



# Effects of Grief Focused Intervention on the Mental Health of Dementia Caregivers: Systematic Review and Meta-Analysis

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## Abstract

**Background:** The objectives of this study were to review systematically the effects of grief-focused interventions, applied to dementia caregivers, on emotional burden including sadness and to provide baseline information for dementia caregivers to maintain mental health by identifying the effect size of intervention using a meta-analysis.

**Methods:** We evaluated literature published from Jan 1, 2000, to Jun 28, 2019. Consequently, we selected five studies to conduct a systematic review. The Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields was used for conducting a quality assessment on the selected literature.

**Results:** The results of the quality assessment showed that the score ranged from 11 to 24 points: one strong, one good, two adequate, and one limited. When the meta-mean was compared before and after grief intervention, the effect size of the random-effect model was 0.31 (95% CI: -0.07, 0.69) showed 'intermediate effect', but the confidence interval was not significant.

**Conclusion:** The grief intervention for dementia caregivers revealed a moderate effect but it was not significant. In order to prove the effectiveness of grief intervention for dementia caregivers, a meta-analysis targeting RCT studies is needed.

**Keywords:** Grief intervention; Dementia caregivers; Meta-analysis; Systematic review

## Introduction

Dementia is a representative geriatric chronic illness. It is caused by impaired memory, orientation, language, behavior, and social function due to the degenerative changes in the brain. Since it requires continuous care, it is one of the important public health policy issues with high priority in the world. World Alzheimer's Report estimated that, as of 2015, there were 4.68 million dementia patients in the world and the prevalence of dementia was high in East Asian countries, which experienced a fast rate of aging (1). According to a nationwide survey in 2013, the dementia prevalence of Taiwan was 8.04% (2), and that of South Korea was 9.18%

(3), indicating that one of ten elderly people suffered from dementia. As the number of patients with dementia increases, it is expected that the care burden, which incurs for families to treat or care senile dementia patients, will continue to increase.

In South Korea, only 0.2% of senile dementia patients are admitted to nursing homes, indicating that 99 of 100 demented patients are cared by family members at home (4). Therefore, families taking care of demented patients experience not only a physical burden but also economic burden (e.g., helplessness and depression) and economic burden due to the cost of treating dementia and



the limitation in economic activities. Particularly, as the disease prolongs, families often experience conflicts due to caregiving and role sharing and their relationship with demented patients can be worsened (5). Moreover, the care burden, stress, and depression of the main caregiver are known as the most common psychological burden adversely affecting the care for demented parents (5). Caring demented patients induces negative feelings (e.g., tension, burden, depression, low self-esteem, guilty conscience, frustration, anxiety, and anger) to caregivers as well as restricts the activity of caregivers (6-9). These negative feelings, burden, and restriction experienced by the caregivers of demented elderly are severer than those experienced by those of cancer patients as well as those of healthy elderly (6-9).

Traditionally, Asian countries such as Taiwan, Japan, and South Korea highly depend on caring within the family. However, as the number of demented elderly is increasing due to aging in South Korea, the South Korean government has established institutional conditions such as a long-term care insurance system, which provides a national care service. However, caring within the family still accounts for the major portion of a demented parent caring. When it is difficult for a family to care for a patient, the quality of demented patient's life is reduced (9). Moreover, as time passes, the social cost is rapidly increased because more demented patients are needed to be admitted to a health institute earlier (8). Therefore, it is an important geriatric health issue to alleviate the care burden of family caregivers who takes care of demented patients and prove the effectiveness of supporting programs to improve their psychological health (10).

The grief-focused intervention for the dementia caregiver means to educate information regarding the disease to family caregivers or enhance voluntary support capability by providing emotional support through counseling or psychoeducation (11, 12). Generally, the concept of grief is one of the negative emotions that caregivers commonly encounter during caregiving (13). It is an enthusiastic and active process in which an individual tries

to compromise and overcome a loss to find a balance when the person loses something personally, biologically, or socially important (13).

Some studies have been conducted to evaluate the effects of dementia family support programs (10, 14). However, some intervention studies have focused on the effects of these programs on the depression, care burden, and quality of life of dementia caregivers (15). Additionally, there was a systematic review study based on the methodological quality assessment evaluating the grief-focused intervention for dementia caregivers (11). Nevertheless, as far as we are aware of, there is no meta-study examining the effect size of the intervention.

