PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION

Xu Tian

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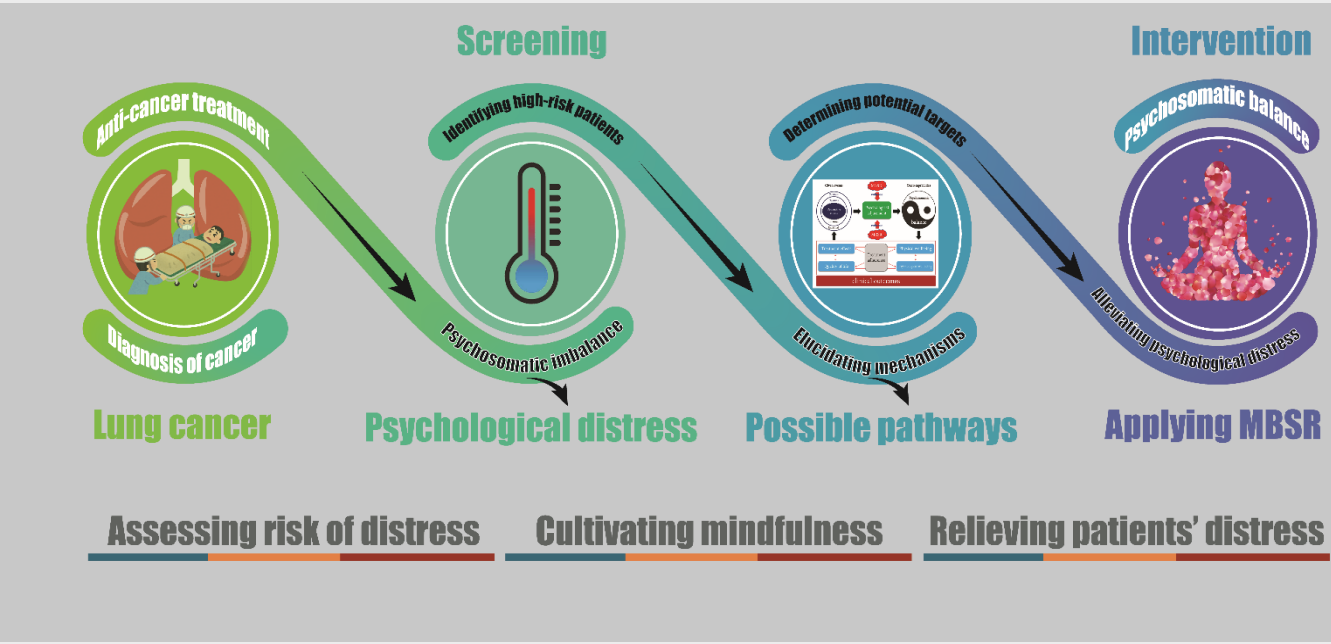
Psychological distress in Chinese lung cancer patients: prediction, psychosocial mechanisms, and intervention

Xu Tian



DOCTORAL THESIS
2023

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
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Psychological distress in Chinese lung cancer patients: prediction, psychosocial mechanisms, and intervention

DOCTORAL THESIS

Supervised by

Dr. **Maria F. Jiménez-Herrera**

UNIVERSITAT ROVIRA i VIRGILI

Nursing Department

Tarragona, 2023

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FAIG CONSTAR que aquest treball, titulat "***Malestar psicològic en pacients xinesos amb càncer de pulmó: predicció, mecanismes psicosocials i intervenció***", que presenta ***Xu Tian*** per a l'obtenció del títol de Doctor, ha estat realitzat sota la meva direcció al Departament ***Departament d'Infermeria*** d'aquesta universitat.

HAGO CONSTAR que el presente trabajo, titulado "***Angustia psicológica en pacientes chinos con cáncer de pulmón: predicción, mecanismos psicosociales e intervención***", que presenta ***Xu Tian*** para la obtención del título de Doctor, ha sido realizado bajo mi dirección en el ***Departamento de Enfermería*** de esta universidad.

I STATE that the present study, entitled "***Psychological distress in Chinese lung cancer patients: prediction, psychosocial mechanisms, and intervention***", presented by ***Xu Tian*** for the award of the degree of Doctor, has been carried out under my supervision at the ***Department of Nursing*** of this university.

Tarragona, 2023

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Xu Tian

Curriculum Vitae

Xu Tian was admitted to Northwest Minzu University in 2009 and started his university life. Four years later, in 2013, he obtained the Bachelor Degree in Nursing Science. Subsequently, Xu Tian furthered his study for the master degree in nursing in Tianjin University of Traditional Chinese Medicine from September 2013 to July 2016.

During these three years, under the guidance of Professor Guomin Song, Director of the Nursing Department of Tianjin University Tianjin Hospital, Xu Tian obtained his Master Degree in Nursing Science in July 2016. During his master studies, Xu Tian mainly focused on orthopedic nursing and evidence-based nursing practice, especially systematic review and meta-analysis. In 2015 and 2016, Xu Tian continuously won the National Scholarships for Postgraduates, and also won the Special Award of the Tianjin Innovation Scholarship for Postgraduates in 2015. In addition, he has also received several other awards and scholarships, and more importantly, he has published about 30 peer-reviewed articles in different levels of academic journals under the guidance of Professor Guomin Song. Many conclusions of these systematic reviews and meta-analyses published by Xu Tian, Professor Guoming Song, and other members of the research team have been cited by many clinical practice guidelines (CPGs).

Upon his graduation in July 2016, Xu Tian joined the Chongqing University Cancer Hospital through the “Talent Introduction Plan” implemented by Chongqing Municipal Health Commission. From October 2016 to October

2021, Xu Tian worked as an Oncology Nurse in this hospital, and received eight research grants of different levels as a principal or secondary investigator. During his clinical practice, Xu Tian published more than 20 academic papers, mainly focused on oncological nutrition, gastrointestinal nursing, and psychosocial rehabilitation for cancer patients. Most importantly, at the end of 2020, Xu Tian was admitted by the research team led by Dr. Maria F. Jiménez-Herrera, the former Dean of the Nursing Faculty at Universitat Rovira I Virgili and the current General Secretary of the University, and started his doctoral study.

During his doctoral study, under the meticulous supervision of Dr. Maria F. Jiménez-Herrera, Xu Tian continued to engage in research work related to the psychosocial rehabilitation of cancer patients, and began his doctoral thesis "*Psychological distress in Chinese lung cancer patients: prediction, psychosocial mechanisms, and intervention*". It is worth emphasizing that under the strong encouragement and meticulous supervision of Dr. Maria F. Jiménez-Herrera, Xu Tian launched the Research Topic focusing on the theme of "Psychosocial Rehabilitation for Cancer Patients" in Frontiers in Psychology in January 2022. Under the careful guidance and recommendation of Dr. Maria F. Jiménez-Herrera, Xu Tian participated in some important academic conferences and won some awards, such as the "Travel Grant Award" approved by ASSMN & KSSMN 2022. He has also been approved as an academic editor by three important nursing journals in 2022, including Journal of Nursing Management, Perspectives in Psychiatric Care, and Nursing Research and Practice.

Based on the systematic and rigorous training under the meticulous supervision of Dr. Maria F. Jiménez-Herrera during his doctoral study, Xu Tian received invitations from more than three affiliated hospitals of university in China to serve as the Vice Director of the Nursing Department. After choosing the most suitable position, Xu Tian will continue to carry out research work in the fields of psychosocial rehabilitation, nursing ethics, and evidence synthesis and translation, and plan some international cooperation programs with Dr. Maria F. Jiménez-Herrera and other distinguished specialists, to promote international academic and clinical communication and development in the nursing field.

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PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Acknowledgement

When I started writing my doctoral thesis, I had a lot of thoughts. Words have always been regarded as the most powerful route for expressing thoughts; however, they lack enough power to fully express my deepest gratitude now. Nevertheless, I have only words to express my infinite gratitude to those who have helped me tremendously during my doctoral studies and who will help me in my future life.

First and foremost, I would like to express my deepest gratitude to my supervisor Dr. Maria F. Jiménez-Herrera for her meticulous and invaluable guidance, patience, and selfless dedication. When we could only communicate online due to COVID pandemic, she chose to use WeChat, a popular Chinese social chat app, to discuss my doctoral thesis for my convenience, rather than having me use WhatsApp or other apps she might be familiar with. One year later, when I first arrived at Tarragona and told this information to her, Dr. Maria F. Jiménez-Herrera immediately arranged the earliest time for our first meet off-line although she had to deal with many affairs and present many academic conferences. Most importantly, one week after had the first off-line meeting, we had a delicious lunch for celebrating her birthday together. In the following days during doctoral studies, she always gave me meticulous guidance in research, great help in life, and great support in emotion. All in all, apart from the guidance, help, and support gave to me by Dr. Maria F. Jiménez-Herrera, I cannot even believe whether I would have achieved all promising findings in my doctoral thesis.

Therefore, I will keep my life-long appreciation to Dr. Maria F. Jiménez-Herrera.

Second, I deeply appreciate experts for taking golden time to review my doctoral thesis and then proposed many friendly but invaluable comments and suggestions, which helped me to greatly improve the quality of my doctoral thesis. Furthermore, I'm also sincerely grateful to the committee members to work for my doctoral thesis defense, breaking the barriers of time and distance. Most importantly, all committee members let me enjoy my thesis defense by giving me their kindness, and give me many invaluable comments and constructive suggestions for improving my doctoral thesis and designing future study. Therefore, I must express my heartfelt thanks to them.

Third, I want to thank all the staff at the URV, for their love, and selfless help and kindness. I would also like to especially thank the staff of CRAI, because almost all my doctoral thesis was written with their accompany. Furthermore, my appreciation is to Professor Guihua Chen, the vice director of Nursing Department at the affiliated Second Hospital of Chongqing Medical University, associate Professor Ling Tang, vice chief nurse in Chongqing University Cancer Hospital, and Professor Guomin Song, the former director of Nursing Department of Tianjin University Hospital, for their supports to me in data collection and research stay.

Fourth, I am most especially grateful to Dr. Linda He, because she tried her best to practice my English, enabling me to communicate fluently with my supervisor and give clear and concise presentation at the academic

conference. Most importantly, we do our best to make each other better, but I am forever indebted to her for her kindness and support.

It had to be said that in China, it is an incredible decision to give up a stable and moderately-paid work. However, I was deeply moved by the unconditional support of all our family members when I told them about my decision to leave my current job to pursue a PhD in Spain. So, in closing the Acknowledgement section, I would like to sincerely appreciate my dearest family for their dedication, generous support and unconditional love.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
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List of abbreviations

A	AGFI	Adjusted GFI
	SAS	Self-rating Anxiety Scale
	ANOVA	Analysis of variance
	AUC	area under the curve
	ADL	Activity of Daily Living Scale
B	BSI-18	Brief symptom inventory-18
	B-IPQ	Brief illness perception questionnaire
C	CINV	Cancer-induced nausea and vomiting
	CRF	Cancer-related fatigue
	CBT	Cognitive behavioral therapy
	CFI	Comparative fit index
	C.R.	Critical ratio
	CLCSS	Cataldo lung cancer stigma scale
	CI	Confidence interval
	CFS	Cancer fatigue scale
	CONSORT	Consolidated Standard of Randomized Trials
	CNKI	China national knowledge infrastructure
D	DT	Distress thermometer

	df	Degrees of freedom
E	EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
F	FFMQ	Five Facet Mindfulness Questionnaire
G	GFI	Goodness of fit index
	GRADE	Grading of Recommendations, Assessment, Development and Evaluation
H	HADS	Hospital anxiety and depression scale
	HAMA	Hamilton anxiety scale
	HAMD	Hamilton depression scale
I	IQR	Interquartile range
	IFI	Incremental fit index
K	KPS	Karnofsky performance status
M	MBSR	Mindfulness-based stress reduction
	MSPSS	Multidimensional Scale of Perceived Social Support
	MCMQ	Medical coping modes questionnaire
	MeSH	Medical subject heading
	MD	Mean difference
	MAAS	Mindful attention awareness scale

	MMSE	Mini-mental state examination
	MBI	Mindfulness-based interventions
N	NCCN	National comprehensive cancer network
	NPV	Negative predictive value
	NFI	Normed fit index
O	OSF	Open science framework
P	POMS	Profile of Mood States
	POMS-SF	Profile of Mood States-Short Form
	PD	Psychological distress
	PPV	Positive predictive value
	PSS	Perceived stress scale
	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
	PSQI	Pittsburgh sleep quality index
Q	QoL	Quality of life quality of life
R	RMSEA	Root-mean-square error of approximation
	ROC	Receiver operating characteristic
	RSES	Rosenberg self-esteem scale
	RCTs	Randomized controlled trials
	RevMan	Review manager

	R-PFS	Revised piper fatigue scale
S	SEM	Structural equation model
	S.E.	Standard error
	STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
	SMD	Standard mean difference
	SAS	Self-rating Anxiety Scale
	SDS	Self-rating Depression Scale
	SUPPH	Strategies Used by people to promote health
	SDS	Self-rating Depression Scale
	SD	Standard deviation
	SPSS	Statistical Package for Social Sciences
T	TNM	Tumor-node-metastasis
U	UC	Usual care

List of publications

Related papers to the thesis

1. **Tian X**, Jin Y, Tang L, Pi YP, Chen WQ, Jiménez-Herrera MF. Predicting the Risk of Psychological Distress among Lung Cancer Patients: Development and Validation of a Predictive Algorithm Based on Sociodemographic and Clinical Factors. *Asia Pac J Oncol Nurs*. 2021, 8(4):403-412. doi: 10.4103/apjon.apjon-2114.

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Unrelated papers to the thesis

1. **Tian X**, Jin YF, Liu XL, Chen H, Chen WQ, Jiménez-Herrera MF. Network meta-analysis of the optimal time of applying enteral immunonutrition in esophageal cancer patients receiving esophagectomy. *Support*

Care Cancer. 2022, 30(9):7133-7146. doi: 10.1007/s00520-022-07058-7.

2. Yi LJ, **Tian X**, Jin YF, Luo MJ, Jiménez-Herrera MF. Effects of yoga on health-related quality, physical health and psychological health in women with breast cancer receiving chemotherapy: a systematic review and meta-analysis. *Ann Palliat Med*. 2021, 10(2):1961-1975. doi: 10.21037/apm-20-1484. (***Yi LJ and Tian X contributed equally to this work.***)

3. **Tian X**, Jin Y, Chen H, Jiménez-Herrera MF. Instruments for Detecting Moral Distress in Clinical Nurses: A Systematic Review. *Inquiry*. 2021, 58:46958021996499. doi: 10.1177/0046958021996499.

4. Huang C, Liang X, Du S, He J, Bai Q, Feng X, Liu X, **Tian X**, Wang J. Therapeutic Effect and Cost-Benefit Analysis of Three Different Nutritional Schemes for Esophageal Cancer Patients in the Early Post-operative Period. Front Nutr. 2021, 8:651596. doi: 10.3389/fnut.2021.651596. (***Tian X was one of the corresponding authors.***)

5. **Tian X**, Yi LJ, Han Y, Chen H, Liu XL, Chen WQ, Jiménez-Herrera MF. Comparative Effectiveness of Enhanced Patient Instructions for Bowel Preparation Before Colonoscopy: Network Meta-analysis of 23 Randomized Controlled Trials. *J Med Internet Res*. 2021, 23(10):e19915. doi: 10.2196/19915.

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8. Jin Y, **Tian X**, Li Y, Jiménez-Herrera M, Wang H. Effects of continuous care on health outcomes in patients with stoma: A systematic review and meta-analysis. Asia Pac J Oncol Nurs. 2021, 9(1):21-31. doi: 10.1016/j.apjon.2021.12.006. (***Jin YF and Tian X contributed equally to this work.***)

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12. Chen, Y, **Tian, X**, Luo, CM, Luo, SL, Lin, L, Jiménez-Herrera, MF. Role of automatic tube compensation as spontaneous breathing trial in critically ill patients: A systematic review and meta-analysis. Signa Vitae, 2020, 1, 9. (***Chen Y and Tian X contributed equally to this work.***)

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Contents

Abstract 16
Resum 22
Resumen 28
Introduction 34
Objectives 40
Background 42
Psychological distress of lung cancer patients 42
Epidemiology of lung cancer 42
Terminologies of psychological distress 42
Incidence of psychological distress in lung cancer 43
Adverse consequences of psychological distress 43
The necessity of screening psychological distress in lung cancer patients 44
Screening tools for psychological distress in cancer patients 44
Distress Thermometer 45
Hospital Anxiety and Depression Scale 46
Profile of Mood States-Short Form 46
The necessity of developing a screening tool specific to lung cancer patients 47
Psychosocial mechanisms of psychological distress 48
Unmodifiable factors 48
Modifiable factors 50
The necessity of elucidating psychosocial mechanisms of psychological distress 50
Psychosocial interventions of psychological distress 51
The impact of MBSR on psychosocial symptoms of cancer patients 52
The necessity of implementing MBSR for alleviating psychological distress 53

The necessity of elucidating the mechanisms of MBSR on psychological distress 53
Methods 56
Results 70
Article 1 72
Article 2 84
Article 3 94
Article 4 106
Article 5 118
Article 6 128
Article 7 138
Article 8 156
Conclusions 170
Limitations 174
Implications for clinical practice 180
Dissemination of investigation 184
Appendix 188
Appendix 1 190
Certificate of Research Stay 190
Appendix 2 194
Registration of study 194
Appendix 3 200
Ethical Approval for Studies 200
Appendix 4 204
Patient's Informed Consent Template 204
Appendix 5 210
Supplementary Table 1 of Article 7 210
Appendix 6 214
Supplementary Table 1 of Article 8 214
Appendix 7 220
Supplementary Table 2 of Article 8 220
Appendix 8 224
Invitation letter for presentation in WCC 2022 224

Appendix 9 228
Invitation letter for presentation in AONS 2021 228
Appendix 10 232
Invitation letter for presentation 1 in 2021 CCO 232
Appendix 11 236
Invitation letter for presentation 2 in 2021 CCO 236
Appendix 12 240
Invitation letter for presentation 3 in 2021 CCO 240
Appendix 13 244
PPT for public-entry lecture 244
Appendix 14 250
Sample pictures for seminars 250
Appendix 15 254
Screenshot for Research Topic 254
Appendix 16 258
Screenshot for Software 258
References 262

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Abstract

Background: Psychological distress is a multifactorial and unpleasant emotional experience, involving changes in psychological, social, spiritual, and physical aspects, with greatly impact on the psychological and physical well-being of cancer patients. Compared to other cancers, lung cancer patients had the highest incidence of psychological distress. Notably, psychological distress is associated with many adverse consequences, such as poor treatment adherence and decreased therapeutic effectiveness. Therefore, the use of validated tools for early and accurate detection of those at high risk of psychological distress from overall lung cancer patients is critical. Unfortunately, there are currently no screening tools for psychological distress specifically for lung cancer patients. Furthermore, the exact psychosocial mechanisms of psychological distress in patients with lung cancer have not yet been clarified, resulting in no effective interventions to effectively alleviate psychological distress.

