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Effectiveness of a perioperative support programme to reduce psychological distress for family caregivers of patients with early-stage lung cancer: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Family caregivers play a key role in providing ongoing long-term care and assistance to their loved ones during cancer treatment. However, family caregivers of patients with lung cancer are frequently unprepared for their roles and they may undergo psychological distress, thus reducing their own quality of life while affecting patients' health outcomes. Interventions that specifically target this population are lacking. This study aims to evaluate the effectiveness of a perioperative support programme on family caregivers of patients with early-stage lung cancer.

Methods and analysis This study is guided by the Stress-Coping Model. Family caregivers of patients diagnosed with early-stage lung cancer and those who are scheduled for lung resection treatment will be invited to participate. Participants will be randomised to groups that either receive the perioperative support programme or usual care. The intervention consists of four face-to-face intervention sessions during the hospital stay and two weekly telephone follow-up sessions after discharge. Primary and secondary outcomes will be assessed at baseline and at 4 and 12 weeks after the intervention. Primary outcomes will include psychological distress and secondary outcomes will include caregiving burden, quality of life, coping style and social support. Generalised estimation equation model will be used to analyse the intervention effects.

Ethics and dissemination The study was approved by the Ethics Committee of the Second Xiangya Hospital of Central South University (LYG2022003). The authors will disseminate the study's findings by publishing them in international scientific journals.

Trial registration number ChiCTR2200058280.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is based on the Stress-Coping Model. The perioperative support programme has the potential to increase family caregivers' coping resources by providing them with appropriate information, skills and support and diminishing psychological distress.
⇒ The intervention is offered during the perioperative period. Attention is focused on caregivers' needs, and the intervention includes coping and communication skill training with psychoeducational strategies.
⇒ Due to time and resource limits, this study will be conducted in a single centre, and the results might not be generalisable to other centres.
⇒ In addition, a 12-week follow-up period is inadequate to judge the long-term effects of the intervention. Further studies with longer follow-up periods are required to establish the long-term effects of the intervention.

INTRODUCTION

Lung cancer is the most frequent malignant tumour in the world[1]; it has the highest morbidity and mortality rates. Approximately 2.1 million new cases and 1.8 million deaths were recorded globally in 2018.[1] Early-stage lung cancer (stages I and II lung cancer in accordance with the TNM staging system, an internationally accepted system used to characterize the extent of disease)[2] accounts for approximately 15%–20% of all newly diagnosed lung cancer cases.[3] The number of individuals diagnosed with early-stage lung cancer is anticipated to increase because of the advances in screening and early detection by low-dose CT scanning.[4] For individuals with early-stage lung cancer, surgery offers the best chance of treatment or long-term survival and the surgical resection rate was 58.9%.[5] As people become increasingly interested in and adopt lung cancer screening,[6] the number of people who have surgery for early-stage disease is likely to increase.

For cancer treatment, surgery is performed soon after the diagnosis. Lung cancer surgery is an episodic and intense event for family caregivers.[7] Patients with lung cancer are discharged from the hospital early after surgery due to changes in the healthcare environment and developments in surgical care with minimally invasive procedures; patient care responsibilities shift from professional caregivers to patients' family members.[8] Family caregivers play a key role in providing ongoing long-term care and assistance to their loved ones during the cancer treatment process.[9] However, these family caregivers are unprepared for their roles; they do not have sufficient resources, such as knowledge and skills of caring for patients, and may undergo severe psychological distress, increasing caregiver burden and decreased quality of life related to their caregiving role.[10–13]Apart from the demanding care responsibilities, family caregivers deal with the uncertainty of the future and grief associated with their loved ones' impending departure.[14]All of these factors could place caregivers under considerable stress, thus reducing their own quality of life and affecting patients' health outcomes and mental health.[15 16] Evidence from current literature that focuses on the psychological distress of family caregivers in lung surgery is scarce. Psychological distress is defined as a state of emotional suffering characterised by symptoms of depression (eg, loss of interest, sadness and hopelessness) and anxiety (eg, restlessness and feeling tense).[17] Family caregivers' mental health was found to be poorer than population norms in a study involving family caregivers of patients with lung cancer and those who were surgically treated.[18] Over 50% of family caregivers of patients with lung cancer suffer from significant anxiety or depressive symptoms.[19–21] This finding emphasises the urgent need for interventions targeting distressed caregivers to improve their ability to cope with the stress of caring for patients with lung cancer.

