



## Research article

# Effects of family dignity interventions combined with standard palliative care on family adaptability, cohesion, and anticipatory grief in adult advanced cancer survivors and their family caregivers: A randomized controlled trial

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## ABSTRACT

**Background:** Family involvement and comfort are equally important in palliative care. Dignity undertook a new meaning and novel challenges as a result of restrictions on visits and companionship during the pandemic. Family-centered family dignity interventions have been shown to be effective in increasing patients' sense of dignity, increasing levels of hope, and reducing psychological distress; however, the effectiveness in enhancing family adaptability and intimacy in the survivor-caregiver binary and reducing expected grief have been inconclusive.

**Objectives:** The primary objective of this study was to assess the efficacy of family dignity interventions on family adaptability and cohesion. The secondary objective was to explore the effects of the interventions on anticipatory grief and psychological distress, and the lasting effect 1 month after the intervention.

**Design:** A single-blinded, two-arm parallel group, randomized controlled trial was conducted in China.

**Settings:** and methods: Ninety-eight dyads who met the inclusion criteria were randomly assigned to the family dignity intervention (n = 51) or standard palliative care group (n = 47) between June and August 2022. Study outcomes were measured at baseline, immediately post-intervention, and at the 1-month follow-up post-intervention evaluation. Data were analyzed using the Kolmogorov-Smirnov test, chi-square test, Fisher's exact test, independent sample *t*-test, Wilcoxon rank-sum test, and generalized estimation equations. The Intention-To-Treat analysis was performed for all available data.

**Results:** In comparison to the control group, significant improvements in family adaptability and cohesion and anticipatory grief over post-intervention and 1-month follow-up were demonstrated among the patients in the intervention group. The intervention group of caregivers had significant improvement in anticipatory grief at post-intervention and 1-month follow-up. The level of psychological distress was significantly lower in the intervention group than the control group ( $p < 0.05$ ) at 1-month follow-up but the differences were not statistically significant at post-intervention. All outcomes showed clear differences from baseline after the intervention and at

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the 1-month follow-up evaluation but not between post-intervention and at the 1-month follow-up evaluation.

*Conclusion:* This study further verifies the actual effect of family dignity intervention program through randomized controlled trials, and provides a reference for improving the family relationship between advanced cancer patients and their family caregivers, and improving their mental health. The addition of family dignity intervention to standard palliative care greatly increased the adaptability and cohesion between survivors and their families, lessened the anticipatory grief of the survivor-caregiver pair, and relieved caregivers' anxiety and despair. We did not detect a statistically significant difference between post-intervention and the 1-month follow-up evaluation, suggesting that the intervention may have a durable impact at least 1 month.

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## What is already known

- Family-centered family dignity interventions have been shown to be effective in increasing patients' sense of dignity, increasing levels of hope, and reducing psychological distress.
- The effectiveness in enhancing family relationship and reducing anticipatory grief in the survivor-caregiver binary were inconclusive.

## What this paper adds

- The addition of family dignity intervention to standard palliative care greatly increased the adaptability and cohesion between survivors and their families, lessened the anticipatory grief of the survivor-caregiver pair, and relieved caregivers' anxiety and despair.
- The effectiveness of family dignity intervention on family relationship and anticipatory may have a durable impact at-least 1 month.
- Future research should concentrate on the innovation in intervention models.

## 1. Introduction

Palliative care is defined by the Worldwide Hospice Palliative Care Alliance as end-of-life medical, psychological, and spiritual care given by medical professionals and volunteers to help people at the end of their lives achieve peace, comfort, and dignity. This definition is based on the idea that palliative care is not only provided to patients but also to their families [1]. Symptom management, emotional and spiritual support, and other palliative care implementation concepts are intended to maximize the quality of life and encourage a dignified death [2].

Some academics have noted that during the global COVID-19 pandemic, dignity was likely to be restricted by caregivers who limited or even prohibited visitation, and families who were unable to visit were denied the chance to advocate for the best medical care or even unable to say goodbye. This resulted in a lack of social support for dying patients, who suffered from more severe symptoms and felt unappreciated, which caused a loss of dignity [3].

To effectively improve the dignity of dying patients, the ABCD rule of dignity enhancement is used, where A represents attitude, B represents behavior, C represents compassion, and D represents dialogue [4]. Family dignity intervention is a family-centered spiritual care approach that adopts the patient-family binary therapy model by fusing family therapy and dignity therapy. It fosters communication between patients and families while enhancing patients' sense of dignity, easing anxiety and depression, fortifying family ties to achieve reconciliation and leave an everlasting family legacy [5], and giving patients more opportunities to foster self-integrity, psychological health, and social skills [6].

Traditional forms of Dignity Therapy, which are equally effective in lowering distressing feelings, such as anxiety and depression, enhancing well-being, hope, and quality of life, and fostering self-expression, self-awareness, and self-continuity, are complemented by family dignity interventions [7–11]. Family mode Dignity Therapy has been available to patients with hematologic tumors, adolescents, palliative care patients, and advanced cancer patients [5,6] by evaluating the impact of Family Dignity Interventions on patients' sense of dignity, the level of hope of patients and caregivers, and negative emotions. However, no studies have been conducted to evaluate the impact and improvement of this family-based intervention on family relationships between survivors and their caregivers.