Objectives: The current thesis aims to firstly develop a valid predictive tool for identifying those at high risk for psychological distress from overall lung cancer patients, and then to explore possible psychosocial mechanisms of psychological distress in lung cancer patients, and next to further evaluate the role of mindfulness-based stress reduction (MBSR) in treating lung cancer patients, and ultimately to evaluate the efficacy of a 4-weeks MBSR program on psychological distress in lung cancer patients and elucidate possible psychosocial mechanisms of exerting efficacy.

Methods: The current thesis designs seven separate studies, and various methods are used in different studies to achieve different objectives. Study 1 uses cross-sectional design to collect possible risk factors of psychological distress in lung cancer patients with the convenience sampling, and then uses structural equation model (SEM) and coincidence rate to develop and validate predictive algorithm, respectively. Study 2 to 5 also use cross-sectional design to collect data on social support, mindfulness, coping style, perceived stress, self-esteem, perceived stigma, illness perception, and distress thermometer (DT), and then use correlation analysis and structural equation modeling to determine the influence pathways and magnitude between different factors. Study 6 is designed as a meta-analysis, including retrieving literature published before November 2021 from PubMed, EMBASE, the Cochrane Library, PsycINFO, China National Knowledge Infrastructure (CNKI), and Wanfang databases, assessing risk of bias using the Cochrane risk of bias assessment tool, evaluating the efficacy of MBSR in lung cancer patients by designing psychological variables and quality of life (QoL) as outcomes, and grading the level of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. Study 7 is a single-center, single-blinded, longitudinal, randomized controlled trial, which includes a four-week MBSR or a waiting-list group. In this study, the efficacy and mechanisms of the four-week MBSR were evaluated by using independent sample *t*-test, repeated measure analysis of variance (ANOVA), and SEM to analyze outcome measures at pre-intervention (T0), the immediate post-intervention (T1), 1 month (T2), and 3 months (T3). Statistical analyses in the first to fifth

studies and the seventh study were conducted using Statistical Package for the Social Sciences (SPSS) version 22.0 and AMOS version 21.0 (Chicago, IL, United States); however, statistical analyses in the sixth study were conducted using RevMan 5.4 (Cochrane Collaboration, Oxford, United Kingdom) and STATA 14.0 (StataCorp, Texas, USA).

Results: In study 1, 441 participants sent back validated questionnaires, and the SEM analysis showed that educational level ($\beta = 0.151$, $P = 0.004$), residence ($\beta = 0.146$, $P = 0.016$), metastasis ($\beta = 0.136$, $P = 0.023$), pain degree ($\beta = 0.133$, $P = 0.005$), family history ($\beta = -0.107$, $P = 0.021$), and tumor, node, and metastasis stage (TNM) ($\beta = -0.236$, $P < 0.001$) were independent predictors for psychological distress. The model built with these predictors showed an area under the curve of 0.693. A cutoff of 66 predicted clinically significant psychological distress with a sensitivity, specificity, positive predictive value, and negative predictive value of 65.41%, 66.90%, 28.33%, and 89.67%, respectively. The coincidence rate between predictive algorithm and distress thermometer was 64.63%.

Study 2 and 3 consistently suggested that social support had significant direct effects on psychological distress, with a β of −0.58 in the second study and a β of −0.710 in the third study. Furthermore, study 2 revealed that confrontation coping and perceived stress partially mediated the association between social support and psychological distress, and study 3 illustrated that self-esteem partially mediated the relationship between social support and psychological distress. Study 4 revealed that mindfulness had a direct effect on psychological distress, reporting a β of −0.107;

however, and the direct association between mindfulness and psychological distress was not detected in the fifth study. Furthermore, study 4 revealed the indirect association between mindfulness and psychological distress through the chain mediating role of stigma and social support, and study 5 revealed that mindfulness indirectly influenced psychological distress through affecting illness perception alone or simultaneously affecting both illness perception and perceived stress.

Study 6 found that MBSR significantly relieved cancer-related fatigue (standard mean difference [SMD], −1.26; 95% confidence interval [CI], −1.69 to −0.82; moderate evidence) and negative psychological states (SMD, −1.35; 95% CI, −1.69 to −1.02; low evidence), enhanced positive psychological states (SMD, 0.91; 95% CI, 0.56–1.27; moderate evidence), and improved quality of sleep (MD, −2.79; 95% CI, −3.03 to −2.56; high evidence). Evidence on MBSR programs' overall treatment effect for QoL revealed a trend toward statistical significance (P=0.06, low evidence).

Study 7 demonstrated that the four-week MBSR significantly alleviated psychological distress (F=15.05, P<0.001), decreased perceived stigma (F=8.260, P=0.005), and improved social support (F=16.465, P<0.001), and enhanced mindfulness (F=17.207, P<0.001) compared with usual care at T1, T2, and T3. All variables significantly changed over time except for copying style (P=0.250). The changes in social support, mindfulness, and perceived stigma mediated the efficacy of the four-week MBSR program on psychological distress (β=-0.292, P=0.005; β=-0.358, P=0.005).

Conclusions: Based on the results of seven separate studies, various

conclusions are drawn, which are summarized below in the order of study.

i. Study 1 develops an easy-to-use predictive algorithm with moderate accuracy, which benefits to identify patients at high risk of psychological distress.

ii. Study 2 and 3 reveal that social support may directly contribute to ameliorate psychological distress, or may indirectly contribute to ameliorate psychological distress by enhancing confrontation coping with cancer, decreasing perceived stress, and increasing self-esteem; and study 4 and 5 unfold that mindfulness may indirectly alleviate psychological distress by enhancing social support, decreasing perceived stigma, and reducing the level of illness perception and perceived stress.

iii. Study 6 demonstrates the positive effects of MBSR on psychological states in lung cancer patients, implying that intervention protocols based on this approach should be recommended as a part of the rehabilitation program for lung cancer patients.

iv. Study 7 shows the benefits of the four-weeks MBSR for psychological distress, social support, mindfulness, and perceived stigma in lung cancer patients, and it also elucidates the mechanisms by which the MBSR alleviates psychological distress by improving social support, enhancing mindfulness, and decreasing perceived stigma, thereby providing insights into applying the MBSR to reduce psychological distress among lung cancer patients.

Key words: lung cancer; psychological distress; predictive tool; social support; self-esteem; coping style; illness perception; disease stigma; mindfulness; preserved stress; mindfulness-based stress reduction; meta-analysis; structural equation model.

Resum

Antecedents: El malestar psicològic és una experiència emocional multifactorial i desagradable, que implica canvis en aspectes psicològics, socials, espirituals i físics, amb un gran impacte en el benestar psicològic i físic dels malalts de càncer. En comparació amb altres càncers, els pacients amb càncer de pulmó tenien la incidència més alta de malestar psicològic. En particular, el malestar psicològic s'associa amb moltes conseqüències adverses, com ara una mala adherència al tractament i una disminució de l'eficàcia terapèutica. Per tant, l'ús d'eines validades per a la detecció precoç i precisa de persones amb alt risc de patiment psicològic dels pacients amb càncer de pulmó en general és fonamental. Malauradament, actualment no hi ha eines de cribratge per a l'angoixa psicològica específicament per als pacients amb càncer de pulmó. A més, encara no s'han aclarit els mecanismes psicosocials exactes de l'angoixa psicològica en pacients amb càncer de pulmó, i no s'ha produït cap intervenció efectiva per alleujar eficaçment el malestar psicològic.

Objectius: La tesi actual té com a objectiu, en primer lloc, desenvolupar una eina predictiva vàlida per identificar aquells que tenen un alt risc de patiment psicològic en pacients amb càncer de pulmó en general, i després explorar possibles mecanismes psicosocials de malestar psicològic en pacients amb càncer de pulmó i, a continuació, avaluar més el paper. de la reducció de l'estrès basada en la consciència (MBSR) en el tractament de pacients amb càncer de pulmó i, finalment, per avaluar l'eficàcia d'un

programa MBSR de 4 setmanes sobre malestar psicològic en pacients amb càncer de pulmó i dilucidar els possibles mecanismes psicosocials d'exercir eficàcia.

Mètodes: La tesi actual dissenya set estudis separats i s'utilitzen diversos mètodes en diferents estudis per aconseguir diferents objectius. El primer estudi utilitza un disseny transversal per recollir possibles factors de risc de malestar psicològic en pacients amb càncer de pulmó amb el mostreig de conveniència, i després utilitza el model d'equació estructural (SEM) i la taxa de coincidència per desenvolupar i validar l'algorisme predictiu, respectivament. Del segon al cinquè estudis també utilitzen el disseny transversal per recollir dades sobre suport social, mindfulness, estil d'afrontament, estrès percebut, autoestima, estigma percebut, percepció de la malaltia i termòmetre de socors (DT) i després utilitzen l'anàlisi de correlació i l'estructura estructural. modelització d'equacions per determinar les vies d'influència i la magnitud entre diferents factors. El sisè estudi està dissenyat com una anàlisi me-ta, que inclou la recuperació de la literatura publicada abans del novembre de 2021 de PubMed, EMBASE, Cochrane Library, PsycINFO, China National Knowledge Infrastructure (CNKI) i bases de dades Wanfang, avaluant el risc de biaix mitjançant el risc Cochrane de eina d'avaluació del biaix, avaluant l'eficàcia de MBSR en pacients amb càncer de pulmó mitjançant el disseny de variables psicològiques i la qualitat de vida (QoL) com a resultats, i classificant el nivell d'evidència mitjançant el sistema d'avaluació, desenvolupament i avaluació de les recomanacions (GRADE). El setè estudi és un assaig controlat aleatoritzat, d'un sol centre, cec, longitudinal i que inclou un MBSR de quatre setmanes

o un grup de llista d'espera. En aquest estudi, es van avaluar l'eficàcia i els mecanismes del MBSR de quatre setmanes mitjançant la prova t de mostra independent, l'anàlisi de variància de mesures repetides (ANOVA) i el modelatge d'equacions estructurals per analitzar les mesures de resultats abans de la intervenció (T0), el postintervenció immediata (T1), 1 mes (T2) i 3 mesos (T3). Les anàlisis estadístiques del primer al cinquè estudis i el setè estudi es van realitzar mitjançant Statistical Package for the Social Sciences (SPSS) versió 22.0 i AMOS versió 21.0 (Chicago, IL, Estats Units); tanmateix, les anàlisis estadístiques del sisè estudi es van realitzar mitjançant RevMan 5.4 (Cochrane Collaboration, Oxford, Regne Unit) i STATA 14.0 (StataCorp, Texas, EUA).

Resultats: En el primer estudi, 441 participants van enviar qüestionaris validats, i l'anàlisi SEM va mostrar que el nivell educatiu (β=0,151, P=0,004), residència (β=0,146, P=0,016), metàstasi (β=0,136, P=0,023), el grau de dolor (β=0,133, P=0,005), els antecedents familiars (β=−0,107, P=0,021) i l'estadi de tumor, node i metàstasi (β=−0,236, P<0,001) eren predictors independents de malestar psicològic. El model construït amb aquests predictors mostrava una àrea sota la corba de 0,693. Un tall de 66 va predir un malestar psicològic clínicament significatiu amb una sensibilitat, especificitat, valor predictiu positiu i valor predictiu negatiu del 65,41%, 66,90%, 28,33% i 89,67%, respectivament. La taxa de coincidència entre l'algoritme predictiu i el termòmetre de socors va ser del 64,63%.

El segon i el tercer estudi van suggerir constantment que el suport social

va tenir efectes directes significatius sobre el malestar psicològic, amb un β de -0,58 en el segon estudi i un β de -0,710 en el tercer estudi. A més, el segon estudi va revelar que l'afrontament de la confrontació i l'estrès percebut van mediar parcialment l'associació entre suport social i malestar psicològic, i el tercer estudi va il·lustrar que l'autoestima mediava parcialment la relació entre suport social i malestar psicològic. El quart estudi va trobar que la consciència tenia un efecte directe sobre el malestar psicològic, informant d'un β de -0,107; tanmateix, i l'associació directa entre mindfulness i malestar psicològic no es va detectar en el cinquè estudi. A més, el quart estudi va revelar l'associació indirecta entre la consciència i l'angoixa psicològica a través del paper mediador de la cadena de l'estigma i el suport social, i el cinquè estudi va revelar que la consciència va influir indirectament en l'angoixa psicològica mitjançant l'afectació de la percepció de la malaltia sola o simultàniament tant en la percepció de la malaltia. i l'estrès percebut.

El sisè estudi va trobar que MBSR va alleujar significativament la fatiga relacionada amb el càncer (diferència mitjana estàndard [SMD], -1,26; interval de confiança [IC] del 95%, -1,69 a -0,82; evidència moderada) i estats psicològics negatius (SMD, -1,35; IC del 95%, -1,69 a -1,02; evidència baixa), estats psicològics positius millorats (SMD, 0,91; IC del 95%, 0,56-1,27; evidència moderada) i millora de la qualitat del son (DM, -2,79; 95% CI, -3,03 a -2,56; evidència alta). L'evidència sobre l'efecte global del tractament dels programes MBSR per a la qualitat de vida va revelar una tendència cap a la significació estadística (P=0,06, evidència baixa).

El setè estudi va demostrar que el MBSR de quatre setmanes va alleujar significativament el malestar psicològic (F=15,05, P<0,001), va disminuir l'estigma percebut (F=8,260, P=0,005) i va millorar el suport social (F=16,465, P<0, 001) i millora de la consciència (F=17, 207, P<0, 001) en comparació amb l'atenció habitual a T1, T2 i T3. Totes les variables van canviar significativament amb el temps, excepte l'estil d'afrontament (P=0,250). Els canvis en el suport social, la consciència i l'estigma percebut van mediar l'eficàcia del programa MBSR de quatre setmanes sobre malestar psicològic (β=-0,292, P=0,005; β=-0,358, P=0,005).

Conclusions: A partir dels resultats de set estudis separats, s'extreuen diverses conclusions, que es resumeixen a continuació en l'ordre d'estudi.

i. El primer estudi desenvolupa un algorisme predictiu fàcil d'utilitzar amb una precisió moderada, que beneficia a identificar pacients amb alt risc de patiment psicològic.

ii. El segon i el tercer estudi revelen que el suport social pot contribuir directament a millorar el malestar psicològic, o pot contribuir indirectament a millorar el malestar psicològic millorant l'enfrontament per fer front al càncer, disminuir l'estrès percebut i augmentar l'autoestima; i els estudis quart i cinquè mostren que l'atenció plena pot alleujar indirectament el malestar psicològic millorant el suport social, disminuint l'estigma percebut i reduint el nivell de percepció de la malaltia i l'estrès percebut.

iii. El sisè estudi demostra els efectes positius de MBSR en els estats

psicològics en pacients amb càncer de pulmó, la qual cosa implica que els protocols d'intervenció basats en aquest enfocament s'han de recomanar com a part del programa de rehabilitació per a pacients amb càncer de pulmó.

iv. El setè estudi mostra els beneficis del MBSR de 4 setmanes per al malestar psicològic, el suport social, la consciència i l'estigma percebut en pacients amb càncer de pulmó, i també dilucida els mecanismes pels quals el MBSR alleuja el malestar psicològic millorant el suport social, millorant la consciència, i disminuir l'estigma percebut, proporcionant així informació sobre l'aplicació de l'MBSR per reduir el malestar psicològic entre els pacients amb càncer de pulmó.

Paraules clau: càncer de pulmó; malestar psicològic; eina predictiva; suport social; autoestima; estil d'afrontament; percepció de la malaltia; estigma de la malaltia; consciència; estrès conservat; reducció de l'estrès basada en la consciència; metaanàlisi; model d'equació estructural

Resumen

Antecedentes: El malestar psicológico es una experiencia emocional multifactorial y desagradable, que involucra cambios en los aspectos psicológico, social, espiritual y físico, con gran impacto en el bienestar psicológico y físico de los pacientes con cáncer. En comparación con otros tipos de cáncer, los pacientes con cáncer de pulmón tenían la mayor incidencia de angustia psicológica. En particular, la angustia psicológica se asocia con muchas consecuencias adversas, como la mala adherencia al tratamiento y la disminución de la eficacia terapéutica. Por lo tanto, es fundamental el uso de herramientas validadas para la detección temprana y precisa de aquellos con alto riesgo de angustia psicológica de los pacientes con cáncer de pulmón en general. Desafortunadamente, actualmente no existen herramientas de detección para la angustia psicológica específicamente para pacientes con cáncer de pulmón. Además, aún no se han aclarado los mecanismos psicosociales exactos de la angustia psicológica en pacientes con cáncer de pulmón, por lo que no existen intervenciones eficaces para aliviar la angustia psicológica de manera efectiva.

