Effects of Family-Based Dignity Intervention And Expressive Writing On Anticipatory Grief of Family Caregivers of Patient With Cancer: A Study Protocol For A Mixed Methods Study

Naima Seyedfatemi
Iran University of Medical Sciences: Tehran University of Medical Sciences

Tahereh Najafi Ghezeljeh
Iran University of Medical Sciences: Tehran University of Medical Sciences

Jafar Bolhari
Iran University of Medical Sciences: Tehran University of Medical Sciences

Masoud Rezaei (✉ masoud.rezaei68@yahoo.com)
Iran University of Medical Sciences

Research Article

Keywords: Dignity, expressive writing, cancer, caregivers, anticipatory grief

DOI: https://doi.org/10.21203/rs.3.rs-520791/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

Background: Family caregivers of dying cancer patients are affected by grief experiences and bereavement complications. Several approaches such as psycho-emotional care and an increase in spirituality have been suggested to diminish these complications. However, no study has examined the effects of family-based dignity intervention and expressive writing on anticipatory grief in family caregivers of dying cancer patients. This study was done to describe the protocol of a mixed-methods study on the effects of family-based dignity intervention and expressive writing on anticipatory grief in family caregivers of dying cancer patients.

Methods: This mixed-methods study will be done in an embedded explanatory design with two quantitative and qualitative phases. In the first phase (quantitative), a randomized clinical trial will be done, in which 200 family caregivers of dying cancer patients will be randomly assigned to one of the four groups: family-based dignity intervention (group 1), expressive writing intervention (group 2), combined family-based dignity intervention and expressive writing (group 3), and controls (group 4). At baseline, one week and two weeks after the interventions, anticipatory grief will be assessed by a 13-item anticipatory grief scale. After the quantitative phase, the qualitative phase will be conducted through the conventional content analysis approach of Granheim and Lundman, in which an individual semi-structured interview will be taken from participants in the first phase to collect data on their experiences on interventions. Finally, data from quantitative and qualitative phases will be analyzed and discussed.

Discussion: Family caregivers of dying cancer patients usually experience depression, anxiety, and psychological distress due to isolation and inadequate social support. Psychological interventions such as dignity and expressive writing interventions may help caregivers to obtain a better understanding of themselves and to increase their abilities to cope with caregiving difficulties. Therefore, there is a need for a comprehensive study confirming the effects of mentioned interventions on family caregivers of dying cancer patients.

Trial registration: Iranian Registry of Clinical Trials (www.irct.ir) IRCT20210111050010N1. Retrospectively registered 6 February 2021.

Introduction

The diagnosis of cancer is an unpleasant and unbelievable experience for every person and it imposes a high burden on the patient and his/her families [44]. As cancer progresses, patients became physically and psychologically weaker, and their dependency on family increases [3]. In addition to the dependency, caregiving responsibilities of patients are often transferred to family caregivers who are usually spouses, adult children, mother, or father [3, 8]. Therefore, family caregivers, particularly those who take care of dying cancer patients, usually are confronted with several social, physical, and psychological difficulties, which may adversely affect their health [6, 7]. It has been shown that more than 35% of family caregivers experience psychological disorders and feelings of helplessness, hopelessness, and anticipatory grief [15,
This is the reason that caregivers are considered as “second-order patients,” who need supportive care [26].

The religious culture of Iranian caregivers makes a strong relationship between caregivers and patients [41]. For this reason, caregivers look at their responsivities as moral commitment and divine duty [20]. Nevertheless, this religious belief may cause them to hide their needs and caregiving problems [23]. Moreover, there are no specific social organizations in Iran to support caregivers and to diminish their problems [24]. Therefore, family caregivers in Iran, compared with those from developed countries, are at a higher risk of psychological disorders or anticipatory grief.

