Abstract

[Purpose] The aim of this study was to clarify the effect of cognitive behavioral therapy (CBT) for anxiety in caregivers of persons with dementia. [Method] A systematic review of English-language studies was performed following the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions. The databases PubMed, CINAHL, MEDLINE, and Cochrane Library were used. Studies of CBT interventions for anxiety in dementia caregivers were examined. Three randomized controlled trials met the eligibility criteria and were reviewed by two researchers. Studies were evaluated in terms of the outcome and the risk of bias. [Results] Although the frequency and duration of the CBT interventions differed across the three studies, all three reported some reduction in anxiety after the intervention. [Conclusions] The findings indicate that CBT has a positive effect on anxiety in dementia caregivers; however, additional randomized controlled trials are needed to fully determine the usefulness of CBT.

Key words
CBT, dementia, caregiver, systematic review

1. Introduction

In 2016, the proportion of Japan's population that was elderly was 27.3%, and is predicted to reach 38.4% by 2065. According to a 2017 Annual Report on the Aging Society, an estimated 1 in 2.6 people in Japan are over 65 years old (Cabinet Office 2017). The population of persons over 75 years old (the "post-World War II baby boom generation") is predicted to reach 36,770,000 in 2025 and to peak at 39,350,000 in 2042. The elderly population is predicted to then decrease, but it is likely that 25.5% of the population, or 1 in 4 people, will be 75 years old or older in 2065. According to the "Comprehensive Survey of Living Conditions 2017", dementia is the most frequent cause (18.0%) of health care needs in Japan (Ministry of Health, Labour and Welfare 2017). While there has been a decline in Japan's total population, the pace of population aging has increased. With an increasing old-old population, there are likely to be more individuals with dementia who struggle to live independently.

A shift from hospitalization for medical treatment to home care has increased the number of family caregivers for people with dementia. In addition to the provision of standard nursing care for people with dementia, substantial social resources are needed to support family caregivers. Providing care to a family member can place great demands on caregivers and they may experience anxiety about their role. This creates a vicious circle, which can lead to stress reactions and the development of caregiver burden (Ministry of Health, Labour and Welfare 2012, 2014, 2018).

Research studies conducted in several countries have established the effectiveness of cognitive behavioral therapy (CBT) for treating anxiety in caregivers of people with dementia (e.g., Spector et al 2012). Findings have indicated that CBT can improve quality of life (QOL).
Some researchers in Japan have investigated the use of CBT for caregivers (Sato et al 2015, Yuki 2013) and reported that CBT can improve insomnia symptoms and QOL when caregiver burden is experienced, but their studies were not randomized controlled trials. To date, no systematic reviews have included studies that used a randomized controlled trial (RCT) design that can systematically evaluate the effect of CBT on anxiety in dementia caregivers in Japan.

Therefore, a systematic review of the pertinent foreign literature was conducted to examine the effect of CBT on anxiety in dementia caregivers. We were able to confirm CBT as one method to reduce the uneasiness of the dementia caregiver. It is hoped that the findings will inform strategies to increase the social resources devoted to support dementia caregivers and, in turn, reduce the phenomenon of caregiver anxiety.

2. Purpose
The study aim was to clarify the effect of CBT on anxiety in dementia caregivers based on the findings of a systematic review of the pertinent foreign literature.

3. Methods
3.1 Search method
A search was carried out for articles containing the keywords "CBT", "dementia", and "caregiver" using the PubMed, CINAHL, MEDLINE, and Cochrane Library databases. We did not establish the search condition such as designation and the publication form in time. The search was restricted to English language articles that were published up until September 1, 2017.

3.2 Target documents
Eligible studies were RCTs examining CBT interventions for dementia caregiver anxiety. There are previous Japanese studies that have investigated the effect of CBT on caregiver anxiety, but these are not randomized controlled trials and so could not be included in this review (Sato et al 2015, Yuki 2013). Therefore, this review included only foreign literature studies that were written in the English language.

3.3 Extraction and data review method
3.3.1 Article selection
Two researchers performed an initial literature screen independently. The search was not limited to specific intervention conditions, length of the intervention period, frequency of the intervention, or number of groups. Articles that were not relevant to this study, a judgement made based on their titles, were identified and excluded. Thereafter, a second screen was conducted which entailed two researchers independently reading the full text of each article while taking into account the selection criteria. Once articles that did not meet the search eligibility criteria were excluded, the relevant information was extracted from each of the relevant ones. The results of the researchers were collated; in the event of a lack of consensus, a third party was consulted.

