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Development and feasibility of culturally sensitive family-oriented dignity therapy for Chinese patients with lung cancer undergoing chemotherapy



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ABSTRACT

Objective: It is well-documented in the literature that dignity therapy is feasible and effectively improves the end-of-life experience of the terminally ill. In a similar vein, this study aimed to develop and investigate the feasibility of evidence-based and culturally sensitive family-oriented dignity therapy for Chinese patients with lung cancer undergoing chemotherapy.

Methods: Three phases of the Medical Research Council framework were adopted to guide the development of the novel dignity therapy intervention. It was preliminarily designed based on a qualitative study and a systematic review, Erikson's eighth stage of psychosocial development, and the dignity model. The feasibility and acceptability of the intervention were examined in a pilot randomized controlled trial with 12 recruited dyads of patients and family caregivers.

Results: The intervention consists of three face-to-face sessions that facilitate participants' reminiscences and promote their communication. Recruitment and response rates for the feasibility study of the intervention were 92.3% and 75%, respectively. Both patients and family caregivers reported that the intervention alleviated their psychological distress and improved communication.

Conclusions: The Medical Research Council framework serves as a useful scientific basis for modifying dignity therapy with a culturally sensitive approach. The results of the feasibility study suggest that the family-oriented dignity therapy intervention is feasible, acceptable and has the potential to enhance the effects of dignity therapy.

Introduction

Lung cancer is the leading cause of cancer death worldwide and caused approximately 1.8 million deaths in 2020. The majority of patients with lung cancer is diagnosed at stage III or IV and has an overall survival rate of 9.5%–16.8%. Chemotherapy is the use of one or more cytotoxic drugs to disrupt the basic processes of cancer cells to reduce symptoms and prolong life. It is the mainstay adjuvant treatment to prolong survival for lung cancer patients, whether diagnosed in early or advanced stages. However, the prognosis for lung cancer is often poor because of late diagnosis, the age of patients, the presence of comorbidities, and limited therapeutic options. Moreover, patients with lung cancer also often experience high levels of physical and psychological distress due to various adverse effects and long-term sequelae, such as fatigue, hair loss, nausea, vomiting, and depression, which remain great challenges for them and their healthcare providers. ^{4,5}

Within the context of nursing care, dignity is connected to patients' ability to follow their own standards and values; these can be threatened by various problems, such as social factors and deteriorating health. Dignity is therefore a salient concern as patients approach their death. Studies have shown that there is a strong association between an undermined sense of dignity and a desire for death, and depression, anxiety, hopelessness, the feeling of being a burden, and overall poor quality of life. The Extensive attention must therefore be paid to conserve patients' sense of dignity.

Dignity therapy is traditionally an individually oriented psychosocial intervention to facilitate reminiscence and produce a legacy document to enhance the dignity and improve the end-of-life experience for patients with terminal cancer. It was originally based on the dignity model, a framework for interpreting factors that affect an individual's dignity. It is well-documented in the literature that this therapy is feasible and its effects are promising for decreasing patients' dignity-related and

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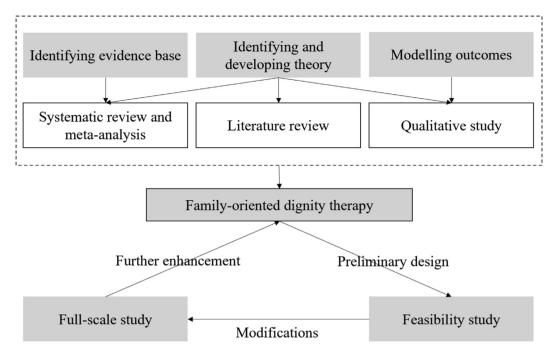


Fig. 1. The development procedure of the family-oriented dignity therapy followed the Medical Research Council framework.

psychological distress. ¹⁰ However, the dignity model and dignity therapy were developed from the perspective of patients with terminal cancer in Canada. Cultural discrepancies between Canada and other countries, such as China, may impair the effectiveness of the therapy. ¹¹ Specifically, in China, the family rather than the individual is seen as the basic unit of life. ¹² Family is often the fundamental source of social, economic, and emotional support for patients, and thus may also have an impact on patients' dignity perception. Therefore, modifications to the original model of dignity therapy are necessary to make it culturally appropriate for Chinese patients.