Anticipatory grief is one of the important problems among family caregivers [7]. They usually think about the threat of death or separation that can initiate a grief reaction, while the patient is physically present and needed of care [28]. Anticipatory grief is a “safeguard against the impact of a sudden death notice” that helps caregivers to cope with bereavement [39]. However, anticipatory grief is a highly stressful and ambivalent experience that may be a reason for the incidence of psychological distress among caregivers [10, 27]. In addition, this feeling may be transferred to patients and affect their treatment process. Therefore, caregivers should try to control their feelings and refrain from expressing grief.

Several psychological interventions have been proposed to support caregivers in their challenges [5, 9, 11, 26]. Recently, it has been shown that family-based dignity intervention and expressive writing are effective approaches in the treatment of psychological disorders [26, 29]. Family-based dignity intervention is a spiritual-psychological intervention taken from dignity therapy methods [40]. This supportive intervention help caregivers to strengthen the sense of hope in themselves and give them an opportunity to talk about their successes, aspirations, and plans [31]. Expressive writing intervention includes sessions of solitary and unlimited writing about positive and negative feelings and experiences caused by stressful events [2, 37]. Overall, talking about successes, aspirations, plans, and also expressing feelings through writing is an appropriate strategy to enhance well-being and may promote the ability of caregivers to cope with chronic grief.

Limited data are available on the effects of family-based dignity intervention and expressive writing on anticipatory grief in family caregivers of dying cancer patients. In addition, most studies assessing the effects of mentioned interventions had been done with a quantitative or to a lesser extent with a qualitative research methodology that both contain several limitations and strengths [21, 26, 42]. Mixing the qualitative and quantitative methods can cover the limitations and bring together the strengths of both methods [19, 34]. Recently, mixed-methods methodology, defined as mixing both qualitative and quantitative methodologies, has been introduced and has captured the interest of healthcare researchers [25]. The mixed-methods approach in interventional studies helps researchers to assess the experiences of participants throughout the intervention period and in this way, researchers can present a better conclusion than the quantitative-only and qualitative-only research approaches [18, 25]. Therefore, the aim of this study was to describe the protocol of a mixed-methods study on the effects of family-based
dignity intervention and expressive writing on anticipatory grief in family caregivers of dying cancer patients.

Methods

Participants: This mixed-methods study will be done in an embedded explanatory design with two quantitative and qualitative phases [4]. We will perform the quantitative phase at first, and then, the qualitative phase will be done on the participants in the first phase. In this study, we will include family caregivers of dying cancer patients who refer to the oncology center of hospitals affiliated to the Iran University of Medical Sciences, Tehran, Iran to receive medical and palliative care for their patients.

Inclusion criteria: We will include caregivers with the following criteria: 1) caregivers who are the first-degree relatives of cancer patients and have the most responsibility for caregiving of them during the last 3 months, 2) those who are caregiving of the cancer patients who are dying or critically ill according to the opinion of the treating physician, and 3) caregivers aged ≥ 18 years.

Non-inclusion criteria: We will not include caregivers who have a history of psychological disorders and those who have a history of death among their first-degree relatives. Also, caregivers who are not the first-degree relatives of dying cancer patients and those who have an experience of psychological interventions (particularly dignity and expressive writing interventions) during the last 6 months will not be included.

Exclusion criteria: Caregivers who are not willing to continue each phase (quantitative and qualitative) of this study will be excluded. Also, those who are not able to contribute to the interviews of qualitative phase will be excluded in that phase. Figure 1 shows the study flowchart.

Ethics: All caregivers will read the terms and conditions written in informed consent and optionally they can accept to participate in the current study. The ethics committee of Iran University of Medical Sciences approved the study (code: IR.IUMS.REC.1399.1097). Moreover, the quantitative phase of this study that is a randomized clinical trial was registered in the Iranian Registry of Clinical Trials (www.irct.ir) with code IRCT20210111050010N1.