3.3.2 PRISMA statement
The PRISMA statement, which replaced the 1999 QUOROM statement (Moher et al 1999), provides guidelines for the reporting of systematic reviews of RCTs (Moher et al 2009) and comprises a checklist of 27 items. The present study followed the PRISMA statement and adopted the PICO approach (Population, Intervention, Comparator, Outcome, Study Design) to clarify the research question. The review focused on studies that included CBT interventions (Interventions) for dementia caregivers (Population), compared the intervention group to a control group (Comparators), and evaluated study bias in relation to outcomes (Outcomes). All studies reviewed had an RCT design (Study Design) and did not administer (Study Design) the intervention to the control group.

3.3.3 Bias risk evaluation of RCTs
The risk of bias of individual studies was assessed in relation to the study outcome. The Cochrane Handbook for Systematic Reviews of
Interventions (Higgins 2011) was used to assess the risk of bias as high, low, or unclear. Bias was assessed in relation to blinding of participants and personnel, blinding of outcome assessment, method of random sequence generation, allocation concealment, participant and researcher bias, incomplete outcome data, selective reporting, and other sources of bias (e.g., the trial was stopped early for benefit*). The results of the bias evaluation were analyzed using Review Manager 5.3 software (Cochran Collaboration, Copenhagen).

3. 3. 4 Evaluation of articles
Two of the researchers made decisions about study eligibility and examined the risk of bias. The findings were discussed until the researchers reached consensus on the final selection of articles.

3. 4 Handling of missing data
Studies with attrition bias render the outcome data incomplete and a full comparison between intervention and control groups cannot be made. The impact of attrition bias on outcomes was assessed in terms of data loss rather than a decrease in attrition rate.

4. Results

4. 1 Search results
A total of 22 articles were identified from PubMed, 9 from CINAHL, 10 from MEDLINE, and 55 from the Cochrane Library 14. After duplicate articles were excluded, 22 foreign

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Figure 1. Target literature
literature articles remained for inspection. Articles were excluded if they did not provide sufficient information about the intervention method, the intervention group, and/or the control group. After excluding studies that did not meet the eligibility criteria, three articles were identified that examined the effectiveness of CBT for anxiety in caregivers of persons with dementia (Figure 1).

4. 2 Location of target studies

Of the three selected studies (Table 1), one was conducted in the United States (Losada et al 2015), one in Italy (Passoni et al 2014), and the other in Switzerland (Aboulafia-Brakha et al 2014).

4. 3 Participant details

Two of the three studies provided clear information about the participants (Table 1). Three eligibility criteria were common to the two studies: participants were the primary caregivers and had been providing continuing care, material things, and several hours of daily care for the past several months; the care period in the two studies was 3–6 months for 60–180 minutes per day. In one of the three studies, participants were randomly allocated to the CBT intervention while the other two studies used semi-random and voluntary sampling techniques. In two of the studies most caregivers were women, and in all three studies all sole caregivers were women. All caregivers were over 55 years of age in the CBT group, control group, and in other non-intervention groups.

4. 4 Structure of the CBT

(1) Intervention frequency: In one of the studies, participants received six sessions; in the other two studies, eight sessions were administered (Table 1).

(2) Intervention duration: In two of the studies, the CBT sessions lasted as long as required; in the other study, sessions lasted between 90 and 120 minutes (Table 1).

(3) Number of participants in each intervention: CBT sessions were delivered individually in one study, whereas in the other two studies the treatment sessions took place in group settings; groups of 7–10 and 6–8 (Table 1).

4. 5 Therapist

Most of the therapists were psychologists or psychotherapists. All therapists had a master's degree or doctorates (Table 1).

4. 6 Effect of the intervention

Two studies used the State-Trait Anxiety Inventory (STAI) to measure changes in anxiety (Table 1). In Passoni et al's (2014) study, the CBT group was compared to a control group and a group that received a self-help manual. Anxiety scores in the intervention group had significantly improved 6 months later (p = .002). In Aboulafia-Brakha et al's (2014) study, there was no statistically meaningful difference between anxiety scores in the CBT group and a group that received a psychology educational program. Losada et al (2015) used the POMS (Profile of Mood States) scale to measure mood states. They found that the CBT group presented a greater reduction in anxiety scores than the control group, but the reduction in anxiety scores post-intervention was greater in the Acceptance and Commitment Therapy (ACT) group than in the CBT group (p = .046). However, there were no significant differences between the ACT and CBT groups at 6-month follow-up (p = .63).

