

# The effect of a multimodal comprehensive care methodology for family caregivers of people with dementia

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## Research Article

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# Abstract

**Background:** Caregivers experience social, physical and psychological burdens in caring for people with dementia. A study was conducted to assess the efficacy of a multimodal comprehensive care methodology training programme for the family caregivers of people with dementia.

**Methods:** This research was a pre-post prospective study. A total of 148 family caregivers of people with dementia participated in a multimodal comprehensive care methodology training programme for six hours (three times for two hours) in three months, which was followed by weekly delivery of information via postcard. The care burden of the caregivers was evaluated by the Japanese short version of the Zarit Burden Interview (J-ZBI) before the training, one month post-training and three months post-training (primary outcome). Each caregiver assessed the symptoms of the people with dementia for whom they provided care with the Behavioral Pathology in Alzheimer's Disease (Behave-AD) (secondary outcome).

**Results:** A total of 117 family caregivers (79%) were assessed three months after training. Over the course of the programme, the care burden significantly decreased from pre-training to three months post-training ( $P < 0.001$ ). The mean care burden scores before, one month after, and three months after the intervention were 13.3, 10.9 and 10.6, respectively. The mean Behave-AD score of 101 people with dementia (68%) three months post-training was lower than that at pre-training, but the difference was not statistically significant (from 13.6 to 11.8,  $P = 0.005$ ).

**Conclusions:** The multimodal comprehensive care methodology training was associated with a reduction in the care burden of family caregivers. These findings suggest that randomized controlled trials with large sample sizes are needed.

**Trial registration:** UMIN Clinical Trials Registry (UMIN-CTR), UMIN000043245.

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## Background

Dementia is a major health problem that causes physical, mental and financial burdens on patients and caregivers. Informal caregivers, mostly spouses and children, play a central role in the care and health preservation of people with dementia who live at home. Although cognitive deficits are the clinical indication of dementia, behavioural and psychological symptoms of dementia (BPSDs) are almost ubiquitous and can dominate disease presentation [1].

Managing BPSDs is one of the most challenging aspects of care, causing caregiver burden and upset [2]. Caregivers of people with BPSDs are more distressed and depressed than those who do not manage such behaviours [3]. There is emerging evidence that caregiver distress associated with BPSDs is a more important predictor of institutionalization and inpatient and emergency department use than the

frequency and severity of BPSDs themselves [4-6]. Unfortunately, no effective treatment options for BPSDs are currently available to family caregivers. Typically, if a caregiver expresses concern about a BPSD to a physician, a sleep medication or anti-psychiatric medication is prescribed to control the symptom. However, medication is an ineffective and potentially dangerous strategy [7, 8]. On the other hand, non-pharmacologic strategies are recommended by multiple medical organisations and expert groups. Currently, some non-pharmacological approaches appear to be effective as interventions for family caregivers [9-12]. However, such approaches, which require intensive and time-consuming training, have not been translated enough to real-world care [9-12].

A previous systematic review by Feast et al. [13] revealed two main reasons for behaviours being reported as challenging by family caregivers who have difficulty dealing with BPSDs: changes in communication and relationships between people with dementia and family caregivers, resulting in feeling bereft, and perceptions of transgressions against social norms associated with misunderstandings about the behaviour of people with dementia. The authors noted that carers who retained the conceptualisation of their relative with dementia as the person they had always known and loved would be able to continue to have a fulfilling relationship with the person with dementia and that the companionship and feelings of care gained from the relationship would help reduce the caregiver's perception of BPSDs as challenging, thus improving their ability to cope.

A French care methodology of Gineste-Marescotti, called Humanitude™, has been extensively carried out in several settings including nursing homes and hospitals in the last 40 years [14]. The methodology is a multimodal comprehensive communication technique and depended on a humanist philosophy that highlights respect for individual freedom, autonomy and dignity. It emphasizes 4 communication skills with patients: gaze, talk, touch and assistance with standing up. In addition, all the care is to be applied in a sequence consisting of 5 stages with these skills of communication: 1) *Pre-preliminaries*, 2) *Preliminaries*, 3) *Sensory circle*, 4) *Emotional consolidation*, and 5) *Appointment* [15].