Sample size calculation: Considering the type I error of 5% (α = 0.05) and type II error of 20% (β = 0.20, power = 80%) and anticipatory grief score as the key variable, we manually, without the use of any software, calculated required sample size using the following formula [33]

\[
n = \frac{2[(a + b)^2 \times \sigma^2]}{(\mu_1 - \mu_2)^2}
\]

n = sample size in each group
\[ \mu_1 = \text{mean for anticipatory grief score in group 1 (considered as 78.17 based on the study of Fowler et al. [14])} \]

\[ \mu_2 = \text{mean for anticipatory grief score in group 2 (considered as 64.49 based on the study of Fowler et al. [14])} \]

\[ \sigma = \text{variance (SD) for the mean of anticipatory grief score; which was considered as 23.1 (the average SDs reported for anticipatory grief score in the 2 groups of Fowler et al. study [14])}. \]

\[ a = \text{conventional multiplier for alpha = 0.05 that was 1.96} \]

\[ b = \text{conventional multiplier for power = 0.80 that was 0.842} \]

Overall, based on the formula and given a 10% drop-out in each group, we will need a sample size of 50 caregivers for each intervention group.

**Study design for the quantitative phase:** In the first phase of the current study (quantitative), a randomized clinical trial will be done. After recruiting 200 family caregivers of dying cancer patients according to inclusion criteria, they will be randomly assigned to one of the four groups: family-based dignity intervention (group 1), expressive writing intervention (group 2), combined family-based dignity intervention and expressive writing (group 3), and controls (group 4). Allocation concealment will be done using the blocked randomization method. For this, we will use six blocks, each with a block size of 4 (A: group 1, B: group 2, C: group 3, and D: group 4), that the order of the letters in these blocks will be different (e.g. ABCD, ACDB, and etc.). Then, a code ranging between 1 and 6 will be assigned to each of these six blocks. For allocating each four caregivers, at first, we will randomly select one of the six blocks using a six-sided dice, and then, caregivers will be assigned to the four intervention groups according to the order of letters in the selected block. Until all groups become complete, the random allocation will continue. It should be noted that random allocation will be done by a person who is unaware of the aim of our study.

After the random allocation, sessions related to the interventions (family-based dignity intervention and expressive writing) will take place at the time that will be set with caregivers. Before the session and one week and two weeks after the interventions, anticipatory grief will be assessed by a 13-item anticipatory grief scale. The diagram for Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) is shown in Fig. 2.

**Family-based dignity intervention:** Family-based dignity intervention will be delivered by a researcher who is experienced in counseling. This intervention will be done based on the protocol introduced by Ho et al., through which, a 60-90-minute intervention interview session will take place for each caregiver in a private room in the palliative care center [21]. In this session, caregivers will be asked to answer 12 open-ended questions related to the Ho et al. protocol. The questions focus on eliciting caregivers’ experiences of living with a cancer patient before and after the diagnosis of cancer. Also, these questions will help
caregivers to review the beautiful memories of living with a cancer patient and express their hopes, wishes, and desired expectations. The responses to these questions will be audio-recorded and then, will be transcribed verbatim in a manuscript for each caregiver. The manuscript will be checked with caregivers and, if needed, corrections will be done. A copy of the manuscript will be delivered to caregivers.

Expressive writing intervention: This intervention will be done based on the Pennebaker method [38]. Before the intervention, caregivers will be instructed by a trained researcher in order to do this writing. The researcher will receive training on expressive writing by participating in a writing art workshop. Caregivers in this group will be asked to write about a prompt, and they will be instructed to “really let go and explore their very deepest emotions and thoughts”. They will be also told to write about either negative or positive family memories and describe their experiences of caregiving in the present and past time. This writing should be done three times (in a week) lasting 20 minutes. In that week, the researcher will remind the writing process using a phone call. They are also assured that they do not need to worry about sentence structure or grammar when writing. After one week opportunity for expressive writing, the manuscript of caregivers will be received.

Combined family-based dignity intervention and expressive writing: For this combined intervention, at first, the session related to family-based dignity intervention will be hold and after that, training on expressive writing will be delivered to caregivers. After one week from the last session, the manuscript of caregivers will be received.

Control group: Caregivers in the control group, as well as those in the intervention groups, will receive routine care such as family counseling and meaning therapy.