Family adaptability and cohesion refers to the closeness and emotional connection between family members, taking into account not just the proximity in time and location but also the shared interests and preferences [12]. Family adaptability and cohesion also includes how the family makes decisions. The concept of family adaptability and cohesion was first proposed and elaborated by Olson, 2011 as a family function model, which proposed that family intimacy, adaptability, and communication between families belong to the family functions category, and the realization of family internal functions has a close relationship. When a family member is diagnosed with terminal cancer, the impact extends beyond the dying patient; the entire family might experience the stress and anguish of the condition. Family members are typically the primary caregivers during palliative care, therefore during the treatment of an illness, family members frequently have to maintain a balance between providing care for the patient and coping with the emotional

misery of his or her near death. Regarding the family in issue, family intimacy and adaptability should be at a moderate level to better play the internal functions of the family. In a typical family, the more intimacy and adaptability there is, the easier it is to carry out family duties. The primary objective of this study was to assess the efficacy of family dignity interventions combined with standard palliative care measures on family adaptability and cohesion and the effect of improving the sense of dignity of advanced cancer survivors and their family caregivers.

Anticipatory grief is a type of grief response that is thought of as a “grief response” prior to the actual loss; it is also referred to as “grief before death” or “grief before bereavement”. Anticipatory grief is common in palliative care, and patients with advanced cancer frequently experience negative emotions like frustration and depression, worry about their condition’s progression, worry about complications, etc., and then the burden of self-feeling appears. Anticipatory grieving in palliative care frequently shows up in the primary caregiver’s physical, emotional, and cognitive features. Physiological effects include sleeplessness, tiredness, tightness in the chest and breathlessness, appetite loss, and even a general feeling of unwellness can affect the body. Relevant surveys revealed that [13], before to the patient’s death, 37% of caregivers reported having sleeplessness, 14% reported feeling physically exhausted, 17.5% reported having poor appetite, 12% reported feeling queasy, and 5% had headaches and pressure in the chest. Following a patient’s death, caregivers experience a physiological reaction, although it is more likely to be emotional. The secondary objective was to determine the effects of the intervention on anticipatory grief and negative mood, and the durable effect 1 month after the intervention. By determining the important role of this intervention method in palliative care, we hope to provide more practical support for mental and psychological care for family-centered palliative care in the future.

## 2. Methods

### 2.1. Design and setting

This trial was a two-group, pragmatic randomized controlled trial in which dyads (cancer survivors and their family caregivers) were recruited from China between June and August 2022. The recruitment and intervention were performed in the Oncology Department of a large-scale Grade A Class Three Hospital (It is the level of medical institutions divided in accordance with the provisions of China’s current “Hospital Grading Management Measures” and other regulations, and it is the highest level in the “three levels and six grades” that Chinese mainland implement for hospitals). The trial was prospectively registered on [ClinicalTrials.gov](https://www.clinicaltrials.gov) (ChiCTR2100054798).

### 2.2. Participants

The inclusion criteria for the participants (survivor–caregiver dyads) were Chinese residents ( $\geq 18$  years of age) and ability to provide consent. In addition, cancer survivors were required to meet the following criteria: (1) malignancy was diagnosed by histological or cytology and stage III or IV according to the TNM staging system and the confirmed diagnosis was at least 1 month prior to study enrolment; (2) aware of the cancer diagnosis, course of disease, and therapeutic treatment; and (3) ability to read and communicate with complete language skills and understanding. The exclusion criteria were as follows: (1) complicated by other severe complications and vital organ injury; (2) life expectancy  $< 2$  weeks of study enrolment; (3) receiving anti-anxiety and/or antidepressant medications (control variables); and (4) received other psychological care within 3 months of study enrolment (control variables).

Family caregivers were expected to assume primary responsibility in caring for the cancer survivor and read and communicate with complete language skills and understanding. The exclusion criteria for family caregivers were as follows: (1) diagnosed with a severe health condition, such as cancer or a long-term chronic disease; (2) receiving anti-anxiety and/or antidepressant medications; and (3) received other psychological care within 3 months of study enrolment.

During the cancer survivor’s hospital stay, the researcher reviewed the medical records to identify eligible dyad participants. When inclusion criteria was confirmed, enrolment, obtaining informed consent, and baseline data collection were conducted by the researcher via face-to-face interview.

### 2.3. Intervention

#### 2.3.1. Standard palliative care

The dyads of the intervention and control groups received the standard palliative care offered at the study settings with the main content being in accordance with the Nanjing Palliative Care Service Specification, the main standard nursing contents included disease-related knowledge education, admission and discharge guidance, diet nursing during chemotherapy, chemotherapy adverse reactions nursing, medication nursing, intravenous catheterization nursing, routine psychological counselling and social support.

#### 2.3.2. Family dignity interventions

In addition to standard palliative care, intervention group dyads received an additional face-to-face psychological interview program, as follows.