There have been a number of studies (10, 14, 15) that evaluated the effects of dementia family support programs including grief since 2010. Therefore, it is necessary to review these studies and conduct meta-studies in order to provide science-based interventions that transcend geographical regions and cultures.

The objectives of this study were to systematically review the effects of grief-focused interventions, applied to dementia caregivers, on emotional burden including sadness and to provide baseline information for dementia caregivers to maintain mental health by identifying the effect size of intervention using a meta-analysis.

## **Methods**

### *Literature review and keywords*

This study was conducted after being approved by Honam University's Institutional Bioethics Committee (No.1041223-201812-HR-26).

We collected literature related to effects of dementia family support programs using six databases (CHINAHL, EBSCO, PUBMED, SCOPUS, Science Direct, and Springer). Additionally, grey literature was searched using Google Scholar and Digital Dissertations on Demand (DDOD). Literature selection and coding manual were made on the counsel from one professor majoring statistics. One researcher who had enough training and ex-

perienced in a meta-analysis and one Ph.D. specialized in speech pathologist conducted a literature search, coding, and methodological quality assessment for study subjects independently for three times from Sep to Nov 2018.

In order to increase the reliability of the results, when there were discrepancies between the researchers, they reached a consensus on the discrepancies by reviewing the original text again or consulting with a third party expert. Full texts of all literature were obtained for the study. Coding recorded the author, title, year of publication, country of publication, type of publication, type of intervention, intervention method, intervention period, dependent variables, and statistics (e.g., mean and standard deviation). This study evaluated literature only published between Jan 1, 2000, and Jun 28, 2019. Search keywords are as follows.

#### **PUB med**

("frontotemporal dementia"(Mesh) OR "dementia, multi-Infarct"(Mesh) OR "dementia, vascular"(Mesh) OR "Alzheimer disease"(Mesh) OR "Lewy Body disease"(Mesh) OR "dementia"(Mesh) OR mild cognitive impairment (tiab) OR MCI (tiab) OR "end-stage dementia"(All Fields)) AND ("caregivers"(MeSH Terms) OR "caregivers"(MeSH Terms) OR caregiving(All Fields)) AND ("grief intervention"(All Fields) OR "grief work"(All Fields) OR ("adaptation, psychological"(MeSH Terms) OR ("adaptation"(All Fields) AND "psychological"(All Fields)) OR "psychological adaptation"(All Fields) OR "coping"(All Fields)) AND significant(All Fields) AND loss(All Fields)) OR "psychosocial loss"(All Fields) OR "stress management"(All Fields) OR "coping mechanism"(All Fields) OR strain(tiab))

#### **Web of Science**

TI= (dementia\$ OR dement\* OR vascular\$ OR mild cognitive impairment\$ OR MCI\$ OR Lewy Body disease\$ OR Alzheimer disease\$) AND TI= (caregiver\* OR caregiving\$) AND TI= (grief intervention\$ OR grief work\$ OR psychological adaptation\$ OR coping significant loss\$ OR psychosocial loss\$ OR stress management\$ OR coping

mechanism\$ OR strain\$)

#### **EBSCO (ASC, CINAHL, Medline)**

TI= (dementia OR dement\* OR vascular OR mild cognitive impairment OR MCI OR Lewy Body disease OR Alzheimer disease) AND TI= (caregiver OR caregiving) AND TI=(grief intervention OR grief work OR psychological adaptation OR coping significant loss OR psychosocial loss OR stress management OR coping mechanism OR strain)

#### **Including and excluding criterions**

Literature was searched in accordance with the selection and exclusion criteria of participants, intervention, comparisons, and outcomes (PICO) (16), which are key items, based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) of the Cochrane Handbook for Systematic Reviews of Interventions (17). The selection criteria for literature analysis were as follows: first, pre- and post-intervention studies on dementia caregivers; second, peer-reviewed publications written in English; third, studies that we could obtain full text; and fourth, studies presenting mean, standard deviation, number of subjects, standard error, 95% confidence intervals (CI), and *t*-value in order to calculate the effect size. Moreover, fifth, when statistics were not available, we contacted the authors directly to obtain appropriate data.