Anticipatory grief scale: The original form of anticipatory grief scale (AGS) was designed by Theut et al. to assess anticipatory grief in spouses of Alzheimer’s patients [43]. This form consisted of 27 items measuring anticipatory grief on a Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The items should be summed into a total score ranging from 27 to 135 with a higher score indicating higher levels of anticipatory grief. However, 8 items (2, 5, 8, 11, 19, 22, 26, and 27) have a positive bearing and therefore must be reversed before the total score is calculated. In addition to the total score of anticipatory grief, the score of seven subscales including anger, guilt, anxiety, irritability, sadness, feelings of loss, and decreased ability to function in performing usual tasks can be reached from this scale. In 2019, Holm et al. [22] introduced a short form of AGS containing 13 items and was named AGS-13 (items 1, 3, 4, 7, 10, 15, 16, 18, 20, 21, 23, 24, 25 of the original form). This scale specifically measures a total score of anticipatory grief in family caregivers of cancer patients and also consists of two subscales, named “Behavioral reactions” and “Emotional reactions”, which capture the behavioral and emotional reactions of grief in caregivers participating in palliative care. To obtain a total score of anticipatory grief in AGS-13, like the original form, the items should be summed into a total score ranging between 13 and 65. Higher scores indicate higher anticipatory grief in caregivers of cancer patients. No item should be reversed before calculating the total score.
Translation, validity, and reliability of AGS-13

Translation: Since the AGS-13 was not used in Iran, we will translate it to Persian based on the method proposed by Guillemin [13]. At first, the permission to use and translate the AGS-13 will be gathered from its developer (Holm et al) [22]. Then, the English version of the instrument will be translated to Persian by two independent health professionals fluent in English and Persian languages and familiar with the concepts of the questionnaire. After that, an expert panel will assess the translations, select the best translation of each item, and finally, a single form will be produced. Then, the initial Persian form of the tool will be translated back to English by two other qualified persons and the best backward translations will be chosen by the same expert panel afterward. The final backward translation form will be sent to the developer of the tool, to be reviewed for probable inadequacy of words and concepts. Consequently, the confirmed Persian version of the tool will be used for the current study.

Validity: Content validity (CV) will be used to assess the validity of AGS-13. The assessment of CV will be done using two qualitative and quantitative methods. In the qualitative method, the opinion of 11 experts in the fields of instrumentation and psychometric measurement, community health nursing, and specialist physicians in the field of psychology and oncology will be received in order to observe and assess grammar, wording, item allocation, and scaling. Then, the quantitative CV will be examined using Content Validity Ratio (CVR) and Content Validity Index (CVI) [1, 45].

Internal consistency: Cronbach's alpha coefficient will be used to measure the internal consistency of the AGS-13 using SPSS software (version 18).

Test-retest reliability: To measure the stability of the AGS-13, 30 caregivers will be asked to fill the scale two times with a two weeks interval. These caregivers will not participate in the main study. Test-retest reliability will be tested using the intra-class correlation coefficient (ICC) with a 95% confidence interval (CI). P-values less than 0.05 will be considered significant.

Statistical analysis for the quantitative phase: All statistical analyses will be done using the SPSS software version 18 (SPSS, Inc. Chicago, IL, USA). The analyses will be performed on the basis of an intention-to-treat (ITT) approach. Therefore, missing values will be treated according to the last-observation-carried-forward method. The Kolmogorov-Smirnov test will be used to examine the normal distribution of quantitative variables. We will normalize the non-normally distributed variables using log transformation. To detect differences in quantitative and categorical variables between the intervention groups, we will use the analysis of variance (ANOVA) and Chi-square test, respectively. To determine the effect of family-based dignity intervention and expressive writing on anticipatory grief, we will use repeated measures ANOVA. In this analysis, the intervention groups (family-based dignity intervention, expressive writing, combined intervention, and control groups) will be considered as the between-subjects factor and the time points (Before and one week and two weeks after the interventions) will be considered as the within-subjects factor. Also, to assess differences between the intervention groups in terms of mean changes of anticipatory grief, the multivariate analysis of covariance (ANCOVA) will be applied by
considering baseline measurements and variables different between the groups as covariates. P-value < 0.05 will be considered as a significant level.