Several psychosocial interventions have been developed for family caregivers of patients with lung cancer. The interventions differ in terms of goals (eg, alleviate anxiety and depression, reduce caregiver burden and improve quality of life), underlying methods (eg, cognitive–behavioural therapy, coping skills training and meditation), delivery format (eg, telephone, online and face-to-face) and addressed participants (eg, dyads and sole caregiver). Studies have explored the effect of psychosocial interventions on caregivers of patients with advanced lung cancer[22 23] and those with non-surgical lung cancer.[24] DuBenske *et al*[22] found that caregivers of patients with advanced non-small cell lung cancer in the intervention group who received the comprehensive health enhancement support system experienced a lower caregiver burden and less negative mood than those in the control group who received standard care after 6 months of the intervention. Badr *et al*[23] also found that caregivers of patients with advanced lung cancer who received psychosocial telephone intervention showed significantly decreased anxiety, depression and caregiver burden compared with the usual care control group at an 8-week follow-up. Aubin *et al*[24] revealed that providing pragmatic intervention for family caregivers of patients newly diagnosed with non-surgical lung cancer was not effective in reducing their anxiety and depression. On the contrary, the qualitative assessment of the intervention by family caregivers was positive as they unanimously appreciated it. However, the results of intervention in the oncology population during advanced lung cancer or non-surgical lung cancer could not be generalised to caregivers of patients with early-stage lung cancer.

A systematic review has collectively identified 22 psychosocial interventions for informal caregivers of patients with lung cancer.[25] The interventions included mindfulness-based stress reduction training, yoga, symptom management, coping skills training, problem-solving, effective communication, self-care, symptom management and palliative care. Findings from the review provided preliminary evidence for the effects of psychosocial interventions on caregivers' psychosocial outcomes, notably in reducing burden and distress (anxiety and depression) and increasing quality of life, self-efficacy and coping abilities. Overall, interventions had positive effects on various outcomes for caregivers of patients with lung cancer. However, only one study included caregivers of patients with early-stage lung cancer. Porter *et al*[26] compared the effectiveness of caregiver-assisted coping skill training and education/support in patients with early-stage lung cancer (80.5% of patients were treated with surgery). They found that in both conditions, caregivers showed improvements in anxiety from baseline to 4-month follow-up.[26] The coping skill training intervention was more beneficial to patients/caregivers with stage II (15.9%) cancers according to exploratory analyses, whereas the education/support intervention was more beneficial to patients/caregivers with stage I (52.6%) cancer.

To date, only one study specifically targeted family caregivers of patients undergoing surgery for early-stage lung cancer. Sun *et al*[27] developed a multimedia self-management intervention that was based on the Chronic Care Self-Management Model targeting readiness and preparedness for lung surgery and postoperative recovery. They found that the intervention was feasible and acceptable in supporting the physical and psychosocial readiness and preparedness for lung surgery and postoperative recovery. They also showed exploratory evidence demonstrating the intervention's potential effect on the emotional quality of life, self-efficacy, activation and knowledge. However, the study paid minimal attention to the caregivers' psychological distress and stress coping. Furthermore, the study was based on participants with an American cultural background, which may not be applicable to Chinese population. Therefore, a randomised controlled trial is proposed in this study to test the efficacy of a perioperative support programme in reducing the psychological distress of family caregivers of patients with early-stage lung cancer.