Dignity therapy is considered a complex intervention because it has several components requiring the active participation of patients and facilitators. A scientific framework is helpful in modifying or developing such a complex intervention to make it evidence-based and culturally relevant to other countries. In 2000, the Medical Research Council (MRC) published a framework, which was updated in 2008, ¹³ to enable researchers to recognize and adopt appropriate methods for developing and evaluating a complex intervention. However, there is a dearth of detailed descriptions of such complex interventions and their development in the literature, hindering efforts to replicate and validate them. ¹⁴ Therefore, this study had the following two aims.

- To describe the development of an evidence-based, theory-driven, and culturally sensitive family-oriented dignity therapy (FDT) to enhance the sense of dignity and decrease the psychological distress of patients with lung cancer undergoing chemotherapy.
- To report the feasibility and acceptability of the FDT in a study population.

Methods

The development process

To develop a complex intervention guided by the MRC framework, the following three stages are required: (1) identification of the evidence base; (2) identification and development of a theory; and (3) modeling of the outcome determinants for intervention components. A description of how each stage of the FDT's design was conducted is presented below (Fig. 1).

Identification of the evidence base

A systematic review was conducted to summarize the dignity therapy and evaluate its effects. Ten articles describing eight studies were analyzed. The reminiscence session and the 'legacy' (a written product based on the content of the reminiscence) were the main intervention components of dignity therapy. The dignity therapy question protocol, originally designed by Chochinov et al, was used to guide the reminiscence process. ¹⁵ This intervention was offered at the patient's bedside or in a private room. In each case, the reminiscence lasted for approximately 1 h and was audio-recorded. Transcripts were generated and edited to provide a clear and readable legacy document. The final-edited transcripts were returned to the patients as soon as possible (typically within four working days).

Although the results of the systematic review indicated that the dignity therapy had equivocal effects on dignity-related distress, the dignity therapy was shown to have a promising effect on patients' end-of-life experiences in terms of decreasing psychological and spiritual distress. The review also suggested that modifications of the therapy were needed to fit the perspective of a local population and enhance its effects. ¹⁶

Identification and development of the theory

During this stage, a theoretical understanding of the likely intervention process of changes was developed. Relevant theories likely to result in effective interventions, such as the eighth stage of Erikson's theory of psychosocial development (EESPD) and the dignity model were identified through a literature review. The EESPD suggests that older people or patients with life-threatening diseases such as lung cancer may experience psychosocial crises due to ego integrity clashing with despair. Reminiscence is an important developmental task for patients to perform to allow them to manage such crises, and it serves them well throughout the remainder of their lives. Satisfactory reminiscence helps a person accept their life, integrate memories into a meaningful whole, and develop a harmonious view of the past, present, and future. 19,20

The dignity model was developed from qualitative research on patients with terminal cancer and provides a way to understand how patients with cancer perceive dignity. The model illustrates that the factors influencing dignity can be divided into three categories: illness-related concerns, dignity-conserving repertoire, and social dignity inventory. It further proposes that burdensome illness-related concerns and a taxing

social dignity inventory have negative effects on dignity, which can be mitigated by a positive dignity-conserving repertoire. The model illustrates the relationships between the factors and indicates that psychosocial interventions can enhance dignity by carefully managing these factors. Our team has adapted the model to Chinese culture.²¹ More details about the modifications to the dignity model are provided in Section 2.1.3.