Objetivos: La tesis actual tiene como objetivo, en primer lugar, desarrollar una herramienta predictiva válida para identificar a aquellos con alto riesgo de angustia psicológica en pacientes con cáncer de pulmón en general, y luego explorar posibles mecanismos psicosociales de angustia psicológica en pacientes con cáncer de pulmón, y luego evaluar más a fondo el papel de la reducción del estrés basada en la atención plena

(MBSR) en el tratamiento de pacientes con cáncer de pulmón y, en última instancia, para evaluar la eficacia de un programa MBSR de 4 semanas sobre la angustia psicológica en pacientes con cáncer de pulmón y dilucidar los posibles mecanismos psicosociales para ejercer la eficacia.

Métodos: La tesis actual diseña siete estudios separados, y se utilizan varios métodos en diferentes estudios para lograr diferentes objetivos. El primer estudio utiliza un diseño transversal para recopilar posibles factores de riesgo de angustia psicológica en pacientes con cáncer de pulmón con el muestreo de conveniencia, y luego utiliza el modelo de ecuación estructural (SEM) y la tasa de coincidencia para desarrollar y validar el algoritmo predictivo, respectivamente. Los estudios segundo a quinto también utilizan un diseño transversal para recopilar datos sobre el apoyo social, la atención plena, el estilo de afrontamiento, el estrés percibido, la autoestima, el estigma percibido, la percepción de la enfermedad y el termómetro de angustia (DT), y luego utilizan análisis de correlación y análisis estructural. modelado de ecuaciones para determinar las vías de influencia y la magnitud entre diferentes factores. El sexto estudio está diseñado como un metanálisis, que incluye la recuperación de literatura publicada antes de noviembre de 2021 de las bases de datos PubMed, EMBASE, Cochrane Library, PsycINFO, China National Knowledge Infrastructure (CNKI) y Wanfang, que evalúa el riesgo de sesgo utilizando el riesgo Cochrane de herramienta de evaluación de sesgos, evaluando la eficacia de MBSR en pacientes con cáncer de pulmón mediante el diseño de variables psicológicas y calidad de vida (QoL) como resultados, y clasificando el nivel de evidencia utilizando el sistema Grading of Recommendations

Assessment, Development and Evaluation (GRADE). El séptimo estudio es un ensayo controlado aleatorizado, longitudinal, simple ciego, de un solo centro, que incluye un MBSR de cuatro semanas o un grupo en lista de espera. En este estudio, la eficacia y los mecanismos del MBSR de cuatro semanas se evaluaron mediante el uso de la prueba t de muestra independiente, el análisis de varianza de medidas repetidas (ANOVA) y el modelado de ecuaciones estructurales para analizar las medidas de resultado antes de la intervención (T0), el postintervención inmediata (T1), 1 mes (T2) y 3 meses (T3). Los análisis estadísticos en los estudios primero a quinto y el séptimo estudio se realizaron utilizando Statistical Package for the Social Sciences (SPSS) versión 22.0 y AMOS versión 21.0 (Chicago, IL, Estados Unidos); sin embargo, los análisis estadísticos en el sexto estudio se realizaron con RevMan 5.4 (Colaboración Cochrane, Oxford, Reino Unido) y STATA 14.0 (StataCorp, Texas, EE. UU.).

Resultados: En el primer estudio, 441 participantes enviaron cuestionarios validados y el análisis SEM mostró que el nivel educativo (β=0,151, P=0,004), residencia (β=0,146, P=0,016), metástasis (β=0,136, P=0,023), el grado de dolor (β=0,133, P=0,005), los antecedentes familiares (β=−0,107, P=0,021) y el estadio del tumor, ganglio y metástasis (β=−0,236, P<0,001) fueron independientes predictores para la angustia psicológica. El modelo construido con estos predictores mostró un área bajo la curva de 0,693. Un punto de corte de 66 predijo malestar psicológico clínicamente significativo con una sensibilidad, especificidad, valor predictivo positivo y valor predictivo negativo de 65,41%, 66,90%, 28,33% y 89,67%, respectivamente. La tasa de coincidencia entre el algoritmo

predictivo y el termómetro de angustia fue del 64,63%.

El segundo y tercer estudio sugirieron consistentemente que el apoyo social tenía efectos directos significativos sobre la angustia psicológica, con un β de -0,58 en el segundo estudio y un β de -0,710 en el tercer estudio. Además, el segundo estudio reveló que el afrontamiento de la confrontación y el estrés percibido mediaron parcialmente la asociación entre el apoyo social y la angustia psicológica, y el tercer estudio ilustró que la autoestima mediaba parcialmente la relación entre el apoyo social y la angustia psicológica. El cuarto estudio encontró que la atención plena tuvo un efecto directo sobre la angustia psicológica, informando un β de −0,107; sin embargo, en el quinto estudio no se detectó una asociación directa entre la atención plena y la angustia psicológica. Además, el cuarto estudio reveló la asociación indirecta entre la atención plena y la angustia psicológica a través del papel mediador en cadena del estigma y el apoyo social, y el quinto estudio reveló que la atención plena influyó indirectamente en la angustia psicológica al afectar la percepción de la enfermedad solo o al afectar simultáneamente la percepción de la enfermedad. y el estrés percibido.

El sexto estudio encontró que MBSR alivió significativamente la fatiga relacionada con el cáncer (diferencia de medias estándar [SMD], -1,26; intervalo de confianza [IC] del 95 %, -1,69 a -0,82; evidencia moderada) y estados psicológicos negativos (SMD, - 1,35; IC 95 %, −1,69 a −1,02; evidencia baja), estados psicológicos positivos mejorados (SMD, 0,91; IC 95 %, 0,56–1,27; evidencia moderada) y mejor calidad del sueño (DM, −2,79; 95 % IC,

−3,03 a −2,56; evidencia alta). La evidencia sobre el efecto general del tratamiento de los programas MBSR para la CdV reveló una tendencia hacia la significación estadística (*P*=0,06, evidencia baja).

El séptimo estudio demostró que el MBSR de cuatro semanas alivió significativamente la angustia psicológica (*F*=15,05, *P*<0,001), disminuyó el estigma percibido (*F*=8,260, *P*=0,005) y mejoró el apoyo social (*F*=16,465, *P*<0,001) y atención plena mejorada (*F*=17,207, *P*<0,001) en comparación con la atención habitual en T1, T2 y T3. Todas las variables cambiaron significativamente con el tiempo, excepto el estilo de copia (*P*=0,250). Los cambios en el apoyo social, la atención plena y el estigma percibido mediaron la eficacia del programa MBSR de cuatro semanas sobre la angustia psicológica (*β*=-0,292, *P*=0,005; *β*=-0,358, *P*=0,005).

Conclusiones: Sobre la base de los resultados de siete estudios separados, se extraen varias conclusiones, que se resumen a continuación en el orden de estudio.

i. El primer estudio desarrolla un algoritmo predictivo fácil de usar con una precisión moderada, que beneficia la identificación de pacientes con alto riesgo de sufrimiento psicológico.

ii. El segundo y tercer estudio revelan que el apoyo social puede contribuir directamente a mejorar la angustia psicológica, o puede contribuir indirectamente a mejorar la angustia psicológica al mejorar la confrontación para hacer frente al cáncer, disminuir el estrés percibido y aumentar la autoestima; y los estudios cuarto y

quinto revelan que la atención plena puede aliviar indirectamente la angustia psicológica al mejorar el apoyo social, disminuir el estigma percibido y reducir el nivel de percepción de la enfermedad y el estrés percibido.

iii. El sexto estudio demuestra los efectos positivos de MBSR en los estados psicológicos de los pacientes con cáncer de pulmón, lo que implica que se deben recomendar protocolos de intervención basados en este enfoque como parte del programa de rehabilitación para pacientes con cáncer de pulmón.

iv. El séptimo estudio muestra los beneficios del MBSR de 4 semanas para la angustia psicológica, el apoyo social, la atención plena y el estigma percibido en pacientes con cáncer de pulmón, y también aclara los mecanismos por los cuales el MBSR alivia la angustia psicológica mejorando el apoyo social, mejorando la atención plena, y la disminución del estigma percibido, lo que proporciona información sobre cómo aplicar el MBSR para reducir la angustia psicológica entre los pacientes con cáncer de pulmón.

Palabras clave: cáncer de pulmón; malestar psicológico; herramienta predictiva; apoyo social; autoestima; estilo de afrontamiento; percepción de la enfermedad; estigma de la enfermedad; conciencia; estrés conservado; reducción del estrés basada en la conciencia; metaanálisis; modelo de ecuación estructural

Introduction

Distress refers to "a multifactorial and unpleasant emotional experience, involving changes in psychological, social, spiritual, and physical aspects," according to the definition given out by the NCCN guideline[1]. Patients and oncologists prefer the term "distress" because it is less stigmatizing; therefore, the NCCN guideline panel used "distress" rather than "psychological distress"[2]. However, both terms are used interchangeably in the literature. So, from the perspective of academic use, psychological distress is still preferentially selected in this thesis.

Cancer patients will suffer from various psychological problems except for various physical symptoms (e.g., fatigue and shortness of breath) due to cancer diagnosis and anti-cancer treatments, especially psychological distress[3,4]. Psychological distress will retain throughout the cancer trajectory[5], having different prevalence according to various studies, cancers, and countries[6], with a range from 20% to 58%[7-10]. Lung cancer remains the first reason of cancer-related death worldwide, accounting for approximately 18% of all cancer deaths, although the incidence of female breast cancer has surpassed that of lung cancer[11]. Compared with other cancers, lung cancer patients reported the highest incidence of psychological distress[12,13]. In addition, a recent meta-analysis reported a mean prevalence of 48.3% of psychological distress in Chinese lung cancer patients[14].

Clinically significant psychological distress is associated with a range of adverse consequences[1], such as interruption of anticancer treatments[15-17], prolonged hospital stay[18], higher suicidal risk[19], poor quality of life

(QoL)[20,21], and higher risk of mortality[22,23]. Moreover, a previous study also evidenced that psychological distress can accelerate the growth of tumor cells[24]. Furthermore, because psychological distress has been recognized as the sixth vital sign[1,25], so it is crucial to use valid predictive tools to identify those lung cancer patients at high risk for psychological distress and, after elucidation of mechanisms, further provide effective interventions to reduce levels of psychological distress.

Currently, several screening instruments are available to assess psychological distress in cancer patients[26], especially Distress Thermometer (DT)[1], Hospital Anxiety and Depression Scale (HADS)[27] and Profile of Mood States-Short Form (POMS-SF)[28]. However, DT can only reveal the degree of psychological distress, not the risk of psychological distress. For HADS, it cannot even accurately assess psychological distress because the instrument only measures anxiety and depression which are merely two symptoms of psychological distress not psychological distress per se[1]. In terms of POMS-SF, few studies have investigated its cut-off value for defining clinically significant psychological distress, and most importantly, the POMS-SF only assess psychological distress from psychological perspective but does not cover the social and spiritual attributes of psychological distress. So, even there are many instruments can be used for psychological distress screening in cancer patients in practice, several common issues also significantly limit their application in screening of psychological distress. Therefore, it is critical to develop a valid and easy-to-use tool specifically for the risk screening of psychological distress in lung cancer patients.

Accurate identification of cancer patients who are at high risk for psychological distress is essential to effectively protect cancer patients from developing clinically significant psychological distress[29]. Therefore, in order to develop effective interventions for psychological distress or clarify the underlying mechanisms of available interventions for alleviating psychological distress more precisely, it is crucial to elucidate the possible mechanisms involved in the development and progression of psychological distress[30]. Previous studies[31-33] have investigated some psychosocial factors of psychological distress in cancer patients, such as social support, perceived stigma, and mindfulness; however, the definitive relationships of these psychosocial factors with psychological distress in lung cancer patients are still not completely elucidated. Therefore, there is an urgent need to determine the pathways and influencing magnitudes of impacts of common psychosocial factors on psychological distress in order to elucidate the possible mechanisms of psychological distress of lung cancer patients from psychosocial perspective.

Several treatment modalities are available for the management of psychological distress in cancer patients, including pharmacologic interventions, complementary and alternative therapies, and psychosocial interventions[1]. However, from the NCCN definition of psychological distress, psychosocial interventions may be more appropriate for the alleviation of psychological distress in practice[34-36]. Among the currently available psychological interventions, MBSR program is most frequently applied in cancer settings[36,37] and may be also the best psychosocial intervention to relieve cancer-related fatigue[38]. However, psychosocial interventions for patients with

cancer have disproportionately targeted women with breast cancer[39,40], it remains unclear the benefits of the MBSR program on other cancer patients. Therefore, it is critical to investigate the therapeutic role of the MBSR program in different cancers. In addition, there is also urgent need to elucidate the possible mechanisms of an appropriate MBSR program on affecting psychological distress in cancer patients.

Following these open questions mentioned above, the current thesis designed the following four parts to generate additional knowledge to bridge these gaps between research findings and clinical practice:

Part I is a cross-sectional survey study (ordering study 1), aiming at determining the association of some important sociodemographic and clinical variables with psychological distress in lung cancer patients, and then using structural equation modeling to develop a predictive algorithm for detecting Chinese lung cancer patients who are at high risk for psychological distress. Finally, the predictive yield of this predictive algorithm is validated through calculating the coincidence rate between the predictive algorithm and DT.

Part II aims at elucidating the possible psychosocial mechanisms of the occurrence and progression of psychological distress in Chinese patients with lung cancer, which includes 4 separate studies. In this part, study 2 investigates the impact of social support on Chinese lung cancer patients' psychological distress and further clarifies the mediating role of perceived stress and coping style; study 3 investigates the effects of social support on psychological distress among Chinese lung cancer patients and further

clarifies the mediating role of self-esteem; study 4 determines the relationship of mindfulness and psychological distress and further clarifies the mechanisms of mindfulness against psychological distress through perceived stigma and social support among Chinese lung cancer patients; and study 5 investigates the association between illness perception and psychological distress and second to determines whether mindfulness affects psychological distress via illness perception and perceived stress in patients with lung cancer.

Part III, study 6, is designed as a meta-analysis to evaluate the impact of the MBSR program on psychological outcomes and quality of life (QoL) in patients with lung cancer, which aims to provide evidence-based strategy for effective intervention of psychological distress in Chinese lung cancer patients.

Part IV, study 7, is a single-center, single-blind, longitudinal, randomized controlled trial, with the aims of evaluating the therapeutic efficacy and clarifying possible psychosocial mechanisms of a four-week MBSR program on psychological distress in Chinese lung cancer patients.

Objectives

Based on the gaps between research findings and clinical practice we detected through literature review, the current thesis aims to achieve the following two major goals: (i) timely and accurate detection of lung cancer patients who are at high risk for psychological distress and (ii) effective intervention of psychological distress in lung cancer patients after elucidating possible psychosocial mechanisms. Furthermore, this thesis designed the following four specific objectives to more precisely achieve the two major goals described above:

1. To investigate how can one regularly, timely, effectively, and objectively detect lung cancer patients at high risk of psychological distress.

2. To study which psychosocial factors may be involved in the occurrence and progression of psychological distress in patients with lung cancer, and further clarify the possible psychosocial mechanisms of psychological distress in lung cancer patients.

3. To evaluate whether MBSR is effective in reducing negative psychological status, enhancing positive psychological status, and improving QoL in lung cancer patients.

4. To determine whether short-term MBSR program can effectively alleviate the level of psychological distress and elucidate which psychosocial pathways may mediate the intervention efficacy of the

short-term MBSR program on the psychological distress in lung cancer patients.

Background

Psychological distress of lung cancer patients

Epidemiology of lung cancer

According to the GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries, lung cancer ranks second among all diagnosed cancers, with an estimated 2,206,771 new cases; however, it remains the first reason of cancer-related death worldwide, accounting for approximately 18% of all cancer deaths (1,796,144 new deaths), although the incidence of female breast cancer has surpassed that of lung cancer[11]. In China, according to the statistics published in 2022, lung cancer ranks first in both incidence and cancer-related mortality, with new cases of 828,100 and cancer-related deaths of 657,000[41], respectively.

Terminologies of psychological distress

Distress refers to "a multifactorial and unpleasant emotional experience, involving changes in psychological, social, spiritual, and physical aspects," according to the definition given out by the NCCN guideline[1]. Patients and oncologists prefer the term "distress" because it is less stigmatizing; therefore, the NCCN guideline panel used "distress" rather than "psychological distress"[2]. However, both terms are used interchangeably in the literature. So, from the perspective of academic use, psychological distress is still preferentially selected in this thesis.

Incidence of psychological distress in lung cancer

Cancer patients will suffer from various psychological problems except for various physical symptoms (e.g., fatigue and shortness of breath) due to cancer diagnosis and anti-cancer treatment, especially psychological distress[3,4]. Psychological distress will retain throughout the cancer trajectory[5], having different prevalence according to various studies, cancers, and countries[6], with a range from 20% to 58%[7-10]. Lung cancer patients have been reported to suffer from clinically significant psychological distress because of several factors such as diagnosis of lung cancer[42] and poor prognosis[43]. Furthermore, compared to patients with other cancers, lung cancer was associated with the highest psychological distress prevalence[12,13], varying from 17.0% to 73.0%[20,44,45]. In addition, a recent meta-analysis reported a mean prevalence of 48.3% of psychological distress in Chinese lung cancer patients[14].