**Study design for the qualitative phase:** The qualitative phase will be done after the completion of the first phase and based on the conventional content analysis approach suggested by Lundman and Granheim [17]. Some caregivers participating in the first phase will be selected for the qualitative phase according to the purposeful sampling that is widely used in qualitative studies [36]. There are several different purposeful sampling strategies; however, in the current study, we will use criterion sampling that appears to be used most commonly in qualitative research [36]. In this sampling method, we will identify the information-rich caregivers related to the patient care based on the pre-defined criteria: 1) those caregivers that have 10 unit change in anticipatory grief at the end of the quantitative phase compared to baseline, 2) caregivers with the score unchanged throughout the first phase. Also, we will include those caregivers that have enough time and are willing to contribute in the qualitative phase.

Qualitative data will be collected using individual, face to face, in-depth and semi-structured interviews, containing open questions, by the main researcher. The desired questions used in the interview will be designed based on the findings obtained from the quantitative phase. Before the interview, the aims of the research will be expressed to the caregivers and they will be assured that the data collected are anonymous and confidential and are used only for this study. All interviews will be carried out in a suitable environment based on the participants' preferences and without someone other than the interviewees. The interview will be started with open-ended questions: “How were the face-to-face meeting we had together?”, “Please describe your experiences in relation to the intervention”, “Compared to before the intervention, have you had any changes in your relationships with your patient?”, “Please talk about what happened to you throughout the study”. Following questions, e.g. can you give an example? /please explain more, will be also used based on the responses of participants to lead the interview to clarify caregivers' perceptions. Interview data will be entirely recorded in three ways: voice recording and taking notes during and after the interview. Of note, interviews will be recorded with the consent of the caregivers. Interviews will continue until the data saturation is reached.

**Data analysis for the qualitative phase:** We will analyze the qualitative data using qualitative content analysis according to the Graneheim and Lundman method [17]. Accordingly, the data will be analyzed immediately after each interview. The audio files will be heard several times, and then, they will be converted into a writing format. The notes were studied line-by-line to extract the codes. At first, target words that contain the main concepts will be determined. The researcher continued reviewing the text by taking notes from the initial assessment until the major codes will be elicited. After that, the code labels indicating > 1 key thought will be directly extracted and determined. Finally, the extracted codes will be categorized into themes and main categories according to their differences and relationships. We will also determine the subcategories of the codes based on differences and similarities.

**Discussion**
Family caregivers of dying cancer patients usually experience different psychological disorders including depression, anxiety, and psychological distress due to isolation and inadequate social support [6, 7]. Anticipatory grief is another complication of caregiving terminally ill patients [32]. Caregivers usually think about how much separation and loneliness can be hard and this thought can initiate a grief reaction, while the patient is physically present and in need of care [28]. Therefore, if these disorders are not managed, they can adversely affect the quality of caregiving and also caregivers’ health [30].

Different strategies such as pharmacological treatments and psychological interventions have been designed to control the psychological disorders [12, 35]. Compared to pharmacological treatments, psychological interventions including psychological counseling have fewer complications and can help in the complete treatment of the disorders [12]. Several psychological interventions have been suggested to help caregivers to control their difficulties [5, 9, 11, 26]. However, little attention has been paid to family-based dignity intervention and expressive writing [26, 29]. These supportive interventions may help caregivers to strengthen the sense of well-being in themselves and give them an opportunity to talk or write about their successes, aspirations, and plans [2, 31, 37]. These interventions have no complications and are much more cost-effective compared to medications.

**Strengths:** This is the first mixed-methods study investigating the effects of family-based dignity intervention and expressive writing on anticipatory grief in family caregivers of dying cancer patients through mixing quantitative and qualitative assessments. Also, it should be noted that the interventions are of low cost and can easily be carried out in palliative care centers. In this study, caregivers are assigned to four groups using block randomization. The sample size of this study is adequate and provides sufficient power to detect the efficacy of interventions. In addition to the effects of family-based dignity intervention and expressive writing alone, the combined effects of these interventions are examined in a separate intervention group.