We found 376 publications through searching the databases and they were chosen through the following steps. First, 77 duplicate publications were excluded using End-Note X7, a bibliographic management program. Second, after removing duplicate publications, we reviewed the abstracts of the remaining 229 publications and excluded 278 publications that did not meet the literature selection criteria. As a result, 21 publications remained. Third, the full texts of the 21 publications were examined to exclude unsuitable publications: one qualitative study, four literature reviews, two studies that were not possible to use the full text of them, and seven publications that had inaccurate outcomes or inconsistent with the study objective. Consequently, this study selected five studies to

conduct a systematic review. Among them, this study conducted a meta-analysis for three studies after excluding two studies that did not provide

statistics (e.g., standard deviation) for carrying out pre- and post-meta mean comparison of two groups (Fig. 1).

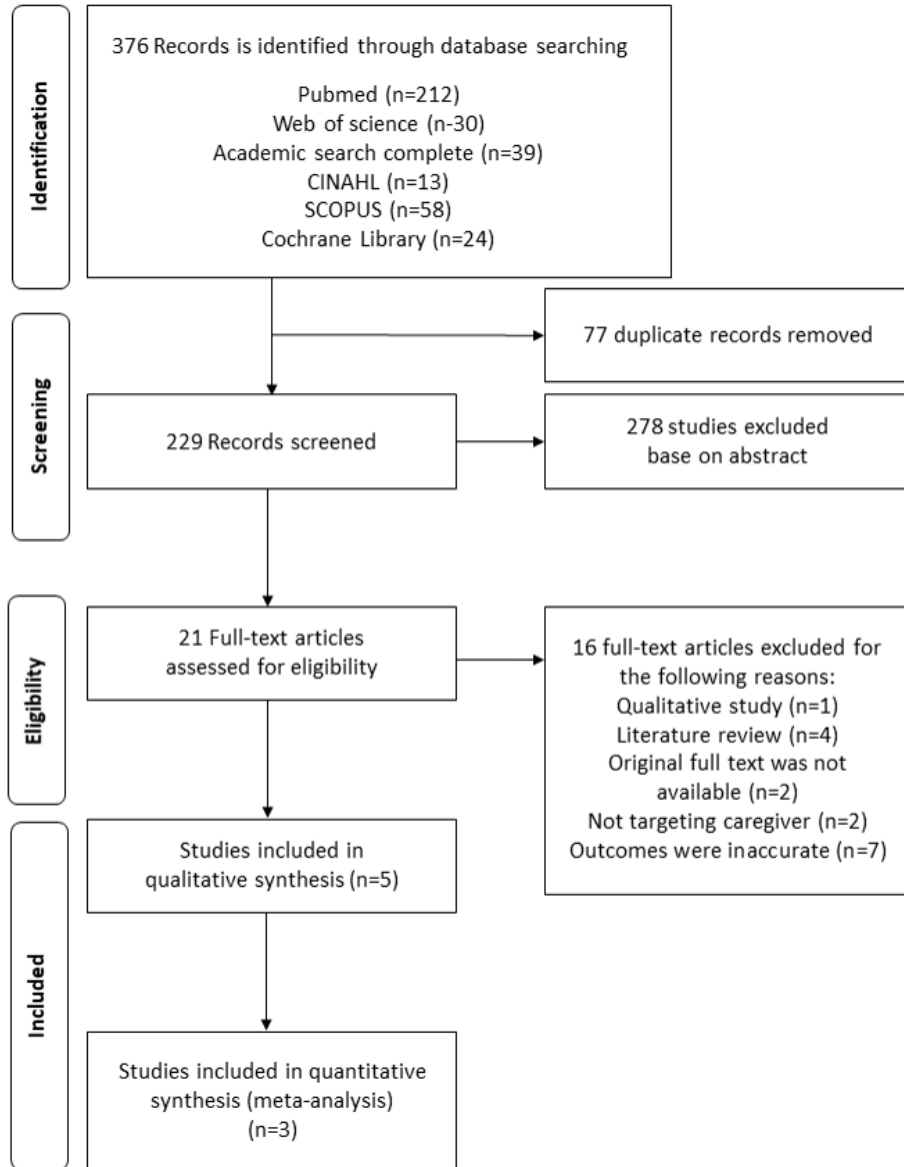


Fig. 1: Flow of studies included from the database search

### Qualitative Assessment

The Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields (SQAC; (2004) (17)) was used for

conducting a quality assessment on the selected literature (Table1). Two researchers performed a quality assessment independently. When there was an inconsistent result, researchers drew a conclusion through discussion.

