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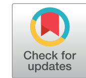
Original Article

Development of a dyadic mindfulness self-compassion intervention for patients with lung cancer and their family caregivers: A multi-method study



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ABSTRACT

Objective: Lung cancer and its prolonged treatment are profoundly unsettling for patients and their family caregivers, and developing dyadic measures to alleviate their negative affectivity is pivotal. This study aimed to develop a complex intervention to alleviate dyadic psychological stress among patients with lung cancer and their family caregivers.

Methods: A stepwise multi-method study was conducted following the Medical Research Council framework. Three phases were adopted, namely: (1) a preparation phase, a systematic review was conducted to identify the evidence base, (2) a development phase, empirical data from a quantitative study and a qualitative study were integrated to identify effective components, and (3) a modification phase, an online Delphi survey was carried out to refine the intervention.

Results: The dyadic Mindfulness Self-Compassion intervention developed in this study consists of six weekly sessions. The key components of the intervention include: (1) getting along with cancer (introductory session targets illness perception), (2) practising mindful awareness (core session for mindfulness), (3) defining dyadic relationships and introducing self-compassion (core session for self-compassion), (4) promoting dyadic communication (maintenance session targets communication skills), (5) promoting dyadic coping (maintenance session targets coping skills), and (6) a summary session reviewing the rewards and challenges of dyadic adaptation named embracing the future.

Conclusions: An evidence-based, theory-driven, and culturally appropriate dyadic Mindfulness Self-Compassion intervention was developed for patients with lung cancer and their family caregivers. Future studies are warranted to pilot and evaluate the usability, feasibility, acceptability, satisfaction, and effectiveness of this complex intervention.

Trial registration: ClinicalTrial.gov NCT04795700.

Introduction

Lung cancer is one of the most common cancers worldwide, with 2.2 million new cases accounting for 11.4% of all new cancer cases.[1] As the leading cause of cancer death (1.8 million deaths, 18% of all cancer mortality for 36 cancers in 185 countries),[1] lung cancer and its prolonged treatment are profoundly unsettling for patients and their family caregivers. Compared with patients who have other cancers, patients with lung cancer have reported worse mental health, significant psychological distress, and a poorer quality of life[2–4] because of the long-term nature and multiple, intensive, and ongoing pressure of this life-threatening disease.[5] The prevalence of anxiety and depressive symptoms among patients with lung cancer are 20.9% to 43.5% and 38.9% to 57.1%, respectively.[6,7] Meanwhile, the family caregivers of

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patients with lung cancer, usually the patients' spouse, children, parents, or other family members, play a crucial role in the complex treatment process by providing patients with direct support in daily difficulties, addressing medical needs, as well as providing emotional, spiritual, and financial support.[8] Previous research indicates that family caregivers of patients with lung cancer show maladaptive behaviours and suffer from challenges in life status and social functioning; nearly half of caregivers reported significant anxiety, depressive symptoms, and psychological distress.[9,10] Given that anxiety and depressive symptoms, the most commonly unmet needs of patients with lung cancer and their caregivers,[11] are strongly associated with their quality of life,[12] the development of dyadic measures to alleviate negative affectivity in these patients and their caregivers is pivotal to improving both patient and caregiver well-being.

Evidence shows that mindfulness and self-compassion are prominent factors of positive psychology that play important roles in maintaining emotional stability and generating a sense of well-being when individuals face stress.[13] Mindfulness is a cognitive skill that aims to help individuals pay attention to the present moment consciously and non-judgmentally with an open, curious, and accepting attitude.[14] The concept of self-compassion, introduced by Neff,[15] refers to an emotional coping strategy in which individuals maintain a clear awareness of negative affectivity when facing painful situations; understand, care for and accept their deficiencies; and then transform negative emotions into positive attitudes.[16] In general, mindfulness focuses on the broad experience of all things, whereas self-compassion emphasizes the self-experience of suffering and pain.[17] As two positive factors with synergistic effects,[15] mindfulness and self-compassion are both protective factors for the mental health of cancer patients that can enhance psychological strength and help them develop self-efficacy and are negatively correlated with negative affectivity, such as anxiety and depressive symptoms.[18,19] Overall, mindfulness and self-compassion are critical in the emotion regulation, and interventions targeting these two factors are expected to be effective by promoting psychologically adaptive emotion regulation, which may be of particular benefit to patients with lung cancer as well as their caregivers who are suffering from significant psychological stress.

Most of the research on psychological stress in the field of lung cancer has explored the coping and adaptation of patients with lung cancer or caregivers at the individual level,[3,4,8,9] with relatively few studies of dyadic coping that have focused on both patients with lung cancer and their caregivers. In addition, developing dyadic interventions for patients with lung cancer and their caregivers is still at an exploratory stage because most existing studies involving dyadic interventions have focused on female patients with breast cancer;[20,21] thus, there remains a gap concerning the applicability and transferability of intervention content because of differences in gender ratios and social roles. Mindfulness Self-Compassion (MSC) training has emerged as a promising health-related stress management approach for patients with cancer or for caregivers alone.[22–24] MSC training, developed by Neff and Germer,[25,26] is based on mindfulness-based stress reduction therapy and covers the component of self-compassion. The training has been demonstrated to be effective in promoting psychological well-being and decreasing negative affectivity,[26,27] indicating its theoretical feasibility for lung cancer patients and caregivers. However, MSC training has not yet been applied in dyads that include patients with cancer and their caregivers, and further development targeting lung cancer is needed.

To address these research gaps, we developed a dyadic MSC (D-MSC) intervention for patients with lung cancer and their family caregivers following the guidance of the Medical Research Council (MRC) framework for developing and evaluating complex interventions.[28,29] The D-MSC intervention in this study was initiated to facilitate dyadic coping and alleviate dyadic psychological stress among patients with lung cancer and their caregivers. During the treatment and recovery process of patients with lung cancer, help and support from caregivers are indispensable to patients, and caregivers also need the cooperation and understanding of patients to facilitate disease management. Therefore, the Theory of Dyadic Illness Management may provide the conceptual underpinning for this dyadic process and complex phenomenon.[30] This theory defines disease management as a dyadic phenomenon in which patients and caregivers participate together, including the following three core elements: dyadic appraisal, dyadic management behaviours, and dyadic health.[30] In the context of this study, dyadic appraisal may refer to the illness perception among patients with lung cancer and their family caregivers. In addition, mindfulness, self-compassion, and dyadic coping among patients with lung cancer and their caregivers can constitute dyadic management behaviours, whereas dyadic health manifests as psychological stress, including anxiety and depressive symptoms, on both sides. Overall, the focus of the intervention developed in this study is on promoting cooperative interactions between patients with lung cancer and their family caregivers by changing dyadic appraisal and improving dyadic management behaviours, thereby promoting the health of the patient–caregiver dyads.