5. Evaluation of the risk of bias

(1) Allocation method (random sequence generation): Two studies used a computer-generated table of key codes; however, in one study, the selection was based on participants who self-selected themselves into the CBT, and a computer-generated allocation method was used only for weighted two groups; (2) allocation concealment: none of the articles clearly described allocation concealment procedures; (3) blinding of participants and researchers: none of the
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<th>Study</th>
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<td>Serena Passoni et al. (2014)</td>
<td>Caregiver’s global care needs (CNA) and in anxiety and depression</td>
<td>CBT group (n=39)</td>
<td>1 psychologist 1 psychotherapist</td>
<td>&lt;Volunteers&gt; Closed groups of 7 to 10 participants, joining six 2-hour meetings every 15 days, in overall period of approximately 3 months.</td>
<td>The GT group had a higher CNA-tot score than the other 2 groups (GT-OM: p&lt;0.013, GT-CO: p&lt;0.001). Effective in reducing caregiver’s anxiety with a significant decrease in the GT group only.</td>
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<td>T.Aboulafia-Brakha et al. (2014)</td>
<td>Effects of the interventions were evaluated with self-report psychological scales and questionnaires related to functional abilities and neuropsychiatric symptoms of the AD relative.</td>
<td>EDUC group Eight 60-minute group sessions 17 participants together</td>
<td>&lt;semi-randomly&gt;</td>
<td>None of the 3 treatment groups have been proven in alleviating depression.</td>
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<td>Andres Losada et al. (2015)</td>
<td>Pre, postintervention, and follow-up measurements assessed depressive symptomatology, anxiety, leisure, dysfunctional thoughts, and experiential avoidance.</td>
<td>6 clinical psychologists (master’s or doctoral training in clinical psychology)</td>
<td>&lt;Randomize&gt;</td>
<td>CBT was superior to the CG condition for depressive symptomatology (at posttreatment and follow-up), but not for anxiety. ACT was superior to the CG condition for depressive symptomatology and anxiety at postintervention, but not at follow-up.</td>
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<td>CBT and ACT interventions consisted of eight weekly individual sessions (total duration = 2 months) lasting about 90 min each.</td>
<td>CBT group (n=42) ACT group (n=45) Control group (n=48)</td>
<td>&lt;CBT Versus CG&gt;</td>
<td>ACT versus CBT conditions differed significantly only on anxiety outcome. Specifically, a significant difference favoring ACT was observed at posttreatment.</td>
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articles clearly described blinding procedures; (4) blinding of outcome assessment: one study used blinding of outcome assessment, but the other two studies did not clearly describe blinded outcome assessment; (5) incomplete outcome data: studies in which the difference in dropout rate between the CBT and control groups was more than 15% were considered to be at high risk of bias. Further evaluation was therefore made of the reasons for dropout in each study. There were no dropouts in six cases. In one case, the reason for the dropout was mentioned, and in one case it was not mentioned. In one study, the difference in dropout rate between the study groups was high; (6) selective reporting: the level of outcome reporting was examined in each article. All studies fully reported outcome data; (7) other biases (e.g., the trial was stopped early for benefit): In all of the target documents, factors that may have affected the outcomes were examined (Figure 2, 3).

6. Discussion

6.1 Participant characteristics

In all three studies, most caregivers were women. However, there were no significant gender differences in the effect of CBT on caregiver anxiety. Caregiver age was not one of the eligibility criteria for study inclusion; however, there were no large differences in caregiver age between studies, so it is unlikely that this factor affected the outcome assessment. However, the studies differed in the frequency and duration of care, and it cannot be said that validity was adequately inspected as an eligibility criterion in the dementia caregiver. Future studies need to examine the influence of frequency and duration of care on outcomes. The range of behavioral and
psychological symptoms of dementia (BPSD), which include shuffling gait and depression, can mean that caregivers of people with dementia experience a relatively larger burden of continuous anxiety and stress compared with caregivers of people with other conditions. An additional problem relates to the generalizability of the findings; the rigorous participant eligibility criteria of the selected studies meant that many members of the target population were excluded from undergoing CBT as dementia caregivers. Thus, it cannot be claimed that the studies used were accurate representations of RCTs; in a similar vein, in two of the studies, participants in the CBT intervention group were individuals who opted to receive CBT treatment. Additional RCTs are therefore required to examine the effect of CBT on anxiety in a broader range of dementia caregivers.