Adverse consequences of psychological distress

Clinically significant psychological distress is associated with a range of adverse consequences[1]. In fact, substantial evidence investigating the adverse consequences of psychological distress had been accumulated to date. For example, studies demonstrated that psychological distress significantly decreased patients' compliance with cancer treatment[15-17] and increased the risk of physical symptoms[17]. One study also revealed that psychological distress was associated with higher suicidal risk[19]. In addition, evidence published recently even suggested that psychological distress

can accelerate the growth of tumor cells and decrease therapeutic effects[24], which may significantly prolong hospital stay[18], reduce the QoL[20,21] and even increase mortality[22,23].

The necessity of screening psychological distress in lung cancer patients

Based on the high incidence of psychological distress and its adverse effects on anti-cancer treatment and patients' prognosis, psychological distress has been recognized as the sixth vital sign[1,25]. Furthermore, given the large number of new lung cancer cases, it is expected that the number of lung cancer patients with clinically significant psychological distress may increase substantially. Early evaluation and screening for distress leads to early and timely management of psychological distress, which in turn improves medical management[29,46]; however, fewer than half of distressed patients with cancer are actually identified and referred for psychosocial help[47,48]. Therefore, in order to prevent the occurrence of clinically significant psychological distress or effectively reduce the adverse effects of psychological distress on the effect of anti-cancer treatment, it is imperative to timely and accurately detect those lung cancer patients who are at high risk for psychological distress[49].

Screening tools for psychological distress in cancer patients

Screening tools have been found to be effective and feasible in reliably identifying distress and the psychosocial needs of patients[50-52]. Currently,

many screening instruments have been used in practice to measure the level of psychological distress in order to effectively detect psychological distress in cancer patients[1]. According to a systematic review of assessment instruments for screening for emotional distress in cancer patients, a total of 33 instruments can be used screen for psychological distress in cancer patients[26], such as Profile of Mood States (POMS), Profile of Mood States-Short Form (POMS-SF), Distress Thermometer (DT), Hospital Anxiety and Depression Scale (HADS), and Brief Symptom Inventory-18 (BSI-18). In addition, automated touch screen technologies, interactive voice response, and web-based assessments have also been used for psychosocial and symptom screening of cancer patients[53-56]. However, among the currently available instruments, POMS-SF, DT and HADS were most frequently employed in practice[57].

Distress Thermometer

The DT, a now well-known tool for initial screening, is developed by the NCCN Distress Management Panel. As an easy-to-use tool, DT has been widely employed to identify the level of psychological distress[1]. Several studies have tested the measurable properties of DT and confirmed the value of measuring psychological distress[58-60]. However, the cut-off value must be calculated again when DT was used for different types of cancer, in diverse cultural settings, and for different aims[61-66], which may significantly increase the inaccuracy of evaluating psychological distress. Moreover, the accuracy of assessing psychological distress will be impaired because of DT is marked subjectively by participants[1]. More importantly, DT

can quantitatively determine the time-specific level of psychological distress, but not the risk of developing clinically significant psychological distress. Therefore, DT is more suitable for evaluating the effect of interventions for psychological distress in cancer patients than for screening populations at high risk of psychological distress.

Hospital Anxiety and Depression Scale

The HADS was actually developed to identify symptoms of anxiety, depression, and psychological distress in the hospital setting[27], which has been extensively utilized in identifying psychological distress because of anxiety and depression are considered as the manifestations of psychological distress. The HADS does not include questions about physical symptoms, thus avoiding the interaction between physical and emotional symptoms. Nevertheless, it is a mistake to simply equate anxiety and depression with psychological distress, which was defined as a negative emotional state characterized by physical and/or emotional discomfort, pain, or anguish[1]. Therefore, the HADS cannot adequately identify patients at high risk of psychological distress.

Profile of Mood States-Short Form

The POMS-SF is developed to assess symptoms of psychological or emotional distress[28], and has been widely employed in cancer settings[67-69]. In the POMS-SF, a total of 37 items are categorized within six subscales, including anxiety, depression, anger, vigor, fatigue, and confusion. The reliability and validity of the POMS-SF have been investigated in two studies,

indicating that the scale is reliable and valid for assessing psychological distress in cancer patients[67,69]. Although a manual is available for interpreting how to use the POMS-SF to assess psychological distress, the information about which score indicate high level of psychological distress is not available in this manual. Moreover, few studies investigated the cut-off value of the POMS-SF for defining clinically significant psychological distress. Most importantly, the POMS-SF only assess psychological distress from psychological perspective but does not cover the social and spiritual attributes of psychological distress. Therefore, it is also not suitable for screening patients who are at high risk for psychological distress.

The necessity of developing a screening tool specific to lung cancer patients

Overall, there are many instruments can be used for psychological distress screening in cancer patients; however, several common issues greatly limit the practical application of these instruments in the screening of psychological distress in cancer patients. As described above, even the three instruments frequently employed in practice, some problems also significantly limit their application in screening of psychological distress. Specifically, attention should be paid for the following four issues: (1) because distress is associated with symptoms of anxiety, depression, fatigue, and sleep disturbance, many instruments use simply anxiety and depression to define psychological distress, resulting in an inaccurate assessment of psychological distress; (2) many instruments are generally applicable to most clinical settings, not specific to certain diseases, resulting in an incomplete assessment of

psychological distress; (3) psychometrical characteristics of some instruments have not been adequately evaluated, limiting their usefulness; and (4) some instruments includes a plethora of negative items and requires responders to spend a lot of time completing it, greatly reducing their acceptability in practice. Considering these practical problems, it is critical to develop a validate and easy-to-use tool specifically for the risk screening of psychological distress in lung cancer patients.

Psychosocial mechanisms of psychological distress

Accurate identification of cancer patients who are at high risk for psychological distress is essential to effectively protect cancer patients from developing clinically significant psychological distress[29]. However, elucidating the mechanisms of psychological distress is a prerequisite for developing effective intervention protocols[30]. Currently, numerous studies have investigated the influencing factors of psychological distress in cancer patients[31-33]. Overall, according to the approach of categorizing risk factors in the previous studies[70,71], we categorize influencing factors of psychological distress in cancer patients into modifiable and unmodifiable influencing factors.

Unmodifiable factors

In the current thesis, influencing factors of psychological distress are considered as nonmodifiable if they are totally unalterable (e.g., age, gender, and race) or if their occurrence or progression is inevitable and strategies currently available for alleviating their severity or delaying their

progression are not well understood or strongly effective. Based on this definition, demographic variables and some disease-related factors are considered as unmodifiable factors in this thesis. Notably, numerous studies have shown that many demographic factors were associated with psychological distress of cancer patients, such as age (younger)[20,72], gender (female)[72-74], education level (senior school and below)[74,75], heavy economic burden[74], marital status[12,76], and smoking history[77]. In addition, some studies have also revealed the associations between disease-related factors and psychological distress, such as family history of cancer[78], type of cancer[12,79], stage of tumor[76], comorbidity[80,81], and cancer pain[82]. However, some of these associations of some factors with psychological distress have not been supported by other studies. For example, the gender difference of psychological distress in cancer patients has not yet been detected[63,83]. It is worth noting that, these conflicting findings are mainly resulted from the differences in types of cancer, indicating the importance of investigating the influencing factors of psychological distress of specific cancer. Furthermore, the associations of some unmodifiable factors with psychological distress have only been investigated by few studies, indicating the need to demonstrate these associations in more studies. In another hand, as unmodifiable factors, it has little reference value for developing effective intervention protocols, because these factors cannot be changed by external interventions. However, because these factors are objectively associated with psychological distress, they can be used in the development of risk screening tools for psychological distress.

Modifiable factors

Conversely, those factors are considered as potentially modifiable if they can be changed, managed, or prevented effectively through external effective interventions (e.g., cancer-induced nausea and vomiting [CINV] and treatment modality). In the current thesis, some treatment-related factors and psychosocial factors are modifiable factors. From the perspective of treatment-related factors, treatment-induced nausea and vomiting, CINV, cancer-related fatigue (CRF), body image, and treatment modalities have been shown to be associated with psychological distress. Meanwhile, some psychosocial factors have also been shown to be associated with psychological distress in cancer patients, such as social support, self-esteem, coping style, perceived stress, perceived stigma, mindfulness, illness perception, type D personality, and intrusive thoughts. Nevertheless, some of these associations do not achieve statistical significance in some studies.

The necessity of elucidating psychosocial mechanisms of psychological distress

Among the modifiable factors, although treatment-related factors can be changed externally, most of these factors almost inevitable because interruption of anticancer therapy is not a judgmatical strategy. More importantly, as a promoter of psychological problems, treatment-related factors mainly lead to the occurrence and development of psychological distress through influencing psychological and social factors. Therefore, it is critical to elucidate the mechanisms of psychological distress from the

psychosocial perspective. As summarized above, although many studies have shown the associations of each of these psychosocial factors with psychological distress in cancer patients, several conflicting conclusions were generated due to the inclusion of a limited number of potential predictors. In addition, only few studies have attempted to investigate the role of the interaction of multiple factors in the occurrence and progression of psychological distress[84]. More importantly, the magnitude of the impact of these psychosocial factors on psychological distress has not been fully investigated. Therefore, there is an urgent need to determine the pathways and influencing magnitudes of impacts of common psychosocial factors on psychological distress in order to elucidate the possible mechanisms of psychological distress of lung cancer patients from psychosocial perspective.

Psychosocial interventions of psychological distress

Currently, several treatment modalities are available for the management of psychological distress in cancer patients, including pharmacologic interventions, complementary and alternative therapies, and psychosocial interventions[1]. Although pharmacologic interventions are beneficial in the treatment of depression and anxiety in adult patients with cancer, the therapeutic effect is significantly compromised resulting from withdrawal from pharmacologic agents[1]. In addition, most pharmacological agents are prescribed to treat anxiety and depression[85,86], not psychosocial and spiritual symptoms. Some studies have revealed the beneficial role of complementary and alternative therapies in the alleviation of symptoms in cancer

patients; however, the quality of the evidence in this area is low[1]. From the NCCN definition of psychological distress, psychosocial interventions may be more appropriate for the alleviation of psychological distress in practice. Notably, a great deal of studies has demonstrated that psychosocial interventions have been effective in reducing distress and improving overall QoL among patients with cancer[39,40,87-89], mainly including mindfulness-based interventions (MBI)[36,90-92], cognitive behavioral therapy (CBT)[93,94], supportive psychotherapy[95,96], psychoeducation[39,97], family and couples therapy[98-100].

The impact of MBSR on psychosocial symptoms of cancer patients

As described above, psychosocial interventions have been effective in improving the psychological well-being of cancer patients[34-36]. Among the currently available psychosocial interventions, MBSR program is most frequently applied in cancer settings[36,37] and may be also the best psychosocial intervention to relieve cancer-related fatigue[38]. The standard MBSR program comprises an 8-week psycho-educational course and four meditative techniques, including sitting meditation, body scan, gentle Hatha yoga, and walking meditation[101-103]. Based on previously published evidence[102,104,105], the practice of mindfulness can guide participants purposefully pay attention to the present moment and nonjudgmentally monitor the unfolding of experiences moment by moment, thus having profound benefit via the mind-body connection. Studies have demonstrated the effectiveness and safety of MBSR program on psychosocial well-being and QoL[36,37,106,107].

The necessity of implementing MBSR for alleviating psychological distress

To date, psychosocial interventions for patients with cancer have disproportionately targeted women with breast cancer[39,40]. Therefore, it is imperative to develop more interventions targeting patients with other cancer types, or inclusion of mixed types. Meanwhile, it is also critical to investigate the therapeutic role of the currently available effective psychosocial interventions in different cancers. In fact, several studies have initially investigated the role of the MBSR program in patients diagnosed with lung diseases, such as lung cancer [108,109] and interstitial lung diseases[110,111]. However, a definitive conclusion regarding the efficacy of the MBSR program for psychological distress has not obtained and should be further investigated in future studies with larger sample sizes. Although lung cancer patients are difficult to study due to a poor prognosis and anti-cancer treatment, there is a need for tailored interventions[112]. As a result, the first task for researchers and practitioners is to systematically evaluate the impact of the MBSR program on psychological states in lung cancer patients by using meta-analytic technique[113], then designing a subsequent clinical trial to validate the therapeutic effect of an appropriate MBSR program on alleviating psychological distress in lung cancer patients.

The necessity of elucidating the mechanisms of MBSR on psychological distress

A previous study has attempted to evaluate the therapeutic efficacy of the

MBSR program on psychological distress from three perspectives, including mindfulness skills, self-compassion, and rumination[109]; however, the exact psychosocial mechanisms by which the MBSR program alleviates psychological distress remain unclear. Previous studies have revealed that several psychosocial factors in cancer patients are associated with psychological distress, such as social support[114], perceived stigma[115], perceived stress[116], intrusive thoughts[84], symptom burden[84], type D personality[84], coping style[78], self-esteem[117], mindfulness[118,119], and illness perception[120,121]. In the current thesis, we have also explicitly investigated the roles of social support, perceived stigma, perceived stress, coping styles, self-esteem, mindfulness, and illness perception in the development of psychological distress in lung cancer patients[30,45,122,123]. However, it remains unclear which pathways may mediate the interventional effects of the MBSR program on alleviating psychological distress in lung cancer patients. It is worth noting that elucidation of possible mechanisms of the MBSR program on alleviating psychological distress is the prerequisite of extending the applicable scope of this intervention. Therefore, there is also urgent need to elucidate the possible mechanisms of an appropriate MBSR program on affecting psychological distress in lung cancer patients.

Methods

The main goals of the current thesis are to develop a valid and easy-to-use predictive tool for screening lung cancer patients at high risk for psychological distress, and then to implement effective interventions to alleviate the psychological distress of these patients. In order to achieve these anticipated goals, seven separate studies were carried out in this thesis, with the following study designs: cross-sectional survey study, systematic review and meta-analysis, and randomized controlled trial (RCT). The flowchart of the whole thesis is shown in figure 1, followed by 8 tables summarizing the methodological outline for each study.

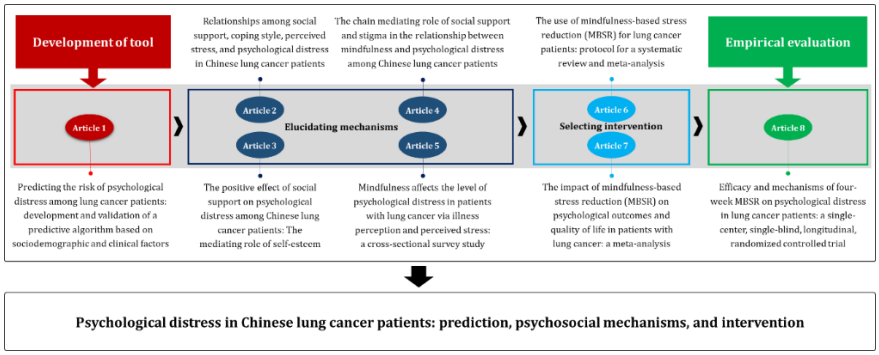

Figure 1. Flow chart of the current thesis

Study 1

Objective	To develop and validate a predictive algorithm to identify lung cancer patients at high risk for psychological distress.
Study design	A cross-sectional descriptive study.

Sample	441 adult lung cancer patients who independently completed and sent back validated questionnaires.
Instruments	Distress thermometer (DT) was used to measure psychological distress, and self-designed general information collection questionnaire designed to collect sociodemographic and clinical variables, including gender, age, nationality, educational level, occupational status, marital status, payment method, residence, the quantity of children, household income, family history, smoking history, drinking history, diagnosis duration, surgical history, metastasis, comorbidity, pain degree, and tumor, node, and metastasis (TNM) stage.
Data collection	All participants fully understood aims and procedures of this study and patients' rights before participating in the survey. Meanwhile, participants were further informed that all questionnaires in this study will be completed anonymously, and collected data were just used to academic dissemination. We obtained oral or written informed consent from all participants before performing formal survey. Moreover, a pilot study suggested a feasibility of conducting the questionnaire survey, and then, all questionnaires were completed by patients in the formal survey. Data were collected by face to face in wards.

Statistical analysis	Structural equation model (SEM) was conducted to determine the associations between all factors and psychological distress, and then constructed a predictive algorithm. Coincidence rate was also calculated to validate this predictive algorithm. We completed all statistical analyses with the Statistical Package for Social Sciences (Chicago, Illinois) and IBM AMOS 21.0 (Chicago, Illinois).

Study 2

Objective	To investigate the impact of social support on Chinese lung cancer patients' psychological distress and further clarify the mediating role of perceived stress and coping style.
Study design	A cross-sectional survey study.
Sample	441 adult lung cancer patients who independently completed and sent back validated questionnaires.
Instruments	Demographic information collection sheet, DT, 12-item Multidimensional Scale of Perceived Social Support (MSPSS), 20-item Medical Coping Modes Questionnaire (MCMQ), and 10-item Perceived Stress Scale (PSS).
Data collection	Investigators informed all candidates the aims and procedures of the study in detail before starting the formal survey. All oral or written informed consents

	were obtained from patients before participating in the study. After a pilot study tested the feasibility of the questionnaire survey, we conducted the formal survey. All questionnaires were independently completed by patients.
Statistical analysis	Descriptive statistics were used to summarize patients' characteristics and their average score for psychological distress, social support, coping style, and perceived stress. Kolmogorov–Smirnov test was used to test normality of all scores, correlation analysis was used to test the relationships among psychological distress, social support, coping style, and perceived stress, and the Bootstrap test was conducted to test a mediating effect of coping style or perceived stress in the relation of social support and psychological distress. We completed all statistical analyses with the Statistical Package for Social Sciences (Chicago, Illinois) and IBM AMOS 21.0 (Chicago, Illinois).