The aim of this study was to describe the process that led to the development of a complex intervention, the D-MSC intervention, to alleviate dyadic psychological stress among patients with lung cancer and their family caregivers, following the MRC framework. The overarching goal of our D-MSC intervention is to reduce the negative affectivity of patients with lung cancer and caregivers, such as anxiety and depressive symptoms, by promoting their mindfulness and self-compassion levels; guiding them to treat cancer, themselves, and each other with an open and friendly attitude; and improving patient–caregiver dyads' communication and coping skills.

Methods

We conducted a multi-method study to thoroughly examine the components of the developmental phase as outlined in the MRC framework for developing complex interventions.[28,29] First, we established a multidisciplinary intervention development team consisting of one psychology expert, one nursing management expert, one clinical oncology expert, two oncology nursing experts, and two research assistants with graduate education in clinical psychology. Moreover, we identified the evidence base, refined a comprehensive intervention framework and effective intervention components, and endeavoured to involve stakeholders at all levels to modify and finalize the D-MSC intervention for patients with lung cancer and their family caregivers. Specifically, the following stepwise process was carried out in this study: (1) a preparation phase, in which a systematic review was conducted to summarize the characteristics of dyadic interventions for patients with lung cancer and their caregivers, (2) a development phase, which included a quantitative study and a qualitative study to explore the dyadic psychological stress process among patients with lung cancer and their family caregivers on the basis of the Theory of Dyadic Illness Management. In addition, a first draft of the effective components and implementation plan was developed on the basis of these empirical results and combined with the original MSC training developed by Neff and Germer,[25,26] and (3) a modification phase, a Delphi survey was carried out to modify and reach a consensus on the D-MSC intervention. An overview of the different phases with the corresponding methodology in this study is presented in Fig. 1. This study was reported according to the GUIDance for rEporting intervention Development studies in health research (GUIDED) checklist.[31]

Preparation phase

Systematic review (I)

The aim of the systematic review in this phase was to summarize the design, content, implementation, and other characteristics of dyadic interventions for patients with lung cancer and their family caregivers to provide the evidence base for the D-MSC intervention. Eligible randomized controlled trials from six English-language databases (the

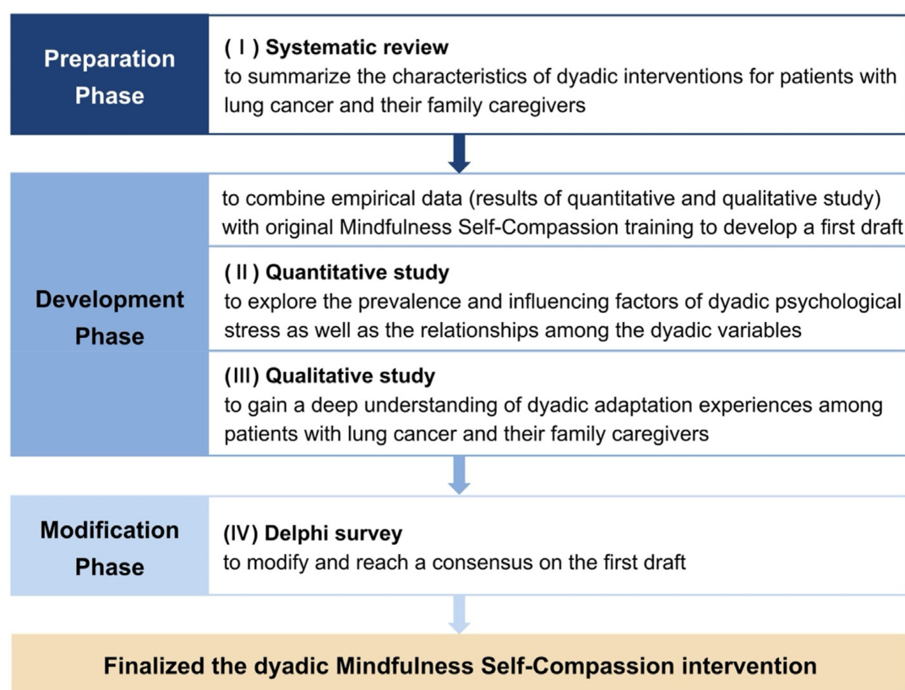

Fig. 1. The development process of the dyadic Mindfulness Self-Compassion intervention.

Cochrane Library, PubMed, Embase, CINAHL, and PsycINFO) and four Chinese-language databases (China National Knowledge Infrastructure, China Science and Technology Journal Database, Wanfang, and SinoMed) were searched from inception to November 2021. The search strategies used a combination of Medical Subject Heading terms and keywords, and the following constructs were applied: lung cancer AND patient AND caregiver AND psychological intervention. The intervention details (contents, approach, and duration) and outcome characteristics of the dyadic intervention were extracted and synthesized to provide evidence for the design of the D-MSC intervention.

Development phase

This phase focuses on gaining deep insight into the dyadic psychological stress process among patients with lung cancer and their family caregivers, as well as identifying effective intervention components. A sequential explanatory mixed-methods design consisting of a quantitative study and a qualitative study was carried out.[32] The initial draft of the D-MSC intervention components was then developed by combining the empirical data with the existing components of the original MSC training.

Quantitative study (II)

The quantitative study aimed to explore the prevalence and influencing factors of dyadic psychological stress among patients with lung cancer and their family caregivers. The relationships among these dyadic data were also examined to explore the underlying mechanism of the psychological stress process among patient–caregiver dyads.

Study design. This was a cross-sectional study.

