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

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Research article

Keywords: Cognitive-behavioral therapy (CBT), dementia, mild cognitive impairment (MCI), depression, anxiety, older Japanese people, feasibility, acceptability

Posted Date: April 4th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-20136/v1>

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Abstract

Background Cognitive-behavioral therapy (CBT) for older people with dementia and depression/anxiety alleviates negative moods. However, CBT research focusing on this population in Japan is limited. This study aimed to evaluate the feasibility and acceptability of a recently developed cognitive-behavioral program for people with dementia or mild cognitive impairment (MCI), focusing on symptom alleviation and patient satisfaction.

Method Sixteen Japanese patients with mild dementia ($n = 3$) and MCI ($n = 13$) participated in the study. A single-arm, pre-post study was implemented in two medical school hospitals in Japan. The CBT program included eight bi-weekly sessions conducted by one clinical psychologist. The feasibility and acceptability outcomes (perceived satisfaction, understanding, and usefulness of the program) were measured before and immediately after completing the sessions, and the psychological outcomes (depression, anxiety, quality of life [QOL], neuropsychiatric symptoms, and caregiver burden) were measured at three periods (i.e., before, immediately after, and three months after the intervention). A linear mixed model was adopted for comparing these outcomes.

Results Three candidates were excluded because of unavailability, lack of interest, and refusal to participate; therefore, 13 candidates (81%) participated in this study. However, three participants dropped out because of lack of motivation and health-related reasons during the program. Finally, ten participants (76.9%) attended all program modules. The mean patient and caregiver satisfaction scores using the Client Satisfaction Questionnaire were 31.0 ± 10.05 and 28.0 ± 2.83 out of 32, respectively. The linear mixed model demonstrated that the time effect was significant at a 99% level for depression ($d = 1.62$), anxiety ($d = 1.39$), and QOL ($d = 1.00$) for the patients, and significant at a 95% level for anxiety ($d = 1.08$) for their caregivers.

Conclusion The study found that this CBT program is feasible and acceptable for older Japanese people with dementia and MCI. The program also improved patients' QOL, alleviated anxiety and depressive symptoms, and decreased caregivers' anxiety.

Background

In 2019, 28.1% of the Japanese population were aged 65 years and older, 13.9% were aged between 65 and 74, and 14.2% were aged 75 years and over.[1] Japan has emerged as a super-aged society and faces an increase in the prevalence of dementia in its population. One in four Japanese people aged 65 years and older has dementia or suspected dementia; the number of patients aged 65 and older with dementia was estimated at approximately 4.62 million in 2012, while 4 million had mild cognitive impairment (MCI).[2]

The Japanese Ministry of Health, Labour and Welfare developed a national strategy for the treatment of dementia, the basic goal being the realization of a society in which people with dementia can live with dignity in comfortable and familiar surroundings for as long as possible. The strategy focuses on several

important challenges regarding dementia, including promoting research and development and disseminating the results for prevention, diagnosis, treatment, and care models. However, no treatment or care methods for people with dementia in Japan have been well established.

It is well known that depression and anxiety are common in older people with dementia and MCI,[3-6] including those in Japan,[7] and these symptoms are associated with deterioration in social functioning and decreased independence[8] as well as an increased risk of institutionalization.[9] Moreover, depression and anxiety result in progression to dementia,[10-12] and these symptoms can also increase the burden on caregivers.[13]

Both pharmacological and non-pharmacological therapies have been designed to treat older people with dementia who suffer from depression or anxiety. However, serious adverse effects from the use of psychotropic drugs in the elderly with dementia have been reported;[14,15] thus, non-pharmacological therapy should be considered first for mild moods and behavioral concerns.[16,17] In addition, mood and behavioral problems frequently co-occur with physical conditions in older people, increasing the risk of adverse drug reactions due to polypharmacy.[18]

Recent studies have reported the efficacy of cognitive-behavioral therapy (CBT) in alleviating depression, anxiety, and improving the quality of life (QOL) of older people with dementia and MCI. [19-21] The underlying concept of CBT is that thoughts and behaviors influence emotions. Therefore, CBT attempts to modify dysfunctional thoughts and behaviors, improve negative emotions, and boost feelings of well-being. However, there has been little research on CBT in the treatment of depression or anxiety in older people with dementia or MCI in Japan.