- (1) theoretical framework

Erikson's theory of psychosocial development [14], which divides human development into eight phases spanning the entire life cycle, serves as the theoretical foundation for this study. Among them, the eighth stage "self-integration to disappointment" is closely related to the connotation of this intervention, integration means the integration of their emotions, the integration of feelings for children, the completion of self-integration is still ready to defend the dignity of life from all economic and physical threats, if the individual successfully passes the previous stages, the heart is full of fulfillment and perfection. The purpose of the notion of inheritance and inheritance in the context of family dignity intervention is to support the process of self-integration by assisting the individual in engaging in discourse with their family and history.

## (2) time frame and contents

The first of four interviews was approximately 30 min in length, during which the interviewees' basic information, including disease progression and psychosocial information, was collected. A good relationship of trust with the interviewees was established and matters related to family dignity interventions were discussed. The second interview was approximately 1 h in length and took place 2–3 days after the first interview. The interview outline provided guidance for the dyads to facilitate recalling their own lives and making personalized adjustments [15]. The entire interview process was recorded and the recording file was transcribed into text in 1–2 days. The third interview was approximately 30 minutes in length, the text was read and checked with the dyads to identify inconsistencies in the description and make corresponding modifications and additions. Approximately 30 min after the fourth interview, the text was given to the dyads, who then decided whether and to whom to pass the text to, and evaluated the efficacy of family dignity interventions.

## (3) setting

The intervention site was a comfortable and quiet office or ward with curtains closed so that participants felt as safe as possible. Among them, participants with good mobility were conducted in the nurse's office, and participants with reduced mobility were carried out in the ward.

## (4) provider

To guarantee the fidelity of the therapy, the study was conducted by certificated researchers (Certificate No. 2020371405069) who had attended Dignity Therapy training courses that were first held in Nanjing, Jiangsu. The knowledge and skills that researchers need to master include the background, content, methods, process, common problems and solutions of family dignity intervention.

## (5) problem-solving training

To ascertain the appropriate duration and consistency in delivering the problem-solving training in the invention, a pilot study ( $n = 2$  survivor–caregiver dyads) was conducted prior to the main study. In addition, written information on problem-solving coping skill training and a series of exercises related to the application of the learned problem-solving skills, such as evaluation of solutions and skills of communication, were provided in the information booklet to improve intervention adherence.

## 2.4. Data collection and outcomes

### 2.4.1. Data collection

Before randomization, the researchers collected baseline sociodemographic data and clinical characteristics of cancer survivors and the family caregivers through medical records data abstraction or inquiry. Study outcomes were measured at baseline, immediately post-intervention, and at the 1-month follow-up evaluation post-intervention. Two trained research assistants blinded to the group allocation collected the data.

### 2.4.2. Research tools

**4.4.2.1. General information questionnaire.** The questionnaire was designed by the investigator, mainly includes three aspects. (1) Demographic characteristics: gender, age group, marital status, education level, etc.; (2) Sociological characteristics: working status, religious beliefs, per capita monthly income of families, reimbursement methods, etc.; (3) Disease-related information: disease diagnosis, time of illness, etc. In the general data survey of family caregivers, items such as relationship with patients, reasons for participating in care, and awareness of patients' conditions were added to the demographic characteristics.

**4.4.2.2. The family adaptability and cohesion evaluation scale.** The primary outcome was family adaptability and cohesion of the survivor-caregiver dyad, as assessed by the Family Adaptability and Cohesion Evaluation Scales score. The scale included two subscales of family cohesion and family adaptability, which were originally used to measure family cohesion and fitness in families with schizophrenia with a total Cronbach's  $\alpha$  coefficient of 0.83 [12] and it was used widespread in terminally ill cancer patients [16]. The scale had 30 entries and was assigned a value of "No" "to" "always using" is the Likert 5-level scoring method of 1~5 points. A higher

score indicated better adaptability and intimacy between family members. We used a Chinese version of the Family Adaptability and Cohesion Evaluation Scales that has been tested after Sinicization [17].

**4.4.2.3. Anticipatory grief the Preparatory Grief in Advanced Cancer Patients scale and the Anticipatory Grief Scale.** Secondary outcome measures were anticipatory grief and psychological distress of survivor-caregiver dyads. We used the Preparatory Grief in Advanced Cancer Patients scale to evaluate the survivors' anticipatory grief and the Anticipatory Grief Scale for caregivers. The Preparatory Grief in Advanced Cancer Patients scale contained 31 entries and seven dimensions (self-awareness, disease adjustment, sadness, anger, religious comfort, somatic symptoms, and perceived social support) to thoroughly assess and adjust the patient's response to cancer. Using the Likert 4 scoring method, the total score is 0–93 points, and the higher the score, the more sadness the patient experiences. The internal consistency of the Preparatory Grief in Advanced Cancer Patients scale was confirmed by the study Cronbach's  $\alpha$  of 0.84, and the Cronbach's  $\alpha$  of each dimension was between 0.82 and 0.86. The Anticipatory Grief Scale for caregivers was written in 1991 by Theut et al., 1991 [18], and sinicized in 2016 by Xin Dajun, 2016 [19], including grief, loss, anger, and other dimensions. The 1–5 scale scoring method was adopted, with a total score of 21–135 points, and the score was positively correlated with the degree of sadness. The content validity was 0.96, and the Cronbach's  $\alpha$  coefficient was 0.90, with good internal consistency and validity.