The EESPD provides the theoretical basis of the intervention: that reminiscence is an important developmental task for addressing psychosocial crises when patients face life-threatening diseases, such as lung cancer. The dignity model forms the empirical foundation of the intervention regarding the reminiscence content. Positive and satisfactory reminiscence is expected to help patients achieve ego integrity, which was measured in the current study using psychosocial variables such as dignity-related distress, depression, spiritual well-being, and life satisfaction.

Modeling outcome determinants for intervention components

To describe the dignity perception of patients with cancer and to provide insights into the promotion of dignity therapy in China, our team conducted a qualitative study of 20 patients with cancer using face-toface, semi-structured, and individual interviews.²¹ The dignity model was used to guide the qualitative interviews and data analysis, and the results of the qualitative study also helped to adapt the model for Chinese culture. Similarities and discrepancies between our qualitative research findings and the dignity model were analyzed. As in the dignity model, the qualitative study found that patients' sense of dignity is related to factors in the categories of illness-related concerns, dignity-conserving repertoire, and social dignity inventory. In addition, one new theme was identified: the importance of family communication and cultural collectivism. ²¹ The results suggest methods for the adaptation of dignity therapy for Chinese culture. That is, because family caregivers are expected to support patients in achieving positive and satisfactory reminiscence and improving their psychosocial well-being, it is recommended that these caregivers are involved in the intervention, especially the reminiscence process, to promote communication and enhance patients' dignity.

Description of the FDT

The results of the qualitative study suggest that in China, family is one of the most important concerns related to patients' dignity. Thus, clinicians must consider the family as an integrated and functional unit that can deliver the dignity therapy. Therefore, this study modified the dignity therapy into a family-oriented form and developed the FDT based on the systematic review, EESPD, the dignity model, and qualitative study. To promote the development and implementation of the FDT, its components, design, and delivery are clearly described below.

$Components\ of\ the\ FDT\ intervention$

The major components of the new FDT intervention are reminiscence and a spiritual diary. The intervention components and related rationale are summarized in Table 1.

Reminiscence. Helping patients achieve positive and satisfactory reminiscence is the most important component of the FDT intervention. We adopted the protocol originally designed by Chochinov for the current study, 9 as our previous qualitative study on dignity perception showed that patients with cancer and who were undergoing chemotherapy in mainland China reported the major themes and subthemes in the dignity model. The protocol was translated by two native speakers of Chinese who have a good command of English. Disagreements were solved by discussion with a third translator. The translated version was sent to two experts in oncology and psychology to assess the appropriateness of the content and tone. Subsequently, a pilot interview with two patients with lung cancer undergoing chemotherapy was carried out to check the comprehensibility and appropriateness of the Chinese version of the protocol.

Table 1The intervention components and related rationales.

Intervention components	Rationales
Reminiscence	
Strategy of reminiscence	 Reminiscence is the most important developmental task for patients with life- threatening disease when facing psychosocial crisis (based on EESPD).
	Reminiscence is the common strategy used in psychosocial interventions in addressing existential distress (based on the literature review).
Reminiscence contents: dignity therapy question protocol	 The dignity therapy question protocol covers the issues of dignity-related factors illustrated in the dignity model.
	Systematic review showed that the dignity therapy question protocol used in the dignity therapy had promising effects on dignity, depression, spiritual well-being and life satisfaction.
Reminiscence by patients and family caregivers	 Qualitative study indicates that it is necessary to address the family culture and communication openness when promoting dignity, family-oriented approach is more appropriate for patients in mainland China.
Spiritual Diary (Named as 'Legacy' in the dignity therapy)	 Offering a product which will extend the patients' influence across time or transcend the death (based on the dignity model to meet patients' legacy needs).
	Reinforce the communication between patients and family caregivers in the sharing session revealed in the qualitative study.

EESPD, the eighth stage of Erikson's theory of psychosocial development.