Study 3

Objective	To investigate the effect of social support on psychological distress among Chinese lung cancer patients and clarify the mediating role of self-esteem.
Study design	A cross-sectional descriptive correlational survey.
Sample	441 Chinese lung cancer patients who independently

	completed and sent back validated questionnaires.
Instruments	Demographic information collection sheet, DT, 12-item MSPSS, and 10-item Rosenberg Self-Esteem Scale (RSES).
Data collection	The leading investigator in the current study determined targeted patients with convenience sampling. The investigator informed all patients about the details of the study aims, specified process, and patients' rights to decline and to withdraw from the study at any time with no negative consequences. Meanwhile, all patients were also informed that all data we collected from them will be protected strictly and only academic use of collected data. Before initiating the formal survey, we performed a pilot survey to test the feasibility of the questionnaire survey. Patients were required to independently answer all questionnaires.
Statistical analysis	Descriptive statistics were used to summarize patients' characteristics and scores of psychological distress, social support and self-esteem. The Kolmogorov–Smirnov was used for normality test. Correlation analysis was conducted to investigate the associations among psychological distress, social support and self-esteem, and the Bootstrap test was conducted to test a mediating effect of self-esteem in the

	relation of social support and psychological distress. We completed all statistical analyses with the Statistical Package for Social Sciences (Chicago, Illinois) and IBM AMOS 21.0 (Chicago, Illinois).

Study 4

Objective	To determine the relationship of mindfulness and psychological distress and further clarify the mechanism of mindfulness against psychological distress through perceived stigma and social support among Chinese lung cancer patients.
Study design	A cross-sectional, correlational, descriptive survey study.
Sample	441 valid Chinese lung cancer patients.
Instruments	Self-designed standard demographic information collection sheet, DT, 39-item Five Facet Mindfulness Questionnaire (FFMQ), 12-item MSPSS, and 31-item Cataldo lung cancer stigma scale (CLCSS).
Data collection	All eligible patients were enrolled based on convenience sampling, and all participants fully understood aims and procedure of this study and patients' rights before participating in the survey. The principal investigator orally informed all eligible patients about the aims and procedures of this study based on written research protocol before conducting the formal

	survey. More importantly, the formal survey was conducted after all patients gave informed consent orally. Patients were required to independently answer all questionnaires.
Statistical analysis	Correlation analysis was firstly performed to assess the associations between mindfulness, social support, perceived stigma, and psychological distress. Then structural equation modelling analysis was conducted to further clarify the mediating effects of perceived stigma and social support on the relationship between mindfulness and psychological distress. Dada was analyzed with the Statistical Package for the Social Sciences (Chicago, Illinois, USA) and IBM AMOS 21.0 (Chicago, Illinois, USA).

Study 5

Objective	The aims of the study were first to investigate the association between illness perception and psychological distress and second to determine whether mindfulness affects psychological distress via illness perception and perceived stress in patients with lung cancer.
Study design	A cross-sectional descriptive survey study.
Sample	295 adult patients who were diagnosed with lung cancer based on definitive and route methods and

	were confirmed to have ability to clearly and accurately read and write.
Instruments	Self-designed demographic information collection questionnaire, DT, 39-item FFMQ, 8-item the Brief Illness Perception Questionnaire (B-IPQ), and 10-item PSS.
Data collection	Participants were recruited with convenience sampling method from a tertiary hospital in Chongqing between January and July 2021. Before conducting the formal survey, all eligible patients were informed about objectives and the risks and benefits of the study and required to sign informed consent. Study questionnaires were independently and anonymously completed by patients.
Statistical analysis	Descriptive statistics for all the variables were calculated using SPSS 22.0 (Chicago, IL, United States). Age, the score of psychological distress, mindfulness, social support, and perceived stigma were expressed as median with interquartile range (IQR) because all did not follow normal distribution according to the results from the Kolmogorov–Smirnov test. The Spearman's rank correlation analysis was conducted to examine the relations between mindfulness, illness perception, perceived stress, and psychological distress. The mediation model was tested using AMOS 21.0. In

	these analyses, we used 2,000 bootstrap resamples and focused on the bias-corrected and accelerated confidence interval (CI).

Study 6

Objective	The aim of the present systematic review and meta-analysis seeks to determine the role of MBSR in lung cancer patients.
Study design	Study protocol for meta-analysis.
Sample	Studies investigating the comparative effects between MBSR and control groups on psychological and physical outcomes will be documented.
Instruments	A predesigned standard information extraction sheet, Cochrane risk of bias assessment tool, and Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.
Data collection	Two authors will be assigned to independently extract essential data with designed information extraction form. The following information will be extracted from eligible studies: basic information eligible study including author, publication year and country, basic information of patients including sample size, age and tumor staging such as TNM stage, basic information of regimes including details of interventions, outcomes and study design, and information of

	methodological quality. Quantitative data will be extracted to estimate effect sizes. Data on effect size that could not be obtained directly will be recalculated when possible. Qualitative information will also be summarized to systematically describe the effects and safety of MBSR.
Statistical analysis	For continuous outcomes, we will calculate the differences between two groups as the standard mean difference (SMD) or mean difference (MD) with 95% CI. For categorical outcomes, we will use risk ratio (RR) with 95% CI to express pooled estimates. Before performing statistical analysis, we will use Cochrane's Q test and the I2 statistic to qualitatively and quantitatively evaluate the heterogeneity across studies accordingly. Nevertheless, we will only perform a random-effects model to calculate all pooled results regardless of actual level of heterogeneity across studies because substantial variations in population, interventions, and outcome measures are inevitable. All statistical analyses will be conducted using Review Manager (RevMan) version 5.3 (Cochrane Collaboration, Oxford, United Kingdom).

Study 7

Objective	This meta-analysis aimed to evaluate the

	effectiveness of the MBSR program on psychological states and QoL in lung cancer patients.
Study design	A systematic review with meta-analysis.
Sample	RCTs investigating the effectiveness of the MBSR program on psychological outcomes and QoL among patients with lung cancer.
Instruments	A predesigned standard information extraction sheet, Cochrane risk of bias assessment tool, and Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.
Data collection	Two reviewers independently extracted essential data from eligible studies using a predesigned standard information extraction sheet, including the first author's name, publication year, country, condition of patients, tumor stage, sample size, mean age, details of the MBSR program, outcomes, and measurements. We extracted the data at the end of the intervention or the last follow-up for statistical analysis. We contacted the corresponding author to obtain the essential data if necessary. The consensus principle was introduced to resolve the disagreement between the two reviewers.
Statistical analysis	Statistical analysis was conducted using RevMan 5.4 (Cochrane Collaboration, Oxford, United Kingdom) and STATA 14.0 (StataCorp, Texas, USA). All outcomes

	were continuous variables in this meta-analysis. We, therefore, used MD or SMD with a 95% CI to express all pooled results. We comprehensively evaluated statistical heterogeneity using the Chi-square test (Cochrane Q) and I2 statistic. Substantial statistical heterogeneity was considered if the p-value was <0.1 and I2 was more than 50%. Nevertheless, we used the random-effects model to conduct a meta-analysis because variations across studies are inevitable in real settings. We also designed a series of subgroup analyses to investigate the influence of the MBSR program on different functional dimensions. We did not perform a publication bias test because the number of eligible studies for individual outcomes did not exceed 10.

Study 8

Objective	This study aimed to evaluate the efficacy of a four-week MBSR program on psychological distress in patients with lung cancer and elucidate its mechanisms.
Study design	A single-center, single-blinded, longitudinal, RCT.
Sample	175 lung cancer patients with proven clinically significant psychological distress or at high risk of suffering from psychological distress.
Instruments	Self-designed demographic and clinical

	characteristics collection sheet, DT, predictive algorithm of psychological distress, 12-item MSPSS, 20-items MCMQ, 10-item RSES, 39-item FFMQ, 10-item PSS, 31-item CLCSS, and 8-item B-IPQ.
Data collection	We designed a face-to-face questionnaire survey to collect data, administered by a trained research nurse at three time points: baseline (T0), the immediate post-intervention (T1), 1-month post-intervention (T2), and 3 months post-intervention (T3).
Statistical analysis	We used descriptive statistics to present participants' demographics. The We used mean ± SD for all continuous variables, and used the Chi-square test and independent sample t-test to compare the variables between the two groups. However, repeated measure analysis of variance (ANOVA) was used to analyze changes or differences of variables between the groups (experimental vs. waiting-list groups), within-group (time), and interaction (group*time) effects. Furthermore, we used structural equation modeling to elucidate the mediating role of significant variables that showed significant differences in the efficacy of a four-week MBSR program on psychological distress between the two groups after intervention. In addition, we adjusted all variables obtained from postintervention using the baseline value. We

	employed IBM SPSS version 22.0 and Amos version 21.0 for statistical analysis.

In the next section, we present all relevant articles to explain the methodological procedures in detail.

Results

Article 1

Tian X, Jin Y, Tang L, Pi YP, Chen WQ, Jiménez-Herrera MF. Predicting the Risk of Psychological Distress among Lung Cancer Patients: Development and Validation of a Predictive Algorithm Based on Sociodemographic and Clinical Factors. Asia Pac J Oncol Nurs. 2021 May 31;8(4):403-412. doi: 10.4103/apjon.apjon-2114.

Original Article

Predicting the Risk of Psychological Distress among Lung Cancer Patients: Development and Validation of a Predictive Algorithm Based on Sociodemographic and Clinical Factors

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ABSTRACT

Objective: Lung cancer patients reported the highest incidence of psychological distress. It is extremely important to identify which patients at high risk for psychological distress. The study aims to develop and validate a predictive algorithm to identify lung cancer patients at high risk for psychological distress. **Methods:** This cross-sectional study identified the risk factors of psychological distress in lung cancer patients. Data on sociodemographic and clinical variables were collected from September 2018 to August 2019. Structural equation model (SEM) was conducted to determine the associations between all factors and psychological distress, and then construct a predictive algorithm. Coincidence rate was also calculated to validate this predictive algorithm. **Results:** Total 441 participants sent back validated questionnaires. After performing SEM analysis, educational level (β = 0.151, P = 0.004), residence (β = 0.146, P = 0.016), metastasis (β = 0.136, P = 0.023), pain degree (β = 0.133, P = 0.005), family history (β = −0.107, P = 0.021), and tumor, node, and metastasis stage (β = −0.236, P < 0.001) were independent predictors for psychological distress. The model built with these predictors showed an area under the curve of 0.693. A cutoff of 66 predicted clinically significant psychological distress with a sensitivity, specificity, positive predictive value, and negative predictive value of 65.41%, 66.90%, 28.33%, and 89.67%, respectively. The coincidence rate between predictive algorithm and distress thermometer was 64.63%. **Conclusions:** A validated, easy-to-use predictive algorithm was developed in this study, which can be used to identify patients at high risk of psychological distress with moderate accuracy.

Key words: Lung neoplasm, prediction model, psychological distress, structural equation model

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Introduction

According to the data released by the International Agency for Research on Cancer, lung cancer accounts for around 11.4% of new cancer cases and 18.0% of cancer-related deaths in 2020.[1] Patients who were identified with lung cancer report significantly high detection rate of psychological distress mainly because of poor 5-year survival rate.[2] Previous studies indicated that approximate 17.0%–73.0% lung cancer patients experienced clinically significant psychological distress worldwide.[3-6] More importantly, compared to other types of cancers, lung cancer patients reported the highest incidence of psychological distress.[7,8]

As a negative emotional state, psychological distress has been established to be associated with poor treatment adherence and physical symptoms.[9] Meanwhile, there are some studies which found that psychological distress may enhance tumor growth and diminish effective treatment response, as well as decrease therapeutic effectiveness.[10,11] As a result, lung cancer patients with clinically significant psychological distress reported poor quality of life[5] and even higher mortality.[12] Therefore, it is critical to early detect patients at high risk of psychological distress from overall lung cancer patients with a validated prediction tool.[13]

Background

Accurately understanding risk factors of causing psychological distress and clarifying the correlations between psychological distress and various predictive factors is crucial for developing a reliable and robust prediction tool for early and accurately predicting the risk of psychological distress among lung cancer patients.[6] To date, a great deal of studies have performed to investigate the predictive factors of developing psychological distress among cancer patients.[14] Meanwhile, many studies have also been conducted in order to understand the predictive factors of psychological distress in lung cancer patients.[14]

In 1999, Keller and Henrich investigated gender difference of psychological distress and found that female patients suffer from more serious psychological distress compared to male patients,[15] which was supported by the study performed by Morrison *et al.* in 2017[16] and performed by Lv *et al.* in 2020.[6] However, the gender difference of psychological distress in lung cancer patients has not yet been detected.[3] Moreover, Lv *et al.* also found that educational level, medical insurance, residence, and occupational status were associated with psychological distress,[6] which was partially consistent with the findings from another study in terms of educational level and occupational status.[3] Meanwhile, Chambers *et al.*[5] and Morrison *et al.*[16] found an age difference of psychological distress, which was also detected in a study by Tian *et al.*[3] Moreover, household income was also noted to be related to the occurrence of psychological distress.[3]

Previous studies also investigated the associations between various clinical variables and psychological distress except for sociodemographic characteristics. Carlson *et al.* found that advanced cancer patients with metastasis suffer from more serious psychological distress,[17] which was also consistent with results found by Morrison *et al.*[16] However, the role of metastasis in causing psychological distress was not determined in Lv *et al.*'s study.[6] Family history, drinking history, and tumor stage were also found to be associated with psychological distress.[3] Moreover, there are some studies[18-21] which suggested that surgery, pain degree, and comorbidity were also the predictors of psychological distress.

Although various predictive factors of psychological distress among lung cancer patients have been examined, several conflicting conclusions were generated due to the inclusion of a limited number of potential predictors. Meanwhile, no study has investigated the predictive effect of combining established predictive factors on psychological distress. As a result, <10% of patients at high risk of psychological distress can been early detected.[13] We therefore performed this study to first identify those predictive factors of psychological distress in lung cancer patients. Then, we set out to develop a predictive algorithm that may assist the clinical practitioners in identifying patients at high risk for psychological distress.

Methods

Study design

A cross-sectional descriptive study was performed to identify the risk factors of psychological distress and further develop a validated predictive algorithm of high-risk psychological distress in lung cancer patients based on optimal predictors. All results were presented in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[22]

Participants

We developed the following criteria to recruit eligible participants according to previous studies:[3,6] (a) adult patients with definitive lung cancer diagnosis and (b) having ability to independently complete questionnaires. We excluded those patients who were identified to have the psychiatric disorder and were therefore unable to cooperate with questionnaire survey or other types of cancer. We first estimated sample size based on the algorithm for cross-sectional survey design:[6]

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

$$N=\left(\mu_{\alpha/2}^{2}\pi\left[1-\pi\right]\right)/\delta^{2}$$

In this algorithm, π and δ indicate the incidence and allowed error, respectively. We calculated an anticipated sample size of 384 after setting α of 0.05, π of 0.5, and δ of 0.5. Meanwhile, we also calculated a sample size of 190 according to the principle of minimum numbers needed to modeling the relationship between all variables and psychological distress with structural equation model (SEM).[23] Theoretical sample size of 384 was determined eventually.

Procedure

This study is strictly in accordance with the provisions of the Declaration of Helsinki. Moreover, the protocol of this study has been approved by the institute review board of all participated hospitals. All lung cancer patients who were admitted to the medical oncology and respiratory department of two tertiary hospitals and five secondary hospitals in Chongqing of China for further treatment were checked for eligibility between September 2018 and August 2019 with convenience sampling method, and all eligible patients were enrolled for questionnaire survey within 48 h of admission to ward. All participants fully understood aims and procedure of this study and patients' rights before participating in the survey. Meanwhile, participants were further informed that all questionnaires in this study will be completed anonymously, and collected data were just used to academic dissemination. We obtained oral or written informed consent from all participants before performing formal survey. Moreover, a pilot study suggested a feasibility of conducting the questionnaire survey, and then, all questionnaires were completed by patients in the formal survey. Data were collected by face to face in wards.

Study variables

In this study, we mainly aimed to determine the optimal predictors of psychological distress in lung cancer patients from sociodemographic and clinical aspects. Therefore, after comprehensively reviewed published studies which investigated impact factors of psychological distress among cancer patients, especially lung cancer patients, the following sociodemographic variables were collected including gender, age, nationality, educational level, occupational status, marital status, payment method, residence, the quantity of children, household income, family history, smoking history, and drinking history. Meanwhile, we also collected the clinical variables as following: diagnosis duration, surgical history, metastasis, comorbidity, pain degree, and tumor, node, and metastasis (TNM) stage. All sociodemographic and clinical variables were collected used the standard sheet.

As the main outcome variable, psychological distress was measured with distress thermometer (DT), which was designed to have a 11-point scale (0 indicates no distress and 10 suggests extreme distress) in a thermometer format.[24] The psychometric properties of DT have been extensively validated in various settings,[25,26] and several studies consistently indicated 4 or above scores as the criteria of defining patients with clinically significant psychological distress.[27,28] Certainly, this criterion of DT ≥4 was also demonstrated to be applicable to Chinese cancer patients, with an area under the receiver operating characteristic curve of 0.885 in an empirical study.[26]

Statistical analysis

We used descriptive statistics including frequency and percentage to summarize participants' sociodemographic and clinical variables. Mean rank was calculated to express the score of psychological distress because of Kolmogorov–Smirnov test indicated a skew distribution. The mean rank of psychological distress between variables was first tested using univariate analysis prior to constructing the prediction model. However, we did not determine independent variables according to the results of univariate analysis, and all sociodemographic and clinical variables were included to modeling prediction structure. We calculated the following indices to evaluate the fitness of the overall model including the ratio of Chi-square (χ^2) to degrees of freedom (df), goodness-of-fit index (GFI), adjusted GFI (AGFI), comparative fit index (CFI), and root mean square error of approximation (RMSEA). According to Kline,[29] model fit was regarded as good when a ratio of χ^2/df was ≤3. For GFI and AGFI, a value of more than indicates a good model fit.[30] Moreover, CFI of ≥0.90[31] and RMSEA of <0.05[32] were also suggesting a good model fit. $P < 0.05$ indicated significance for all analyses. Data were analyzed with the Statistical Package for the Social Sciences (Chicago, IL, USA) and IBM AMOS 21.0 (Chicago, IL, USA).