Setting and participants. The study was conducted in the departments of thoracic surgery, respiratory medicine, oncology, and radiotherapy at four tertiary hospitals in Hunan Province, China, from January to June 2021. The study population included patients with lung cancer and their family caregivers who were both at least 18 years old and who voluntarily participated in the study. The caregivers were family members of the patient with lung cancer, such as his or her spouse, children, parents, or other relative (the inclusion and exclusion criteria are detailed in Supplementary file 1). A minimum sample size of 200 cases is recommended for structural equation modelling research.[33] Considering a 20% invalid response rate, the sample size in this part was calculated to be 250 patient–caregiver dyads.

Data collection. After obtaining signed informed consent forms from participants, the research assistants distributed and collected paper questionnaires in the department and explained the contents of the questionnaires to the patients and the family caregivers separately. Self-report data were collected from patients and family caregivers with respect to depressive symptoms, anxiety, illness perception, mindfulness, self-compassion, and dyadic coping using scales whose reliability and validity have been examined.

Data analysis. We used SPSS version 26.0 (IBM Corp, Armonk, New York) to conduct descriptive analysis, univariate analysis, correlation analysis, and multiple linear regression analysis to comprehensively determine the prevalence of anxiety and depression and its influencing factors in patients with lung cancer and their caregivers. The AMOS version 26.0 (IBM Corp, Armonk, New York) was employed to perform the actor-partner interdependence mediation model to examine the relationships among these dyadic variables.[34] A two-sided test $P < 0.05$ was considered statistically significant.

Qualitative study (III)

To describe the dyadic adaptation experiences among patients with lung cancer and their family caregivers, and to provide deep insight into their dyadic psychological stress process, we conducted a qualitative study of patient–caregiver dyads.

Study design. A qualitative study was conducted using an interpretative phenomenological approach.[35]

Participants. Purposive sampling was used to recruit patients with lung cancer and their family caregivers between July and August 2021. The inclusion and exclusion criteria for sample selection were consistent with

those of the quantitative study. Sampling sufficiency was achieved by means of the data saturation principle.[36]

Data collection. Semi-structured interviews with patients and their family caregivers were conducted on a one-on-one basis to ensure that the interviewees could express their personal views and opinions freely, without interference from others and, at the same time, during the COVID-19 epidemic, to reduce the risk of infection for the researchers and interviewees. The interview outline was developed through a process of collaborative discussions and repeated revisions by relevant experts. It included corresponding questions for both patients and their caregivers, such as "What changes have occurred in your life since your illness?" and "What changes have occurred in your life since taking care of the patients?" The interviews were conducted in person in a place of the participant's choice at a scheduled time. Each interview lasted approximately 30–45 minutes and was recorded with the participant's permission.

Data analysis. NVivo 12 software (2018; QSR International, Melbourne, Australia) was used to manage the in-depth interview data.[37] We analysed the transcripts systematically using Colaizzi's descriptive analysis framework.[38] Any disagreements were resolved by going back to the interview text and through discussion.

Integration of quantitative and qualitative data

The results of the quantitative study were grouped into key themes that correspond to dyadic variables. The interview data were then utilized to interpret the findings and enhance the understanding of the experiences of patient–caregiver dyads concerning these key components.

Modification phase

Delphi survey (IV)

The first draft of the implementation design and intervention components was reviewed and discussed by our multidisciplinary research team. The findings of this review were illustrated in an online Delphi survey[39] sent via email to external experts on clinical oncology, oncology nursing, psychology, and nursing management, who were recruited through purposive sampling from September to November 2021. The inclusion criteria for the experts were as follows: (1) had a master's degree or higher, (2) had at least five years of work or research experience in their field, (3) had a certain level of understanding and experience in oncology nursing, and (4) were willing to participate in the study and actively cooperate with multiple rounds of consultation. The experts were invited to provide comments or suggestions for further modifications and refinements of the D-MSC intervention.

Ethical considerations

Ethical approval was obtained from the Institutional Review Board of our university (IRB No. E202109) and the participating hospital (IRB No. 20210201). Prior to the questionnaire survey and interviews, written informed consent and recorded permission were obtained from all participants. Confidentiality was ensured through the protection of personal information, and all the data were used exclusively for academic purposes.

Results

Results - preparation phase

Systematic review (I)

Our systematic search resulted in 5181 articles; after duplicate removal and selection processes, ten[40–49] were eligible for summarizing the characteristics of dyadic interventions for patients with lung cancer and their family caregivers. The characteristics of the included studies and the main findings are detailed in Supplementary file 2. Table 1 summarizes the specific intervention characteristics of the 10 included trials and their application for the design of D-MSC intervention. In general, the D-MSC intervention in this study is planned to consist of six weekly sessions, each lasting 60–90 minutes. The intervention content will be developed on the basis of the Theory of Dyadic Illness Management and MSC training. The D-MSC intervention is to be delivered by researchers and trained research assistants with graduate education under the supervision of experts who are all licenced psychologists. Moreover, the usability, feasibility, acceptability, satisfaction, and effectiveness of the D-MSC intervention will be evaluated in a future pilot study with corresponding questionnaires and semi-structured interviews.

Results - development phase

A total of 300 questionnaires were distributed to patients with lung cancer and their family caregivers in the quantitative study, and 254 valid questionnaires were analysed, for a response rate of 84.7%. Moreover, 11 patients with cancer and nine caregivers participated in the interviews, of which seven patient–caregiver dyads were included. The main findings of the quantitative and qualitative studies are presented in Supplementary files 3 and 4, respectively, and the merged results of the quantitative and qualitative data are presented in Table 2.

The quantitative data and qualitative findings describe the dyadic adaptation process among patients with lung cancer and their family caregivers in a similar approach but enrich each other, and the results of these two parts can be integrated to guide the development of D-MSC intervention. On the basis of the Theory of Dyadic Illness Management, Fig. 2 shows the intervention framework for the D-MSC intervention by integrating the empirical data. The results of the quantitative study indicated that patients with lung cancer and their family caregivers experienced severe psychological stress responses, necessitating dyadic interventions to help them adapt to cancer. The quantitative study further explored the relationships among dyadic variables and revealed that mindfulness and self-compassion mediate the effect of dyadic appraisal on dyadic coping, which provides targets for dyadic interventions intended to alleviate the psychological stress responses of patients with lung cancer and their family caregivers. Moreover, the actor–partner interdependence mediation model revealed the underlying mechanism by which patients' illness perceptions, mindfulness, self-compassion, and dyadic coping all have interactive effects on caregivers' anxiety and depressive symptoms and vice versa (Fig. 2). Above all, these quantitative results informed the formulation of the intervention sessions and a logical sequence for the D-MSC intervention.