**Limitations:** Despite using validated questionnaires for assessment of anticipatory grief, misclassification of caregivers in terms of this variable cannot be fully excluded. Since the interventions used in the current study are interview-based, we cannot blind the caregivers to the interventions. Although we try to control for variables different between the groups in statistical analysis, we cannot entirely exclude the effects of residual confounders or differences on our findings.

**Abbreviations**

AGS: Anticipatory Grief Scale

**Declarations**

**Ethics approval and consent to participate:** This study was confirmed by the ethic committee of Iran University of Medical Sciences with the code IR.IUMS.REC.1399.1097. Moreover, it was registered in the Iranian Registry of Clinical Trials (www.irct.ir) with code IRCT20210111050010N1. All participants will
read the terms and conditions written in an informed consent and optionally they can accept to participate in the current study.

**Availability of data and materials:** All data generated or analyzed during this study are included in this published article.

**Competing interests:** This study received funding from the Iran University Medical Sciences, Tehran, Iran.

**Consent for publication:** All authors approved this version of manuscript for submission.

**Funding:** This trial was supported by the Iran University Medical Sciences, Tehran, Iran. The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

**Authors' contributions:** MR, NS, and TNG contributed to design and developed methodology. JB and MR contributed to manuscript writing. NS has reviewed the manuscript and validated the methodology. All authors read and approved the final manuscript.

**Acknowledgements**

The authors wish to express their gratitude for the support received from the Nursing Care Research Center, Iran University of Medical Sciences. Moreover, the authors will appreciate the oncology and palliative care staff of Firouzgar Hospital for their grateful assistance. The authors also wish to thank all the cancer patient caregivers who voluntarily gave of their time to participate in this trial. Moreover, the authors would like to thank Dr. Maja Holm at the Department of Nursing Sciences of Sophiahemmet University, Stockholm, Sweden for his valuable assistance in selecting and use of Grief Scale version that given the group of people under study.

**Study status:** The recruitment phase of this study was started in Feb 2021 and now it is ongoing. Family-based dignity intervention and expressive writing will be conducted for 3 weeks for each participant. Participants will be assessed at baseline, one week and two weeks after the interventions for anticipatory grief. Data analysis and evaluation will be conducted after data entering. The final results of this study will then be published.

**References**

1. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity Res. Social Adm Pharm. 2019;15:214–21.

2. Baker S, Gersten R, Graham S. Teaching expressive writing to students with learning disabilities: research-based applications and examples. J Learn Disabil. 2003;36:109–23. discussion 149–150.

3. Bevans M, Stemberg EM. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. Jama. 2012;307:398–403.
4. Bressan V, Bagnasco A, Aleo G, Timmins F, Barisone M, Bianchi M, Pellegrini R, Sasso L. Mixed-methods research in nursing - a critical review. J Clin Nurs. 2017;26:2878–90.

5. Cheng ST, Au A, Losada A, Thompson LW, Gallagher-Thompson D. Psychological Interventions for Dementia Caregivers: What We Have Achieved, What We Have Learned. Curr Psychiatry Rep. 2019;21:59.

6. Coelho A, de Brito M, Barbosa A. Caregiver anticipatory grief: phenomenology, assessment and clinical interventions. Curr Opin Support Palliat Care. 2018;12:52–7.

7. Coelho A, de Brito M, Teixeira P, Frade P, Barros L, Barbosa A. Family Caregivers’ Anticipatory Grief: A Conceptual Framework for Understanding Its Multiple Challenges. Qual Health Res. 2020;30:693–703.

8. Cormio C, Bafunno D, Catino A, Galetta D, Misino A, Montagna ES, Ricci D, Petrillo P, Logroscino AF. P3. 05 – 004 Psycho-Social Function and Caregiver’s Burden in Patients with Advanced Lung Cancer: Topic: Symptoms. Therapeutic Interventions Journal of Thoracic Oncology. 2017;12:1414–5.