Results

Sample characteristics

We distributed 450 questionnaires during survey, and 441 valid questionnaires were received finally, with a validated response rate of 98.0%. The participants had a median age of 60.0 (interquartile range: 52.0–67.0) and most were male (71.4%) and Han nationality (98.6%). Most participants did not get adequate education (68.0%), and a significant number of participants were jobless (44.9%). Most participants got married (99.3%) and had medical insurance (97.3%), and more than half of them had no drinking history (53.7%) and diagnosis duration

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

of <6 months (53.1%). In addition, most participants lived in urban (69.4%), had one or two children (99.4%), but no family history (87.8%) and no comorbidity (74.1%). However, most of these participants were at the advanced stage (85.7%) and most experienced metastasis (62.6%). Moreover, a minority of these participants experienced moderate-to-severe pain (19.0%), but most participants did not receive surgery (61.9%). The details of participants' characteristics are shown in Table 1.

Influencing factors for psychological distress

Univariate analysis suggested that eight variables including age, educational level, occupational status, household income, drinking history, diagnosis duration, family history, and TNM stage were substantially related to psychological distress. Younger participants experienced a higher level of psychological distress ($P = 0.046$), and participants having work also experienced significant psychological distress ($P = 0.038$). Participants who were from middle-income family had lower level psychological distress ($P < 0.001$), and participants who were newly diagnosed with lung cancer had the highest level of psychological distress ($P = 0.001$). Moreover, participants who were at the early stage reported a higher level of psychological distress ($P < 0.001$). Those participants with drinking history ($P = 0.031$) and without family history ($P = 0.029$) had a higher level of psychological distress. Meanwhile, higher educational level also caused the increasing of the level of psychological distress ($P = 0.031$). The details are shown in Table 1.

Structural equation modeling of the factors predicting psychological distress

We used SEM technique to further inveterate the association between sociodemographic and clinical variables and psychological distress in order to identify the independent predictive factors of psychological distress. We coded all variables to meet the requirement of performing structural equation modeling, and the coded information is summarized in Table 2. We used maximum likelihood to perform SEM for determining the predictive effect of each variable on psychological distress. The structural model of variables and psychological distress is displayed in Figure 1, and the regression weights of psychological distress and various variables are summarized in Table 3. Meanwhile, the correlations of all error variables are documented in Table 4. The results revealed that the structural model adequately fitted the data ($\chi^2/df = 0.412$, GFI = 1.000, AGFI = 0.980, CFI = 1.000, and RMSEA = 0.000 [90% confidence interval, 0.000–0.073]).

Among those 19 paths, 13 paths did not achieve statistical significance, and the remaining 6 paths were statistically significant with all critical ratios of more than 2.0. Specifically, educational level ($\beta = 0.151$, $P = 0.004$), residence ($\beta = 0.146$, $P = 0.016$), metastasis ($\beta = 0.136$, $P = 0.023$), and pain degree ($\beta = 0.133$, $P = 0.005$) positively predicted psychological distress, however, family history ($\beta = -0.107$, $P = 0.021$) and TNM stage ($\beta = -0.236$, $P < 0.001$) negatively predicted psychological distress.

Psychological distress predictive algorithm

Based on the results from SEM analysis, we developed the following predictive algorithm of psychological distress: risk score = (0.151 × educational level + 0.146 × residence + 0.136 × metastasis + 0.133 × pain degree − 0.107 × family history − 0.236 × TNM stage) × 100, with an overall risk score distribution of −75–120. We calculated the risk score of each surveyed participant with the above predictive algorithm, and obtained an overall risk score distribution of −65–78. Then, we also calculated an area under the curve (AUC) of 0.693 for our predictive algorithm, which is depicted in Figure 2. Meanwhile, we also determined a cutoff value of −9, which was corresponding to a sensitivity of 65.4%, a specificity of 66.9%, a positive predictive value of 28.33%, and a negative predictive value of 89.66% when Youden's index got a maximum value of 0.323. Furthermore, in order to improve the feasibility of the predictive algorithm in clinical practice, we inserted a constant of 75 into the algorithm to eliminate negative risk score, and the user needed to do decimals to round up and round down numbers. Therefore, an updated predictive algorithm was constructed as following: risk score = 75 + (0.151 × educational level + 0.146 × residence + 0.136 × metastasis + 0.133 × pain degree − 0.107 × family history − 0.236 × TNM stage) × 100. As a result, the overall distribution of risk score was ranging from 0 to 195. Certainly, the cutoff value was also changed to be 66 eventually.

Next, we applied this predictive algorithm to our surveyed participants for further validating its predictive performance, and detected 51 participants at high risk from those 78 participants who were identified with clinically significant psychological distress with DT and 234 participants at low risk from 363 participants who were identified without clinically significant psychological distress with DT. Finally, a coincidence rate of 64.63% was achieved. Finally, 40.82% of participants were identified to get clinically significant psychological distress using our predictive algorithm.

Discussion

Psychological distress has been recognized as an important consequence of cancer diagnosis and treatment because

Table 1: Comparison of psychological distress among 441 participants according to demographic and clinical variables

Variable	Frequency	Proportion (%)	Mean rank of PS	Z or χ^2	P
Gender					
Male	315	71.4	219.51	−0.479	0.632
Female	126	28.6	224.71		
Age (years)					
18-39	12	2.7	266.00	8.005	0.046
40-49	57	12.9	249.26		
50-59	141	32.0	218.64		
≥60	231	52.4	213.13		
Nationality					
Han	435	98.6	220.44	−0.976	0.329
Minority	6	1.4	261.75		
Educational level					
Primary	120	27.2	215.34	8.891	0.031
Junior high	180	40.8	208.43		
Senior high	84	19.1	243.55		
University	57	12.9	228.42		
Occupational status					
Not working	198	44.9	217.48	6.560	0.038
Working	54	12.2	254.50		
Retired	189	42.9	215.12		
Marital status					
Married	438	99.3	220.21	3.798	0.051
Divorced/widowed	3	0.7	336.50		
Payment method					
Medical insurance	429	97.3	221.58	−0.703	0.482
Private payment	12	2.7	200.38		
Residence					
Urban	306	69.4	216.96	−1.24	0.214
Rural	135	30.6	230.17		
Quantity of children					
0	3	0.6	155.00	2.531	0.282
1	234	53.1	216.23		
≥2	204	46.3	227.44		
Household income (rmb)					
<20,000	39	8.8	259.77	22.224	<0.001
20,000-50,000	123	27.9	204.87		
50,000-100,000	192	43.5	207.38		
>100,000	87	19.8	256.48		
Diagnosis duration (month)					
<1	51	11.6	269.09	16.492	0.001
1-6	183	41.5	211.85		
7-12	84	19.0	233.80		
>12	123	27.9	205.93		
Family history					
No	387	87.8	224.99	−2.177	0.029
Yes	54	12.2	192.42		
Smoking history					
No	159	36.1	218.00	−0.459	0.646
Yes	282	63.9	222.69		
Drinking history					
No	237	53.7	211.18	−2.157	0.031
Yes	204	46.3	232.40		
Surgery					
No	273	61.9	216.76	−1.102	0.270
Yes	168	38.1	227.89		

Contd...

Table 1: Contd...

Variable	Frequency	Proportion (%)	Mean rank of PS	Z or χ^2	*P*
Metastasis					
No	165	37.4	229.43	−1.328	0.184
Yes	276	62.6	215.96		
Comorbidity					
No	327	74.1	225.78	−1.649	0.099
Yes	114	25.9	207.30		
Pain					
No pain	183	41.5	207.33	7.323	0.062
Mild	174	39.5	233.41		
Moderate	81	18.4	227.67		
Severe	3	0.06	155.00		
TNM stage					
I	42	9.5	247.79	62.803	<0.001
II	21	4.8	387.07		
III	48	10.9	212.38		
IV	330	74.8	208.28		

PS: Psychological distress; TNM: Tumor, node, and metastasis

Table 2: Coding of categorical variables

Variable	Coding
Gender	1=male, 2=female
Age	1=18-39, 2=40-49, 3=50-59, 4=≥60
Nationality	1=Han nationality, 2=minority
Educational level	1=primary, 2=junior high, 3=senior high, 4=university
Occupational status	0=not working, 1=working, 2=retired
Marital status	1=married, 2=divorced/widowed
Payment method	1=medical insurance, 2=private payment
Residence	1=urban, 2=rural
Quantity of children	0=childness, 1=1 child, 2=≥children
Household income	1=<20,000; 2=20,000-50,000; 3=50,000-100,000; 4=>100,000
Diagnosis duration	1=<1, 2=1-6, 3=7-12; 4=>12
Family history	0=no, 1=yes
Smoking history	0=no, 1=yes
Drinking history	0=no, 1=yes
Surgery	0=no, 1=yes
Metastasis	0=no, 1=yes
Comorbidity	0=no, 1=yes
Pain degree	0=no pain, 1=mild, 2=moderate, 3=severe
TNM stage	1=I, 2=II, 3=III, 4=IV

TNM: Tumor, node, and metastasis

it was negatively associated with decreased therapeutic effectiveness, increased risk of morbidity and mortality, and poor quality of life.[24] Patients with lung cancer reported to have the highest incidence of psychological distress compared to other types of cancer.[8,17] Unfortunately, no validated screening tool specifically focused on lung cancer has been developed for early detection of patients at high risk of psychological distress although several studies have identified some risk factors of psychological distress.[3,6,16] In this study, a predictive algorithm with a moderate predictive accuracy (AUC = 0.693) was first developed and validated. Noteworthy, a cutoff value of 66 identified that 40.82% of lung cancer patients were at high risk of psychological distress, which was supported by results from several previous studies.[8,17,33]

In this study, total 19 risk factors were included for the final investigation, and younger age, higher educational level, working, extremely low or high household income, shorter diagnosis duration, no family history, drinking history, and advanced cancer stage were first identified as the risk factors of psychological distress. Furthermore, educational level, residence, family history, TNM stage, metastasis, and pain degree were included to develop predictive algorithm eventually, which were all reported previously to have predictive effects on psychological distress in lung cancer patients. However, the predictive role of other important risk factors, especially age and gender which have been identified previously to be the independent risk factor of psychological distress,[5,15,16,34] was not demonstrated. We therefore suggested performing more studies with larger sample size to further assess their association.

To our knowledge, several screening tools have been applied in practice for assessing the level of psychological distress in cancer patients.[24] Of these tools, DT and Hospital Anxiety and Depression Scale (HADS) were used most extensively. As an easy-to-use tool, DT has been recommended by the National Comprehensive Cancer Network to identify the level of psychological distress.[24] However, the cutoff value must be calculated again when DT was used for different types of cancer, in diverse cultural settings, and for different aims,[18,28,35-38] which may significantly increase the inaccuracy of psychological distress. Moreover, the accuracy of assessing psychological distress will be impaired because DT is marked subjectively

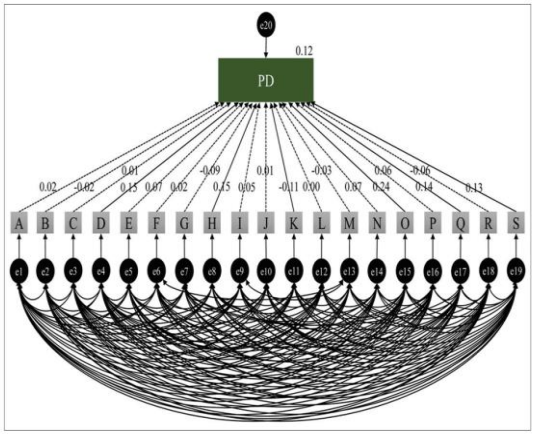

Figure 1: Path diagram of psychological distress and different demographic and clinical variables. Solid arrow indicates significant difference. A to S presents gender, age, nationality, educational level, occupational status, marital status, payment method, residence, quantity of children, household income, diagnosis duration, family history, smoking history, drinking history, surgery, metastasis, comorbidity, pain, and tumor, node, and metastasis stage, respectively

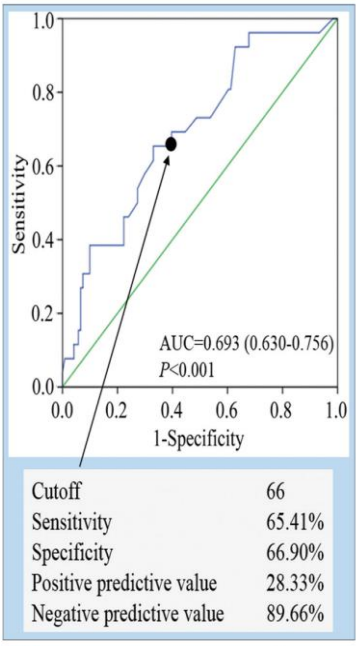

Figure 2: Receiver operating characteristic curve of the predictive algorithm. Black dot indicates cutoff value of 66

Table 3: Regression weights of psychological distress and different demographic and clinical variables

Pathway	Standard estimate	SE	CR	*P*
PD				
Gender	0.022	0.178	0.312	0.755
Age	−0.016	0.007	−0.280	0.779
Nationality	0.009	0.439	0.194	0.846
Educational level	0.151	0.060	2.885	0.004
Occupational status	0.068	0.072	1.126	0.260
Marital status	0.021	0.631	0.459	0.646
Payment method	−0.088	0.331	−1.837	0.066
Residence	0.146	0.148	2.411	0.016
Quantity of children	0.050	0.110	0.992	0.321
Household income	0.010	0.071	0.178	0.859
Family history	−0.107	0.158	−2.310	0.021
Diagnosis duration	0.001	0.058	0.019	0.985
Smoking history	−0.028	0.174	−0.379	0.705
Drinking history	0.065	0.106	1.379	0.168
TNM stage	−0.236	0.070	−3.973	<0.001
Surgery	0.059	0.105	1.288	0.198
Metastasis	0.136	0.139	2.270	0.023
Comorbidity	−0.060	0.126	−1.214	0.225
Pain degree	0.133	0.070	2.783	0.005

PS: Psychological distress; SE: Standard error; CR: Critical ratio; TNM: Tumor, node, and metastasis

by participants.[24] For the HADS, it was actually developed to measure the level of anxiety and depression in the hospital setting.[39] The HADS was extensively utilized in identifying psychological distress because anxiety and depression were considered to be manifestations of psychological distress. However, it is a mistake to simply equate anxiety and depression with psychological distress, which was defined as a negative emotional state characterized by physical and/or emotional discomfort, pain, or anguish.[24] Therefore, the HADS cannot adequately