Theoretical framework

The Stress-Coping Model[28] is used as the theoretical framework for this study. According to the model, stress occurs when a situation is demanding and appropriate resources are not available to maintain psychological equilibrium for coping effectively. When a loved one is diagnosed with lung cancer, the family caregivers are at risk of experiencing various negative outcomes. Family caregivers may also experience stress associated with the uncertain consequences of the diagnosis, side effects during treatment and the patients' ongoing physical and psychological problems. Then, they may activate coping responses and seek social support. Caregivers experience psychological distress when coping abilities or resources available to caregivers are perceived to be inadequate or insufficient to meet the demands of care.[29] The perioperative support programme in the present study could potentially increase family caregivers' coping resources by providing them with appropriate information, skills and support and diminishing psychological distress.

Aims

This study aims to assess the effectiveness of a perioperative support programme integrating coping and communication skill training with psychoeducational strategies on the outcomes of family caregivers of patients with early-stage lung cancer, as follows: psychological distress (primary outcome), caregiving burden, quality of life, coping style and social support. In addition, a qualitative component of the study will document the perceived usefulness of the intervention by family caregivers and its effects on psychological distress in the intervention group.

METHODS AND ANALYSIS

Design and setting

The study is a single-blind, parallel-group, randomised controlled trial. The intervention will be delivered perioperatively and it involves four face-to-face sessions with the caregiver, followed by two weekly telephone follow-up sessions after discharge. Caregiver outcomes will be measured at baseline (T0), 4 weeks (T1) and 12 weeks (T2) after the intervention. The study will be conducted in two wards of the thoracic surgery department at a university-affiliated hospital in Changsha, China. The flow chart for the randomised controlled trial is shown in figure 1.

Participants

Family caregivers of patients with stages I or II lung cancer who are scheduled to undergo lung resection surgery are eligible to participate. The inclusion criteria for family caregivers are as follows: (1) identified by patients as primary caregivers who will provide daily assistance and emotional support during patients' perioperative period; (2) aged 18 years or older; (3) able to read and speak Chinese; and (4) able to provide written informed consent. The exclusion criteria are as follows: (1) caregivers who are undergoing active cancer treatment; (2) caregivers who have received a similar support intervention and (3) caregivers who are paid.

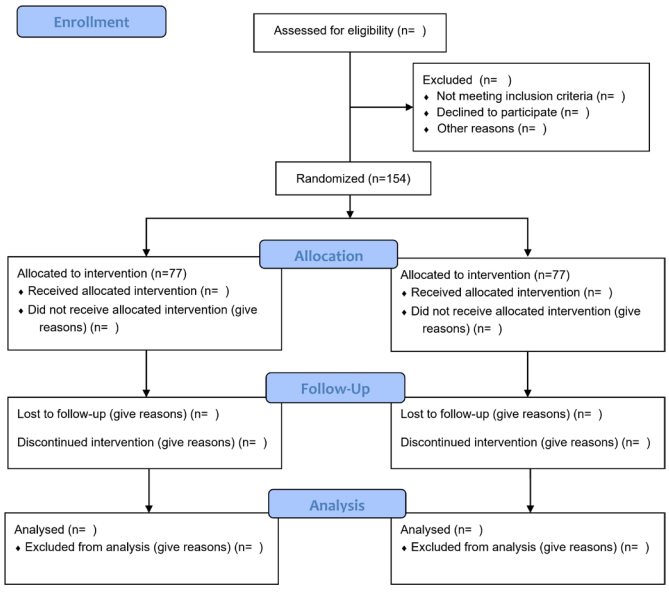

Figure 1 Flow chart of the study.

Recruitment

Research staff will work closely with the thoracic surgeons on a daily basis to identify eligible patients on admission. Eligible patients will be identified from the electronic patient data management system by the principal investigator. When eligibility is established, the principal investigator will contact the eligible family caregivers of patients and explain the study purpose, answer questions and ascertain interest in enrolment. If the caregivers agree to enrol, informed consent will be obtained. An example of the consent form is included in the online supplemental material. Family caregivers will be subjected to a complete baseline assessment after providing informed consent. The reasons for not taking part in the study and the reasons for exclusion will be documented. Participant recruitment has started in May 2022.