9. Dam AEH, de Vugt ME, van Boxtel MPJ, Verhey FRJ. (2017) Effectiveness of an online social support intervention for caregivers of people with dementia: the study protocol of a randomised controlled trial Trials 18: 395.

10. Dicks SG, Burkolter N, Jackson LC, Northam HL, Boer DP, van Haren FMP. Grief, Stress, Trauma, and Support During the Organ Donation. Process Transplant Direct. 2020;6:e512.

11. Dimitropoulos G, Landers A, Freeman V, Novick J, Schmidt U, Olmsted M. A feasibility study comparing a web-based intervention to a workshop intervention for caregivers of adults with eating disorders. Eur Eat Disord Rev. 2019;27:641–54.

12. Dyer SM, Harrison SL, Laver K, Whitehead C, Crotty M. An overview of systematic reviews of pharmacological and non-pharmacological interventions for the treatment of behavioral and psychological symptoms of dementia. Int Psychogeriatr. 2018;30:295–309.

13. Epstein J, Osborne RH, Elsworth GR, Beaton DE, Guillemin F. Cross-cultural adaptation of the Health Education Impact Questionnaire: experimental study showed expert committee, not back-translation, added value. J Clin Epidemiol. 2015;68:360–9.

14. Fowler NR, Hansen AS, Barnato AE, Garand L. Association between anticipatory grief and problem solving among family caregivers of persons with cognitive impairment. J Aging Health. 2013;25:493–509.

15. Gilliland G, Fleming S. (1998) A comparison of spousal anticipatory grief and conventional grief Death Stud 22: 541–569.

16. Given BA, Northouse L. Who cares for family caregivers of patients with cancer? Clin J Oncol Nurs. 2011;15:451–2.

17. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004;24:105–12.

18. Hadi MA, Alldred DP, Closs SJ, Briggs M. (2013) Mixed-methods research in pharmacy practice: basics and beyond (part 1) Int J Pharm Pract 21: 341–345.
19. Hadi MA, Closs SJ. Applications of mixed-methods methodology in clinical pharmacy research. Int J Clin Pharm. 2016;38:635–40.

20. Hashemi M, Irajpour A, Taleghani F. Caregivers needing care: the unmet needs of the family caregivers of end-of-life cancer patients. Support Care Cancer. 2018;26:759–66.

21. Ho AHY, Car J, Ho MR, Tan-Ho G, Choo PY, Patinadan PV, Chong PH, Ong WY, Fan G, Tan YP, Neimeyer RA, Chochinov HM. (2017) A novel Family Dignity Intervention (FDI) for enhancing and informing holistic palliative care in Asia: study protocol for a randomized controlled trial Trials 18: 587.

22. Holm M, Alvariza A, Fürst CJ, Öhlen J, Årestedt K. Psychometric evaluation of the anticipatory grief scale in a sample of family caregivers in the context of palliative care. Health Qual Life Outcomes. 2019;17:42.

23. Hydary L. (2015) Common breast cancer family care giving problems.

24. Iranmanesh S, Hosseini H, Esmaili M. Evaluating the "good death" concept from Iranian bereaved family members' perspective. J Support Oncol. 2011;9:59–63.

25. Johnson RB, Onwuegbuzie AJ. (2004) Mixed methods research: A research paradigm whose time has come Educational researcher 33: 14–26.

26. Leung YW, Maslej MM, Ho C, Razavi S, Uy P, Hosseini MA, Avery J, Rodin G, Peterkin A. (2019) Cocreating Meaning Through Expressive Writing and Reading for Cancer Caregivers J Palliat Care: 825859719871538.

27. Levy LH. Anticipatory grief: its measurement and proposed reconceptualization. Hosp J. 1991;7:1–28.

28. Lindemann E. Symptomatology and management of acute grief. 1944 Am J Psychiatry. 1994;151:155–60.

29. Martínez M, Arantzamendi M, Belar A, Carrasco JM, Carvajal A, Rullán M, Centeno C. 'Dignity therapy', a promising intervention in palliative care: A comprehensive systematic literature review. Palliat Med. 2017;31:492–509.

