for participants as well as caregivers because of the low internal consistency of the Japanese version of HADS-D (Bjelland et al., 2002).

Quality of Life-Alzheimer's Disease Scale (QOL-AD)

The QOL-AD is designed to measure QOL in older adults with cognitive impairment (Logsdon et al., 2002). It contains 13 items measuring 13 domains rated on a four-point scale.

It has good internal reliability (Cronbach's alpha coefficient = .82 to .84) (Matsui et al., 2006). This instrument consists of two formats: a self-reported format completed by an older adult and an informant format completed by a caregiver. We used this scale for both the participants and their caregivers.

For caregivers

Neuropsychiatric Inventory Questionnaire (NPI-Q)

The NPI-Q is a brief version of the NPI (Cummings et al., 1994). This questionnaire is a 12-item caregiver-informant scale intended for self-administration, measuring the severity of neuropsychiatric symptoms (NPI-Q) on a scale from 0 to 3, with total scores ranging from 0 to 36 (Kaufer et al., 2000). The NPI-Q has good test-retest reliability (= .80 to .94) and large inter-scale correlations with the NPI (= .71 to .93) (Kaufer et al., 2000). The Japanese version of the NPI-Q has demonstrated similar results, with adequate validity and reliability (Matsumoto et al., 2006). We administered this questionnaire to the caregivers to assess participants' neuropsychiatric symptoms.

Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a self-reported questionnaire measuring depressive symptoms (Muramatsu et al., 2007; Spitzer et al., 1999). It includes nine items rated on a four-point scale ranging from 0 to 3. The PHQ-9 has good internal consistency (Cronbach's alpha coefficient = .86 to .89), construct validity, and clinical usefulness (Kroenke & Spitzer, 2002; Martin et al., 2006). We administered this scale to the caregivers.

Japanese version of the Zarit Caregiver Burden Interview—short version (J-ZBI_8)

The J-ZBI_8, the shortened version of the Zarit Caregiver Burden Interview (Zarit et al., 1980; Zarit & Zarit, 1990), is a self-reported instrument with eight items measuring subjective care burden. The J-ZBI_8 has demonstrated good reliability (Cronbach's alpha

coefficient = .89) and construct validity (Arai et al., 2003). We administered this to the caregivers.

Post-intervention assessment measures

Participants again completed the GDS-15, HADS-A, QOL-AD, and their caregivers again answered the NPI-Q, PHQ-9, HADS-A, J-ZBI_8, and QOL-AD. The both also answered the Client Satisfaction Questionnaire (CSQ-8) and two simplified questions for checking their understanding and usefulness and evaluating the program's feasibility at the post-assessment period only. The CSQ-8 is an eight-item self-report measure for respondents' satisfaction with mental health services (quality of service, kind of service, whether needs were met, whether they would recommend the program to a friend, amount of help received, ability to deal with problems, overall satisfaction, and return needed) (Bowling, 1995). A sample item is: "How satisfied are you with the amount of help you have received?" The items are rated on a four-point scale, with total scores ranging from eight to 32; higher scores indicate greater satisfaction. The CSQ-8 has demonstrated good reliability (Cronbach's alpha coefficient = .83) (Tachimori & Ito, 1999).

Additionally, we asked participants and their caregivers about the program's comprehensibility ("Do you understand the content of this program?") and usefulness ("Do you think this program is useful for you?") with simplified questions. These questions were answered on a four-point scale: 0: Not at all, 1: A little, 2: Moderately, and 3: Very. Moreover, we asked the participants to respond freely about their impression of this program.

Three-month follow-up measures

Participants again completed the MMSE, GDS-15, HADS-A, QOL-AD, and their caregivers again answered the NPI-Q, PHQ-9, HADS-A, J-ZBI_8, and QOL-AD.

Statistical Analysis

In addition to examining the feasibility and acceptability of this program, we calculated descriptive statistics of all outcome variables and used a Linear Mixed Model (LMM) to compare the outcome scores evaluating the impact of this program. We included time as a fixed factor and participants as a random factor in our linear mixed model. Furthermore, we used the REstricted Maximum Likelihood method (REML) and Cohen's *d* to calculate the effect size. A significance level of $p < 0.05$ was adopted. The LMM is a sound modeling choice for repeated measures data and considered beneficial for small, unaveraged, repeat-measured data, as in this study (e.g., Muth et al., 2016). We did not conduct pre-power analysis to calculate the sample size required to produce an effect because of the study's small sample size. All statistical analyses were performed using IBM SPSS Statistics, version 22.