**Table 1:** STANDARD QUALITY ASSESSMENT CRITERIA for Evaluating Primary Research Papers from a Variety of Fields

<i>Criteria</i>	<i>YES (1)</i>	<i>PARTIAL (1)</i>	<i>NO (0)</i>	<i>N/A</i>
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

### *Meta-Analysis*

#### *Calculating and interpreting effect size*

The effect sizes were analyzed using the 'meta' package of R version 3.5.2. The statistics used in the analysis were the mean and standard deviation of the exposed group and the unexposed group. Moreover, the standard deviation of mean (SMD) was calculated using Hedge's *g* for examining the effect size. The weighted mean effect size considering the sample size variation among studies was used for the mean effect size and the significance of the effect size was evaluated based on the 95% confidence interval. The  $\leq 0.20$ , 0.5, and  $\geq 0.80$  were interpreted as "small effect", "medium effect", and "large effect".

#### *Homogeneity test*

Homogeneity test was conducted to evaluate the statistical heterogeneity of the effect sizes derived from individual studies and it revealed that *Q*-df was  $\geq 0$  and *I*<sup>2</sup> was  $\geq 75\%$ . Therefore, it was

proved that there was variance among the individual studies and the heterogeneity of each effect size was large. As a result, this study used the random-effects model for this meta-analysis.

#### *Publication bias testing*

Publication bias was tested in order to prove the validity of meta-analysis' results. The results of funnel plots and adjusted funnel plots suggested that there was no publication bias considering that studies were distributed near the effect estimates. The trim-and-fill method was applied for adjusting visual asymmetry, and it was confirmed that the risk ratio before an adjustment and that after adjustment was similar.

### **Results**

#### *General characteristics of literature*

General characteristics of literature are shown in Table 2.

**Table 2:** General characteristics of literature

<i>Author/Reference</i>	<i>Study Subjects</i>	<i>Measurement Method</i>	<i>Subject Selection Criteria</i>	<i>Intervention</i>	<i>Major Results</i>
Ott et al (15)	20 caregivers for demented patients	1. Grief : Marwit–Meuser Caregiver Grief Inventory-Short-Form(MMCG-SF) 2. Coping Strategies. : Brief Cope(BC)	Spouse caregivers of a demented patient English is a native language Equal to or older than 18 years old Living with a caregiver	Intervention : Easing the Way - Intervention for 8 months, Minimum three sessions to maximum eight sessions in 3-4 week interval. Conducted between 1 and 2 hours.	Change in grief and well-being 1) Grief : Baseline (M=56.68, SD=11.28) significantly (p=0.026) decreased after intervention (M=51.91, SD=11.10)
Paun et al (21)	34 Alzheimer Caregivers	1. Alzheimer’s Disease Trajectory: Chronic Grief Management Intervention (CGMI)	Not mentioned.	Intervention : Conducted an intervention on increasing caregivers’ knowledge (late stage ADRD and long-term care), skills (communication and conflict resolution), to process their chronic grief for 12 weeks	(Caregiver report evaluation) 1. The topic was very useful and helpful in nursing 2. Expressed satisfaction with the manual. 3. Need to provide enough time for a caregiver to express his or her feelings. 4. Needed intervention over 12 weeks.
Paun et al (19)	Total 83 subjects Intervention – 34 subjects Control – 49 subjects	1. Caregiver chronic grief - Marwit-Meuser Caregiver Grief Inventory (MM-CGI)	Who can read or speak in English Care recipients who were diagnosed with AD or related dementia Major caregivers of patients	Intervention 1) Intervention group : 8 hours of intervention for 12 weeks  2) Control group : 1.5 months, 4.5 months contacted via phone calls	Intervention group’s Loss of relationship (ES=0.296), Heartfelt sadness, and longing (ES=0.380) were improved compared to the baseline stage.
MacCourt et al (20)	Total 200 Participants 1) Intervention – 123 participants 2) Control – 77 participants	1. Caregiver Grief Inventory 2. Shortened version of The Brief COPE	Recruitment strategy was contingent upon location within British Columbia using local media and referrals from the Alzheimer’s Society of British Columbia.	Intervention : Face-to-face and phone session participants received coaching for one hour per session on average.	The control group and the intervention group were not significantly different in grief, coping, and resilience. The empower score of the control group was significantly higher than that of the intervention group.
Meichsner et al (18)	Total 273 participants 1) Telephone-based intervention - 149 participants 2) control group – 134 participants	2. pre-death grief : Caregiver Grief Scale(CGS)	Primary caregivers livings with demented patients.	Intervention group :12 times of 50 minutes intervention over 6 months  Control group : Information about dementia and caregiving	Adjusted model: Study group, Care situation, sociodemographic  Baseline: .026 Change factor: -.696*