The purpose of the present study was to determine whether the multimodal comprehensive care methodology training programme would reduce family caregiver burden in caring for people with dementia. Secondly, we investigated BPSDs in people with dementia.

## Methods

### *Study design, setting, and participants*

A pre-post prospective study was conducted. This study adheres to the CONSORT guidelines. Participants were consecutively recruited in November 2016. They were recruited from a community in Fukuoka, the 5<sup>th</sup> largest city of Japan. The inclusion criteria were being a primary family caregiver for a patient clinically diagnosed with dementia and residing with the patient. The monthly 2-hour training programme was held three times in Fukuoka from December 2016 to Feb 2017. After each training session, the

participants received weekly postcards over three months containing information about the methodology, for a total of 12 postcards.

### ***Procedure***

Prior to the training, the participants completed the Japanese short version of the Zarit Burden Interview (J-ZBI) to assess caregiver burden [16, 17]. They also completed the Behavioral Pathology in Alzheimer's Disease (Behave-AD) to evaluate behavioural and psychological symptoms in the people with dementia for whom they provided care [18, 19]. A monthly 2-hour multimodal comprehensive care methodology training programme was provided three times, which was followed by weekly delivery of information via a total of 12 postcards. One month and three months after the training, secondary surveys were conducted to obtain the post-intervention J-ZBI scores of the participants and the post-intervention Behave-AD scores of the people with dementia (Figure 1).

### ***Instruments***

#### ***J-ZBI***

The ZBI is one of the most widely used measures of caregiver burden and assesses the impact of caregiving on caregivers, including physical, mental, social and economic aspects [16]. In this study, the short version of the J-ZBI, which has been linguistically validated, was used [17]. This questionnaire is an 8-item instrument that has been widely used and validated among caregivers. It uses a 5-point Likert scale anchored by "strongly disagree" and "strongly agree" (range: 0-32). The participants completed the J-ZBI. The scale was administered before the training (pre-training), one month later, and three months later (post-training).

#### ***Behave-AD***

The Behave-AD is the most widely used instrument for the evaluation of dementia-related behavioural changes based on informant interviews [18]. The questionnaire is a 26-item instrument that has been widely used and validated among caregivers and uses a 4-point scale. It addresses delusions, hallucinations, activity disturbances, aggressiveness, diurnal rhythm disturbances, affective disturbances, anxieties and phobias. The people with dementia were assessed using the Japanese version of the Behave-AD, which has been linguistically validated [19]. The assessor of each patient was his or her participating family caregiver; the Behave-AD was completed prior to the study and one month and three months after the intervention.

### ***Outcome measures***

The primary outcome was the difference in the J-ZBI scores from before the training (pre-training) to three months later (post-training). The secondary outcome was the difference in the Behave-AD scores between pre-training and post-training.