Results

Feasibility and Acceptability

Table 2 illustrates the participants' demographic data. Initially, 16 participants and 12 caregivers were recruited from one hospital department. However, three of these participants (two dementia and one MCI) were excluded because of unavailability ($n=1$), lack of interest ($n=1$), and refusal to participate ($n=1$). Three more participants (one dementia and two MCI) dropped out during the program because of lack of motivation ($n=1$) and health-related reasons ($n=2$). Thus, ten MCI participants and their caregivers ($n=7$) attended all program sessions, the post-intervention session, and three-month follow-up and were included in the analysis. Among the three older adults who participated without their caregivers, two reported that they wanted to participate alone because they did not want to inconvenience their families and one said that he/she had lost his/her spouse, and was estranged from other

relatives. Each of these three participants participated in this study independently. As assessed by the MINI, no participant had any physical or psychiatric disorders.

The average time for each session was 36.04 ± 3.24 minutes. Fidelity was scored for each session with 13 participants, including three dropouts (a total of 89 sessions), and the average score was 22.84 ± 3.07 , with a maximum of 30 (for participants who completed all sessions, the score was 24.19 ± 1.55). There were no adverse events during the trial.

Additionally, comparing the participants' mean K6 scores at the first and the last session yielded a difference of -4.11 [95% CI $(-7.55, -0.67; p = 0.02)$], with a Cohen's d effect size of 0.74 [95% CI $(-0.05, 1.43)$]. The results for caregivers indicated a difference in means of -2.05 [95% CI $(-5.32, 1.22; p = 0.18)$], with a Cohen's d effect size of 0.50 [95% CI $(-0.29, 1.30)$].

Table 3 indicates the mean scores of program satisfaction obtained using the CSQ-8. Both the participants and their caregivers demonstrated high perceived levels of program satisfaction, comprehensibility, and usefulness.

[Insert Tables 2 and 3 about here]

Additionally, following comments were made by the participants based on their free feedback on the program. These are excerpts from the broader collection of comments from participants gathered during the study.

"It was very helpful and this counseling changed my way of thinking a lot. I used to blame everything that was wrong with me on my MCI and was pessimistic, but now I can think, "It doesn't matter if I worry about it now," and I feel my anxiety has lessened as a result. When I have trouble, I try to picture the therapist's face and imagine what the therapist would say in such a situation. The homework I did here and reporting on my recent

situation helped me to sort out my feelings, and I am sad to think that the place will be closed.” (67 years old, male)

“When I am alone, I tend to slack off on everything, but I was able to encourage myself to work by thinking about what I am going to report here. I would like to continue my daily activities this time around, and I will remember to do the breathing exercises. My family said that I might have brightened up a little.” (82 years old, female)

“Without this counseling, I don't think I would have resumed my handicraft hobby. It gave me a good opportunity. I think I understood the content of the sessions, which I thought were difficult, with the help of my daughter, who attended the sessions with me.” (79 years old, female)

“I found the second half of the session on my thoughts difficult. I felt that the task of increasing my daily activities and becoming more energetic suited me better, and both relaxation methods seemed to suit me, and I am getting better at sleeping at night.” (80 years old, female).

“I think I understood most of the content of the session. Before I started counseling, I used to take my forgetfulness very seriously, but now I say to myself, ‘What is the point of thinking about it?’ I feel more cheerful than before. My daughter also said to me, ‘You are able to move more than before, and you don't talk about your anxiety anymore’.” (76 years old, female).

“It was a very new way of thinking for me to understand my feelings in terms of a model, and I think it was significant for me to be able to understand the vicious circle that goes around and around.” (80 years old, male)

Scores for Each Outcome at the Three Stages

We conducted statistical analyses to compare scores obtained for each outcome at the three periods during the study for the 13 participants, all of whom attended at least one session (on average, 6.8 ± 2.2 sessions). Supplementary Table 1 illustrates the scores for each outcome over the study period. We used a mixed-effect regression model with time as a fixed effect and participants as a random effect to compare each score. The effect of time was significant for participants at the 99% level for the GDS-15, HADS-A, and QOL-AD, and for caregivers at the 95% level for the HADS-A. The Cohen's *d* effect sizes were large for all these measures.