The qualitative study explored the dyadic adaptation experiences among patients with lung cancer and their family caregivers. The findings indicated that both patients and caregivers experienced positive and negative emotions, were impacted by a series of life changes, presented diverse communication patterns, demonstrated self-compassion behaviours, and adopted complex coping styles to adapt to cancer. With respect to the process of cancer treatment and care, both patients and caregivers summarized some of the rewards and challenges of dyadic adaptation to cancer. These key findings of the qualitative study confirmed that emotional and lifestyle changes on the part of both patients and their caregivers interact with and dynamically influence each other, supporting the quantitative results. It is worth noting that the qualitative findings supplement the characteristics and manifestations of communication patterns among patients with lung cancer and their family caregivers, highlighting the importance of dyadic communication. This further refines the intervention contents and suggests that dyadic communication is a crucial part of dyadic management behaviour. In addition, the emergent themes include the rewards and challenges of dyadic adaptation to cancer, providing a practical reference for stimulating participants' interest in the D-MSC intervention and improving their compliance. Meanwhile, it is recommended that the benefit finding of patients and caregivers should be added as an outcome when evaluating the effectiveness of the D-MSC intervention.

Table 1
The characteristics of dyadic interventions and their application.

Category	Characteristics	Application
Theoretical framework	Dyadic interventions for patients with lung cancer and their family caregivers were mostly developed based on stress and coping theory and mindfulness therapy	This study will develop a D-MSC intervention based on the theory of dyadic illness management and the original MSC training
Intervention contents	Most dyadic interventions were complex interventions containing multiple components, mainly including information support, skill development, marriage or family relationships, and psychoeducation	The intervention contents in this study will incorporate the MSC training developed by Neff and Germer • For dyadic appraisal (illness perception), the D-MSC intervention will provide informational support concerning the disease and treatment • For mindfulness and self-compassion, the D-MSC intervention will provide courses on practising mindfulness, discovering self-compassion, and practising loving-kindness • For dyadic communication, strategies represented by emotional self-disclosure will be provided • For dyadic coping, the D-MSC intervention will provide stress-coping techniques for both patients and caregivers • For rewards and challenges of dyadic adaptation to the illness, the D-MSC intervention will provide a review and summary of self-compassion techniques and guide patients and caregivers to embrace their life
Intervention providers	Most dyadic interventions were delivered by psychologists, psychotherapists, nurses, social workers, systematically trained instructors (such as mindfulness instructors), etc.	• The main interventionist of D-MSC intervention has obtained the qualification of psychological counselor and the completion certificate of a mindfulness course, who has extensive experience in mindfulness group training and has been conducting MSC training for about two years under supervision • The intervention team also included two research assistants with graduate education in clinical psychology or related fields and three oncology nurses • The interventions will be delivered under the supervision of two nursing professors, an MSC instructor, and a clinical management expert, who were all licensed psychologists
Intervention approach	The dyadic interventions were primarily delivered face-to-face and a combination of face-to-face sessions and telephone-based support. Some of the interventions were conducted through online websites or mobile applications	Considering that the implementation period is still affected by COVID-19, the D-MSC is intended to be delivered through a combination of face-to-face sessions and online support
Intervention duration and dose	• The dyadic interventions usually lasted for two to ten weeks and were conducted mostly in six or eight sessions, either weekly or bi-weekly. The duration of each session ranged from 30 to 150 minutes, with 30–45 minutes being the most common • The original MSC training indicates that the intervention usually lasts for six, eight, or ten weeks, once a week. Each session lasted for 45–90 minutes, with 15–30 minutes of home practice per day	The D-MSC will include a total of six weekly sessions, each session is about 60–90 minutes, with 15 minutes of home practice scheduled each day. In addition, the six sessions will be divided into two face-to-face sessions and four online conference sessions
Time points	The data was collected at baseline, at the end of intervention, and mainly two to 12 months post-intervention	The time points for data collection in the pilot study will be pre-intervention, post-intervention, and one-month follow-up
Intervention effects	Most dyadic interventions reported psychosocial outcomes for both patients and caregivers, including mental health, quality of life, dyadic relationships, etc.	This study will explore the effect of D-MSC intervention on improving anxiety, depression, illness perception, mindfulness, self-compass, dyadic communication, and dyadic coping in patients with lung cancer and their caregivers
Intervention evaluation	Previous studies mainly employed questionnaires and semi-structured interviews to assess the usability, feasibility, acceptability, and satisfaction of dyadic interventions	This study intends to evaluate the usability, feasibility, acceptability, and satisfaction of the D-MSC intervention

MSC, Mindfulness Self-Compassion; D-MSC, Dyadic Mindfulness Self-Compassion.

Results - modification phase

Delphi survey (IV)

The first draft of the intervention design, components, and strategies was developed by combining the results of the preparation phase and development phase. The draft was agreed upon in a two-round online Delphi survey involving two oncologists, five oncology nurses (three nurses with a master's degree, two with a Ph.D. degree), two licenced psychologists, and two professors in nursing management. These experts come from nine renowned institutions and general hospitals in regions such as Hunan, Hubei, Fujian, Jiangsu, Shanghai, Shaanxi, and Hong Kong, China, with an average age of 43.20 ± 9.66 years and an average work experience of 19.40 ± 13.38 years. In the first round, only some minor comments were made. For example, it was suggested that "the impact of the psychological stress on cancer treatment and care" should be explained in advance to increase the enthusiasm of patients and their caregivers and to attract the participants' attention to dyadic psychological stress. It was also recommended that the intervention start with physical activities and then move on to psychological activities, thereby avoiding embarrassment for the participants and reducing the difficulty of the implementation plan. Several experts argued that recalling painful experiences and sharing negative experiences may arouse a resurgence of negative affectivity in participants, causing self-blame and emotional loss and that therefore this section should be removed. In the second round, comments were made on some details of the sessions. It was emphasized that the training context for mindfulness and self-compassion should be specific and relevant to the illness or caregiving process, such as waiting for test results, suffering side effects after chemotherapy, or experiencing exhaustion after caregiving. These comments received strong agreement from experts with regard to the refinement of the D-MSC intervention and were thus accepted. We modified the first draft of the D-MSC intervention according to the comments of the two-round Delphi survey after discussion by the research team.