Our previous qualitative study on patients' dignity perception indicated that openness of communication between patients and their family caregivers was important for decreasing patients' feelings of isolation and helplessness in their fight against cancer. Therefore, in the FDT intervention, patients identified one significant family caregiver to reinforce communication between patients and family caregivers by promoting understanding and emotional expression. The questions for family caregivers were drawn from the dignity therapy question protocol, allowing family caregivers to speak on issues related to a patient's achievements, lessons they had learned from the patient, or other issues they wanted to express to the patients. By prior arrangements, patients and family caregivers sit together during the reminiscence process to expand their memories of the same issues and promote their understanding of each other.

Spiritual diary

The reminiscence process is recorded, transcribed, edited, and then returned to the patients and family caregivers to read and check before a final version, the Spiritual Diary, is produced (this name was revised after the end of the feasibility study). The Spiritual Diary is produced according to the dignity model to meet patients' needs for leaving something lasting, which will extend their influence across time or transcend death. The Spiritual Diary also serves as a mediating tool that patients and family caregivers can use to share their feelings and thoughts, and to reinforce communication and emotional expression between them.

The first author of this study, a registered nurse who received dignity therapy training, completed the Spiritual Diary editing. The training was organized by Professor Harvey Max Chochinov, the author who developed the dignity model and dignity therapy. Training included group teaching on the theoretical basis, a dignity therapy demonstration, Spiritual Diary editing, and simulation exercises. Transcript editing includes the following aspects: (1) basic clarifications to eliminate colloquialisms and portions of the transcript not related to dignity conservation; (2) chronological corrections; and (3) discussion with patients followed by tagging and editing of content that may inflict significant harm or suffering upon patients.

Design of the intervention

Dosage of the intervention. There were two sessions in the original dignity therapy approach: a first session to explain the purpose and procedure of the intervention, and a second session to provide patients with the opportunity to recall past events. However, the results of our qualitative study suggest that reinforcement of communication and emotional expression between patients and family caregivers was also important to promote a sense of dignity. Therefore, an additional sharing session was added into the FDT model, to allow patients and family caregivers to express their feelings and thoughts after reading the Spiritual Diary.

Format of the intervention. As suggested by the literature and a systematic review, the reminiscence process was organized by the facilitator into a face-to-face format. Face-to-face conversation helps build a trusting relationship between a facilitator and participants, enabling participants to recall events and express their feelings freely. The facilitator can also express support and care for participants during the reminiscence process, thereby cultivating a sense of respect, understanding, and comfort. To protect patients' privacy, each session is designed for one patient and his/her family caregivers rather than as a group intervention. This format was influenced by subthemes of the social dignity inventory in the dignity model, such as privacy and social support.

Intervention delivery. The intervention, guided by the development phase of the MRC framework, consists of three face-to-face sessions organized by the intervention facilitator. The explanation session introduces and explains the intervention process. The reminiscence session, held 1 day after the first session, prompts patients and their family caregivers to recall memorable events in the patients' lives based on the dignity therapy protocol. This session is audio-recorded, and the recording is transcribed. The final product that is elaborated from the reminiscence transcript is ultimately given to the patient after an edited version is sent to patients and family caregivers to check for any mistakes or inappropriateness. In the final sharing session, the facilitator arranges for patients and family caregivers to share their feelings and thoughts (Table 2).

Feasibility study

A single-blinded randomized controlled trial was conducted to examine the feasibility and acceptability of providing a FDT intervention for patients with lung cancer undergoing chemotherapy. Eligible patients and their family caregivers were recruited and randomly allocated to the intervention or control group. It was assumed that a full-scale study would involve a total of 112 dyads consisting of patients and their family caregivers, based on a common effect size for the psychosocial intervention of 0.60, a level of significance of 0.05, a statistical power of 0.8, and an attrition rate of 20%. Accordingly, 10% (at least 11 dyads) of a full-scale study sample size was required for a feasibility study.