Randomisation

Eligible family caregivers will be randomly allocated to intervention and control groups by a research assistant who is not involved in other processes of the study. The randomisation scheme will be performed with a web-based randomisation tool (www.randomization.com). Grouping will be performed through blocked randomisation (block size of four or six). Allocation numbers will be concealed with sealed opaque envelopes. Owing to the nature of the intervention, the participants and the intervener will not be blinded. However, outcome assessors will be blinded to group allocation.

Intervention and control group

Participants assigned to the intervention group will be invited to attend the perioperative support programme.

Table 1 Overview of the perioperative support programme

Session	Objective	Contents
1st (day of admission)	► Build a cooperative relationship with caregivers ► Screen caregivers for stressors, psychological distress and assess their needs ► Improve caregivers' knowledge of early-stage lung cancer	► Explain the purpose and process of the study to caregivers and establish mutual trust and respect relationship ► Conduct focus group interviews with caregivers to gain knowledge about their stressors, psychological distress and needs in caring for perioperative patients ► Provide caregivers with disease-related health education (the courses cover basic knowledge of early-stage lung cancer, such as prevalence and incidence, risk factors and aetiology, diagnostic procedures, surgical treatment, pulmonary rehabilitation, complication prevention, prognosis and matters needing attention
2nd (day 1 of admission)	► Encourage caregivers to cope with stress and psychological distress actively ► Improve caregivers' communication skills with patients ► Improve caregivers' self-care skills	► Encourage caregivers to explore their resources and sources of stress and discuss how to use coping skills actively to ease their psychological distress ► Provide caregivers with communication skills, including asking questions, reflective listening, keeping calm, expressing feelings and recognising signs of psychological distress in themselves and patients ► Instruct caregivers on how to take care of themselves, including identification of strategies for reducing fatigue and improving sleep, prioritisation of activities, spending time for leisure activities, seeking support and management of one's own healthcare
3rd (the day before surgery)	► Assist caregivers in managing the symptoms of lung cancer ► Strengthen caregivers' problem-solving skills	► Provide effective strategies for caregivers in managing patients' pain, fatigue, shortness of breath, psychological distress and other symptoms related to lung cancer and its treatment ► Assist caregivers in identifying caregiving barriers and strategies for fostering a positive caregiving experience and promoting family caregiver self-care
4th (at discharge)	► Manage common concerns associated with lung cancer treatment ► Discuss realistic goals with caregivers ► Reinforce caregivers' coping skills	► Help caregivers set realistic rehabilitation goals for patients ► Identify barriers to participation in pulmonary rehabilitation at home and how to overcome them ► Discuss possible abnormal symptoms at home and strategies to manage them ► Formulate strategies for living with uncertainty and future concerns
5th–6th (days 2 and 7 after discharge)	► Identify and resolve challenges and psychological distress that caregivers face during patients' rehabilitation at home	► Assess each caregiver's life condition, mental health status and potential challenges through telephone calls and formulating solution strategies ► Activate caregivers and promote self-care ► Instruct caregivers to seek medical assistance in time if patients have complex medical problems

The programme was developed by a multidisciplinary team that included two thoracic surgeons, three clinical nurses, two psychologists and five family caregivers of patients with early-stage lung cancer. The intervention will be delivered by the principal investigator, who is an oncology nurse with 4 years of experience. It is composed of four 1-hour face-to-face group (four to six participants per group) sessions and two weekly 15-minute telephone follow-up sessions. The intervention begins at admission and continues for as long as 2 weeks after hospital discharge. The sessions are delivered at different times (the detailed intervention times are presented in table 1) in the perioperative setting. This design was selected to diminish information overload and burden for family caregivers. The intervention aims to improve caregivers' perioperative care knowledge and coping skills to reduce psychological distress and caregiver burden and improve their quality of life. Details of the intervention for each session are presented in table 1.

The principal investigator documents any tailoring of the intervention to meet caregivers' needs, caregivers' engagement in the session and caregivers' verbalisation of understanding of the session content. The dose of the intervention will be tracked by recording the duration of each session, any additional contacts with the caregiver and any missed visits by the caregiver.