## ***Multimodal comprehensive care methodology training programme***

As the intervention, we implemented a French multimodal comprehensive care methodology training programme. In 1979, Gineste and Marescotti developed a multimodal comprehensive care methodology called the Humanitude™ [14, 15]. Humanitude™ refers to the set of particularities that allow us to feel that we are members of the human species and to recognize other human beings as members of the same species. They defined this recognition as established by using what they called the 4 pillars: gaze, talk, touch, and vertical body. They developed this care methodology based on the considerations of dignity, freedom and autonomy in the daily care provided to dependent and vulnerable persons. The methodology focuses on 4 elements of communication with patients: gaze, talk, touch, and assistance with standing up. Additionally, all care is provided in a sequence consisting of 5 stages: 1) Notification (*Pre-preliminaries*), 2) Preparation (*Preliminaries*), 3) Integration of communication (*Sensory circle*), 4) Emotional consolidation (*Emotional consolidation*), and 5) Next appointment (*Appointment*). The aim of Notification (Stage 1) is to announce the presence of the caregiver, avoid surprise approaches and respect the patient's privacy and autonomy. Preparation (Stage 2) represents the initial establishment of a relationship through the relationship pillars (gaze, speech and touch), and it allows the caregiver to obtain consent for the relationship from the person receiving the care. Integration of communication (Stage 3) includes the provision of care with a consistent positive emotional environment between the caregiver and the patient. At the end of the care, Emotional consolidation (Stage 4) is a stage of cognitive and mental stimulation that leaves a positive impression of the relationship and care in the emotional memory of the person receiving it, facilitating consent to the relationship and the acceptance of future care. Next appointment (Stage 5) is the final moment of the relationship, in which commitment to future care is affirmed because the emotional memory is functioning even if they have advanced dementia. At this stage, goodbyes are said, and a new meeting is scheduled, which prevents a feeling of abandonment [14]. The programme administered in the current study consisted of training participants in skills that could be used at home using this multimodal comprehensive care methodology. The training was performed by a certified instructor. The instructor provided lectures, demonstrations and role-play workshops to teach the participants how to adapt the methodology to people with dementia. After each monthly training programme, we sent weekly postcards with information about the methodology as "a goal for this week" to the participants for three months.

## ***Statistical analysis***

The normality of all data was verified by the Shapiro-Wilk test. A Wilcoxon signed rank test was used to test for significant differences between the pre-training and post-training J-ZBI scores and Behave-AD scores. The paired-samples t-test was used to test for significant differences in the categories of the J-ZBI scores. The baseline characteristics of the people with dementia were compared using the Fisher's exact test for categorical variables and the Mann-Whitney U test for continuous variables. These analyses were performed using R statistical software (version 3.5.3). Statistical significance was defined when  $P < 0.05$ .

## **Results**

A total of 148 family caregivers were enrolled in the study to complete the multimodal comprehensive care methodology training programme. Prior to the training, information on the 148 people with dementia who the participants provided daily care was obtained.

### **Comparison of the J-ZBI scores**

Among the 148 participants, the post-training response rate was 131 (89%). According to Gough and Hall, a response rate of at least 75% is needed to ensure the representativeness of the sample for surveys mailed to professionals [20]. In the analysis of the J-ZBI scores, 14 participants were excluded due to missing data. A total of 117 (79%) patients were assessed after these adjustments.

The distribution of the participants and the results of the pre-training and the post-training J-ZBI scores are shown in Table 1. The J-ZBI scores showed a statistically significant improvement (from 13.3 to 10.6,  $p<0.05$ ) from pre-training to post-training. Decreases in scores from pre- to post-training were observed among the participants regardless of age, gender, and spouse-child relationship. In particular, there were significant reductions in the care burden among participants younger than 65 years, participants older than 65 years, female participants, and children of people with dementia.

**Table 1.** Pre-training and post-training results of the Japanese short version of the Zarit Burden Interview scores

	N	Mean Score (95% CI)			P-value
		Pre-intervention	1 month	3 months	
Burden Interview score	N=117	13.3	10.9	10.6	<b><i>P&lt;0.001<sup>a</sup></i></b>
Over 65 years old	N=45	13.3	10.9	10.7	<b><i>P=0.02<sup>a</sup></i></b>
Under 65 years old	N=72	13.2	10.9	10.5	<b><i>P&lt;0.001<sup>a</sup></i></b>
Male	N=22	13.4	11.0	10.7	<b><i>P=0.09<sup>b</sup></i></b>
Female	N=95	13.3	10.9	10.6	<b><i>P&lt;0.001<sup>a</sup></i></b>
Spouse	N=23	13.5	11.0	10.8	<b><i>P=0.09<sup>b</sup></i></b>
Child	N=75	13.3	10.9	10.6	<b><i>P&lt;0.001<sup>a</sup></i></b>

<sup>a</sup> Wilcoxon signed rank test

<sup>b</sup> Paired-samples t-test

The bold numbers are significant *P*-values ( $p<0.05$ ) before training and three months after training.