The finalized D-MSC intervention for patients with lung cancer and their family caregivers consists of six weekly sessions, including an introduction session, two core sessions, two maintenance sessions, and a summary session. In addition, the intervention is divided into 32 intervention activities corresponding to 12 intervention goals. The D-MSC intervention will last for six weeks and will be delivered by instructors trained in mindfulness and who have graduate education in health psychology or mental health nursing. A detailed description and design of all intervention components and implementation strategies are presented in

Table 2
The integration of quantitative and qualitative data.

Variable	Quantitative data	Qualitative data
Dyadic appraisal	The illness perception of patients with lung cancer and their caregivers was both at a moderate level	Theme: The challenges of dyadic adaptation to cancer Subtheme: Inadequate cancer information
Dyadic management behaviours	The mindfulness of patients with lung cancer and their caregivers was both at a moderate level	• Demonstrating self-compassion behaviours: living in the moment (patients with lung cancer cherish their present life and do not worry excessively about the future and treatment progress) • Experiencing positive emotions: accepting cancer and death (patients and caregivers acknowledge the reality of cancer and maintain an open and accepting attitude)
	The self-compassion of patients with lung cancer and their caregivers was both at a moderate level	Demonstrating self-compassion behaviours: appearing self-compassion motivations, pursuing self-compassion, and facing self-compassion dilemmas
	The dyadic coping of patients with lung cancer and their caregivers was both at a relatively low level, much lower than that of patients with breast cancer and their spouses. Furthermore, stress communication, self-empowerment coping, and partner empowerment support coping among patients with lung cancer and their caregivers need to be strengthened, and their negative coping needs to be improved	Adopting complex coping styles: proactive coping, supportive coping, empowerment coping, and negative coping
Dyadic psychological stress	The prevalence of depressive symptoms among both patients with lung cancer and caregivers was 21.3% and 29.5%, respectively; the prevalence of anxiety in patients with lung cancer and caregivers was 22.0% and 33.5%, respectively. In addition, the prevalence of anxiety or depressive symptoms in both patients and caregivers was 24.0%; the prevalence of anxiety or depressive symptoms in either patient or caregiver was 48.0%	Experiencing negative emotions: shock and fear, lost and regret, worry and scary, and have difficulty in decision making
Relationships among dyadic variables	Mindfulness and self-compassion mediate the effect of dyadic appraisal (illness perception) on dyadic management behaviours (dyadic coping); mindfulness and self-compassion also mediate the effect of dyadic management behaviours (dyadic coping) on dyadic stress (anxiety and depressive symptoms). In addition, the patient's illness perception, mindfulness, self-compassion, and dyadic coping all have an interactive effect on the caregiver's anxiety and depressive symptoms, and vice versa	• Adapting to a series of life changes: changes in roles and responsibilities, changes in self-care ability, changes in social activity, and changes in dyadic relationships • Presenting diverse communication patterns: proactive consistent type, passive self-digesting type, implicit type, aggressive type, stubborn autonomous type, and avoidant cautious type • Considering the challenges of dyadic adaptation to cancer (financial burden, disagreements about confidentiality of cancer, caregiving burden, and ethical dilemmas) while reinforcing the rewards of dyadic adaptation to cancer (promoting dyadic relationships, considering life issues, and fulfilling personal values)

Table 3. The first session, which focuses on getting along with cancer, is introductory and is delivered face to face at the hospital to target dyadic appraisal (illness perception), with the main purpose of introducing the D-MSC intervention and the research team and drawing the participants' attention to the psychological stress among patients and caregivers. The second session, named practising mindful awareness, is a core session that is delivered face to face at the hospital and focuses on the mindfulness of patients and caregivers. It is aimed at introducing mindful awareness and practising mindfulness-related techniques. The third session, defining dyadic relationships and introducing self-compassion, is also a core session and is delivered online at home. It targets self-compassion, and its main purpose is to emphasize the importance of self-compassion and the practice of self-compassion techniques. In addition, the fourth and fifth sessions, named promoting dyadic communication and promoting dyadic coping, respectively, are both maintenance sessions delivered online and are intended to promote dyadic communication and dyadic coping among patients with lung cancer and their family caregivers. In these two maintenance sessions, communication skills and psychological stress-coping skills are taught. Finally, a summary session, embracing the future, is delivered online and reviews the learned sessions and summarizes the rewards of the D-MSC intervention.

Discussion

This study reported on the entire development process of the evidence-driven, theory-based, and culturally appropriate D-MSC intervention for patients with lung cancer and their family caregivers. The rigor and efficacy of the research procedure were enhanced by following the MRC framework for complex intervention development.[28,29] In compliance with the framework, the D-MSC intervention was designed systematically and scientifically using the best available evidence on dyadic intervention in terms of effective intervention components, sessions, and delivery modality. In the development phase, the empirical data from a quantitative and a qualitative study were integrated to identify effective components of the dyadic management process on the basis of the Theory of Dyadic Illness Management and the original MSC training. Moreover, a Delphi survey involving stakeholders at all levels was followed when modifying and finalizing the complex intervention. Importantly, this collaborative multi-method study involved efforts from experts, health care professionals, and researchers throughout the entire process, as well as patients with lung cancer and their family caregivers in the quantitative and qualitative studies. As a result of this iterative process, a D-MSC intervention for patients with lung cancer and their family caregivers was generated. This study provides a comprehensive theoretical and empirical basis for the design of the D-MSC intervention. Within the MRC framework, the preparation, development, and modification phases of the D-MSC intervention were detailed to enable continual refinement in future studies, particularly focusing on aspects such as the usability, feasibility, and acceptability of the intervention that were not addressed.[29] Moreover, the intervention components and implementation plans will be applied and described in the setting of our proposed randomized controlled trials.