The final five publications on grief-focused intervention were analyzed by publication year, the number of subjects, subject recruitment method, publication type, and ethics approval. These publications were published in 2010, 2011, 2015, 2017, and 2018 (one publication for each year). The number of subjects ranged from 20 to 273. Study subjects were recruited through community agencies, parish nurses, posters distributed to support groups, newspaper companies and other partner organizations, media request, nursing home leaflets, news, and letter. One study was a single group pre-post design study, three studies were control group pre-post design, and the other was a preliminary study. All five studies were approved by an ethics committee.

#### *Methodological quality assessment of grief intervention study*

The results of the quality assessment showed that

the score ranged from 11 to 24 points: one strong, one good, two adequate, and one limited (Table 3). The analyzed literature included the study objective, study design, subject characteristics, assessment means, and conclusions were presented in detail. Three studies mentioned the recruitment methods, inclusion criteria, and exclusion criteria (15, 18, 19). Two studies randomly divided samples (18, 19). However, no studies conducted binding for the subject intervention or recruited subjects after calculating the power of the samples in the preliminary study design stage. In the variance estimation of major findings, one study did not report quantitative results (20). Only one study controlled disruption variables (18). Four studies reported the study results specifically (15,18-20). A pilot study that received low scores in the analysis method, the variance estimation of major findings, and quality assessment on results reporting (21).

**Table 3:** The results of the quality assessment

<i>Study</i>	<i>Items on standard quality assessment checklist</i>														<i>Total</i>
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>	<i>7</i>	<i>8</i>	<i>9</i>	<i>10</i>	<i>11</i>	<i>12</i>	<i>13</i>	<i>14</i>	
Ott et al (15)	+	+	+	+	-	N/A	N/A	+	±	+	+	-	+	+	19
Paun et al (21)	+	+	-	+	-	N/A	N/A	+	±	-	-	-	-	+	11
Paun et al (19)	+	+	+	+	+	-	-	+	±	+	+	-	+	+	21
MacCourt et al (20)	+	+	±	+	-	-	-	+	±	+	±	-	+	+	17
Meichsner et al (18)	+	+	+	+	+	-	-	+	±	+	+	+	+	+	23

+ =yes (2 point), ±=partial (1 point), -=no (0 point), N/A=Not Applicable

#### *Measuring the mental health of dementia caregivers*

The mental health of dementia caregivers was measured multidimensionally including grief, demographic information, anxiety, and affirmation. Caregiver Questionnaire (15), Demographic and Caregiving Characteristics Questionnaire (20), and East Boston site for the Established Populations for Epidemiologic Studies of the Elderly project were used to measure demographic data (19). Marwit–Meuser Caregiver Grief Inventory-Short-Form (MMCG-SF) (15), Marwit-Meuser Caregiver Grief Inventory (MM-CGI) (19), Caregiver Grief Scale (CGS) (18), and Caregiver Grief Inventory

(20) were used to measure the grief of caregivers. The mental health of caregivers was examined in addition to depression. Depression and anxiety were measured by the Center for Epidemiologic Studies Depression Scale (CES-D) (15) and a Positive States of Mind (15). Self-efficacy was measured by General Self-Efficacy Scale (15). Additionally, coping strategies were measured by Brief Cope (BC) (15) and Shortened version of The Brief COPE (20). The knowledge of caregivers was evaluated by Knowledge of Alzheimer's Test (KAT) (19), while skill outcome was measured by the Family Perception of Caregiving Role (FPCR) (19). Exacerbators of grief in the long-term care

facility environment used 61-item FPCR (19).