6.2 Structure of the CBT

In two of the studies, the CBT intervention was carried out weekly for approximately 90 minutes over a 2-month period. In the other study, it was weekly for approximately 120 minutes over a 3-month period. As a result, it may be argued that there was not a large difference in general CBT intervention time. However, it is difficult to compare the validity of interventions that were carried out over different time periods; the duration of the interventions in the studies reviewed here varied by 1 month. Structured, sustained contact with a therapist could have reduced anxiety in dementia caregivers; further studies are needed to clarify the effect of intervention duration on outcomes.

6.3 Effect of the intervention

The instruments used to measure anxiety were the STAI and the POMS. All studies reported a reduction in anxiety for the CBT group compared to the control group, but not all studies found a statistically significant between-group difference. While this suggests that CBT can reduce anxiety in dementia caregivers, the differences in participant characteristics mean that additional studies are required to conclude that CBT can reduce anxiety in this population.

6.4 Possibility of bias in the review process

The Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) recommends that more than two researchers review the studies independently. In this study, two researchers who represented the study leaders carried out the review and discussed the article selection until consensus was reached. We believe that this process increased the reliability of the review. The high dropout rate raised the possibility of attrition bias, especially as the reviewed studies employed small numbers of participants. However, further evaluation of dropout rates and reasons for dropout indicated only small differences in attrition between the intervention and control groups; this is suggestive of a low risk of attrition bias.

7. Suggestions for future CBT studies

7.1 Effect of CBT on anxiety

This review of the foreign literature examined the effect of CBT on anxiety in dementia caregivers. There were several problems with the quality of the evidence in these studies. The three studies differed in the instruments used to measure anxiety, participant characteristics and eligibility criteria, intervention method, and intervention type. CBT reduced anxiety in the dementia caregivers in all the target documents, but it is necessary to assess the effect of mediating factors, such as insurance availability or the social resources of each country, on caregiver anxiety. This is necessary because results differ between target countries even when such resources are available. In addition, the studies varied in terms of the number of participants recruited. Further RCTs are needed to fully determine whether CBT has an effect on anxiety in dementia caregivers.

7.2 The need for continuous CBT

Of the three RCT trials reviewed, only two examined the sustainability of intervention
effects by conducting post-intervention follow-up assessments. All studies reported a reduction in anxiety scores after the intervention, but Losada et al. (2015) reported an increase in depression scores in a follow-up after the intervention. Although firm conclusions cannot be drawn from this study alone, it is possible that the effect of the CBT training was not sustained because the treatment was not continuous. In addition, the knowledge gained by caregivers from the intervention may have been diluted between the end of the intervention and the follow-up evaluation point. It is also possible that the worsening of dementia symptoms and/or physical function in the people requiring care may have increased caregiver anxiety and depression.

Although the dropout rate midway through the interventions was high and the sample sizes were small, we concluded that attrition bias was unlikely to have affected the study outcomes. However, study dropout is likely to affect the quality of an intervention, particularly if therapy is provided in group settings. Therefore, further studies are needed with larger samples. A continuous CBT intervention places great demands on researchers, such as the need to find a dedicated location for treatment. Studies in countries outside Japan have begun to use alternative forms of CBT delivery, such as sessions of DVD- or telephone-based CBT, and these types of interventions need to be evaluated in more detail.

This review of the foreign literature provides evidence that CBT can have a positive effect on anxiety in dementia caregivers. However, the findings highlight the need for additional RCTs in Japan to shed further light on this effect.

8. Conclusion and study limitations

The findings indicate that CBT led to a reduction in anxiety in caregivers of persons with dementia. The results of the studies reviewed consistently suggest that CBT has a positive effect on anxiety. However, these findings must be treated with caution as the studies reviewed here had small sample sizes, and therefore their findings may not be representative of all dementia caregivers. Also, in this study, we used only a qualitative evaluation of risk of bias, which is not sufficient for the review of the target documents. Thus, future systematic reviews of studies on this topic need to incorporate quantitative approaches to the risk assessment of the evidence.

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