Numerous studies[4,50–52] have demonstrated that dyadic interventions and mindfulness-based interventions significantly reduce psychological stress, especially anxiety and depressive symptoms, among patients with lung cancer and their family caregivers. However, previous dyadic interventions for patients with lung cancer and their family caregivers have mostly been conducted in developed countries, such as the United States and the Netherlands.[47,48] The development phase of our quantitative study also revealed a high prevalence of anxiety and depressive symptoms among patients with lung cancer and their family caregivers in China. Moreover, within the Chinese Confucian culture of collectivism, individuals are obligated to care for their parents, and spouses are expected to mutually support each other.[53] This underscores the importance of integrating the strengths of caregivers into the process of

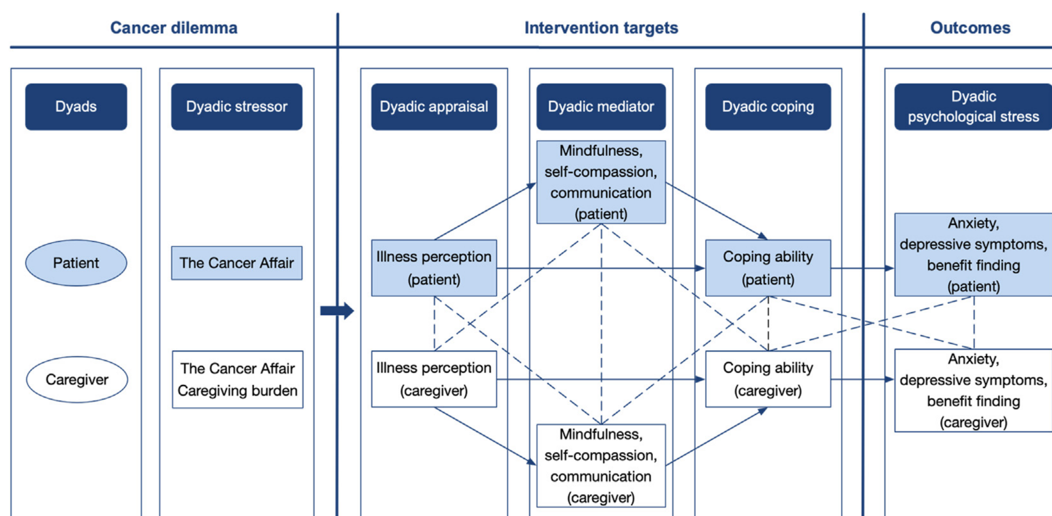

Fig. 2. The intervention framework for the dyadic Mindfulness Self-Compassion intervention. Note: Based on the Theory of Dyadic Illness Management, the intervention framework was formulated by integrating the empirical data from the quantitative data and qualitative findings. The results of the quantitative study indicated that mindfulness and self-compassion mediate the effect of illness perception on dyadic coping. In addition, the patient's illness perception, mindfulness, self-compassion, and dyadic coping all have an interactive effect on the caregiver's anxiety and depressive symptoms, and vice versa. The qualitative findings supplemented dyadic communication as a target and suggested that benefit findings of patients and caregivers should be added as an outcome. This framework comprehensively demonstrated the intervention targets of the developed dyadic Mindfulness Self-Compassion intervention to eventually alleviate psychological stress among patient–caregiver dyads.

adaptation for patients with lung cancer. Therefore, a culturally appropriate dyadic intervention for patients with lung cancer and their family caregivers in China is urgently needed. Two prominent factors influencing psychological stress, mindfulness and self-compassion, provide an emerging perspective for the development of a dyadic intervention for patients with lung cancer and their family caregivers.[54] Self-compassion draws on humanistic perspectives and advocates caring for yourself as you care for others,[55] which can meet the needs of lung cancer patients and caregivers for personal connection in dyadic interventions. In addition, mindfulness is one of the components of compassion, which, together with compassion, derives from the Buddhist idea of ‘loving kindness’, a friendly, tolerant attitude towards everything in the world, including oneself and others.[55] The concept of family is paramount for cancer in the context of Chinese culture, with a strong emphasis placed on collectivism and interdependence.[56,57] This cultural framework supports the dyadic approach of our complex intervention, which involves both patients with lung cancer and their caregivers. By fostering a shared experience of mindfulness and self-compassion, the dyadic intervention aligns with traditional Chinese values that prioritize familial support and harmony. This alignment not only enhances the relevance of the intervention but also encourages participation from both patients with lung cancer and caregivers, thereby reinforcing their relational bond during challenging times. Notably, the development and implementation of the D-MSC intervention in this study are theoretically important and feasible.

Findings from the iterative process of the multi-method study guided by the MRC framework informed the design and intervention contents of the D-MSC intervention, and the Theory of Dyadic Illness Management and the original MSC training were incorporated. This study is consistent with the process of developing complex interventions described in several previous articles[58–60] and may serve as an example of how to develop a complex intervention through multiple methods. The D-MSC intervention aims to adjust patients' and caregivers’ perceptions of cancer; instruct them to view cancer, themselves, each other, and others with an open and friendly attitude; and learn to care for themselves. In addition, the communication and coping skills of patient–caregiver dyads are improved, thereby reducing anxiety and depressive symptoms. The D-MSC intervention was designed to consist of six weekly sessions, each focusing on illness perception, mindfulness, self-compassion, dyadic communication, and dyadic coping. These components, representing the corresponding dyadic variables of the Theory of Dyadic Illness Management, act both independently and interdependently.[61,62] For example, the second and third sessions, which target mindfulness and self-compassion, respectively, can act independently as simple training to benefit patients with lung cancer and their family caregivers while also acting interdependently with the other sessions to reduce psychological stress for patient–caregiver dyads because mindfulness and self-compassion mediate the effect of dyadic appraisal (illness perception) on dyadic management behaviours (dyadic coping). Thus, it can be inferred that multiple intervention components in our D-MSC intervention may have a significantly stronger impact than single measures.