### *Intervention about caregiver's grief*

The grief of the dementia caregiver continuously affects caregivers not only while the patients are alive but also after they are dead. Interventional programs using information provision, education, and interviews are designed in order to reduce their psychological burden. It was found that these intervention programs reduced the psychological burden (e.g., depression and grief) of these caregivers. "Easing the way" (15), a multi-factor intervention program, was designed to decrease the grief experienced by caregivers. It was found that 8 months of intervention decreased all domains (the grief, depression, anxiety, self-efficacy, and positive state in all areas of mind) compared to the initial conditions. Additionally, caregivers residing with care recipients maintained an improved score during the follow-up period, but their grief and depression increased when care recipients died or moved to a nursing home (15).

The effects of coaching were evaluated on the grief of caregivers of dementia patients (20). First, in this study, grief, coping, and resilience were not different between the intervention group and the control group in the initial stage. However, the empowerment of the control group was significantly higher than that of the intervention group. Second, after the intervention, grief, coping, and resilience increased significantly more in the intervention group than in the control group. However, there was no different in empowerment between the two groups. Third, in terms of the change within a group, grief, coping, resilience, and empowerment were improved only in the intervention group (20).

Pre-death had a negative effect on the grief of caregivers. The pre-death grief effects of participants were evaluated over 6 months using a cognitive-behavioral therapy (CBT)-based intervention (18). After controlling the study group, care situation, and sociodemographic variables, the dynamics of pre-death grief were examined. The results showed that that of the intervention group decreased significantly more than that of the control

group (Beta=-.912) (18).

Since caregivers take care of patients for a long time, the grief experienced by them is likely to already be chronic emotion. The effects on caregivers' grief reduction were examined by using Chronic Grief Management Intervention (CGMI) through a 12-week long preliminary study (21). It was possible to obtain appropriate help for the nursing situation through a questionnaire. It was also confirmed that they were satisfied with the provided manual. CGMI was verified through a 12-weeks long experimental study. In the baseline stage, the loss of a relationship and heartfelt sadness and longing scores were higher in the intervention group than in the control group (21). However, the heartfelt sadness and longing score of the intervention group was significantly improved compared to the control group. In the final stage, the guilt of the intervention group reduced and it was significantly different from that of the control group.

### *Results of meta-analysis*

The mean effect sizes of three studies on grief intervention effects were analyzed (Fig. 2).

When the meta-mean was compared before and after intervention, the effect size of the random-effect model was 0.31 (95% CI: -0.07, 0.69) showing 'intermediate effect', but the confidence interval was not significant. Since MacCourt et al (20) did not present standard deviation among studies included in the meta-analysis, 'the standard deviation of the difference between sample means' was estimated using the standard deviation of Paun et al (19), which used the same measurement tool. Therefore, in the meta sub-analysis (Fig. 3), the effect size was calculated after excluding a study (20). In the meta sub-analysis, the effect size was 0.14 (95% CI: -0.07, 0.35) showing 'a small effect', but the confidence interval was not significant (Fig. 4).

The cumulative meta-analysis was conducted in order to track how the results and trends changed over time (Fig. 5). More recent studies had higher SMD value, but the confidence level of all studies included in the analysis (95% confidence interval) was not significant.