Discussion

Approximately 80% of the initially recruited participants and their caregivers consented to participate in this CBT program. Additionally, 77% of those who participated completed the full eight sessions, the assessment at post-intervention and follow-up three months later. Three participants with dementia left the study. The study results and discussion are therefore limited to Japanese older adults with MCI.

Notably, there is some debate about the relationship between people living with dementia and feelings of familiarity, but people experiencing non-familiarity may experience anxiety, loss of sense of direction, anxiety about personal safety, social exclusion, and decreased outings (e.g., Margot-Cattin et al., 2021). Although this trial was conducted at a medical institution frequently attended by the participants and their caregivers, it was assumed that they were unfamiliar with the program's psychological assistance (i.e., the counseling offered by the program). Unfortunately, the needs of older adults for psychological counseling and their resistance to such services have not been fully clarified in Japan, but it is believed that the utilization rate of psychological counseling among the Japanese population is lower than in other countries. For those who are likely to show

resistance to novel situations (except in the case of a sudden change in health), it may be possible to ease their resistance by meeting directly with them several times before providing psychological support services, building a rapport through interactions, and then introducing the services.

The participants and their caregivers did not experience any adverse events or worsened psychological distress as assessed by the K6 scale, resulting from the interventions across all sessions. Fidelity scores were high indicating that the program was delivered as intended. The fidelity score might also be satisfactory because the study team carefully discussed each session. We believe that the situation/events would be different with daily support services, similar to those available in a community setting; thus, the fidelity results must be interpreted carefully. These feasibility results are similar to those reported by previous studies (Spector et al., 2015; Stanley et al., 2013).

In terms of program delivery, each session took approximately 30 to 40 minutes and was shorter than previous CBT programs (Spector et al., 2015; Stanley et al., 2013). This brevity of time did not constitute a burden on older people with MCI and instead helped them maintain their concentration. After the program, the satisfaction scores on the CSQ-8 scale were high. This indicates that almost all participants and their caregivers who completed every session were satisfied with the program. The program's comprehensibility and usefulness after completing the full sessions were also high. Based on these results, we can conclude that this CBT program has sufficient feasibility and acceptability. In the future, we will modify this program as a treatment program more specific to "MCI" or "dementia" as in Spector et al. (2015) and Charlesworth et al. (2015), and brush up the content of sessions to make them easier for participants to understand and continue. The program needs to be revised as a treatment program specifically for "MCI" or "dementia."

Although this is a small-sample, single-arm study, with no control group, this study's results indicate that patients' anxious and depressive symptoms, as well as QOL, improved from pre- to post-intervention. Furthermore, these results were mostly maintained at the three-month follow-up assessment, suggesting that the program's effects were sustainable, as shown by the scores on the GDS-15, HADS-A, and QOL-AD scales. These results are mostly consistent with those obtained in previous studies (Orgeta et al., 2015; Spector et al., 2015; Stanley et al., 2013), although they differed from this study in terms of the number of sessions, the pace at which sessions were conducted, and the inclusion criteria for participants. Some interventions included in this program, such as behavioral activation, relaxation, and cognitive restructuring, could have contributed to the positive results. Therefore, this study suggests that CBT may be effective for both older Japanese people with cognitive decline, as well as those from other countries. However, while the Spector et al. (2015)'s program was structured specifically to treat anxiety symptoms, the present program was structured to improve general mood (e.g., by treating anxiety and depression). It is possible that the difference in focus in treatment may have influenced the results of this intervention. Clarification of the treatment target may influence participant attitudes toward treatment and motivation, and is one of the most important aspects of pre- and post-intervention comparisons in such clinical trials. This issue should be addressed in future studies.

Contrary to previous studies (Orgeta et al., 2015; Spector et al., 2015), the results of this study indicated that caregivers' anxious symptoms, as shown by the HADS-A scores, also improved following the program. Additionally, the effect of time was significant, and caregivers' scores on the other instruments also improved following the program. The caregivers attended the CBT sessions and were involved with and exposed to information, activities, and homework. This might have affected the older adults and reduced the

caregivers' anxiety scores. Because the needs and motivations of the participating caregiving family members varied greatly, this study did not give specific instructions to the family members present as to the extent to which they would or would not be involved in the sessions or homework, but simply told them, "To the extent that family members are able, we would like you to support the person with MCI by talking to the person with dementia and providing support when the relative with MCI is in need." However, it is quite possible that the family caregivers in attendance were naturally listening to the CBT session and may have been learning skills. Additionally, for family caregivers who were worried about what would happen to their MCI relatives in the future and felt that there was nothing they could do, the fact that they received some kind of professional support brought some sense of relief, which may have contributed to lowering their anxiety scores, although the effect of this program is not known. This point may not be unrelated to the fact that the participants in this study were older adults with MCI, not dementia, and their family caregivers. Thus, the results suggested that the program may also have a positive effect on caregivers through mutual participation. Therefore, the findings of this study confirm the benefits of CBT-based programs for both participants and caregivers, even over short periods, and fewer sessions.