 Table 2

 Summary of the delivery process of the family-oriented dignity therapy.

Sessions	Date	Contents
Explanation session	Day 1	An explanation for the intervention development and study process Providing the dignity therapy question protocol
Reminiscence session	Day 2	Reminiscence by patients and family caregivers simultaneously Audio-recorded
		Recording was transcribed and edited Spiritual Diary returned to patients after 24 h
Sharing session	Day 5 or 6	Reflect on their feelings towards to the reminiscence process and Spiritual Diary
		Read and share or express their feelings and thoughts to each other

Participants

Patients who satisfied all of the following inclusion criteria were invited to participate in the study: (1) adult patients diagnosed with lung cancer and undergoing chemotherapy; (2) those who were aware of their cancer diagnosis; (3) those who could identify one significant family caregiver with whom they could receive the intervention; and (4) those could read and communicate in Chinese (Mandarin). Patients were excluded if they met the following exclusion criteria: (1) patients and/or family caregivers with cognitive impairment (i.e., dementia), as determined by a physician; (2) patients and/or family caregivers diagnosed with psychiatric illness; (3) those who were currently participating in other psychosocial intervention studies; or (4) patients and/or family caregivers who were too ill to participate in the study as determined by a physician.

Intervention

The participants in the intervention group received the FDT and usual care. The participants in the control group received attention control, a condition mimicking the treatment intervention to balance the Hawthorne and placebo effects. Aside from the usual care offered by the hospital, patients in the control group received three attention contacts similar in timeline and duration but different in content to the contacts with those in the intervention group. The first contact was on the first day of hospital admission, and patients and family caregivers were informed of the time and contents of the second contact. In the second contact, a research assistant delivered a health education session on chemotherapy, including preparation before treatment, common side effects of chemotherapy, and management strategies. The third contact included a health education session on nutrition and daily life after discharge. The contents of the health education session were covered in the usual care that patients in both groups could obtain from their nurses.

Outcomes

The outcomes of the feasibility study indicate the feasibility and acceptability of the FDT intervention.

The feasibility of the intervention was evaluated in terms of the response rate (the percentage of eligible patients who agreed to participate), the completion rate (the percentage of participants who completed the intervention), and data collection procedures. In addition to sociodemographic data on the patients and family caregivers, information was also collected on patients' dignity-related distress, depression, and spiritual well-being, using The Patient Dignity Inventory, Patient Health Questionnaire-9, and Functional Assessment of Chronic Illness Therapy—Spiritual Well-being, respectively. These tools are reliable and appropriate for evaluating the effects of the intervention, as was demonstrated in our previous systematic review. ¹⁶

The acceptability of the intervention was mainly evaluated using a qualitative method. Qualitative interviews were conducted after the completion of FDT to obtain participants' perceptions of the intervention. Content analysis was used to analyze the qualitative data based on the research aims of identifying participants' perceptions of the benefits and harms of the intervention, satisfaction with the intervention, and suggestions for the intervention.

Results

Characteristics of participants

The characteristics of the patients and their family caregivers are summarized in Tables 3 and 4. The mean age of the patients was 50.17 years (SD = 7.04). All patients were married and comprised a balance of men and women. The mean age of the family caregivers was 50.05 years (SD = 8.16).

Outcome variables

The mean scores of the outcome variables at baseline and after the completion of the intervention are shown in Table 5. The mean scores for

Table 3 Sociodemographic and clinical variables of patients (n = 12).