Aims of this study

Prior to this study, we administered a newly developed CBT-based program to a Japanese older female diagnosed with MCI who reported anxious and depressive moods and complained about discomfort in her limbs and abdomen, the underlying cause of which was unidentified.[22] Results showed that the program reduced the patient's depressive symptoms and improved her QOL. However, the study was a single case report. Consequently, the purpose of this study was:

1. To expand previous research by further examining the feasibility and acceptability of this program for older Japanese patients diagnosed with either dementia or MCI.

We defined the examination of feasibility and acceptability in this study with the following five viewpoints in mind:

- 1) >33% referrals were recruited for the study,
- 2) expected follow-up rate of >70% and,
- 3) attendance of > six sessions adherence, in reference to the previous study. [20,21]

4) The intervention could be delivered with fidelity.

5) We would be able to collect outcome measures which will be consistent with the CBT for dementia randomized controlled trial (RCT) for mood and QOL. This is the first study investigating the feasibility of CBT treatment for people with decreased cognitive function in Japan.

Methods

Participants

Participants were recruited based on the inclusion criteria outlined below:

- 1) diagnosed with mild dementia or MCI, with a score of at least 20 points on the Mini-Mental State Examination (MMSE) (see “Assessment” below).
- 2) living within reasonable traveling distance of a hospital (i.e., within 30-60 minutes).
- 3) being able to perform homework assignments for at least 15 minutes every day.
- 4) being 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 that precludes CBT.
- 4) physical health problems which made engagement in psychological treatment 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, difficulty in comprehending the program, or severe cognitive decline prior to commencement of the program.
- 7) hospitalization due to severe depression or anxiety, self-injury, or suicide attempt.

These criteria were not consistent with the CBT criteria adopted in previous dementia studies. [20,21] As this study was the first trial of the CBT program for dementia and MCI, setting more detailed criteria allowed us to conduct it with utmost care and caution.

Setting and Recruiting Procedure

This study was a single-arm, pre-post study (Figure 1) conducted between 2016 and 2018 (for 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%). Due to the exploratory nature of the study, a convenience sampling approach was used. In previous studies, participants could receive the CBT sessions at their own homes, [21] but outreach psychological services are not yet available in Japan. Thus, we conducted the program at an outpatient department. Participants with MCI or dementia were referred to the doctors (i.e., psychiatrists and neurologists) in the research team. We also requested the 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 per month, rewards, and round-trip travelling expenses) to ensure that they were fully informed prior to agreeing to participate.

[Insert Fig. 1 about here]

Ethical Approval

The Ethics Committee of Nippon Medical School Hospital (27-01-543) approved the design of this research and the publication of this paper prior to the commencement of the program. Participants were asked to provide written informed consent. The study protocol adhered to the ethical standards outlined in the Declaration of Helsinki (as revised in Brazil).[23] Participants could take part in this program without incurring any expense. In addition, 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. The aforementioned study terms were explained to them prior to obtaining their informed consent.

Intervention

The CBT program for people with dementia or MCI, developed [22] by referring to previous studies, [20,21,24-26] was individualized with the aim of improving the mental health and QOL of participants. Clinical psychologists, psychiatrists, and neurologists who specialized in geriatrics discussed how the CBT sessions should be structured and developed an original manual for this program. Furthermore, we prepared case examples for inclusion in the manual based on our clinical experience with older Japanese people. Therefore, the development of the program did not require any further consideration of culturally relevant aspects.

The program consisted of eight sessions (Table 1) on topics such as psychoeducation, behavioral activation, relaxation training (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.[27] A brief workbook discussing the topics was provided to each participant at no charge. Reading a topic for the next session as homework was

optional. A brief assessment of psychological distress was conducted at the beginning of each session and participants were asked to attempt the CBT skills learned in the sessions. Additionally, they were encouraged to make notes in the workbook. Although each session lasted for approximately 60 minutes once a week in a previous study on CBT for dementia, [20] we set our session duration to be between 30 and 40 minutes, which was conducted every two weeks to account for the participants' loss of concentration and burden of hospital visit.

As previous studies recommended that CBT sessions for dementia include family caregivers, [20,21,25,28] we requested the participants' caregivers to participate in each session. Regarding the number of CBT sessions, previous studies [20,21] conducted 10 to 23 sessions in their programs. However, since most Japanese individuals diagnosed with dementia or MCI were unfamiliar with the CBT and considering the burden on the participants who had to visit the implementation sites, we decided on a shorter, eight-session program.