**4.4.2.4. The Hospital Anxiety and Depression Scale.** We used the Hospital Anxiety and Depression Scale to assess the psychological distress of dyads, as compiled by Zigmond in the 1980s (Zigmond and Snaith., 1983) [20]. The Hospital Anxiety and Depression Scale is mainly used to assess the degree of anxiety, depression, and other emotions in patients with physical diseases. The Hospital Anxiety and Depression Scale has good confidence and validity in cancer patients (Deodhar et al., 2022) [21]. The Hospital Anxiety and Depression Scale contains 14 items that are divided into 2 subscales (anxiety and depression). A total score of 0–7 represents no depression or anxiety, a total score of 8–10 points represents possible or critical depression or anxiety, and a total score of 11–20 points indicates that there may be significant depression or anxiety. The Cronbach's  $\alpha$  coefficients for the anxiety and depression subscales are 0.76 and 0.79, respectively.

**4.4.2.5. The Patient Dignity Inventory scale.** We used the Patient Dignity Inventory scale compiled by Chochinov [15] to assess the dignity of survivors. The reliability and validity evaluation of the scale showed that the Cronbach coefficient was 0.92 points and the split-half reliability was 0.89, including 5 dimensions: physical and mental pain; independence; self-awareness; social roles, and social support (total of 25 items). Using a 5-point Likert-type scale, participants assigned a difficulty level to each task, ranging from “no difficulty” (1 point), to “very serious difficulty” (5 points) with a total score of 25–125 points; the higher the score, the more severe the damage to the patient's dignity. Specifically, 25–49 points represented mild dignity impairment, 50–74 points represented moderate dignity impairment, 75–99 represented severe dignity impairment, 100–125 points represented very severe dignity impairment, and a total score  $\geq 150$  points was defined as “existential loss of dignity.”

## 2.5. Sample size

The sample size calculation was based on a study of the Patient Dignity Inventory scale score change after intervention [22], in which a 6.15-point difference in scores was found between survivors with and without intervention. The mean  $\pm$  Standard Deviation score for this of control participants was reported to be  $63.26 \pm 9.31$ . Assuming an  $\alpha = 0.05$  and 80% power to detect a 6.15-point difference between the groups, a sample size of 37 was required. To account for attrition, enrolment was increased by 20%, resulting in 44 survivors per group or a total of 88 survivors.

## 2.6. Randomization and blinding

This was a randomized assessor-blinded controlled trial. After informed consent, the dyads were randomized to the family dignity interventions pathway or standard palliative care based on a schedule of a randomly-permuted number. Because of the nature of the intervention, full blinding of all study personnel and dyads was not feasible; however, to minimize bias, we attempted to blind data analysts. Before subjects were enrolled, the resulting random allocation sequences were placed in opaque, sequentially encoded, sealed envelopes; only after the researcher had established the subjects' eligibility were the envelopes opened, and the subjects were assigned to the relevant comparison groups.

## 2.7. Statistical methods

IBM SPSS version 26.0 was used for data entry and analysis. Descriptive statistics summarized participant characteristics using numbers and percentages, as appropriate. Unadjusted mean and standard deviation values were computed for the primary and secondary continuous variables at baseline, post-treatment, and 1 month post-treatment. The normality of continuity data was determined with the Kolmogorov-Smirnov test. A chi-square or Fisher's exact test was used to compare the basic data from the intervention and control groups at baseline. All tests of hypotheses were two-sided and a 5% level of significance was used throughout the analysis [23]. For outcomes measured at a single time point, continuous variables were compared between treatment groups using an independent sample *t*-test or the Wilcoxon rank-sum test based on data distribution. For multiple measurements, generalized estimation equations were used to analyze the primary and secondary measurement outcome variables with time and group included as fixed

effects to account for the correlation between repeated measurements for the same dyads [24]. The Intention-To-Treat analysis was performed for all available data. For data involving study subjects who were lost to follow-up after the intervention and at the time of the follow-up evaluation, we used the mean of the population over time [25].