Given that this complex intervention was developed and formulated on the basis of extensive findings, including evidence from systematic reviews of the literature, empirical results of quantitative and qualitative studies, and suggestions from multidisciplinary experts, this D-MSC intervention should be an acceptable, feasible, and effective program. First, the evidence base identified from the systematic review not only clarified the current need for a more comprehensive description of the intervention development process,[63] but also summarized the characteristics related to the intervention design and implementation of the dyadic interventions for patients with lung cancer and their family caregivers. The systematic review generally provided a foundation of evidence based on identified gaps in current dyadic interventions and offered valuable suggestions with regard to the effective components, intervention providers, approach, duration and dose, and evaluation of the D-MSC intervention. Furthermore, previous recommendations for developing complex interventions have emphasized the importance of program theory.[29,64] Our intervention framework, which was refined on the basis of empirical data from the quantitative study and qualitative study, played a pivotal role in offering a comprehensive overview of the D-MSC intervention's design and implementation. By synthesizing the empirical data and the Theory of Dyadic Illness Management, the sessions that targeted corresponding dyadic variables of the intervention framework were established. Finally, suggestions and feedback from multidisciplinary expert teams about complex interventions are vital for identifying improvements in feasibility and applicability,[65] such as reductions or adjustments to intervention activities and word expressions. Overall, by integrating the results of the theory, systematic review, quantitative study, qualitative study, and Delphi survey, the D-MSC

Table 3
Description and design of the dyadic Mindfulness Self-Compassion intervention.

Session	Target variable	Theme	Approach	Purposes	Instruction and techniques
1. Introduction session	Dyadic appraisal (illness perception)	Getting along with cancer	Face-to-face at the hospital	(1) To help the participants understand the purpose and contents of the intervention	• Introduce the members of the research team and the science and general content of the D-MSC intervention • Describe the psychological services available to the participants and the possible benefits and risks for participating in the intervention
				(2) To develop an intervention group and establish good relationships with the participants	• Encourage participants to make personal introductions to each other • Encourage patients and caregivers to share their feelings concerning cancer and describe the impact of lung cancer on their lives • Establish a WeChat group to provide timely online feedback, communication, and contact
				(3) To clarify participants' expectations and form a group contract	• Develop group norms, form a group agreement, sign a letter of commitment, and then take an oral oath • Encourage participants to share their feelings and expectations
				(4) To introduce the impact of psychological stress on the treatment and recovery process of cancer	• Introduce the symptoms of various common psychological stress during cancer and caregiving • Explain the adverse effects of psychological stress (mainly anxiety and depressive symptoms)
2. Core session	Dyadic management behaviours (mindfulness)	Practising mindful awareness	Face to face at the hospital	(1) To practice MSC techniques, focusing on understanding mindfulness-related knowledge and techniques	• Meditation practice: “Compassionate breathing” (a mindfulness technique that involves deep, intentional breathing combined with the cultivation of empathy and compassion towards oneself and others) Scenario simulation is used to guide participants to become aware of their breathing • Explain the theory: Participants are encouraged to identify the automatic guidance state of the brain, learn about mindfulness, and practice awareness of the present moment • Practical exercises: Practice “Soles of the Feet” meditation (directing attention to a neutral part of the body, specifically the soles of the feet, when emotions or thoughts trigger aggression) and self-compassion in daily life, such as relaxing touch and massaging each other • Interactive sharing: Summary, feedback, and problem discussion after all activities
				(2) Assignment	• Booklet study: Wandering thoughts, what is mindfulness, and informal practice of “Soles of the Feet” meditation • Practice for patients and caregivers: According to the audio instructions, the patient and the caregiver will practice informal practice, “Soles of the Feet” meditation, for 15 minutes once a day during this week, and record the content, duration, and feelings in the training log
3. Core session	Dyadic management behaviours (self-compassion)	Defining dyadic relationships and introducing self-compassion	Online at home	(1) To define the dyadic relationships among patients and caregivers and emphasize the importance of self-compassion	• Meditation practice: “Compassionate breathing” • Interactive sharing: Recall the content of the previous session, each group of families shares their experiences in homework practice and analyses their practice problems • Warming-up game: “Identity Swap”, telling “myself in my eyes” from the patients' or caregivers' perspective • Explain the rationale of self-compassion and answer misunderstandings about self-compassion • Explain the theory: Everyone needs care, not only to be tolerant of others but also to be tolerant of yourself • Scenario simulation: Guide participants to recognize the difference between treating themselves and their loved ones by reflecting on “how we treat ourselves”
				(2) To strengthen MSC and practice loving-kindness	Give examples of ways to show loving-kindness to yourself and patients or caregivers, and practice the “loving-kindness meditation” (sending good vibes to yourself and the people around you) to cultivate loving-kindness to yourself and patients or caregivers

(*continued on next page*)

Table 3 (*continued*)

Session	Target variable	Theme	Approach	Purposes	Instruction and techniques
				(3) Assignment	• Booklet study: Self-compassion and relaxing touch techniques • Practice for patients and caregivers: According to the pre-recorded audio, the patient and the caregiver will practice loving-kindness meditation for 15 minutes once a day and record the content, duration, and feelings in the training log
4. Maintenance session	Dyadic management behaviours (dyadic communication)	Promoting dyadic communication	Online at home	(1) To promote effective communication between patients and caregivers	• Meditation practice: "Compassionate breathing" • Interactive sharing: Recall the content of the previous session, each group of families shares their experiences in homework practice and analyses their practice problems • Explain the theory: Highlight the importance of communication in coping with psychological stress and explain common communication types and their characteristics between patients and caregivers • Practical exercises: Practice emotional self-disclosure, in which patients and caregivers express their opinions and feelings around common concerns such as cancer recurrence, symptom distress, diet management, etc., and practice reflective listening.
				(2) Assignment	Practice for patients and caregivers: Practice emotional self-disclosure for 15 minutes once a day during this week, and record the content, duration, and feelings in the training log
5. Maintenance session	Dyadic management behaviours (dyadic coping)	Promoting dyadic coping	Online at the hospital	(1) To improve dyadic coping skills	• Meditation practice: "Compassionate breathing" • Interactive sharing: Recall the content of the previous session, each group of families shares their experiences in homework practice and analyses their practice problems • Explain the theory: Introduce common ways for patients and caregivers as a dyad to cope with psychological stress
				(2) To provide psychological stress management skills	• Practical exercises: Practice psychological stress management skills, including naming the emotions, being aware of emotions, and practising "Soften, Soothe, Allow" meditation (navigating and working through difficult emotions with self-compassion) • Interactive sharing: Encourage Participants to share examples of successful coping with issues regarding cancer or caregiving
6. Summary session	The rewards and challenges of dyadic adaptation to cancer	Embracing the future	Online at home	(1) To provide informal MSC techniques for daily life	Review and comprehensively practice MSC techniques in daily life, including compassionate breathing, "Soles of the Feet" meditation, and loving-kindness meditation
				(2) To review the sessions and learned skills	• Summarize the intervention and praise participants' progress • Encourage Participants to discuss the challenges and rewards of cancer treatment or caregiving, and to share experiences in practising these intervention activities. Moreover, researchers provide advice on persistence, and help participants plan to reinforce the learned skills in their future life