Table 4: The correlations of all error variables

Correlation			Estimate	Correlation			Estimate	Correlation			Estimate	Correlation			Estimate	Correlation			Estimate
e18	<-->	e19	−0.015	e12	<-->	e18	0.107	e2	<-->	e16	0.066	e9	<-->	e12	−0.071	e2	<-->	e8	−0.147
e17	<-->	e18	0.039	e11	<-->	e18	0.015	e1	<-->	e16	−0.031	e8	<-->	e12	−0.152	e1	<-->	e8	0.004
e16	<-->	e17	0.060	e10	<-->	e18	0.014	e13	<-->	e15	−0.102	e7	<-->	e12	−0.104	e5	<-->	e7	−0.130
e15	<-->	e16	0.042	e9	<-->	e18	0.021	e12	<-->	e15	0.221	e6	<-->	e12	−0.052	e4	<-->	e7	−0.030
e14	<-->	e15	−0.078	e8	<-->	e18	−0.223	e10	<-->	e15	−0.317	e5	<-->	e12	−0.030	e3	<-->	e7	−0.020
e13	<-->	e14	−0.015	e7	<-->	e18	−0.099	e9	<-->	e15	0.082	e4	<-->	e12	0.086	e2	<-->	e7	−0.121
e12	<-->	e13	0.119	e6	<-->	e18	−0.049	e8	<-->	e15	0.067	e3	<-->	e12	0.004	e1	<-->	e7	−0.106
e11	<-->	e12	0.024	e5	<-->	e18	0.195	e7	<-->	e15	−0.087	e2	<-->	e12	0.116	e4	<-->	e6	−0.015
e10	<-->	e11	0.076	e4	<-->	e18	0.004	e6	<-->	e15	0.044	e1	<-->	e12	0.052	e3	<-->	e6	−0.010
e10	<-->	e9	−0.088	e3	<-->	e18	0.020	e5	<-->	e15	0.033	e9	<-->	e11	−0.012	e2	<-->	e6	−0.095
e8	<-->	e9	0.188	e2	<-->	e18	0.316	e4	<-->	e15	−0.204	e8	<-->	e11	−0.116	e1	<-->	e6	−0.052
e7	<-->	e8	0.161	e1	<-->	e18	−0.167	e3	<-->	e15	0.000	e7	<-->	e11	−0.059	e3	<-->	e5	0.066
e6	<-->	e7	−0.014	e15	<-->	e17	0.572	e2	<-->	e15	0.308	e6	<-->	e11	−0.033	e2	<-->	e5	0.328
e5	<-->	e6	−0.087	e14	<-->	e17	−0.042	e1	<-->	e15	−0.068	e5	<-->	e11	0.029	e1	<-->	e5	−0.034
e4	<-->	e5	0.265	e13	<-->	e17	−0.062	e12	<-->	e14	−0.121	e4	<-->	e11	0.132	e2	<-->	e4	−0.161
e3	<-->	e4	0.059	e11	<-->	e17	0.052	e11	<-->	e14	−0.094	e3	<-->	e11	−0.044	e1	<-->	e4	0.024
e17	<-->	e19	−0.002	e10	<-->	e17	−0.150	e10	<-->	e14	0.118	e2	<-->	e11	−0.011	e1	<-->	e3	0.012
e16	<-->	e19	−0.071	e9	<-->	e17	0.140	e9	<-->	e14	−0.080	e1	<-->	e11	−0.050	e12	<-->	e17	0.358
e15	<-->	e19	0.045	e8	<-->	e17	−0.094	e8	<-->	e14	0.064	e8	<-->	e10	−0.413	e2	<-->	e13	−0.197
e14	<-->	e19	−0.057	e7	<-->	e17	−0.129	e7	<-->	e14	0.012	e7	<-->	e10	−0.094	e1	<-->	e2	−0.115
e13	<-->	e19	−0.194	e6	<-->	e17	0.065	e6	<-->	e14	0.089	e6	<-->	e10	−0.071	e2	<-->	e3	0.016
e12	<-->	e19	−0.096	e5	<-->	e17	0.117	e5	<-->	e14	−0.023	e5	<-->	e10	0.359				
e11	<-->	e19	0.105	e4	<-->	e17	−0.065	e4	<-->	e14	0.042	e4	<-->	e10	0.359				
e10	<-->	e19	0.020	e3	<-->	e17	0.011	e3	<-->	e14	0.009	e3	<-->	e10	0.058				
e9	<-->	e19	−0.025	e2	<-->	e17	0.206	e2	<-->	e14	−0.053	e2	<-->	e10	−0.090				
e8	<-->	e19	−0.024	e1	<-->	e17	−0.070	e1	<-->	e14	0.077	e1	<-->	e10	0.015				
e7	<-->	e19	0.103	e14	<-->	e16	−0.065	e11	<-->	e13	−0.060	e7	<-->	e9	0.015				
e6	<-->	e19	−0.085	e13	<-->	e16	−0.035	e10	<-->	e13	−0.005	e6	<-->	e9	−0.074				
e5	<-->	e19	0.032	e12	<-->	e16	−0.001	e9	<-->	e13	0.079	e5	<-->	e9	−0.066				
e4	<-->	e19	−.011	e11	<-->	e16	−0.025	e8	<-->	e13	−0.007	e4	<-->	e9	−0.135				
e3	<-->	e19	−0.018	e9	<-->	e16	0.088	e7	<-->	e13	0.048	e3	<-->	e9	0.087				
e2	<-->	e19	0.062	e8	<-->	e16	0.003	e6	<-->	e13	−0.062	e2	<-->	e9	0.246				
e1	<-->	e19	−0.056	e7	<-->	e16	−0.043	e5	<-->	e13	−0.074	e1	<-->	e9	0.055				
e16	<-->	e18	0.038	e6	<-->	e16	−0.007	e4	<-->	e13	−0.005	e6	<-->	e8	0.125				
e15	<-->	e18	0.042	e5	<-->	e16	−0.009	e3	<-->	e13	−0.007	e5	<-->	e8	−0.537				
e14	<-->	e18	−0.049	e4	<-->	e16	−0.005	e1	<-->	e13	0.748	e4	<-->	e8	−0.364				
e13	<-->	e18	−0.152	e3	<-->	e16	−0.053	e10	<-->	e12	−0.008	e3	<-->	e8	−0.036				

identify patients at high risk of psychological distress. According to the updated definition, we developed the initial predictive algorithm of psychological distress through including sociodemographic and clinical variables based on participants from seven different hospitals with different levels. Meanwhile, this predictive algorithm will objectively calculate the corresponding risk score after entering the value of each predictive factor. Therefore, compared to reported tools, our predictive algorithm has potential of objectively and accurately identifying participants at high risk of psychological distress.

Two main limitations in this study must be further interpreted. First, psychosocial factors were not included despite the fact that 19 sociodemographic and clinical factors have been considered. However, it remains an issue that inclusion of psychological factors may greatly decrease the feasibility of predictive algorithm because psychological states will be assessed with various complex questionnaires. Second, external validation was not performed after developing the predictive algorithm. However, we further evaluated the accuracy of our predictive algorithm through calculating the coincidence rate.

Conclusions

In this study, some important independent sociodemographic and clinical predictive factors for clinically significant psychological distress in lung cancer patients were identified, and a validated, easy-to-use predictive algorithm with fair predictive yield was developed.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Implications for practice

By applying this predictive algorithm, a considerable number of subjects at the clinically significant level for psychological distress who will benefit more from psychological intervention programs can be early and precisely identified. Therefore, the predictive algorithm has great potential as a validated screening measure for use in research, evaluating the effects of intervention programs designed to decrease the level of psychological distress among lung cancer patients through measuring accumulation of psychological distress.

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Conflicts of interest

There are no conflicts of interest.

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

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Article 2

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Original Article

Relationships among Social Support, Coping Style, Perceived Stress, and Psychological Distress in Chinese Lung Cancer Patients

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ABSTRACT

Objective: Social support is associated with improved psychological distress in cancer patients. This study investigates the impact of social support on Chinese lung cancer patients' psychological distress and further clarifies the mediating role of perceived stress and coping style. **Methods:** A cross-sectional survey study examined social support and psychological distress in 441 patients diagnosed with lung cancer from seven hospitals in Chongqing, China, between September 2018 and August 2019. Coping style and perceived stress were considered to be potential mediators of adjustment outcomes. **Results:** We found a detection rate of 17.7% for psychological distress among Chinese lung cancer patients. Social support was in significantly negative association with psychological distress, which was partially mediated by confrontation coping and perceived stress. **Conclusions:** Social support appears to contribute to ameliorate psychological distress by enhancing confrontation coping with cancer and enhancing perceived stress. There is a need for the development and evaluation of psychological intervention program to enhance the buffering effects of social support in lung cancer patients.

Key words: Lung cancer, psychological distress, social support, perceived stress, coping style, structural equation model

Introduction

Lung cancer is one of the most common malignant tumors.[1] It is estimated to have 2,100,000 new cases and 1,800,000 deaths of lung cancer in 2018 worldwide.[2] In China, lung cancer is also the leading cause of cancer-related death.[3] Cancer patients will suffer from several negative outcomes such as adverse symptoms and interruption of treatment, which will then cause psychological distress.[4] It is reported that lung cancer patients experience the highest prevalence of psychological distress[5] due to negative impact from several aspects such as poor 5-year survival rate of <40%.[6] One study reported that more than one-third of lung cancer patients experienced elevated depression before initiation of the treatment.[7] Lynch *et al.* found that 44.12% of 34 lung cancer patients reported psychological distress among.[8] Moreover, Chambers' study suggested that 51.0%

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

of 151 participants reported elevated distress.[9] In China, the reported incidence of psychological distress among lung cancer patients was varied from 30.00% to 73.00%.[10]

Psychological distress has persistent negative impact on psychological health, compliance with treatment, and quality of life (QoL) among cancer patients,[11] and thus it has been defined as a risk factor of psychosomatic symptoms.[12-14] Social support has a buffering or protective effects on psychosocial adjustment.[15] Several studies have also determined the protective effects of social support on psychological distress.[16-18] Burnette and colleagues found a negative association between social support and psychological distress among 377 cancer caregivers.[16] Min *et al*. also demonstrated that social support was negatively associated with psychological distress.[19]

Coping is an individual's characteristic behavior for responding to stress, which can be categorized into three aspects including confrontation coping, accommodation coping, and avoidance coping.[20] Studies demonstrated that confrontation coping and accommodation coping benefits psychological adjustment as a positive coping style.[20,21] Whereas, patients who tend to adopt avoidance coping will experience more negative outcomes because they will not positively seek additional support sources to deal with difficulties.[21] Evidence suggested that psychological distress is closely associated with psychological adjustment as a strong predictor.[22] Coping style is, therefore, considered to be potentially related to psychological distress, and the association between coping style and psychological distress has been demonstrated.[23,24]

Stress is regarded as a state in which individual's regulatory capacity cannot meet the threshold of processing the environmental demands or mental strain.[25] Individual will conduct a subjective assessment for individual's degree of stress and ability of processing stress when experienced stress,[26] which is defined as perceived stress. Studies have demonstrated that perceived stress will influence individual psychological adjustment.[26,27] Individual will positively conduct psychological adjustment to ameliorate psychological distress when they perceived the threat from the higher stress, which has been demonstrated by published study.[27]

Based on the previous findings, we concluded that social support, coping style, and perceived stress is obviously the three major variables affecting psychological distress. In addition, more importantly, some studies have revealed that social support can directly influence the coping style[20,21,28,29] and perceived stress[30-33] among cancer patients. However, published studies only simply investigated the associative relationship between two variables, and the potential association of these three variables with psychological distress in lung cancer patients is not yet clear, which considerably limits practitioners to develop interventions for targeting social support. Hence, we performed this study to investigate the impact of social support on Chinese lung cancer patients' psychological distress and further clarify the role of perceived stress and coping style as mediators of effects.

Methods

The present study was conducted based on a descriptive and correlational design. The ethics commission of the Chongqing University Cancer Hospital reviewed and approved the study protocol (Approval No. CUCH_P20180225). Investigators informed all candidates the aims and procedures of the study in detail before starting the formal survey. All oral informed consents were obtained from patients before participating in the study. We reported all data in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting observational studies.[34]

Sample and setting

Eligible lung cancer patients were enrolled from seven hospitals including two tertiary hospitals and five secondary hospitals in Chongqing, China. After a pilot study tested the feasibility of the questionnaire survey, we conducted the formal survey. All questionnaires were independently completed by patients between September 2018 and August 2019. We calculated sample size according to the principle of minimum numbers needed to perform structural equation modeling (SEM).[35] Patients were enrolled if the following inclusion criteria were met: (1) lung cancer was established pathologically; (2) adults patients (18 years or older) who have independent ability of reading, understanding, and writing information; and (3) did not participate in other surveys which has similar study aims. We excluded patients with serious physical diseases, mental disorder, and consciousness disorder from this study. Finally, a total of 450 lung cancer patients were recruited in the investigation and 441 questionnaires were considered to meet the criteria of analysis, with an effective response rate of 98.0%. The process of participants' selection is delineated in Figure 1.

Instruments

Demographic information sheet

The demographic information sheet was developed by the leading investigator (X. T.). Potential demographic variables which may have impact on psychological distress were identified from published literature. We designed 12 demographic variables in this study finally, including age, gender, educational level, work status, marital status, residence, home income, family history (yes or no), smoking history (yes or no), drinking history (yes or no), surgery history (yes or no), pain, and tumor-node-metastasis (TNM) stage.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

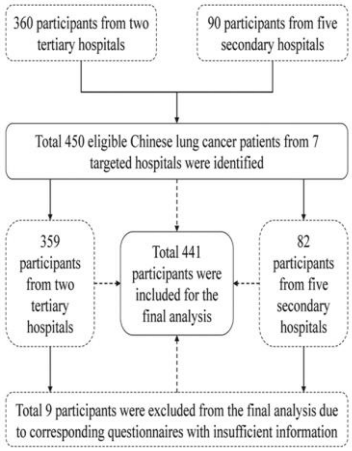

Figure 1: The flow diagram of participants' selection

Psychological distress

In this study, we used a distress thermometer (DT) to measure psychological distress. The DT is a single item with an 11-point scale (0 and 10 represents no distress and extreme distress, respectively) in a thermometer format.[13] Several studies have tested the psychometric properties of DT and confirmed the value of measuring psychological distress.[36-38] According to the criteria, patients will be defined to have clinically significant distress if a score of 4 or above was reported.[39,40] In China, an empirical study demonstrated that the optimal cutoff point of DT was also 4, with an area under the receiver operating characteristic curve of 0.885.[37]

Social support

In the preset study, we used the 12-item Multidimensional Scale of Perceived Social Support (MSPSS) to measure the level of social support from three aspects including family, friends, and significant others.[41] Eligible lung cancer patients were requested to rate each item on a 7-point Likert scale (1 = very strongly disagree to 7 = very strongly agree). The total score of the perceived social support ranges from 12 to 84 points. A previous study has tested the psychological properties of MSPSS and reported that the coefficient alpha values of subscales were ranging from 0.81 to 0.98.[42] The Chinese version of MSPSS has been validated[43] and thus was used to measure the level of perceived social support in our study. Reliability Cronbach's alpha was 0.90 in this study.

Coping style

We used a 20-item Medical Coping Modes Questionnaire (MCMQ), which rated on a 4-point Likert scale from 1 to 3,[44] in this study. The coping style questionnaire was divided into three subscales including confrontation coping (active coping), avoidance coping, and giving up coping (accommodation). Finally, the score of each subscale was calculated, and the higher score indicated that individual is more likely to adopt the corresponding coping style. The MCMQ has been validated in China scenario and then formed Chinese version of MCMQ.[45] Cronbach's alpha for each of the three subscales were higher than 0.65, except for avoidance coping (0.60). In the current study, Cronbach's alpha coefficients were 0.67, 0.68, and 0.74 for confrontation coping, avoidance coping, and giving up coping, respectively.

Perceived stress

In this study, we used the 10-item Perceived Stress Scale (PSS), which was developed by Cohen *et al*.[46,47] to measure stress, which was evaluated on a 5-point Likert scale from 0 to 4. The total possible score was ranging from 0 to 40 points, and a higher score indicated a greater stress level. Cronbach's alpha was 0.84 at the instrument development stage. The Chinese version of PSS has been validated, with a Cronbach's alpha of 0.619.[48] In our study, the Cronbach's alpha was 0.73.

Statistical analysis

All statistical analyses were completed using the Statistical Package for the Social Sciences (Chicago, Illinois, USA) and IBM AMOS 21.0 (Chicago, Illinois, USA). Descriptive statistics were used to summarize patients' characteristics and their average score for psychological distress, social support, coping style, and perceived stress. Kolmogorov–Smirnov test indicated that the scores of psychological distress, social support, coping style, and perceived stress did not follow the normal distribution, so Spearman's rank correlation analyses were calculated to test the relationships among psychological distress, social support, coping style, and perceived stress. Bootstrap test was conducted to test a mediating effect of coping style or perceived stress in the relation of social support and psychological distress. We evaluated the overall model using the criteria of fit index. According to Schreiber,[49] the Chi-square (χ^2) test value should not be statistically significant ($P > 0.05$), $1 < \chi^2/$ degrees of freedom (df) <3, goodness of fit index (GFI) >0.90, adjusted GFI (AGFI) >0.90, comparative fit index (CFI) ≥0.90, incremental fit index (IFI) >0.90, normed fit index (NFI) >0.90, and root-mean-square error of approximation (RMSEA) <0.05 (with 90% confidence interval [CI]). A *P* value of 0.05 was considered to represent statistical significance (two-tailed).

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Results

Demographic characteristics and descriptive statistics

Table 1 presents the demographic characteristics of 441 patients. A total of 315 (71.4%) patients were male. The age of majority of patients was more than 50 years (372 patients, 84.4%). A total of 127 (27.2%) patients graduated from primary school, 180 (40.8%) had junior middle school education, 84 (19.1%) had senior high school education, and 57 (12.9%) held a college degree or higher degree. Most patients did not attend work (198 patients, 44.9%) or retired from work (189 patients, 42.9%). 438 patients (99.3%) were married and 3 (0.7%) were divorced or widowed. 306 patients (69.4%) reside in the urban area. For the household income, 39 (8.8%) patients reported under ¥20,000; 123 (27.9%) made between ¥20,000 and ¥50,000; 192 (43.5%) made between ¥50,000 and ¥100,000; and 87 (19.8%) made more than ¥100,000. 54 (12.2%), 282 (63.9%), and 204 patients (46.3%) have family history, smoking history, and drinking history, respectively. 168 (38.1%) patients underwent surgery. Most patients experienced mild-to-severe pain (258 patients, 58.5%), and most patients were diagnosed at advanced stage (378 patients, 85.7%), which were defined as III and IV stage.

Table 1: Characteristics of participants (n=441)

Characteristics	Frequency (%)	Z or χ^2	P
Gender			
Male	315 (71.4)	−0.479	0.632
Female	126 (28.6)		
Age (year)			
18-39	12 (2.7)	8.005	0.046
40-49	57 (12.9)		
50-59	141 (32.0)		
≥60	231 (52.4)		
Educational level			
Primary	120 (27.2)	8.891	0.031
Junior high	180 (40.8)		
Senior high	84 (19.1)		
University	57 (12.9)		
Work status			
Not working	198 (44.9)	6.560	0.038
Working	54 (12.2)		
Retired	189 (42.9)		
Marital status			
Married	438 (99.3)	3.798	0.051
Divorced/Widowed	3 (0.7)		
Residence			
Urban	306 (69.4)	−1.240	0.214
Rural	135 (30.6)		
Household income (¥)			
<20,000	39 (8.8)	22.224	<0.001
20,000-50,000	123 (27.9)		
50,000-100,000	192 (43.5)		
>100,000	87 (19.8)		
Family history			
No	387 (87.8)	−2.177	0.029
Yes	54 (12.2)		
Smoking history			
No	159 (36.1)	−0.459	0.646
Yes	282 (63.9)		
Drinking history			
No	237 (53.7)	−2.157	0.031
Yes	204 (46.3)		
Surgery			
No	273 (61.9)	−1.102	0.270
Yes	168 (38.1)		
Pain			
No pain	183 (41.5)	7.323	0.062
Mild	174 (39.5)		
Moderate	81 (18.4)		
Severe	3 (0.06)		
TNM stage			
I	42 (9.5)	62.803	<0.001
II	21 (4.8)		
III	48 (10.9)		
IV	330 (74.8)		

TNM: tumor-node-metastasis

Overall, the median score of psychological distress was 2 with an interquartile range of from 2 to 3. The medium score of social support, coping style, and perceived stress was 66 (61–70), 50 (48–52), and 20 (17–22), respectively. Among 441 lung cancer patients, 78 were detected to have a DT score of 4 or above, with a detection rate of 17.7%.