2.8. Deviations from the registered trial protocol

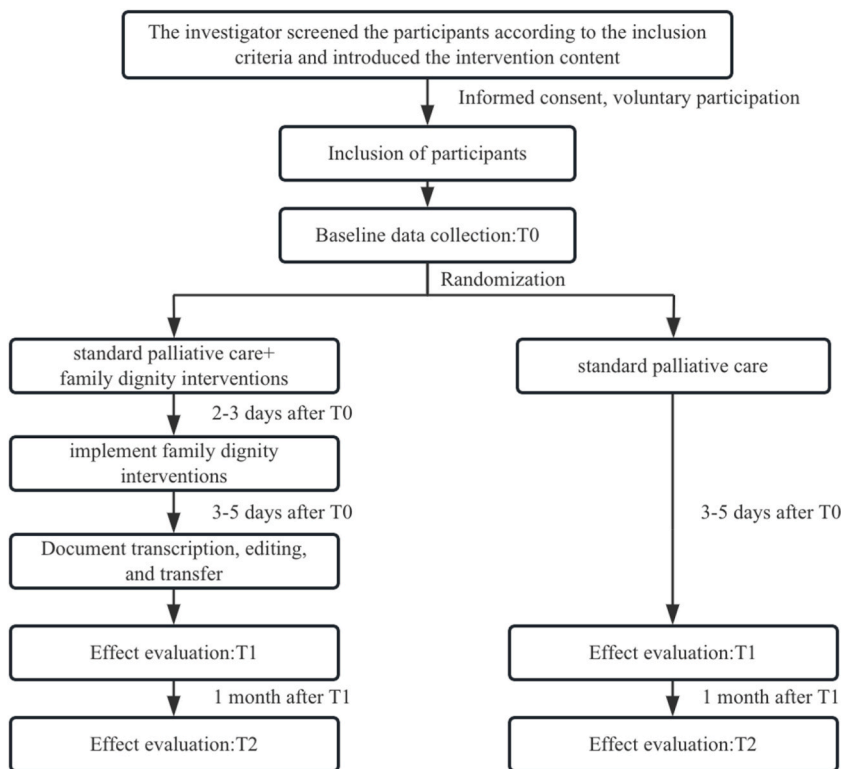
We made a number of deviations from our protocol. The registered study protocol in an actual randomized controlled trial is supplemented and modified by this study. First, as opposed to the 62 pairs specified in the enrolment protocol, 98 pairs of binaries were actually recruited for this study based on a more accurate technique for calculating sample size. Second, the study’s report focused on family adaptation and intimacy rather than patient dignity in the enrolment process since those two factors are the primary indicators of family functioning, which is the focus of the study’s investigation into the impact of family dignity interventions (see Fig. 1).

3. Results

Recruitment ran from June to August 2022 and the final 1-month follow-up evaluation was completed in August 2022. Fig. 2 demonstrates the flow of participants throughout the trial. Of the 98 dyads who were randomly assigned, 94 (95.9%) were evaluated at the 1-month post-intervention follow-up appointment and were included in the analysis.

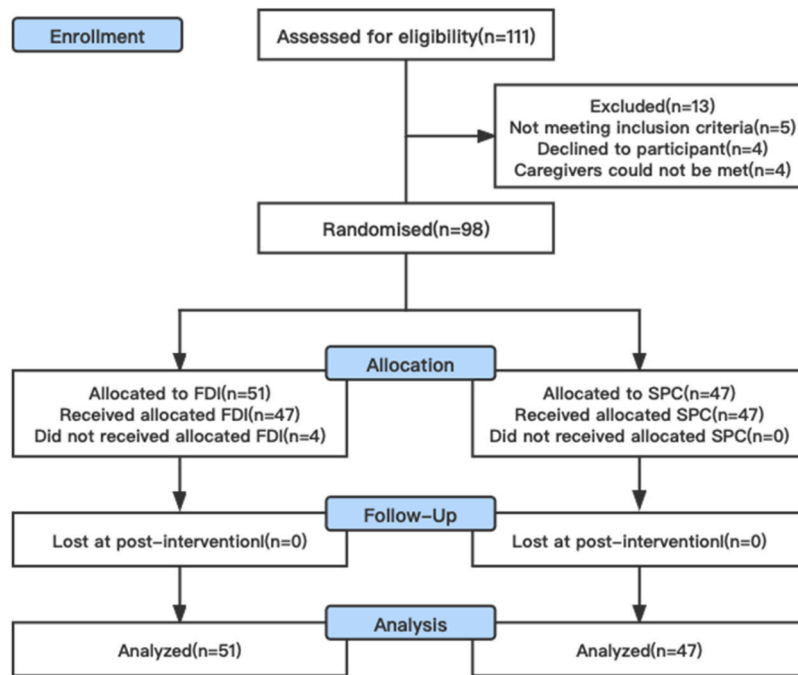
Tables 1 and 2 show the baseline sociodemographic and clinical characteristics of all survivors and family caregivers, respectively. No statistically significant differences were observed between the groups with respect to most characteristics or outcome variable comparisons at baseline.

Table 3 provides the mean and standard deviations for the study outcomes at each assessment point and shows the effects of the measures on the intervention and control groups simultaneously across baseline to post-intervention using independent sample t-tests. The control group and baseline measurements were selected as reference categories. Significant improvements in family closeness and anticipatory grief over post-intervention to 1-month follow-up were demonstrated among the survivors in the intervention group compared to the control group. The intervention group of caregivers had significant improvement in anticipatory grief at post-intervention and 1-month follow-up. The level of psychological distress was significantly lower in the intervention group (n = 51) than the control group (n = 47; t = 3.131, p < 0.05) at 1-month follow-up but the differences were not statistically significant at post-intervention. Although survivors in the intervention group had a better perceived sense of dignity and lower level of psychological



Annotation: T0: baseline T1: post-intervention T2: 1-month follow-up

Fig. 1. Flow chart of the intervention procedures.



Annotation: FDI: Family Dignity Interventions SPC: Standard Palliative Care

Fig. 2. Flow diagram of participants.

distress than the counterparts in the control group across post-intervention to 1-month follow-up, the differences were not statistically significant. The intervention did not appear to increase the family closeness of caregivers because statistically significant differences in post-intervention and at the 1-month post-intervention follow-up evaluation were not detected between the study groups.