30. Moon PJ. Anticipatory Grief: A Mere Concept? Am J Hosp Palliat Care. 2016;33:417–20.

31. Mullen RF, Kydd A, Fleming A, McMillan L. Dignity in nursing care: What does it mean to nursing students? Nurs Ethics. 2019;26:390–404.

32. Nielsen MK, Neergaard MA, Jensen AB, Bro F, Guldin MB. Do we need to change our understanding of anticipatory grief in caregivers? A systematic review of caregiver studies during end-of-life caregiving and bereavement. Clin Psychol Rev. 2016;44:75–93.

33. Noordzij M, Tripepi G, Dekker FW, Zoccali C, Tanck MW, Jager KJ. (2010) Sample size calculations: basic principles and common pitfalls Nephrology dialysis transplantation 25: 1388–1393.

34. O'Cathain A, Murphy E, Nicholl J. Integration and publications as indicators of" yield" from mixed methods studies. Journal of mixed methods research. 2007;1:147–63.

35. O'Donnell ML, Metcalf O, Watson L, Phelps A, Varker T. A Systematic Review of Psychological and Pharmacological Treatments for Adjustment Disorder in Adults. J Trauma Stress. 2018;31:321–31.
36. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research Adm. Policy Ment Health. 2015;42:533–44.

37. Pennebaker JW. Writing about emotional experiences as a therapeutic process. Psychological science. 1997;8:162–6.

38. Pennebaker JW. Expressive Writing in Psychological. Science Perspect Psychol Sci. 2018;13:226–9.

39. Rando TA. Anticipatory grief: the term is a misnomer but the phenomenon exists. J Palliat Care. 1988;4:70–3.

40. Scarton LJ, Boyken L, Lucero R, Fitchett G, Handzo G, Emanuel L, Wilkie DJ. Effects of Dignity Therapy on Family Members: A Systematic Review. Journal of hospice palliative nursing: JHPN: the official journal of the Hospice Palliative Nurses Association. 2018;20:542.

41. Soleimani MA, Lehto RH, Negarandeh R, Bahrami N, Chan YH. Death Anxiety and Quality of Life in Iranian Caregivers of Patients With. Cancer Cancer Nurs. 2017;40:E1–10.

42. Stievano A, Sabatino L, Affonso D, Olsen D, Skinner I, Rocco G. Nursing's professional dignity in palliative care: Exploration of an Italian context. J Clin Nurs. 2019;28:1633–42.

43. Theut SK, Jordan L, Ross LA, Deutsch SI. Caregiver’s anticipatory grief in dementia: a pilot study. Int J Aging Hum Dev. 1991;33:113–8.

44. Xiao J, Chow KM, Liu Y, Chan CWH. (2019) Effects of dignity therapy on dignity, psychological well-being, and quality of life among palliative care cancer patients: A systematic review and meta-analysis Psychooncology 28: 1791–1802.

45. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. J Caring Sci. 2015;4:165–78.

Figures
Figure 1

Study flowchart

Will be assessed for eligibility

Will be randomized (n=200)

We will not include:
1) Those who are not the first-degree relatives of dying cancer patients
2) Caregivers who have a history of psychological disorders
3) Those who have a history of death among their first-degree relatives
4) Those who have an experience of psychological interventions during the last 6 months

Will be allocated to the family-based dignity intervention (n=50)

Will be allocated to the expressive writing intervention (n=50)

Will be allocated to the combined intervention (n=50)

Will be allocated to the control group (n=50)

Follow-up: Anticipatory grief assessment

Follow-up: Anticipatory grief assessment

Follow-up: Anticipatory grief assessment

Follow-up: Anticipatory grief assessment

Caregivers will complete the trial and data will be analyzed

Caregivers will complete the trial and data will be analyzed

Caregivers will complete the trial and data will be analyzed

Caregivers will complete the trial and data will be analyzed
## Figure 2

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) chart of the enrolments and assessments during randomized controlled trials The "X" refers to what is done in the given period

Abbreviations: WK: week

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRITFillablechecklist15Aug20131.doc](#)