### **Comparison of the BehaviorBEHAVE-AD scores**

Among the 148 people with dementia, the post-training response rate was 82% (122 patients). The characteristics of the 148 patients are described in Table 2. In the analysis of the Behave-AD scores, some people were excluded due to the following reasons: non-response (26 patients), missing Behave-AD

data (19 patients), hospital admission (1 patient) and death (1 patient). A total of 101 people were assessed after these adjustments. Sixty-eight (67.3%) people were women, 36 (35.6%) were 75-84 years old, and 47 (46.5%) were over 85 years old. The most common cause of dementia was Alzheimer's disease (n=42, 41.6%). The people's support and care need levels were collected. The public long-term care insurance system in Japan classifies frail older adults according to seven levels ('support need levels' 1 and 2 and 'care need levels' 1–5, where larger numbers indicate more severe need) using a nationally standardized and validated algorithm. The level is determined according to older adults' physical and mental care needs [21]. In Japan, older people who were classified as higher than care need level 3 were found to be more likely to be institutionalized than those who were classified as care need level 2 or lower [22]. Forty-six people (45.5%) had care needs levels of 3, 4, and 5. Thirty-seven people (36.6%) had taken any sleep medications or antipsychotic medications.

**Table 2.** Characteristics of the people with dementia

	Total (n=148)	Data available (n=101)	Loss to follow up <sup>a</sup> (n=47)	<i>P</i> - value <sup>b</sup>
Age, <i>n</i> (%)				
65-74 years	28 (18.9)	18 (17.8)	10 (21.3)	0.06
75-84 years	51 (34.5)	36 (35.6)	15 (31.9)	0.5
≥85 years	69 (46.6)	47 (46.5)	22 (46.8)	0.29
Women, <i>n</i> (%)	102 (68.9)	68 (67.3)	34 (72.3)	0.57
Aetiology of dementia, <i>n</i> (%)				
Alzheimer's disease	63 (42.6)	42 (41.6)	21 (44.7)	0.73
Lewy body dementia	9 (6.1)	8 (7.9)	1 (2.1)	0.27
Vascular dementia	10 (6.8)	9 (8.9)	1 (2.1)	0.17
Other type of dementia	4 (2.7)	2 (2.0)	2 (4.3)	0.59
Dementia with undetermined aetiology	62 (41.9)	40 (39.6)	22 (44.7)	0.48
Support need level, <i>n</i> (%)				
Level 1	9 (6.1)	7 (6.9)	2 (4.3)	0.71
Level 2	5 (3.4)	2 (2.0)	3 (6.4)	0.32
Care need level, <i>n</i> (%)				
Level 1	40 (27.0)	28 (27.7)	12 (25.5)	0.84
Level 2	21 (14.2)	11 (11.0)	10 (21.3)	0.13
Level 3	33 (22.3)	23 (22.8)	10 (21.3)	1.0
Level 4	16 (10.8)	15 (14.9)	1 (2.1)	0.02
Level 5	9 (6.1)	8 (7.9)	1 (2.1)	0.27
Medication, <i>n</i> (%)	59 (39.9)	37 (36.6)	22 (46.8)	0.28

<sup>a</sup> loss to follow up: 26 patients were excluded due to non-response, 19 patients were excluded due to missing OHAT data, 1 patient was excluded due to hospital admission and 1 patient was excluded due to death.

<sup>b</sup> The Mann-Whitney U test and Fisher's exact test were used to compare the available data and the data of those lost to follow up. The threshold for statistical significance was set at  $p < 0.05$ .