## 4. Discussion

### 4.1. Interpretation of results

When family dignity interventions was added to standard palliative care, the adaptability and cohesion between survivors and their families were significantly increased, the anticipatory grief of the survivor-caregiver pair was lessened, and caregiver anxiety and despair were decreased. We did not discover a statistically significant difference between post-intervention and the 1-month post-intervention follow-up evaluation, suggesting that the intervention may have a durable impact.

Advanced cancer not only endangers the health of patients, but also imposes great psychological distress and stress on patients to a certain extent. At the same time, the physical and mental health of family caregivers of patients with advanced cancer will also change with the patient's illness, which is reflected in the lack of family roles of patients, family caregivers need to master how to care for and care for patients with advanced cancer while undertaking some of the patient's original work, and with the continuous development of the disease, family caregivers not only have to face the dying of cancer patients, but also cope with their own grief. The stress caused by illness can affect family relationships between patients and caregivers, and good family support and relationships are one of the guarantees for the implementation of high-quality palliative care services [26]. In this study, patients and their family caregivers were taken as research subjects, and the effect of the intervention was evaluated through their joint participation in family dignity intervention, and it was found that family relationship adaptability and intimacy of patients could be significantly improved through family dignity intervention.

Communication is the defining characteristic of family function [27–29]. The current study used a communication strategy that was appropriate for advanced cancer survivors and their families. Family members interact emotionally and share information with one another while following the instructions of intervention implementers. Family members also share feelings and thoughts as the disease progresses and the family encounter the consequences of cancer invasiveness. By adapting to the disease and improving the disease experience, the current study improved family functioning [30–33] consistent with existing research [34]. The findings, however, revealed that caregivers did not significantly improve family adaptability and cohesion, which could be attributed to the following: only 2.3% of caregivers have little or no knowledge of survivors' progression; only 2.4% of caregivers participated in care because there was no one else to take care of the cancer survivors; the caregivers had to take care of the passive care state; and based on an analysis of the results of the relevant items most of the answers were willing to share and communicate with family members, which

**Table 1**  
Baseline sociodemographic and clinical characteristics of all survivors.

Characteristics	Intervention group (n = 51)		Control group (n = 47)		p value
	n	(%)	n	(%)	
Sex					0.472
Female	16	(31.40)	18	(38.30)	
Male	35	(68.60)	29	(61.70)	
Age of survivors (years)					0.562
18~25	0	(0.00)	0	(0.00)	
26~30	0	(0.00)	0	(0.00)	
31~40	11	(21.60)	8	(17.00)	
41~50	9	(17.60)	14	(29.80)	
51~60	17	(33.30)	14	(29.80)	
>60	14	(27.50)	11	(23.40)	
Disease diagnosis					0.112
Breast cancer	33	(64.70)	29	(61.70)	
Gastric cancer	6	(11.80)	1	(2.10)	
Colorectal cancer	4	(7.80)	3	(6.40)	
Lung cancer	8	(15.70)	10	(21.30)	
Bladder cancer	0	(0.00)	1	(2.10)	
Gallbladder cancer	0	(0.00)	1	(2.10)	
Esophageal carcinoma	0	(0.00)	2	(4.30)	
Education level					0.184
Primary school or less	3	(5.90)	6	(12.80)	
Junior high school	12	(23.50)	12	(25.50)	
Technical secondary or high school	23	(45.10)	12	(25.50)	
University or undergraduate	13	(25.50)	17	(36.20)	
Master's degree or above	0	(0.00)	0	(0.00)	
Marital status					0.295
Married	51	(100.00)	46	(97.90)	
Single	0	(0.00)	0	(0.00)	
Divorced	0	(0.00)	0	(0.00)	
Widow	0	(0.00)	1	(2.10)	
Number of children					0.481
Childless or otherwise	1	(2.00)	2	(4.30)	
Has 1 child	36	(70.60)	28	(59.60)	
Has 2 or more children	14	(27.50)	17	(36.20)	
Working conditions					0.240
Working	5	(9.80)	1	(2.10)	
Not at work, due to illness	18	(35.30)	23	(48.90)	
Not at work, not due to illness	14	(27.50)	9	(19.10)	
Normal retirement	14	(27.50)	14	(29.80)	
Monthly income per capita of the household (RMB)					0.623
<3000	2	(3.90)	3	(6.40)	
3000~5000	15	(29.40)	19	(40.40)	
5001~10000	24	(47.10)	18	(38.30)	
10001~20000	9	(17.60)	7	(14.90)	
>20000	1	(2.00)	0	(0.00)	
Reimbursement method					0.008
At your own expense	0	(0.00)	0	(0.00)	
Employee medical insurance	25	(49.00)	22	(46.80)	
Publicly-funded medical care	4	(7.80)	9	(19.10)	
Domestic health insurance	10	(19.60)	0	(0.00)	
New Agricultural Cooperation Commercial insurance	11	(21.60)	0	(0.00)	
Commercial insurance	1	(2.00)	16	(34.00)	
Duration of illness					0.151
Less than 3 months	3	(5.90)	5	(10.60)	
3~6 months	6	(11.80)	13	(27.70)	
6~12 months	13	(25.50)	9	(19.10)	
Greater than 1 year	29	(56.90)	20	(42.60)	
Religious beliefs					0.510
No religious affiliation	50	(98.00)	45	(95.70)	
Buddhism	1	(2.00)	2	(4.30)	
Christian	0	(0.00)	0	(0.00)	
Islam	0	(0.00)	0	(0.00)	
Otherwise	0	(0.00)	0	(0.00)	
Place of residence					0.897
City	33	(64.70)	31	(66.00)	
Countryside	18	(35.30)	16	(34.00)	