This small-scale study emphasizes the potential usefulness of CBT for older people with cognitive decline in Japan. Notably, this study was the first trial of CBT in Japan for older adults with cognitive decline. To date, there have been few reports on the use of CBT among older adults. When targeting older adults with cognitive decline, it may be necessary to adapt the program structure, interventions, and session content for this population. Future scholars should address this issue. In addition, although this may be a slight digression from the focus of this study, it is known that psychiatric symptoms, such as depression and anxiety, can affect cognitive function and vice versa. Recently, the bi-directional relationship between such psychiatric symptoms and cognitive function has been discussed (e.g., Gale,

Allerhand, & Deary, 2012; Wu et al., 2021); however, the direction of this causal relationship remains controversial. Nevertheless, the results of these studies still suggest that an intervention may impact cognitive function in older adults with reduced symptoms of depression and anxiety. Unfortunately, the current study did not find any changes in MMSE scores measuring cognitive function before and after the intervention. More broadly, no studies have yet reported improvements in psychiatric symptoms and consequent improvements in cognitive function as a result of psychosocial interventions; moving forward, scholars would do well to consider this relationship.

This study also has clinical importance in that it might increase the number of non-pharmacological choices for treating older people with cognitive decline in Japan. Compared to group therapy, individualized treatment is time-consuming; however, it can be used with a diverse group of people with cognitive decline. Moreover, inviting caregivers into sessions can be helpful for the progression of the sessions, in that caregivers can remind participants to attend the sessions and do their homework, and, more importantly, become coaches for the participants by learning CBT skills together. The Japanese government has aspired to establish a society where people with dementia can live in comfortable and familiar surroundings for as long as possible. Considering that their options for psychological treatment and relevant evidence are lacking for Japan, this CBT program can be expected to support them and ultimately contribute to achieving this societal goal.

Limitations

The present study has several limitations. The criteria for evaluating the feasibility and acceptability in this study were based only on previous studies on CBT for dementia (Spector et al., 2015; Stanley et al., 2013), and these criteria are expected to be sufficient for evaluation. Further, study participants had mixed conditions (e.g., age, participation with or without caregivers). These differences may have affected their results. For example, although

older adults of different ages participated in this study, the factor of age seems very closely related to cognitive decline. In addition, caregiver participation may have been a memory aid for or brought a sense of security to the MCI participant; additionally, caregivers may have helped the participants complete their homework. Thus, we should have considered that the varying ages of the participants could have affected the results of this intervention and therefore that it remains unclear whether caregivers should participate in the CBT program. Moreover, although the participants ultimately included 10 people with MCI, it is difficult to lump them all together, as there were differences in age, subjective symptoms related to cognitive function, and attitudes toward the possibility of developing dementia in the future. In this sense, it cannot be said that the 10 participants in this study were somewhat evenly distributed. To ascertain this, intervention with some control over the characteristics of the participants is required. The more detailed inclusion/exclusion criteria in this study were different to the previous randomized controlled trial studies (Spector et al., 2015; Stanley et al., 2013). In addition, we conducted the CBT program in a hospital outpatient department, not in a community setting, such as participants' homes (Stanley et al., 2013) or any other familiar place for them. This was mainly because we could not deliver the program at home as an outreach service, which may have affected the results. Since these participants and caregivers were already proactive regarding health as seen by their visits to the psychiatric outpatient department in a large academic hospital, most of them were highly motivated to participate; different motivations might be seen in patients who were not visiting a hospital. By conducting this CBT program with highly motivated participants, satisfactory results of feasibility and acceptability might be shown. Moreover, financial remuneration (round-trip travelling allowances and rewards for each assessment) may have played a role in continued participation. In particular, the fact that the location of the study was different from that of previous studies may have caused the low number of participants in this study (e.g.,

recruitment, obtaining consent, and participating in the study). Thus, we cannot compare our results directly with those of previous randomized controlled trial studies. Therefore, in the future, we plan to investigate the retention and attendance rates of this CBT program with an implementation environment similar to previous studies on CBT for dementia and MCI. Finally, in conducting studies on CBT with older adults, it is important to have the guidance of therapists or supervisors who are familiar with treating or supporting them. Unfortunately, this could not be achieved in this study because the number of such specialists is very limited in Japan, and CBT with older people is still underdeveloped.