Characteristics	Mean (SD)	N (%)
Age (years)	50.17 (7.04)	
Gender		
Female		6 (50.0)
Male		6 (50.0)
Marital status		
Married		12 (100)
Single/divorced/widow		0
Education level		
Primary school or less		0
Junior high school		4 (33.3)
Senior high school or above		8 (66.7)
Primary caregiver		
Spouse		9 (75.0)
Children		2 (16.7)
Others		1 (8.3)
Income		
< 1000 RMB (USD 140)		5 (41.7)
(1000-3000 RMB) (USD 140-420)		3 (25.0)
> 3000 RMB (USD 420)		4 (33.3)
Insurance		
NRCMI		8 (66.7)
BMIUW		3 (25.0)
BMIUR		1 (8.3)
Others		0
Chemotherapy time		
< 2 months		4 (33.3)
≥ 2 months		8 (66.7)

NRCMI, New Rural Cooperative Medical Insurance refers to the peasant medical mutual assistant system that is guided and supported by the government and voluntarily participated by peasant; BMIUW, Basic Medical Insurance for Urban Workers a social insurance system to compensate workers for economic losses due to disease risks; BMIUR, Basic Medical Insurance for Urban Residents is the medical insurance system for the unban minors and unemployed residents who did not participate in the BMIUW; USD, The United Stated Dollars.

dignity-related distress and depression decreased over the course of the study, while the mean scores for a spiritual well-being increased.

Feasibility of the study

Thirteen eligible patients were approached, and 12 agreed to participate, equating to a response rate of 92.3%. One patient refused to participate in the study due to a lack of interest. During the feasibility study, three dyads failed to complete the intervention, as two patients had physical limitations, and one family caregiver had no time. Thus, only five dyads completed the intervention, and four dyads completed the control treatment. The completion rate was 75%. Data were collected via a face-to-face interview over 5–25 min.

 $\label{eq:table 4} \textbf{Social-demographic and clinical characteristics of family caregivers (n=12)}.$

Characteristics	Mean (SD)	N (%)
Age (years)	50.05 (8.16)	
Gender		
Female		6 (50.0)
Male		6 (50.0)
Education level		
Primary school or less		0 (0)
Junior high school		6 (50.0)
Senior high school		6 (50.0)
Income		
< 1000 RMB (USD 140)		4 (33.3)
(1000-3000 RMB) (USD140-420)		3 (25.0)
> 3000 RMB (USD 420)		5 (41.7)

USD. The United Stated Dollars.

Table 5Outcome variables at baseline and after the completion of the intervention.

Outcome variables	Baseline $(n = 12)$	After the completion of the intervention $(n = 9)$	
	Mean (SD)	Mean (SD)	
Dignity-related distress Depression Spiritual well-being	34.25 (7.29) 4.75 (3.55) 35.0 (11.72)	33.67 (12.35) 4.56 (4.07) 38.56 (11.29)	

SD, Standard deviation.

Acceptability of the study

There were five dyads of patients and family caregivers in the intervention group; one patient declined to participate in the interviews due to physical limitations, and two family caregivers declined due to time limitations. The total sample therefore included four patients and three family caregivers. Four themes were identified after content analysis: perceived benefits, perceived harms, satisfaction with the intervention, and suggestions for improvement (Table 6).

Perceived benefits

The perceived benefits reported by the participants included the alleviation psychosocial distress and the improvement of family relationships. Both patients and family caregivers agreed that the intervention helped them manage their pessimism. Two family caregivers thought the intervention helped alleviate patients' psychological burden. Three patients reported that the intervention helped them find meaning in life.

Both patients and family caregivers reported that the intervention improved family relationships by promoting communication and understanding. One family caregiver reported that "it was a good opportunity to share our thoughts, as we seldom talk about these matters. The document is a wonderful way to record our cherished memories".

Harm

One patient reported that it was unpleasant when the intervention facilitator asked about the dreams and hopes of her family. "I am fine now, despite the cancer, but being asked [that question] was like being asked to [write my] will". No harm was reported by the family caregivers.

Satisfaction

All of the patients and family caregivers were satisfied with the intervention. Five participants reported that they were willing to participate in FDT in the future and to recommend the intervention to others.