**Table 2**  
Baseline sociodemographic and clinical characteristics of all caregivers.

Characteristics	Intervention group (n = 51)		Control group (n = 47)		p value
	n	(%)	n	(%)	
Sex					0.768
Female	34	(66.70)	30	(63.80)	
Male	17	(33.30)	17	(36.20)	
Age of caregivers (years)					0.147
18~25	0	(0.00)	0	(0.00)	
26~30	0	(0.00)	2	(4.30)	
31~40	6	(11.80)	8	(17.00)	
41~50	10	(19.60)	15	(31.90)	
51~60	15	(29.40)	12	(25.50)	
>60	20	(39.20)	10	(21.30)	
Education level					0.249
Primary school and below	4	(7.80)	10	(21.30)	
Junior high school	14	(27.50)	13	(27.70)	
Technical secondary or high school	15	(29.40)	7	(14.90)	
University or undergraduate	17	(33.30)	16	(34.00)	
Master's degree or above	1	(2.00)	1	(2.10)	
Relationship with survivors					0.057
Spouse	51	(100.00)	42	(89.40)	
Children	0	(0.00)	3	(6.40)	
Sibling	0	(0.00)	2	(4.30)	
Parents	0	(0.00)	0	(0.00)	
Otherwise	0	(0.00)	0	(0.00)	
Reasons for involvement in care					0.026
No one to take care of	8	(15.70)	14	(29.80)	
Responsibility	18	(35.30)	22	(46.80)	
Happy to take care of	25	(49.00)	11	(23.40)	
Degree of disease awareness					0.013
Fully understood	22	(43.10)	9	(19.10)	
Generally understand	25	(49.00)	27	(57.40)	
Know some	4	(7.80)	11	(23.40)	
Do not understand	0	(0.00)	0	(0.00)	

also confirmed that the family function was important.

Grieving is inescapable in palliative care, beginning with the diagnosis of a life-threatening illness to the gradual physical and mental decline of the patient [35]. Caregivers clearly experience a great deal of psychological distress and eventual loss throughout palliative care [35]. A nationwide prospective cohort study [36] reported that 7.6% of the caregivers experienced complicated grief and 12.1% exhibited depressive symptoms 6 months after the loss of a family member. The levels of grief and depressive symptoms were higher before the loss than during bereavement, indicating that caregiver distress accentuates grief symptoms. The intervention used in the current study was family-centered with caregivers involved in reducing anticipatory grief [37].

In terms of improving survivors' sense of dignity, the results of the current study are different from previous studies [10,38], and an analysis of the study population showed that survivors had between slightly impaired and unimpaired dignity at baseline, no impairment after the intervention, and no statistically significant difference in dignity after the intervention. Of the survivors, 50% were diagnosed for >1 year year, had a high level of awareness of the progression of the disease, and have entered the acceptance period of the disease. Of the survivors, 100% were covered by health insurance and the financial level may have contributed to the high baseline level of survivors' dignity in this group.

In addition, it is worth noting that the intervention appears to have a long-term effect, which is not consistent with the results of relevant studies [39,40] and may be related to the nature of the intervention itself. A brief intervention has an immediate effect [40] but over time the survivor's condition gradually changes and the aggravation of symptoms or the pain caused by the disease itself may increase the mental and psychological burden of the dyad, thus weakening the effect of the intervention [41]. Therefore, the current study could not determine the effect on the long-term effect of the intervention. The results of this study are different, though, and the interpretation of the findings may be attributable to the fact that the conversation document has a long-lasting impact on the comfort of the succeeding families as a permanent inheritance.

#### 4.2. Strengths and limitations discussion

This trial had several advantages. First, the trial was prospectively registered and incorporated design features known to minimize bias, such as allocation concealment and treatment intent analysis [42]. Second, to better ensure the fidelity of the intervention [43], the participants in the trial participated in the first Dignity Therapy training course in Jiangsu Province before the start of the trial and obtained the training certificate. In order to ensure the scientific nature of the research, scientific and effective evaluation indicators are developed after consulting the literature and discussion by the research group. The research team for this project is made up of a number of nursing graduate students, nursing managers, and palliative care experts, with relevant knowledge and experience.