This study primarily aimed to examine the feasibility and acceptability of this CBT program, not the efficacy thereof. It was a single-arm trial without random sampling. As complete datasets were available for the few participants ($n=10$) in this trial, we did not conduct power analyses to evaluate the sample size required to produce an effect. Therefore, the quantitative results obtained may only be indicative rather than definitive. Therefore, this program's efficacy should be validated through controlled studies with larger samples.

In conclusion, the findings suggest that, to a limited extent, a short-term program based on CBT could be a feasible and acceptable intervention for older people with cognitive decline in Japan. Furthermore, the results of this program suggested that having family caregivers present at CBT sessions may reduce the caregivers' own anxiety. Further research using larger samples is required for additional insights regarding its efficacy.

Ethical Statement

The Ethics Committee of Nippon Medical School Hospital (27-01-543) approved the design of this research and the publication of this paper before the commencement of the program. Participants provided written informed consent. The study protocol adhered to the ethical standards outlined in the Declaration of Helsinki (as revised in Brazil) (World

Medical Association, 2013). Participants could take part in this program without incurring any expense, as round-trip travelling allowances for each session and rewards (3,000 yen) for each assessment (three assessments: pre-intervention, post-intervention, and the three-month follow-up) were provided to participants.

Key Practice Points

- A newly developed eight-session CBT program piloted prior to this study was met with high levels of satisfaction both from patients and their caregivers and resulted in very few dropouts, no adverse events, and no deterioration of mental health conditions over the course of the program.
- This intervention was found to have improved the depressive and anxious symptoms of older patients with MCI and lessened the anxious symptoms of their family caregivers pre and post the program and three months after this. Given the small sample size, however, the results of this study should be interpreted as indicative rather than definitive.
- The implementation of the CBT program with older people with mild cognitive impairment showed exciting results that could also improve the mood of the family members present. It is hoped that we will explore the mechanism underlying the effectiveness of this program shortly.

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Figure captions

Figure 1. The flow of participants through the study

This figure shows the flow from recruitment to invitation and participation in this program. Thirteen participants met our inclusion criteria and three participants dropped out during the program. Finally, ten participants attended all eight sessions of the program.