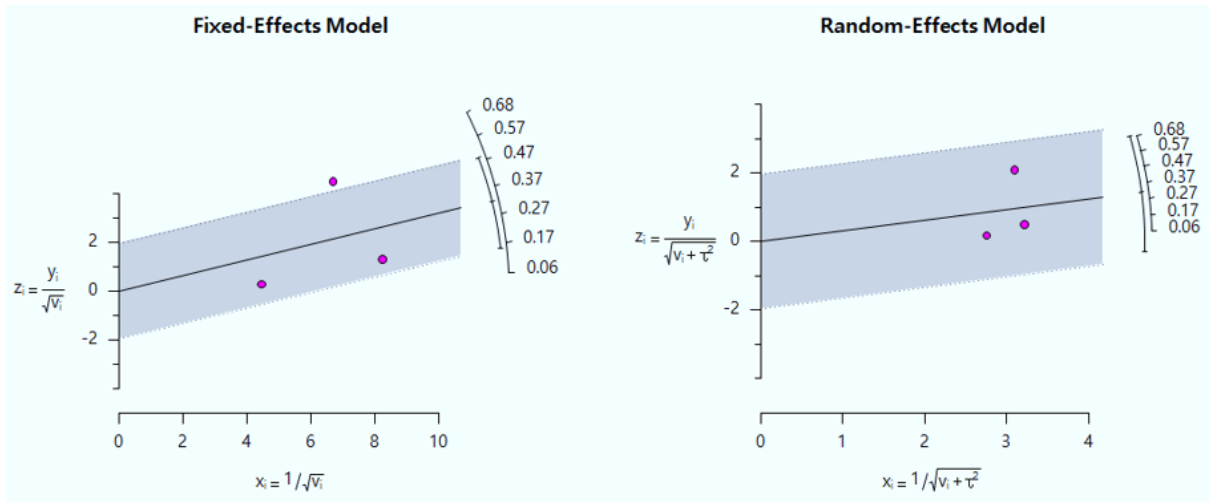


Fig. 2: Radial plot of studies

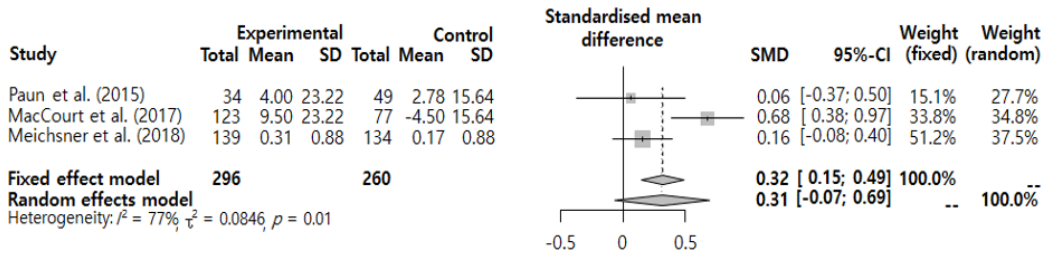


Fig. 3: Forest plot showing the grief intervention effects on dementia caregivers

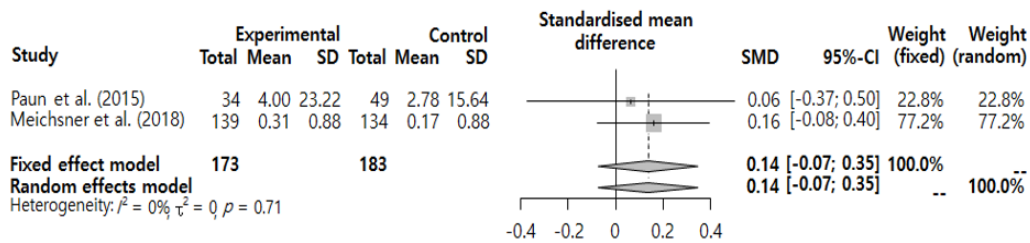


Fig. 4: Forest plot showing the grief intervention effects on dementia caregivers

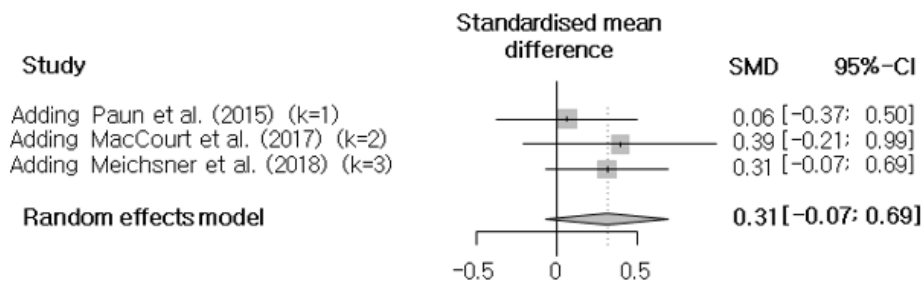


Fig. 5: Cumulative meta-analysis about the grief intervention effects on dementia caregivers