**Table 3**  
Scores for the study outcomes and the effects of the measures.

Outcomes	Intervention group (n = 51)		Control group (n = 47)		p value
	mean	sd	mean	sd	
<b>Survivors</b>					
<i>T0</i>					
Family adapt-ability and cohesion	98	9.73242	102.3617	7.62840	0.016
Anticipatory grief	68.8431	15.29101	67.8723	12.50499	0.733
Psychological distress	36.0588	2.32733	34.7021	2.17610	0.004
Dignity	50.3137	15.07911	46.0851	12.71396	0.138
<i>T1</i>					
Family adapt-ability and cohesion	117.5882	12.32425	103.2766	7.00218	<0.001
Anticipatory grief	90.8824	11.60801	69.0213	10.95939	<0.001
Psychological distress	33.1569	2.00372	34	2.45835	0.065
Dignity	41.451	8.17145	44.5957	11.99032	0.136
<i>T2</i>					
Family adapt-ability and cohesion	116.8039	12.24585	103.766	7.20571	<0.001
Anticipatory grief	89.1569	11.09842	68.8511	10.64032	<0.001
Psychological distress	34.0196	1.94412	33.1489	2.91159	0.088
<b>Caregivers</b>					
Dignity	43.0784	7.79703	44.9362	11.55780	0.358
<i>T0</i>					
Family adapt-ability and cohesion	97.7451	8.74493	101.8511	7.70934	0.016
Anticipatory grief	57.3137	10.45656	70.0213	12.38949	<0.001
Psychological distress	36.098	2.1378	34.383	1.54009	<0.001
<i>T1</i>					
Family adapt-ability and cohesion	100.6078	7.86658	102.9149	7.98049	0.153
Anticipatory grief	62.6863	8.66831	71.7021	11.63188	<0.001
Psychological distress	34.1373	2.65345	33.4894	1.75539	0.155
<i>T2</i>					
Family adapt-ability and cohesion	99.4314	7.94545	102.1702	7.89419	0.090
Anticipatory grief	61.2157	7.88749	72.5532	11.02528	<0.001
Psychological distress	34.9608	2.68299	33.4681	1.94323	0.002

Annotation: T0: baseline T1: post-intervention T2: 1-month follow-up.

The following are some of the limitations of the trial. First, like previous studies [34], a further limitation of the trial was that some participants dropped out. One of four participants withdrew due to introversion and poor communication, and the other three participants were interrupted due to relapse or rapid progression of the disease leading to worsening symptoms and a low mood. It should be acknowledged that attrition rates are generally high in studies involving patients with advanced cancer [41], and although we used an Intention-To-Treat analysis of intervention outcomes in extrusion cases, there may have been some unmeasured biases. Second, the nature of this intervention meant that we could not blind participants and could not mask treatment providers [44]. Incomplete blinding can lead to biased results. Blindness is a common difficulty in trials that randomize patients to an enhanced care pathway versus usual care, and is primarily addressed by hiding group assignments from researchers conducting outcome assessments and data collection [45]. The family dignity intervention's failure to significantly increase the patient's sense of dignity, in contrast to the intervention's intended effect, was also revealed by the results. As a result, the study's power may not have been sufficient, and the results should be interpreted with care. It should also be emphasized that the translation bias and reliability and validity of the scales used in this intervention were not evaluated in this study, and we would like to accept that the study was not generalized because the intervention was conducted in a Chinese cultural setting.

#### 4.3. Implications for practice and future research

More participant experiences, including the intervention providers, need to be analyzed in an upcoming, corollary study. Nursing professionals trained to execute family dignity interventions for patients and their caregivers at the appropriate time include clinical nurses, who have the most frequent contact and conversations with patients, and considerable experience in both specialty and customized care. Communication helps lessen their bad feelings and improve the relationship between the patient and the caregiver. Additionally, because directing family dignity interventions communication is a complicated process, it is necessary for nurses to become proficient in the necessary abilities to capture concealed subjects with fair avoidance. Therapy needs a reasonably peaceful and private atmosphere, which is more easily constrained by time and place, and traditional family dignity treatments are typically done in wards. Innovative intervention models are needed. More thorough studies are needed to investigate internet-based family dignity treatments and to confirm the outcomes. The majority of earlier studies have been very brief, therefore further research is needed to determine the long-term benefits of family dignity interventions and how they affect the standard of long-term family care.

## 5. Conclusion

This study further verifies the actual effect of family dignity intervention program through randomized controlled trials, and provides a reference for improving the family relationship between advanced cancer patients and their family caregivers, and improving their mental health. The addition of family dignity intervention to standard palliative care greatly increased the adaptability and cohesion between survivors and their families, lessened the anticipatory grief of the survivor-caregiver pair, and relieved caregivers' anxiety and despair. We did not detect a statistically significant difference between post-intervention and the 1-month follow-up evaluation, suggesting that the intervention may have a durable impact at least 1 month.

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## Ethics declarations

This work was approved by ethics committee of Jiangsu Province Hospital and Nanjing Medical University First Affiliated Hospital and the ethics approval number is 2021-SR-477. All informed consent was obtained before complication.

## CRedit authorship contribution statement

**Nannan Wang:** Project administration. **Kun Wang:** Formal analysis. **Xinyu Lu:** Funding acquisition. **Shuyu Zhang:** Data curation. **Xuhan Sun:** Data curation. **Yuxi Zhang:** Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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