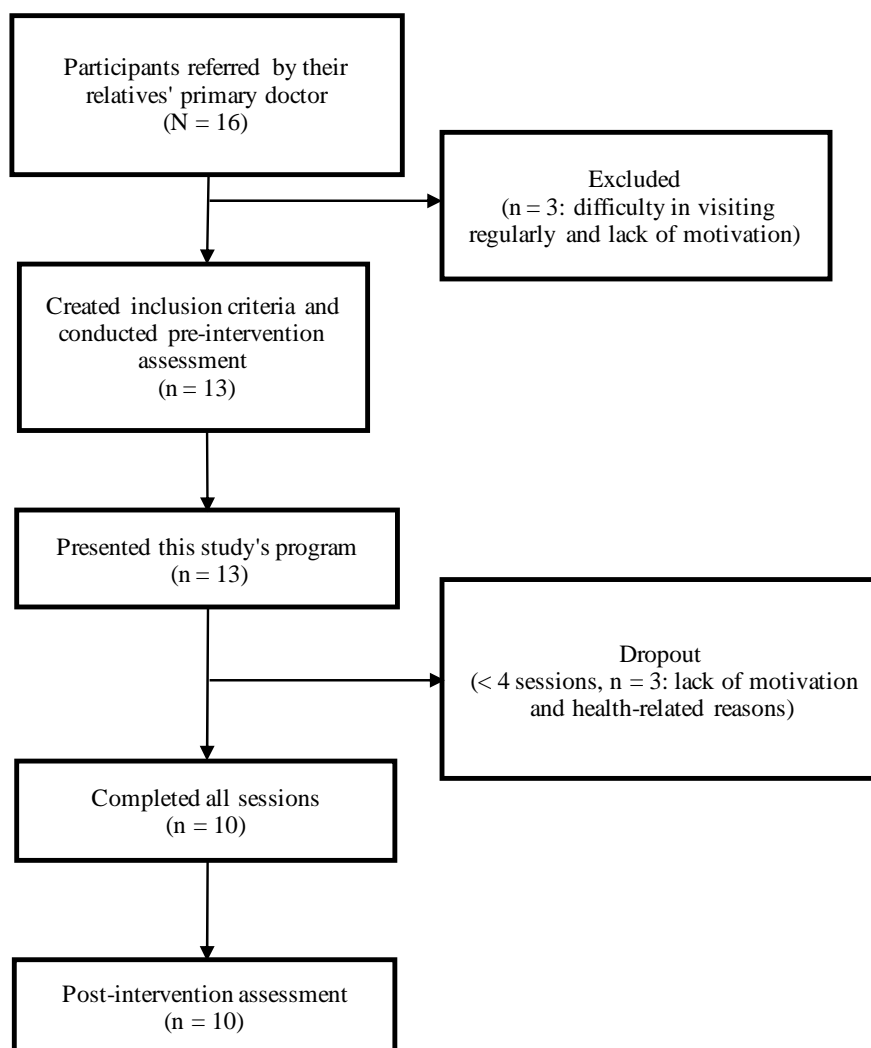


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Table 1. Cognitive-behavioral program framework

	Title	Content	Homework
Session 1	Introduction to Stress and the Cognitive-Behavioral Model	Psychoeducation about the cognitive-behavioral model and negative spiral of stress. Setting a goal.	Mood monitoring
Session 2	Exploring Pleasant Activities	Behavioral Activation: explaining the relationship between mood and behavior. Exploring pleasant activities for the participant.	Recording activities
Session 3	Coping with Barriers	Reviewing Session 2 and discussing how to manage realistic and psychological barriers when the participant tries to perform any activities.	Recording activities and barriers
Session 4	Relaxation Training: Deep Breathing	Practice of deep, regular breathing, and examining the participant's mood change.	Relaxation: deep breathing
Session 5	Relaxation Training: Progressive Muscle Training	Practice of progressive muscle training and examining the participant's mood change.	Relaxation: progressive muscle training
Session 6	Awareness of Unhelpful Thoughts	Cognitive Restructuring: discussing the relationship between mood and thought. Identifying unhelpful thoughts.	Recording unhelpful thoughts
Session 7	Coping with Unhelpful Thoughts	Reviewing Session 6 and discussing how to manage the participant's unhelpful thoughts. Finding the participant's favorite words or phrases for improving their mood.	Finding words for coping with unhelpful thoughts
Session 8	Reviewing and Preparing for the Future	Reviewing all of the sessions and preparing for any possible issues in the future.	-
Optional 1	Communication Patterns	Introduction to three communication patterns (passive, aggressive, and assertive) and discussing how to be assertive and express oneself effectively, as needed.	Assertiveness training

	Introduction to problem-solving methods	
Optional 2	Problem-Solving	and discussing how to manage the
		Problem-solving
		participant's realistic problems, as needed.

The program in this study had eight sessions conducted every two weeks including psychoeducation, behavioral activation, relaxation, and cognitive reconstruction. Optional sessions were prepared but not implemented in this trial.

Table 2. Study participants' demographic data (N = 10)

Demographic Characteristic	Mean (SD)
Age (years)	
Participant	77.50 (5.62)
Caregiver	51.60 (10.20)
Gender	
	N (%)
Participant: Female	7 (70.0)
Caregiver: Female	7 (100)
Duration of education (years), mean (SD)	
Participant	13.70 (1.89)
Caregiver	14.0 (1.63)
Relationship with relative requiring caregiving (N = 7)	
Wife	2 (28.6)
Daughter	5 (71.4)
Employment status	
Participant: Employed	3 (30.0)
Caregiver: Employed	5 (71.4)
Marital status	
Participant: Married	10 (100)
Caregiver: Married	7 (100)
Relative's diagnosis	
Mild cognitive impairment	10 (100)
Living arrangements	
Living together	10 (100)

Table 3. Mean scores and standard deviations of feasibility and acceptability outcomes

Outcomes	Post-intervention	
	Mean (Standard Deviation)	
Participants (N = 10)		
CSQ-8	31.0	(10.05)
Understanding	3.0	(0.00)
Usefulness	2.9	(0.32)
Caregiver (N = 7)		
CSQ-8	28.0	(2.83)
Understanding	2.9	(0.38)
Usefulness	2.7	(0.49)

This table shows only outcomes with respect to feasibility and acceptability and program satisfaction, understanding, and usefulness. CSQ-8: Client Satisfaction Questionnaire. Understanding: one item evaluating participants' and caregivers' understanding of the program. Usefulness: one item evaluating whether participants and caregivers perceive the program as useful.