[Insert Table 1 about here]

The program was delivered by a Japanese clinical psychologist (the therapist) who was familiar with CBT and had more than 10 years of training. Prior to 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 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 by a member of the research team, 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: prior to the commencement of the program (pre-intervention; week 0), immediately after the completion of the program (post-intervention; week 17), and three months thereafter. At each interview, participants completed the measuring instruments. 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. 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.

Pre-intervention assessment measure

The Mini-International Neuropsychiatric Interview (MINI). The MINI (DSM-IV; ICD-10) [29] is a brief, structured interview that was used at the baseline assessment to evaluate the participants on the exclusion and inclusion criteria.

Post-intervention assessment measures

The Client Satisfaction Questionnaire (CSQ-8). The CSQ-8 is a self-reported, eight-item instrument measuring participants' 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).[30,31] Some sample items are: "To what extent did the program meet your needs?" and "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).[31] We administered this questionnaire both to participants and their caregivers at the post-intervention assessment to evaluate the feasibility of the program.

Post-assessment reports. We asked participants and their caregivers about the program's comprehensibility (i.e., "Do you understand the content of this program?") and usefulness (i.e., "Do you think this program is useful for you?"). These questions were answered on a four-point scale: 0: Not at all, 1: A little, 2: Moderately, and 3: Very.

Three-period measures

Mini-Mental State Examination (MMSE). The MMSE is a brief measure of cognitive function used worldwide, with total scores ranging from 0 to 30.[32,33] The MMSE has been shown to be a valid test for cognitive function and has good test-retest reliability (= .89).[32] We used this instrument to evaluate the level of participants' cognitive decline relative to the exclusion criteria for this study and to assess score changes across the three assessment periods.

Geriatric Depression Scale-15 (GDS-15). The GDS-15 is a 15-item, self-reported scale measuring depressive symptoms in older people, [34,35] 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. [35,36] This scale was administered to the participants only.

Hospital Anxiety and Depression Scale-Anxiety (HADS-A). The HADS is a 14-item, self-reported scale measuring anxiety and depression [37,38] 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. [39,40] We used the HADS-A for both participants and their caregivers because the Japanese version of the HADS-D reportedly has low internal consistency.[41]

Quality of Life-Alzheimer's Disease Scale (QOL-AD). The QOL-AD is designed to measure QOL in older adults with cognitive impairment.[42] It contains 13 items measuring 13 domains (physical health, energy, mood, living conditions, memory, family, marriage [or a close relationship], friendship, self as a whole, ability to do chores, ability to do something fun, financial capabilities, and life as a whole) rated on a four-point scale. It has good internal reliability (Cronbach's alpha coefficient = .82 to .84).[43] 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.

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.[44] It contains six items on a five-point scale ranging from 0 to 4. We used the K6 at each session to monitor the mental health condition of both the participants and their caregivers and to assess whether a CBT session had a detrimental effect on the participants' conditions.

Neuropsychiatric Inventory Questionnaire (NPI-Q). The NPI-Q is a brief version of the NPI.[45] 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.[46] The NPI-Q has good test-retest reliability (= .80 to .94) and large inter-scale correlations with the NPI (= .71 to .93).[46] The Japanese version of the NPI-Q has demonstrated similar results, with adequate validity and reliability.[47] 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. [48,49] 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. [50,51] 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, [52,53] 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, comparable to the original version.[54] We administered this to the caregivers.

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 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 and Cohen's *d* to calculate the effect size. A significance level of $p < 0.05$ was adopted. 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, sixteen participants (five males and 11 females, mean age 73.60 ± 10.05) with their caregivers ($n=12$) were recruited from one hospital department. However, three of these participants were excluded because of unavailability ($n=1$), lack of interest ($n=1$), and refusal to participate ($n=1$). Consequently, 13 out of 16 participants (81%) agreed to participate in this study. However, three participants dropped out during the program because of lack of motivation ($n=1$) and health-related reasons ($n=2$). Finally, ten out of 13 participants (77%; three males and seven females, mean age 77.50 ± 5.62) with their caregivers ($n=7$) attended all program sessions. On average, each session lasted 36.04 ± 3.24 minutes. Fidelity was scored for each session with 13 participants, including the three dropouts (a total of 89 sessions), and the average score was 22.84 ± 3.07 , where 30 was the highest (for participants who completed all sessions, the score was 24.19 ± 1.55). All participants remained in the study, including the post-intervention (10/10; 100%) and three-month follow-up (10/10; 100%).