Suggestions for improvement

Suggestions were made on how to improve the interview questions and the documents of the intervention. One patient suggested that cues were provided when asking questions about important memories, such as identifying points in time during childhood, before getting married, after the birth of a baby, and after retiring. Another patient suggested that instead of asking patients about their hopes or dreams for their family, we should ask "How do you think about your loved ones at present or in the future?" and "What do you expect from your loved ones?". Suggestions for the legacy document included those regarding the name of the document. The document was originally named "life memoir," which a patient said made her feel unhappy; that is, as if she was in her last days. One family caregiver suggested that it would be useful to add some disease information and health education to the document.

Discussion

This study used the MRC framework to develop a culturally sensitive FDT with a rigorous methodology to ensure its effectiveness and cultural

Table 6Feedback from patients and family caregivers after completion of the intervention.

Themes and subthemes	s	Patients $(n = 4)$	Family caregivers $(n = 3)$
Perceived benefits	Alleviating psychosocial distress	Regulate emotion	Alleviate patients' psychological burden
		Find the life meaning	 Regulate emotion
	Improving family relationship	Improve the relationship	 Help to record cherish memory
		 Promote communication 	 Improve the relationship
		Promote understanding	 Promote communication
Harm		 One question asked patients' dream and hope to their family, the sentence may trigger negative feelings related to testament and death 	No harm
Suggestions		 Provide clues when asking important memories Revise one question in a more comfortable way Recommend the document to be concise with less words 	Add some disease information and health education
Satisfaction		Satisfied with the procedureWilling to choose againWilling to recommend to others	Satisfied with the procedureWilling to choose againWilling to recommend to others

suitability to a Chinese context. Thus, it is an exemplar of the adoption of the MRC framework for developing dignity therapy and promoting psychosocial well-being in patients with lung cancer and undergoing chemotherapy. The feasibility study revealed that the family-oriented approach is feasible and acceptable in the Chinese context. The qualitative data also indicated that the intervention has the potential to alleviate the psychological distress of both patients and family caregivers.

The rigor and efficacy of the FDT were enhanced by following the MRC framework for the complex intervention development. In compliance with the MRC framework, the FDT was designed systematically and scientifically using the best available evidence on dignity therapy, in terms of effective intervention components, sessions, the delivery modality, and the characteristics required for an intervention facilitator. In the theory development process, the EESPD and the dignity model were integrated to guide the intervention strategy of reminiscence and the details of the dignity therapy question protocol. The adoption of the MRC framework also ensured that there was a strong relationship between the outcome and the outcome determinants for a target population and practical environment. 21 A qualitative study on Chinese patients' dignity perception was conducted to identify factors affecting patients' dignity, which showed that good communication between patients and family caregivers enhanced patients' sense of dignity.²¹ By integrating the results of the systematic review, theory, and the qualitative study, the dignity therapy modified to have a family-oriented approach is likely to enhance dignity and improve psychological and spiritual well-being for patients with lung cancer undergoing chemotherapy.

The feasibility study showed that the FDT was feasible and was acceptable to Chinese patients. The reasons for attrition were mainly related to the side effects caused by the chemotherapy and the time commitment required from family caregivers. However, the attrition rate was nevertheless acceptable, as the patients were experiencing chemotherapy treatments. Although one participant was advised to revise the expression of some interview questions, all of the patients and family caregivers were satisfied with the intervention. Moreover, more than half of the patients and family caregivers expressed willingness to participate in such an intervention in the future and to recommend the intervention to others.

Statistical analysis was not performed due to the small sample size, but the qualitative comments on the intervention indicated that the FDT has the potential to alleviate dignity-related psychological and spiritual distress. The qualitative interviews showed that family caregivers also benefited from the intervention, as it helped to alleviate their psychological distress. This was because the intervention provided family caregivers with opportunities to disclose their true feelings and thus release emotional pressure. Similar findings have been observed in other studies, in which family-involved dignity therapy positively affected family caregivers, such as by improving family cohesion and alleviating psychological distress. ^{22,23} Future studies are

recommended to further capture the effects of the intervention on family caregivers, especially effects on their communication and psychological well-being.