Table 2 Overview of study outcomes and measurement details

Variables	Measures	T0 Baseline	T1 4 weeks after intervention	T2 12 weeks after intervention
Primary outcome				
Psychological distress	Hospital Anxiety and Depression Scale	×	×	×
Secondary outcomes				
Caregiving burden	Zarit caregiver burden interview	×	×	×
Quality of life	The Quality of Life Family Version	×	×	×
Coping style	Simplified Coping Style Questionnaire	×	×	×
Social support	Social Support Rate Scale	×	×	×

Participants assigned to the control group will receive usual care consisting of pain management, perioperative care and rehabilitation exercise.

Sample size and power calculations

Considering that distress is the primary outcome, the total Hospital Anxiety and Depression Scale (HADS)[30] score (range=0–42) will be used to calculate the sample size. A two-sided t-test on the total HADS score will require 64 participants in each group to have 80% power to detect a medium-sized difference (effect size=0.5)[31] with α=0.05. Considering the attrition rate of 17%, 154 participants will be included.

Outcome measurements and assessments

For caregivers in the intervention and control groups, outcome assessments will be obtained in person at baseline or by telephone calls during follow-ups by a trained research assistant, who will be blinded to the group allocation. The main collection points are baseline (T0), 4 weeks (T1) and 12 weeks (T2) after the completion of the intervention. Table 2 shows the overview of study outcomes and measurement details. At baseline, the sociodemographic data of the caregivers will be obtained to assess the groups' comparability, and thus, the results' external validity. All study outcomes will be collected using validated tools.

Primary outcome

Psychological distress

The primary outcome of this study will be the distress of family caregivers, to be assessed by the HADS.[30] This 14-item scale includes two seven-item subscales that assess anxiety and depression in the past week. Each subscale has a score range of 0–21. A global score of 15 or more on the 14-item scale (ranging from 0 to 42) indicates clinically significant distress.[32] This tool is widely used in research to assess anxiety, depression and distress in various populations with a range of health conditions[33–35] and in the general populations without any specific medical disease,[36] including family caregivers of patients with cancer.[37] The Chinese versions of HADS have been shown to be reliable and valid among caregivers of patients with cancer, with Cronbach's α coefficients of anxiety and depression subscales being 0.857 and 0.851, respectively.[38]

Secondary outcomes

Caregiving burden of caregivers

Caregiver burden will be measured using the Zarit caregiver burden interview (ZBI) developed by Zarit *et al*.[39] The scale consists of 22 items that are scored on 5-point Likert scales (0=never, 4=almost always). The scores for each item are summed to obtain a total score, with a range of 0–88 (0–20: low or absence of burden; 21–40: mild to moderate burden; 41–60: moderate to severe burden; 61–88: severe burden).[40] The Chinese version of ZBI is a valid and reliable tool (Cronbach's α=0.87) for assessing caregiver burden.[41 42]

Quality of life

The Quality of Life Family Version will be used to assess the quality of life of caregivers of patients with cancer. This scale was developed by Ferrell and Grant,[43] translated to Chinese version and validated by Liu *et al*.[44] The Chinese version instrument consisted of 35 items categorised into four subscales (physical health conditions, psychological health conditions, social conditions and spiritual health conditions). The scoring will be based on a scale ranging from 0 (worst outcome) to 10 (best outcome). The scale has been evaluated over the total and subscale scores. A high score indicates high level of quality of life. The scale demonstrates good reliability (Cronbach's α=0.794) and construct validity.[44]

Coping style of caregivers

The caregivers' coping style preferences will be assessed using the Simplified Coping Style Questionnaire (SCSQ). This 20-item scale is divided into two subscales: active coping and passive coping. Participants will be asked to respond using a 4-point Likert scale ranging from 0 (never) to 4 (very often). Each subscale's mean score will be calculated, with a higher score showing a higher tendency of using that specific coping strategy.[45] The

SCSQ has been shown to have good reliability and validity in Chinese population, with internal consistencies of 0.89 and 0.78 for active and passive coping subscales, respectively.[46]

Social support of caregivers

The Social Support Rate Scale developed by Xiao will be used to evaluate caregivers' social support.[47] This 10-item scale assesses three areas of social support: subjective support, objective support and support utilisation. The total score (range of 12–66) will be calculated by adding all of the items together. A high score indicates high levels of perceived social support.