The results of the pre-training and post-training Behave-AD scores are shown in Table 3. The Behave-AD scores showed a statistically significant improvement (from 13.6 to 11.8,  $p < 0.05$ ) from pre-training to post-training. There were significant improvements in dementia-related behavioural changes among people who needed high levels of care and people who had taken sleep medications or antipsychotic medications.

**Table 3.** Mean pre-training and post-training Behavioral Pathology in Alzheimer's Disease scores ( $n=101$ )

		Mean Score (95% CI)			<i>P</i> -value <sup>a</sup>
		Pre-intervention	1-month	3-months	
Behave-AD	N=101	13.6	11.3	11.8	<b><i>P=0.005</i></b>
Alzheimer's disease	N=42	13.7	11.4	11.9	<b><i>P=0.07</i></b>
need levels $\geq 3$	N=46	13.6	11.3	11.8	<b><i>P=0.004</i></b>
medication	N=37	13.7	11.4	11.9	<b><i>P=0.003</i></b>

<sup>a</sup> Wilcoxon signed rank test

The bold numbers are significant *P*-values ( $p < 0.05$ ) before training and three months after training.

## Discussion

The findings of this study show that the multimodal comprehensive care methodology training for family caregivers decreased their care burden in caring for people with dementia.

This study has two strengths. First, our study revealed that there was a reduction in the care burden among family caregivers regardless of age, gender, and spouse-child relationship. A majority of studies on the gender of caregivers have reported a higher burden among females [23]. There is also some evidence that caring for an older adult spouse with a disability or chronic condition increases one's risk of impaired physical and mental health [24, 25]. Despite this evidence, our present results suggest that this methodology training can be used for diverse family caregivers. The reason is that this methodology is considered not intensive and time-consuming but rather is a widely deliverable and sustainable approach for family caregivers; in addition, the weekly postcards after each monthly 2-hour training session provided a reminder of the methodology for family caregivers over three months.

Second, the proposed methodology is supported by the Humanitude™ concept. Many communication training interventions for caregivers of people with dementia have been performed. However, many interventions have not been supported by a clear conceptual framework [26]. This methodology training provides practical care communication skills based on a neurological theory of dementia and humanist philosophy and as well as lectures about dementia-related knowledge and care [14]. Family caregivers' perceptions of BPSDs as challenging are associated with a sense of a declining relationship between people with dementia and family caregivers [13]. Interpersonal and family contexts have been noted to be contributory factors in the development and course of BPSDs [27, 28]. The goal of the proposed methodology is to build a good relationship between caregivers and care receivers while creating a sense of sharing a good time together in the process. Caregivers experience greater fulfilment in their work when they feel that their method of caring for patients is effective.

This study documented post-training diminution of behavioural and psychological symptoms of people with dementia as well as a reduction of the family caregiver burden. Previous studies have shown that communication training interventions for family caregivers reduced the care burden [29-31]. However, among them, no studies resulted in statistically significant changes in the behavioural and psychological symptoms of people with dementia. Our study showed that the post-training Behave-AD scores of people with dementia who needed high levels of care were lower than their pre-training scores. Considering that behavioural problems and psychological symptoms were found to be the primary factor associated with caregiver burden for caregivers of people with dementia [32], the present results may suggest that the multimodal comprehensive care methodology training decreased the care burden of family caregivers by controlling the neuropsychiatric symptoms of people with dementia. In addition, our study also revealed that the Behave-AD post-training scores of people with dementia who had taken any sleep medications or antipsychotic medications were lower than their pre-training scores. These medications often have been used to reduce psychosis and sleep disturbance. However, pharmacological options have modest to no benefits compared to those of placebo but have serious risks, including mortality in older adults with dementia [33]. Our present results may suggest that the methodology is one of the management options for BPSDs. However, our results about the Behave-AD scores are of serious concern given that 47 patients were lost to follow up among the 148 patients with dementia. In terms of patient characteristics, more patients included in the post-training data a care need level of 4 than those lost to follow up. On the other hand, patient characteristics such as age, gender, aetiology of dementia, support need level 1 or 2, and care need level 3 or 5 showed no significant differences between the included patients and those lost to follow up. The results regarding the patient characteristics are not sufficient to reveal the similarity between the two groups. Therefore, the Behave-AD post-training data likely showed an overestimated intervention effect. Further studies are needed with a control group to reveal the relevance of the intervention.