The suggestions provided by the patients and family caregivers will be adopted to improve the intervention. First, revisions will be made to the dignity therapy question protocol. Cues regarding timepoints will be provided as supplements when asking patients to describe their important memories. In additions, the wording of a question about patients' hopes or dreams will be revised to provide more guidance to patients. Second, due to possible changes in discharge arrangements, the time of the reminiscence session will be decided before clarifying discharge arrangements with hospital staff. Specifically, the reminiscence sessions should be held at least 2 days before discharge, so that the participants can receive their transcripts and participate in the sharing session before their discharge date. Third, "Spiritual Diary" might be a better choice for the name of the legacy document, as it fits the intent of the reminiscence and is less likely to induce negative feelings in the participants than the name "life memoir." These suggestions will support the development of a full-scale trial of the FDT intervention in China and in other countries with similar cultures and contexts.

The MRC framework strongly recommends the use of process evaluation to obtain essential knowledge on process changes that should be made in future studies. ²⁴ A process-focused evaluation using both quantitative and qualitative approaches could be used to examine the FDT intervention's fidelity, supplement the interpretation of the FDT intervention's effectiveness, and help explain why FDT works. ²⁵ Quantitative analysis of the characteristics will offer guidance on what kinds of participants will respond best to the intervention. Qualitative data will provide information on contextual factors that may affect the intervention's implementation, which can support iterative modifications of the FDT for successful delivery in nursing practice.

Limitations and implications

The study has some limitations. Although a small sample size is acceptable for a feasibility study to test a procedure, only five dyads were recruited in the qualitative interview after the completion of the intervention, which may have limited our exploration of participants' perceptions of the FDT. Hence, the perceived benefits reported by patients and family members may not be definitive. In addition, the FDT model was modified based on a qualitative study of patients in Southern China, and therefore, the intervention may not be generalizable to the cultural contexts in other areas and countries.

However, our study has research and practical significance. First, the development process for FDT provides template for future research on the application dignity therapy in other parts of the world. Second, given the paucity of psychosocial interventions to address dignity-related distress in modern nursing care, this study develops and enriches dignity-

conserving knowledge to guide clinical practice. If the FDT is confirmed to be effective, it could be applied in nursing practice to promote therapeutic communication between nurses, patients, and family caregivers and to improve satisfaction with hospital and nursing care.

Conclusions

The extended and stepwise procedure of the MRC framework was used to develop evidence-based and culturally sensitive FDT to promote the psychosocial well-being of patients with lung cancer undergoing chemotherapy. The FDT consists of three face-to-face sessions to promote reminiscence by and communication between patients and their family caregivers. This feasibility study suggests that the FDT intervention is feasible, acceptable, and has the potential to enhance the effects of dignity therapy. This article helps to fill the research gap on complex intervention development. It is also expected to contribute to current knowledge of dignity-conserving care for patients with lung cancer undergoing chemotherapy.

Author contributions

Conceived and designed the analysis: Jinnan Xiao, Ka Ming Chow, Carmen WH Chan; Collected the data: Jinnan Xiao; Contributed data or analysis tools: Jinnan Xiao; Performed the analysis: Jinnan Xiao; Wrote the paper: Jinnan Xiao, Siyuan Tang, Ka Ming Chow, Carmen WH Chan.

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Declaration of competing interest

None declared.

Ethics statement

All procedures performed in studies involving human participants were following the ethical standards of the institutional and/or national research committee (University Survey and Behavioral Research Ethics Committee: SBREC 105-18, the Joint Chinese University of Hong Kong-New Territories East Clinical Research Ethics Committee: No. 2018.400 and the ethical committee of Xiangya Nursing School of Central South University: No. 2018017) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consents were obtained from all individual participants included in the study.

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