Patient and public involvement

Family caregivers of patients with early-stage lung cancer, thoracic surgeons, clinical nurses and psychologists were involved via focus groups in the development of trial components in the study mentioned above. Before the start of the pilot study, family caregivers were invited to participate in the main sessions of the perioperative support programme to ensure clarity and comprehension. After the pilot study, caregivers will be invited to provide their perspectives on the format of the programme, the content of each session and the questionnaire. As a subsequent step, the feedback from participants of the feasibility study will be used to further optimise the intervention for the following efficacy evaluation study. After the end of the whole study, a focus group interview will be carried out among participants in the intervention group by the principal investigator to obtain their perspectives on the acceptability and usability of the perioperative support programme.

Data analysis

The intention-to-treat analysis will be used in the study. All analyses will be performed using SPSS Statistics (IBM SPSS Statistics for Windows, V.26.0), and the significance level will be set at 0.05. Continuous data will be summarised using means, medians, SDs, IQRs and ranges. Distributions will be tested for normality via Shapiro-Wilk test. Student's t-test or Wilcoxon test will be used to compare continuous data. Categorical data will be compared by $\chi 2$ or Fisher's exact test. A generalised estimating equation model will be used to compare the differential changes in outcomes between the intervention and control groups across three endpoints (T0, T1 and T2).

ETHICS AND DISSEMINATION

The study was approved by the Ethics Committee of the Second Xiangya Hospital of Central South University (LYG2022003) and was registered on the Chinese Clinical Trial Registry (ChiCTR2200058280). All study participants will be informed in detail about the study's aims and procedures and required to sign a consent form to be filed with the study documents. They could withdraw from the study for any reason at any moment.

The information gathered in this study will be treated with confidentiality. All data will be securely stored at the Second Xiangya Hospital of Central South University and accessible only to those who are directly associated with the study and have signed the confidentiality agreement.

The study will be carried out in line with any proposed and approved revisions, and the Declaration of Helsinki's ethical principles. The authors will disseminate the study's findings by publishing them in international scientific journals.

DISCUSSION

Family caregivers are essential to caring for patients with cancer, as they are their major source of support.[9] However, their lives are upended by such responsibility, and they ignore their own health to support their cancer-stricken relative.[48 49] Family caregivers need to be provided with the resources, information and support to stay healthy and continue their caregiving role.[50 51] Most previous caregiver studies focused on patients who are nearing the end of their lives. Few support interventions that specifically target family caregivers in thoracic surgery could be found in the literature. The perioperative support programme was developed to provide tailored support for family caregivers of patients with early-stage lung cancer. This intervention differs from those described in previous studies in that it is tailored to the specific needs of family caregivers of patients with early-stage lung cancer. It is also offered during the perioperative period, which focuses attention on caregiver needs and includes coping and communication skill training with psychoeducational strategies. The hypothesis is that family caregivers who receive the intervention will have less psychological distress and caregiver burden and have a higher quality of life than caregivers in the control group.

This study is timely and special for several reasons. The intervention has a one-of-a-kind timing, and its delivery will start in the preoperative setting. This factor is critical because the time to perform the intervention on family caregivers is short due to patients' early discharge. Studies involving family caregivers that begin before cancer surgery are few.[52] Furthermore, the intervention is tailored to the needs of caregivers and it incorporates coping and communication skill training into the caregiver's psychoeducational intervention.

This study has a few limitations that must be considered. First, due to time and resource limits, this study will be conducted in a single centre, and the results may not be generalisable to other centres. Second, a 12-week follow-up period is inadequate to judge the long-term effects of the intervention. Further studies with longer follow-up periods are required to establish the long-term effects of the intervention. Finally, patient health outcomes are not included in this study, and whether the intervention contributed to patients' recovery is unknown.