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 $(-0.29, 1.30)$]. Thus, the progression of this CBT program did not worsen the K6 scores for either the participants or their caregivers through all sessions. Finally, none of the participants had any physical conditions or psychiatric disorders, as assessed by the MINI.

[Insert Table 2 about here]

Program satisfaction

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 Table 3 about here]

Scores for Each Outcome at the Three Stages

We conducted statistical analyses to compare the scores obtained on each outcome at the three intervention stages during the study for the 13 participants, all of whom attended at least one session (on average, 6.8 ± 2.2 sessions). Additional file 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

Main findings

Approximately 80% of the initially recruited patients and their caregivers consented to participate in this CBT program. Additionally, 77% of those who participated completed the full eight sessions, the post-intervention assessment, and the follow-up assessment three months later. As a result of the interventions, the participants did not experience any adverse events, side effects, or worsened psychological distress, as assessed by the K6 scale. Moreover, the fidelity scores were high, which shows that the program was delivered as intended. The fidelity score can also be considered to be satisfactory, because the study team carefully discussed each session during our peer supervision. We believe that the situation/events would be different with daily support services, such as a community setting; thus, the fidelity results must be interpreted carefully. These feasibility results did not differ considerably from those reported by previous studies. [20,21]

In terms of program delivery, as explained above, each session took approximately 30 to 40 minutes and were shorter than previous CBT programs. [20,21] This brevity of time did not constitute a burden on older people with dementia or MCI, and instead, helped them maintain their concentration.

Subsequent to the program, participant and caregiver 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, as perceived by the participants and caregivers after completing the full sessions, were also high. Based on these results, we can conclude that this eight-session CBT program has sufficient feasibility and acceptability.

The effectiveness of CBT for older people with depression or anxiety, excluding those who had dementia or MCI, has already been reported.[55,56] Although this is just a single-arm study with a small sample, and there was not a control group, the results of this study 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 effects of the program 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, [19-21] although they employed longer time periods than we did and included participants with moderate dementia. 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 even for older people with reduced cognitive function.

Contrary to previous studies, [19,20] 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. Thus, although this program mainly targeted older people with dementia or MCI, the results suggested that the program may have a positive effect on their caregivers as well, through mutual participation. One study protocol on CBT for people with dementia and their caregivers, comprising 25 combined sessions over nine months, has already been published, [28] although results have not yet been reported. However, the findings of this study confirm the benefits of CBT-based programs for both participants and their caregivers, even over short periods.

This small-scale study emphasizes the potential usefulness of the CBT in Japan. This study also has clinical importance in that it might increase the number of non-pharmacological choices for treating older people with dementia or MCI in Japan. This is relevant given the detrimental effects of pharmacological treatments on this population's health. Compared to group therapy, individualized treatment is time-consuming; however, it can be used with a diverse group of people with dementia or MCI. Moreover, inviting caregivers into sessions can be helpful for the progression of the program, in that caregivers can remind participants to attend the sessions and do their homework, and, more importantly, become a sort of coach by learning CBT skills together. As mentioned above, the Japanese government aspires 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 provide them support 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 and dementia [20,21], and these criteria are expected to be sufficient for evaluation. Further, the participants in this study had mixed conditions (MCI and mild dementia) and participated with or without their caregivers; therefore, their results may have been affected by their differences. Thus, it is unclear whether this CBT program might be feasible, acceptable, or effective for both of them or either. The more detailed inclusion/exclusion criteria in this study were different to the previous RCT studies.[20,21] In addition, we conducted the CBT program in a hospital outpatient department, not in a community-setting, such as participants' homes (e.g. [21]) 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 attending 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. These factors may have influenced the results, and the difference in the implementation site could have caused the paucity of participants. Thus, we cannot compare our results directly with those of previous RCT 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 and dementia.

Regarding the fidelity of this CBT program, the mean score was high. However, the research members carefully discussed each session during our peer supervision, thus there is no wonder that the fidelity scores were high. We believe that the situation/events would be different with daily support services, such as a community setting. Spector et al. [20] evaluated therapists' adherence to CBT with the Cognitive Therapy Scale-Revised,[57] which measures CBT competence (CBT general skills and specific skills). However, we did not use this scale but a brief fidelity checklist. Thus, the fidelity scores must be interpreted carefully.