Despite our results, further well-controlled studies are required. Previous studies have not clearly shown whether some communication training interventions have a tangible impact on the development of specific communication skills that are consistently translated into practice. Morris et al. [26] noted that

one of the reasons for this lack of a tangible impact may be that, despite the many controlled studies of interventions for caregivers, communication skills training is often one aspect of multi-component training programmes. However, relatively few studies have reported the impact of training interventions on caregivers' ability to utilize specific communication skills. The assessment of the effectiveness of the Humanity™ care methodology intervention for family caregivers, which is underpinned by a clear theory, will require randomized controlled studies with large sample sizes.

Several limitations should be discussed. First, this study was a pre-post prospective study, not a randomized controlled trial. Therefore, it is possible that confounding factors influenced the association between the training and the J-ZBI and Behave-AD scores. Second, the sample size of this study was small. Third, the outcome assessment time frame in this study might be a weakness with respect to the assessment of care burden. Our study showed that the Behave-AD scores three months after training were slightly higher than those one month after training. While family caregiver burden may have been significantly reduced immediately after training, the study provides limited insights about the long-term efficacy of the training.

## Conclusions

This study was conducted to assess the effectiveness of a multimodal comprehensive care methodology training to reduce the care burden of family caregivers. The multimodal comprehensive care methodology training was associated with a reduction of the care burden of family caregivers. Because this was a single-arm, pre-post study, the findings suggest that randomized controlled trials with large sample sizes will be needed.

## List Of Abbreviations

J-ZBI: Japanese short version of the Zarit Burden Interview

Behave-AD: Behavioral Pathology in Alzheimer's Disease

BPSDs: Behavioural and Psychological Symptoms of Dementia

## Declarations

### *Ethics approval and consent to participate*

Written informed consent was obtained from all participants. This research was approved by the Medical Ethical Committee of National Hospital Organization Tokyo Medical Center. This research was conducted in accordance with the Ethical Guidelines for Epidemiological Research in Japan and the Declaration of Helsinki.

### *Consent for publication*

Not applicable.

### ***Availability of data and materials***

The datasets used during the current study are available from the National Hospital Organization Tokyo Medical Center, but restrictions apply regarding the availability of these data and they are not publicly available. However, the data are available from the corresponding author upon reasonable request and with permission from the National Hospital Organization Tokyo Medical Center.

### ***Competing interests***

The authors declare that they have no competing interests.

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### ***Authors' contributions***

MH conceived and designed this study. MH and MK collected and analysed the data. MK wrote the draft of the main paper. MK and MH discussed the results and interpretations and were involved in the critical revisions of the manuscript. All authors read and approved the final version of the manuscript.