Outcomes	Estimated Marginal Means (SE)			Pre vs. Post						Pre vs. 3-m Follow-Up					Post vs. 3-m Follow-Up				
	Pre	Post	3m follow-up	p-value (time)	Mean Differences		Effect Size		Mean Differences		Effect Size		Mean Differences		Effect Size				
					Mean	95% CI	p-value	<i>d</i>	95% CI	Mean	95% CI	p-value	<i>d</i>	95% CI	Mean	95% CI	p-value	<i>d</i>	95% CI
Patient (n = 10)																			
MMSE	25.85 (0.72)	24.90 (0.75)	25.28 (0.75)	.123	-0.96	[-1.89, -0.03]	.131	0.60	[-0.07, 1.27]	-0.56	[-1.49, 0.37]	.666	0.35	[-0.29, 0.99]	0.40	[-0.54, 1.34]	> .999	0.25	[-0.39, 0.88]
GDS-15	7.15 (0.95)	2.93 (1.01)	2.93 (1.01)	< .001	-4.22	[-5.74, -2.71]	< .001	1.62	[0.71, 2.52]	-4.22	[-5.74, -2.71]	< .001	1.63	[0.71, 2.52]	0.00	[-1.54, 1.54]	> .999	0.00	[-0.63, 0.63]
HADS-A	4.92 (0.68)	1.85 (0.73)	1.55 (0.73)	< .001	-3.08	[-4.36, -1.79]	< .001	1.39	[0.55, 2.22]	-3.38	[-4.66, -2.09]	< .001	1.52	[0.65, 2.39]	-0.30	[-1.62, 1.02]	> .999	0.13	[-0.50, 0.76]
QOL-AD	27.19 (2.08)	33.09 (2.20)	31.19 (2.21)	.006	6.02	[2.51, 9.52]	.006	1.00	[0.25, 1.74]	4.12	[0.61, 7.62]	.071	0.68	[-0.01, 1.37]	-1.90	[-5.47, 1.67]	.836	0.31	[-0.33, 0.95]
NPI-Q	8.56 (1.70)	5.63 (1.90)	3.05 (1.90)	.060	-2.93	[-7.41, 1.54]	.542	0.39	[-0.25, 1.04]	-5.50	[-9.98, -1.02]	.060	0.74	[-0.01, 1.43]	-2.57	[-7.26, 2.12]	.764	0.33	[-0.31, 0.97]
Caregiver (n = 7)																			
PHQ-9	6.33 (1.30)	4.34 (1.41)	3.34 (1.41)	.101	-2.00	[-4.82, 0.82]	.452	0.51	[-0.29, 1.30]	-3.00	[-5.82, -0.18]	.117	0.76	[-0.08, 1.60]	-1.00	[-3.91, 1.91]	> .999	0.25	[-0.52, 1.01]
HADS-A	4.89 (1.06)	2.76 (1.15)	1.25 (1.21)	.022	-2.12	[-4.45, 0.20]	.208	0.67	[-0.15, 1.49]	-3.64	[-6.09, -1.19]	.022	1.08	[0.16, 2.01]	-1.51	[-4.04, 1.01]	.639	0.44	[-0.34, 1.23]
J-ZBI_8	6.78 (2.03)	4.72 (2.18)	4.90 (2.27)	.488	-2.06	[-6.09, 1.97]	.851	0.38	[-0.40, 1.15]	-1.88	[-6.14, 2.38]	> .999	0.32	[-0.45, 1.09]	0.18	[-4.18, 4.55]	> .999	0.03	[-0.72, 0.79]
QOL-AD	28.33 (1.64)	32.16 (1.82)	28.44 (1.82)	.118	3.82	[-0.28, 7.92]	.194	0.69	[-0.14, 1.51]	0.11	[-3.99, 4.21]	> .999	0.02	[-0.74, 0.77]	-3.71	[-8.01, 0.58]	.247	0.65	[-0.17, 1.46]