## Discussion

We conducted a systematic review and meta-analysis on the effects of grief intervention on dementia caregivers using studies published between 2000 and 2019. The results of the quality assessment showed that the score ranged from 11 to 23, indicating relatively low bias risk so it was concluded that the data was appropriate to synthesize and present the results of the study. However, in terms of the methodology, only two studies used randomized controlled trials and no studies calculated the appropriate sample size. It is very different from the results of the previous meta-analysis studies (22, 23) on the dementia family support program, which showed that the proportion of randomized controlled trial studies was high. The difference could be because the studies on grief intervention for dementia caregivers mainly used a qualitative method (24) or a case study approach (25).

Although quantitative studies on the grief of dementia caregivers have been increasing since 2015, most of them have been carried out by convenience sampling and the number of quantitative studies is still insufficient. Therefore, it is necessary to actively conduct randomized controlled trial studies and intervention studies, which conduct power test in advance.

Researcher blindness was the area with the highest bias risk because the analyzed studies did not mention it. This is because, due to the characteristics of the family support intervention program, random allocation is possible but it is often very hard to blind where a mediator and a subject belong to. Moreover, people providing an intervention can easily distinguish the intervention so it is limited to conduct blind thoroughly. Future studies need to make various attempts on the method of blinding the intervention provider or the subject.

In this meta-analysis, the grief intervention of dementia caregivers had no significant effect. This result could be due to two reasons. First, there is a possibility that short-term grief intervention might not be effective. Duke (26) evaluated the psychological changes of the subjects from before

experiencing the spouse's death to after experiencing it. There were four psychological stages: "role change due to the illness of a spouse", "the loss of the caregiving role due to the death of a spouse", "the change in interpersonal relationship after the death of a spouse", and "adaptation to the reality at an unstable state" (26). The expected grief went through four stages: shock, pain, survival, and stability (13). These psychological changes suggest that a subject needs enough time for experiencing grief and re-adapting to the environment and negative emotions such as despair or depression repeat. For example, a qualitative study on the preparatory grief of cancer patients showed that patients' emotion moved in a negative direction (sadness and despair) due to chemotherapy or physical agony during the interview (27). The grief intervention duration of the studies included in this meta-analysis ranged from a minimum of 12 weeks to a maximum of 8 months. Moreover, they were heterogeneous. These factors could affect the significance of intervention effects.

Second, the number of studies was too small to evaluate the intervention effects. Therefore, the magnitude of the variance became large to make the confidence interval of the effect size insignificant. Although the total effect size was not significant for the studies analyzed in this meta-study, the direction of each study's effect size moved toward the decrease in sadness consistently. Therefore, in order to prove the possibility that the number of studies influenced the significance level of the effect size, it is necessary to carry out a meta-analysis including more intervention studies in the future. Furthermore, additional validation of intervention methods and intervention periods is required to demonstrate the effects of intervention based on evidence.

The importance of this meta-study is that it provided a scientific basis for investigating the effects of grief intervention on the mental health of the dementia caregiver. The limitations of this study are as follows. First, because this study only searched publications in English, studies written in French or Germany were not included. Second,

there were only three studies for calculating variance, so the results should be interpreted carefully. Third, this study included studies with a high bias risk.

## Conclusion

The grief intervention for dementia caregivers revealed a moderate effect but it was not significant. The most studies on the grief intervention for dementia caregivers were non-randomized control trials and blind was not conducted. Therefore, it could affect the effect assessment. In order to prove the effectiveness of grief intervention for dementia caregivers, a meta-analysis targeting RCT studies is needed.

## Ethical considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

## Acknowledgements

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## Conflict of interest

The authors declare that there is no conflict of interest.

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