MSC, Mindfulness Self-Compassion; D-MSC, Dyadic Mindfulness Self-Compassion.

intervention was drafted and modified to increase dyadic adaptation and reduce dyadic psychological stress among patients with lung cancer and their family caregivers.

Notably, a mixture of methods incorporating both quantitative and qualitative approaches during the development phase of this study provides a strong basis for comprehending and elucidating effective components.[66] On the one hand, the results of the quantitative study, alongside the findings of the qualitative study, demonstrated that the psychological stress and life changes experienced by patient–caregiver dyads interact with each other and have a dynamic impact.[67] This verifies the dyadic effects in the process of adapting to cancer among patients with lung cancer and their family caregivers and provides a foundation for the dyadic form. On the other hand, patient–caregiver dyads' communication patterns (active and consistent patterns), self-compassion behaviours (focusing on the present and being kind to themselves), and coping styles (proactive coping, supportive coping, and empowerment coping) have been found to play critical roles in adapting to cancer. These findings illustrated a systemic–transactional view of stress and coping in dyads[68,69] and were aligned with Sherman's findings that patients with breast cancer present high levels of self-compassion,[27,70] which complements the targets in the development of the D-MSC intervention. Therefore, the perceptions and experiences of patients and their caregivers were fully explored in the development phase and considered in the D-MSC intervention.

Strengths and limitations

This study has several strengths. First, we employed a multi-method study that included a preparation phase, a development phase, and a modification phase, which was a lengthy and resource-intensive process. The evidence base, empirical data, and effective components were scientifically formulated and modified through an iterative and stepwise process of a systematic review, a quantitative study, a qualitative study, and an online Delphi survey. Second, we involved a broad range of stakeholders during the development of the D-MSC intervention, including multidisciplinary experts (i.e., experts in clinical oncology, oncology nursing, psychology, and nursing management), researchers, patients with lung cancer, and their family caregivers. We believe that the comprehensive perspective from different stakeholders and the contextual conditions allowed us to identify a variety of factors.[71] Moreover, the evidence-based, theory-driven, and culturally appropriate intervention, which targets dyadic appraisals and dyadic management behaviours among patients with lung cancer and their family caregivers, aimed to reduce their psychological stress. Our intensive development of the D-MSC intervention may enrich MSC training and dyadic interventions to guide clinical practice and result in a highly promising psychosocial approach to helping patients with lung cancer and their family caregivers. Above all, the multi-method development process of the D-MSC intervention serves as a template for developing a complex intervention. The adoption of the MRC framework, alongside rigorous reporting, also guaranteed the reproducibility of our intervention.[28,29]

However, there are some limitations to our study. First, the effective components were generated on the basis of quantitative and qualitative studies conducted among participants in southern China. Therefore, the D-MSC intervention may not be universally applicable to cultural contexts in other regions and countries. In addition, the different stages of lung cancer and their specific characteristics were not fully considered in this study, potentially weakening the intervention's targeting. Furthermore, the feedback from patients and their caregivers was not included in the intervention revision, which may have led to a mismatch between the intervention and their actual needs. Finally, this study merely applied and reported the development process of the D-MSC intervention; its usability, feasibility, acceptability, satisfaction, and preliminary effectiveness remain uncertain. Future pilot studies and subsequent large-scale trials with long-term follow-up, according to the MRC guidelines,[29] are warranted and recommended because these endeavours can significantly enhance the intervention implementation process and the feasibility of the D-MSC intervention.

Conclusions

This study illustrates the iterative and stepwise development of the D-MSC intervention, which was created in accordance with the guidelines of the MRC framework for developing complex interventions, for patients with lung cancer and their family caregivers to alleviate their dyadic psychological stress, especially anxiety and depressive symptoms. The intensive development process included supporting evidence from a systematic review, the findings of a quantitative study alongside a qualitative study, and suggestions from an online Delphi survey. The D-MSC intervention consists of six weekly sessions that target illness perception, mindfulness, self-compassion, dyadic communication, dyadic coping, and the challenges and rewards of dyadic adaptation. As a next step, this complex intervention could be evaluated with respect to its usability, feasibility, acceptability, satisfaction, and preliminary effectiveness through a pilot study with an accompanying process evaluation to further refine it as well as future implementation strategies.

CRediT authorship contribution statement

Juan Li: Writing – Review & Editing, Supervision, Methodology, Formal analysis, Data Curation, Funding acquisition, Conceptualization. **Tianji Zhou**: Writing – Original Draft, Visualization, Validation, Methodology, Formal analysis, Funding acquisition, Conceptualization. **Chan Li**: Writing – Original Draft, Methodology, Investigation, Formal analysis. **Jie Zou**: Writing – Review & Editing, Visualization, Validation, Investigation. **Jie Zhang:** Writing – Review & Editing, Methodology, Conceptualization. **Bo Yuan**: Writing – Review & Editing, Investigation, Formal analysis. **Jingping Zhang**: Writing – Review & Editing, Supervision, Project administration, Methodology, Data Curation, Conceptualization. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Ethics statement

The study was approved by the Institutional Review Board of Xiangya School of Nursing, Central South University (IRB No. 202109). All participants provided written informed consent.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, JZ, upon reasonable request.

Declaration of generative AI and AI-assisted technologies in the writing process

No AI tools/services were used during the preparation of this work.

Declaration of competing interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

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