This study addresses the critical need to test an intervention on the basis of the perioperative needs of family caregivers to better support and educate them. If this intervention is effective, it could potentially reach all caregivers who are responsible for providing perioperative care to their loved ones. The research team is currently pilot testing the perioperative support programme to assess its feasibility, acceptability and preliminary efficacy. The pilot study involving 70 participants has been completed and statistical data analyses are currently underway. The details of the pilot study will be reported elsewhere.

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Contributors SZ, CY, TL and JL contributed to the study conception and design, attaining the funding to support the project and preparing documents for ethical approval. SZ developed the intervention together with CY, LK, JL and LL. SC is supervising statistician and provided statistical support, while JL and LL provided overall advice and content for the study protocol. SZ and CY contributed content to the original manuscript and have assisted with revisions. All authors provided critical revisions and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

Informed Consent

Informed Page

Title of study: Effectiveness of a perioperative support program to reduce psychological distress for family caregivers of patients with early-stage lung cancer: A Randomized Controlled Trial

Principal investigator: Ms. ZHU Song, The Second Xiangya Hospital, Central South University

Purpose of the study: This study aims to evaluate the effectiveness of a perioperative support program on family caregivers of patients with early-stage lung cancer.

Contents of the study: You will be invited to participate in a perioperative support program. If you agree to participate, you will be randomly assigned to either A or B group. Participants in the A group will receive usual care consisting of pain management, perioperative care and rehabilitation exercise. In addition to usual care, participants in the B group will receive a perioperative support program conducted by the principal investigator, including four 1-hour face-to-face group sessions and two weekly 15-minute telephone follow-up sessions. The intervention begins at admission and continues for as long as two weeks after hospital discharge. Participants in both groups will receive a 12-week follow-up. All participants will be invited to complete a list of questionnaires at 3 time points: before, 4 and 12 weeks after the intervention.

Target participants: Around 154 family caregivers of patients with stage I or stage II lung cancer who are scheduled to undergo lung resection surgery will be recruited to

the study. **Inclusion criteria** for family caregivers are as follows: (1) identified by the patients as primary caregivers who will provide daily assistance and emotional support during patients' perioperative period; (2) aged 18 years or older; (3) able to read and speak Chinese and (4) able to provide written informed consent. The **exclusion criteria** are as follows: (1) caregivers who are themselves undergoing active cancer treatment; (2) caregivers who have received a similar support intervention and (3) caregivers who are paid.

Risks: This procedure has no known risks. You may experience some mild fatigue and discomforts during the procedure, such fatigue and/or discomforts will be kept to a minimum because the tasks are self-paced and you are free to take short breaks.

Benefits: You will receive a manual containing pain management, perioperative care and rehabilitation exercise. In addition, if you are assigned to the B group, you will be invited to attend the perioperative support program. This program may improve your perioperative care knowledge and coping skills to reduce psychological distress and caregiver burden, as well as improve your quality of life.

Information protection: Any information obtained in this study will remain very strictly confidential and will be used for research purposes only. Codes, not names, are used on all test instruments and documents to protect confidentiality. Your name or any other subject identifiers will not be described in the study report. All research records will be stored securely and safely in a locked cabinet. Only the research team will have access to research records.

Voluntary participation: Your participation is voluntary. You can choose to stop at

any time without negative consequences. Your participation in this study will not affect the services you are receiving from your healthcare center.

Contact details: The study has been approved by the Ethics Committee of the Second Xiangya Hospital of Central South University (LYG2022003). If you have any questions about the research, please feel free to contact Ms. ZHU Song (telephone number: 86-18867350035).

Thanks for your time to consider attending this study.

The Second Xiangya Hospital

Central South University

ZHU Song

Informed Consent

Signature Page

Statement of Consent

I have read the above information and have received answers to any questions I asked. I understood the nature of this study and agree that the information collected will be kept by the researcher for five years beyond the end of the study.

By signing below I indicate my consent to:

☐ Take part in the study.

Signature of Participant: _____ Date: _____

Signature of Person Obtaining Consent: _____ Date: _____