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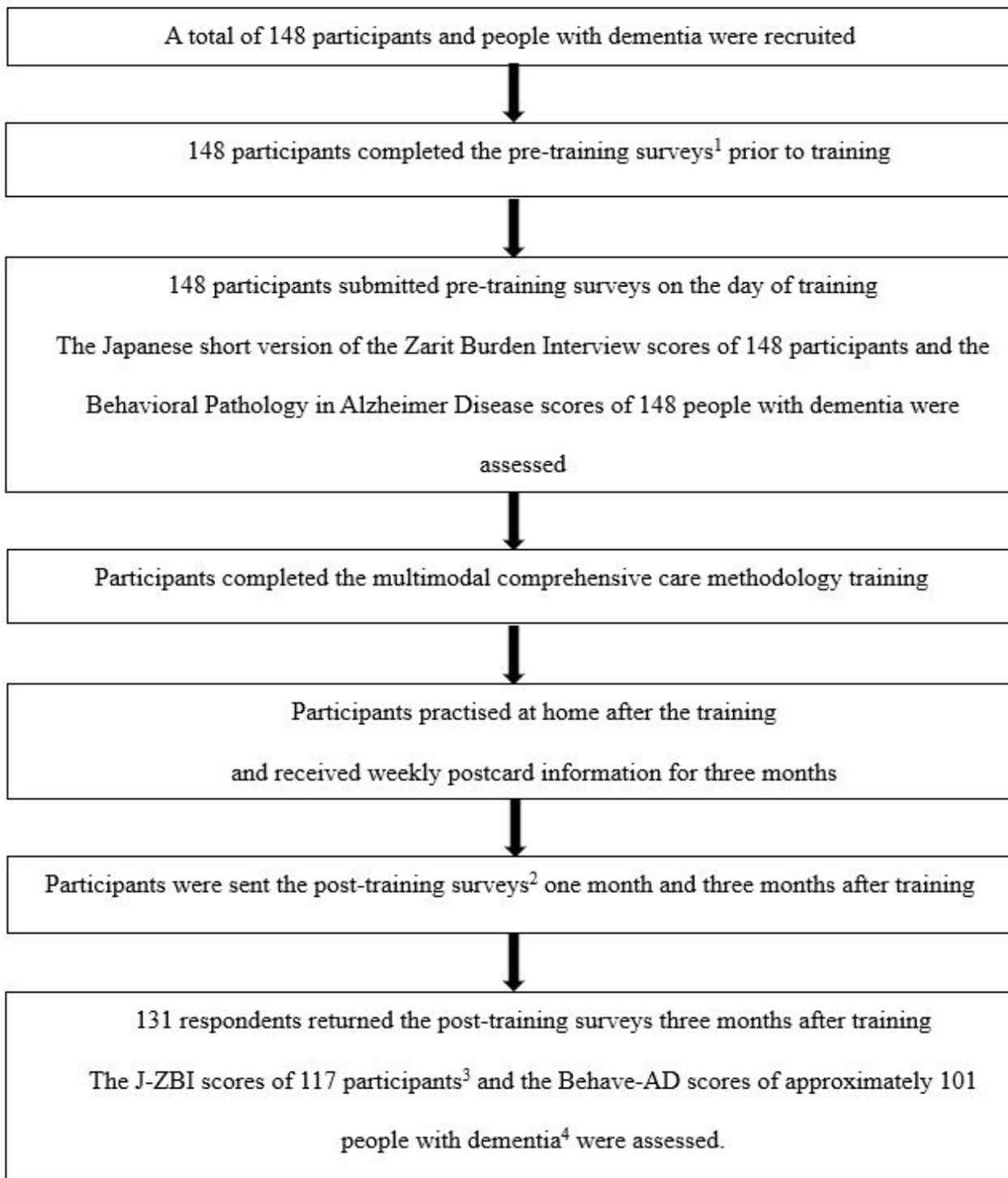
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## Figures



**Figure 1**

Procedure of the multimodal comprehensive care methodology training 1: Pre-training surveys: completion of the Japanese short version of the Zarit Burden Interview by the participants and the Behavioral Pathology of Alzheimer's Disease by the participants with regard to people with dementia. 2: Post-training surveys: completion of the Japanese short version of the Zarit Burden Interview by the participants and the Behavioral Pathology of Alzheimer's Disease by the participants with regard to

people with dementia one month and three months after training. 3: Fourteen participants were excluded due to missing data. 4: Twenty-one people with dementia were excluded due to the following reasons: missing data, hospital admission, and death.