Additionally, unlike previous studies on CBT for dementia, only one therapist presented the program to all participants on this study because of the absence of other therapists who had implemented CBT for older patients. This means that we could not demonstrate whether other psychotherapists in Japan could use this CBT program for older patients with dementia or MCI with similar results.

The main purpose of this study was 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, the efficacy of this CBT program should be validated through controlled studies with larger samples.

Conclusions

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 dementia or MCI in Japan. This is supported by the high index of perceived program satisfaction, comprehensibility, and usefulness. Although the data suggest that this CBT program might alleviate anxiety symptoms, decrease depressive symptoms, and improve the QOL for patients with dementia or MCI, it might also help their family caregivers. Further research using larger samples is required for additional insights regarding its efficacy.

Abbreviations

CBT – Cognitive behavioral therapy

CSQ – Client Satisfaction Questionnaire

GDS – Geriatric Depression Scale

HADS-A – Hospital Anxiety and Depression Scale-Anxiety

HADS-D – Hospital Anxiety and Depression Scale-Depression

J-ZBI_8 – Japanese version of the Zarit Caregiver Burden Interview–short version

K6 – Kessler Psychological Distress Scale

MCI – Mild cognitive impairment

MMSE – Mini-Mental State Examination

NPI-Q – Brief version of the Neuropsychiatric Inventory Questionnaire

PHQ – Patient Health Questionnaire

QOL – Quality of life

QOL-AD – Quality of Life-Alzheimer’s Disease scale

RCT – Randomized controlled trial

Declarations

Ethics Approval and Consent to Participate

This research was approved by the Ethics Committees of Nippon Medical School Hospital (27-01-543). Participants were asked to provide written informed consent. The study protocol adhered to the ethical standards outlined in the Declaration of Helsinki (as revised in Brazil).

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available to protect participants’ privacy. However, the datasets are available with the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was supported by JSPS KAKENHI under grant numbers JP26590165 and JP18K13356. The funding body was not involved with the design of the study; or collection, analysis, and interpretation of the data; or writing the manuscript.

Authors' contributions

MK and TN designed the study and supervised the data collection. MK wrote the paper and AS provided advice on the study and assisted with writing the paper. AI and AN collected the data and assisted with writing the article. AT was responsible for the statistical design of the study and for carrying out the statistical analysis. TN supervised the CBT sessions in this study, and SK supervised the whole study.

Acknowledgments

We would like to express our appreciation to all the participants, their family caregivers, and all staff in the Psychiatric outpatient clinic at the Nippon Medical School Hospital and Musashi Kosugi Hospital Dementia Center. In particular, we would like to thank Ms. Maho Araki, Ms. Mari Yamashita, Ms. Mai Kato, Ms. Chigusa Inagaki, and Ms. Rumi Nemoto, who are clinical psychologists and certified public psychologists, for their assistance with the assessments and interventions. We are also grateful to Dr. Toshiaki Kikuchi, Dr. Ryo Shikimoto, and Dr. Naomi Kokubo for their valuable comments. Finally, we would like to thank Editage (www.editage.jp) for English language editing and the SATISTA Corporation (www.satista.jp) for advice regarding statistical analysis.

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Tables

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

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 ($n = 16$)

Demographic Characteristic	Mean (SD)
Age (years)	
Patient	73.6 (10.05)
Caregiver	58.0 (11.65)
N (%)	
Gender	
Patient: Female	11 (68.8)
Caregiver: Female	11 (91.7)
Duration of education (years), mean (SD)	
Patient	13.35 (1.66)
Caregiver	14.0 (1.71)
Relationship with relative requiring caregiving ($n = 12$)	
Wife	3 (25.0)
Husband	1 (8.3)
Daughter	8 (66.7)
Employment status	
Patient: Employed	3 (18.8)
Caregiver: Employed	6 (50.0)
Marital status	
Patient: Married	16 (100)
Caregiver: Married	12 (100)
Relative's diagnosis	
Mild cognitive impairment	13 (81.3)
Alzheimer's disease	3 (18.8)
Living arrangements	
Living together	16 (100)

These data involved 16 patients who were initially recruited and invited to this study.

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

Outcomes	Post-intervention	
	Estimated Marginal Means (SE)	
Patient (<i>n</i> = 13)		
CSQ-8	31.0	(-10.05)
Understanding	3.0	(0.00)
Usefulness	2.9	(-0.32)
Caregiver (<i>n</i> = 9)		
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.

SE: Standard error

Figures

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.

Supplementary Files

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- [AdditionalFile1.xlsx](#)