Relationships between psychological distress, social support, coping style, and perceived stress

Table 2 documents the results of correlation analyses of psychological distress, social support, coping style including confrontation coping, avoidance coping and giving up coping, and perceived stress. The results of the Spearman's rank correlation analyses showed that most variables are significantly correlated with one another other than the correlation between coping style and perceived stress. Moreover, avoidance coping and giving up coping were all not significantly correlated with psychological distress.

Table 2: Spearman's correlation coefficient of study variables (n=441)

Variables	1	2	3	4	5	6	7
1. Psychological distress	1						
2. Perceived stress	0.131**	1					
3. Social support	−0.444**	0.110*	1				
4. Coping style	0.113*	0.067	0.096*	1			
5. Confrontation coping	0.134**	0.026	0.152**	0.661**	1		
6. Avoidance coping	0.026	−0.012	0.093*	0.624**	0.121*	1	
7. Giving up coping	−0.002	0.082	−0.118*	0.390**	−0.132**	0.104*	1

*P<0.05, **P<0.01

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Table 3: Decomposition of standardized effects from the path model

Variable of effect	Social support					Perceived		Confrontation coping
	Confrontation coping	Avoidance coping	Giving up coping	Perceived stress	Psychological distress	Giving up coping	Psychological distress	Psychological distress
Total effects	0.155	0.113	−0.164	0.110	−0.524	0.096	0.192	0.191
Direct effects	0.155	0.113	−0.175	0.110	−0.575	0.096	0.192	0.191
Indirect effects	0.000	0.000	0.011	0.000	0.051	0.000	0.000	0.000

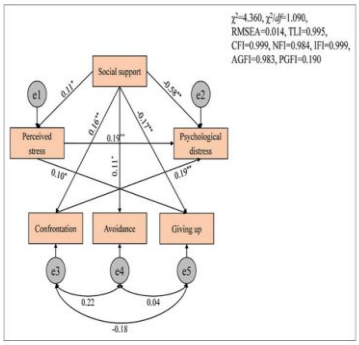

Figure 2: A path diagram of direct and indirect influences of social support, perceived stress and coping style on psychological distress among Chinese lung cancer patients ($n = 441$). $^{*}P < 0.05$, $^{**}P < 0.01$

The mediating effect of coping style and perceived stress on the relationship between social support and psychological distress

SEM with maximum likelihood was used to analyze the path correlations, which are presented in Table 3 and Figure 2. The results showed a better fitness between construct model and the data (χ^2/df = 1.090, GFI = 0.997, AGFI = 0.983, CFI = 0.999, IFI = 0.999, NFI = 0.984, RMSEA = 0.014 [90% CI, 0.000–0.075]).

As illustrated, social support had significant direct effects on psychological distress ($\beta = -0.58$, $P < 0.001$), confrontation coping ($\beta = 0.16$, $P < 0.001$), avoidance coping ($\beta = 0.11$, $P = 0.02$), giving up coping ($\beta = -0.17$, $P < 0.001$), and perceived stress ($\beta = 0.11$, $P = 0.02$) among lung cancer patients. The direct pathways from perceived stress to giving up coping ($\beta = 0.10$, $P = 0.04$) and psychological distress ($\beta = 0.19$, $P < 0.001$) were all statistically significant. Meanwhile, the direct pathway from confrontation coping to psychological distress ($\beta = 0.19$, $P < 0.001$) was also statistically significant. The results of bias-corrected bootstrap method indicated that the indirect pathways between social support and psychological distress through confrontation coping or perceived stress were significant, respectively. The results from bootstrap test for significance of indirect pathways are summarized in Table 4. The results suggested that perceived stress or confrontation coping plays a mediating role in the relationship between social support and psychological distress.

Discussion

Main findings

The aim of the present study is to examine the impact of social support on psychological distress among Chinese lung cancer patients and determine whether coping style and perceived stress mediating the association between social support and psychological distress. The current study stemmed from a fact that the mechanism by which social support influences psychosocial distress among lung cancer patients remains unclear. In our study, only 17.7% of the analyzed patients reported clinically significant psychological distress, which was greatly lower than some previous findings.[10,37] However, there also are some studies found a relatively lower detection rate of psychological distress in Chinese lung cancer patients,[50,51] which were all consistent with our result. After checking the demographic information of all analyzed patients, we found that the vast majority of patients were at advanced stage and thus have greatly low expectation for treatment effectiveness and prognosis, which may be the major reason of causing relatively low detection rate of psychological distress.[37] Certainly, usage of DT for the measurement of psychological distress may be also a potentially important reason because this instrument is not just for cancer patients as a nonspecific type of tool.[37] More important is that most of the enrolled participants received psychological interventions when they were initially hospitalized to ward.[52] Moreover, patients will experience serious stigma when who were diagnosed with advanced lung cancer,[53] and therefore, patients tend to deliberately conceal their psychological distress.[50]

Social support has been identified as a buffering or protective source on distress and psychosocial adjustment.[15] A great deal of studies has established the importance of involving social support sources such as caregivers, spouses, or partners in educational and psychosocial intervention regimes.[54] In the current study, we found a directly negative correlation between social support and psychological distress among Chinese lung cancer patients, which was

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Table 4: Bias-corrected bootstrap test for all indirect pathways

Pathway	Estimate	Bootstrap confidence	*P*
Psychological distress ← social support	−0.575	−0.629-−0.523	0.001
Confrontation copings ← social support	0.155	0.071-0.240	0.005
Perceived stress ← social support	0.046	0.014-0.080	0.021
Psychological distress ← confrontation coping	0.191	0.123-0.262	0.001
Psychological distress ← perceived stress	0.192	0.134-0.258	0.001

consistent with findings from previous studies.[16,55] Studies which were performed to investigate the influencing factors on psychological distress also consistently indicated that social support is one of the most important factors of reducing the severity of psychological distress.[56,57] One study focusing on breast cancer patients also suggested that higher level of social support was in association with higher benefit when a critical threshold of social support was reached.[58] Therefore, professional and nonprofessional social supports should be provided for lung cancer patients for the purpose of buffering the adverse consequences resulted from psychological distress and then improve the QoL.

The coping style is an important person's characteristic strategies to maintain or achieve healthy psychological status through improving environmental adaptability when patients experienced difficulties.[59] Different coping styles including confrontation coping, accommodation coping, and avoidance coping have impact on individual's emotional and mental health status.[23] Evidence indicated that patients with high level of positive attitude may have more expectation and confidence in addressing adverse challenge and vice versa.[60] In the present study, confrontation coping was defined to cope with the stressor positively.[29] We found confrontation coping mediating the relationship between social support and psychological distress, and confrontation coping was also in positive association with psychological distress. Evidence suggested that patients characterized by confrontation coping style were most likely to communicate with their physician for seeking disease- and treatment-related information[20] and then reduce the level of psychological distress. However, a previous systematic review concluded no significant association between engagement coping strategies and psychological distress.[24] These inconsistent results may be resulted from the different structure of psychological distress and coping style measurements, heterogeneity of the sample, or variation in statistical methods. Moreover, the association between negative coping style including avoidance coping and giving up coping (accommodation coping) and psychological distress was not statistically significant, which was also inconsistent with previous findings.[23,24] Thus, further investigation on the relationship between coping style and psychological distress in lung cancer patients should be conducted.

In addition, in this study, we also found that perceived stress partially mediated the relationship between social support and psychological distress, with a positive correlation between perceived stress and psychological distress, which was consistent with previous results.[27,61] Perceived stress will influence the person's psychological adjustment as a positive source of coping diseases, and we therefore assumed that perceived stress will influence psychological distress because psychological distress is a strong predictor of psychological adjustment.[22] Interestingly, a study investigating the relationship among perceived stress, coping style, and psychological distress in Chinese physicians demonstrated our hypothesis.[62] Moreover, Segrin *et al.* also found that stress can predict psychological distress in breast cancer survivors and their family caregivers.[63] Hence, it is critical to emphasize the role of enhancing the level of perceived stress when interpreting the buffering effects of social support on psychological distress. Moreover, psychological intervention programs for involving elements of buffering perceived stress should be developed to enhance the protective effects of social support on psychological distress.

Limitations

Although several valuable findings were identified in the present study, we must acknowledge some limitations which may have adverse impact on the conclusions. First and foremost is that the nature of cross-sectional survey design limits the ability of establishing causality between the proposed variables. And thus, further study with longitudinal design will be necessary to prospectively clear the mechanism of social support in buffering the adverse results from psychological distress. Second, we used convenience sampling method to enroll potentially eligible patients, and thus the sample is not representative. Further investigation with random sampling method should be designed. Third, we assessed psychological distress, social support, coping style, and perceived stress using self-reported questionnaires in the present study. Hence, the results may be inflated due to subjective bias from participants and investigators. Additional studies considering physiological assessment and ecological momentary assessment should be performed.

Conclusions

The minority of Chinese lung cancer patients experienced psychological distress at a clinically significant level. Perceived stress and confrontation coping mediated the protective effects of social support on psychological distress.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Implications for practice

This study enhanced our understanding on the association among social support, coping style, perceived stress, and psychological distress in lung cancer patients. From our current findings, practitioners can enhance the benefits of social support programs through strengthening confrontation coping and perceived stress and then reduce the adverse consequences resulted from psychological distress.

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Conflicts of interest

There are no conflicts of interest.

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

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Article 3

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RESEARCH ARTICLE

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The positive effect of social support on psychological distress among Chinese lung cancer patients: The mediating role of self-esteem

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Abstract

Aim: To investigate the effect of social support on psychological distress among Chinese lung cancer patients and clarify the mediating role of self-esteem.

Design: A cross-sectional descriptive correlational survey of 441 Chinese lung cancer patients was designed.

Methods: Self-esteem was supposed to play a mediating role in the association between social support and psychological distress. We collected demographic information, the Distress Thermometer, Multidimensional Scale of Perceived Social Support and Rosenberg Self-Esteem Scale.

Results: Our revised model demonstrated an acceptable fit to the data (χ^2 = 37.489, comparative fit index (CFI) = 0.965, Tucker-Lewis index (TLI) = 0.926, root mean square error of approximation [RMSEA] = 0.099). Social support had a direct effect on self-esteem and psychological distress, and self-esteem had also a direct effect on psychological distress. Meanwhile, self-esteem also partially mediated the relationship between social support and psychological distress among Chinese lung cancer patients.

KEYWORDS

lung cancer, psychological distress, self-esteem, social support, structural equation model

1 | INTRODUCTION

Lung cancers remain ranking the first position in incidence and mortality among all cancers in China (Liu et al., 2018) and even worldwide (Siegel et al., 2018). It is reported that patients with lung cancer will experience a great deal of negative psychological problems, of which psychological distress has been reported to have the highest of incidence (Zabora et al., 2001) due to the negative impact from several aspects such as low 5-year survival rate and undetermined aetiologies (Goldstraw et al., 2016). Psychological distress among cancer patients has been extensively investigated, and several studies suggested that it may be negatively associated with several adverse outcomes such as interruption of treatment strategies and poor physical health status (Kroenke et al., 2013). Therefore, it is imperative to investigate all potential factors which have protective effects on psychological distress among lung cancer patients for the purpose of developing precisely effective intervention programme.

Xu Tian and Yanfei Jin have contributed equally to this work as joint first author.

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Social support, as an important positive source of coping negative conditions, has been reported to be negatively associated with psychological distress among cancer patients, and several studies even found social support can improve the adverse effects resulted from psychological distress (Burnette et al., 2017; Demirtepe-Saygili & Bozo, 2011; Schulz & Schwarzer, 2004; Teixeira & Pereira, 2013; Tuinman et al., 2006). However, some studies have also suggested no statistically significant positive association between social support and psychological distress among cancer patients (Matzka et al., 2016; Oancea et al., 2018). To date, few researches have been performed to investigate the relationship between social support and psychological distress among lung cancer patients, and the latest one suggested that social support can significantly and directly predict the level of psychological distress (Lv et al., 2020). Nevertheless, the specified association between social support and psychological distress among lung cancer patients has not yet been completely determined due to scattered evidence, and the potential mechanisms of social support against psychological distress have also not yet been further investigated. These issues eventually limited nursing practitioners to develop reliable intervention programmes which have protective effects on psychological distress among lung cancer patients.

What does this paper contribute to the wider global clinical community

1. Social support was negatively associated with psychological distress in lung cancer patients and also be suggested to have a protective effect on psychological distress as a positive source.
2. Self-esteem also negatively affects psychological distress as a positive personal character which is critically important to rebuild self-role in society.
3. Social support relieves adverse outcomes resulted from psychological distress through enhancing the level of self-esteem among lung cancer patients.

2 | BACKGROUND

Issued data approximately revealed, around the world, 2,100,000 new lung cancer cases and 1,800,000 lung cancer-related deaths (Bray et al., 2018). Lung cancer has obviously become the prevalent cause threatening public health worldwide as the increasing in incidence and mortality (Siegel et al., 2018). Similarly, lung cancer has also been reported as one of the leading cancer-related reasons of causing death (Liu et al., 2018). Those patients who were diagnosed with cancer will experience a series of distressing conditions such as adverse symptoms, interruption of treatment strategies and decreased health-related quality of life (QoL), which are all determined to be associated with psychological distress (Kroenke et al., 2013). It is reported that the 5-year survival rate of lung cancer patients is still to stay low, and the aetiologies of lung cancer have not yet been completely clarified (Goldstraw et al., 2016). As a result, patients with lung cancer experience several significant negative psychological symptoms, of which psychological distress has been defined as the critical adverse outcome which can negatively affect psychological and physical health and QoL (Zabora et al., 2001). For example, one study suggested that 44.12% lung cancer patients experienced psychological distress (Lynch et al., 2010), and another study found 51.0% participants suffered from elevated distress (Chambers et al., 2015). It is important to note that studies focused on Chinese lung cancer patients reported an incidence of psychological distress between 30.00%–73.00% (Pi et al., 2020) although a conclusive incidence is not yet clear.

As stated above, cancer patients with higher psychological distress will persistently experience several serious adverse outcomes such as lower compliance with treatment, worsen psychological health and decreased QoL (Akizuki et al., 2003). Therefore, psychological distress has been cited as a predictor of adverse psychosomatic symptoms (Gundelach & Henry, 2016; Rana et al., 2015; Riba et al., 2019). Social support is defined as a positive source to address negative conditions and thus has been extensively cited as an essential element of the psychological intervention programme for the purpose of improving psychological status (Kim & Jang, 2020). Most of studies have revealed that social support can relieve the negative effects caused by psychological distress (Burnette et al., 2017; Demirtepe-Saygili & Bozo, 2011; Schulz & Schwarzer, 2004; Teixeira & Pereira, 2013; Tuinman et al., 2006). For example, Burnette and colleagues found that social support was negatively associated with psychological distress in 377 cancer caregivers (Burnette et al., 2017). Moreover, Min and colleagues also found a negative relationship between social support and psychological distress (Min et al., 2013). However, more studies should be conducted to further establish the association between social support and psychological distress among lung cancer patients because limited numbers of studies investigated this question.

Self-esteem is defined as a positive personal character which is critically important to rebuild self-role in society (Curbow et al., 1990). A higher self-esteem is benefit to cope with the physical and psychological stress resulted from diseases and treatments (Pearlin et al., 1981). Some studies have suggested a negative association between self-esteem and psychological distress in cancer patients (den Heijer et al., 2011; Kobayashi et al., 2008; Rodin et al., 2009). For example, Rodin and colleagues found that low self-esteem plays a risk factor for psychological distress in 406 patients with metastatic gastrointestinal or lung cancer (Rodin et al., 2009). Certainly, the specified relationship between self-esteem and psychological distress is still needed to be further investigated due to inadequate numbers of eligible studies.

After interpreting the previous findings, we can believe that social support and self-esteem are the major social and psychological variables which can affect psychological distress among patients with lung cancer, respectively. Additionally, some studies also revealed a potential association between social support and self-esteem in cancer patients although this association was still

conflicting (Li et al., 2015; Tuinman et al., 2006; Wang et al., 2014; Xiaoyun & Fenglan, 2020). More importantly, as a positive individual source, social support was regarded as the motive power of enhancing self-esteem and eventually relieving adverse effects of distress. Therefore, we speculated that self-esteem may act as a mediating role in the relationship between social support and psychological distress. However, published studies only simply investigated the associative relationship between social support and self-esteem, and the potential relationship of these two variables to psychological distress among patients with lung cancer remains not clear. Therefore, we designed the current survey study to comprehensively investigate the impact of social support and self-esteem on psychological distress among Chinese lung cancer patients and then further clarify the role of self-esteem as mediators of an effects.

3 | STUDY

3.1 | Design

We performed the current survey study with a descriptive and correlational design. We reported all results in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist, developed by the EQUATOR Network (Enhancing the Quality and Transparency Of health Research) (see Appendix S1) (von Elm et al., 2014).

3.2 | Ethical approval

Our protocol has been approved by our hospital's Institutional Review Board (IRB) before initiation of the formal survey. The formal survey was conducted when all potential candidates were informed about the objectives and process of our study. All patients made a response to major investigator that they agree to participate in this survey voluntarily.

3.3 | Participants

We recruited all potentially eligible lung cancer patients from two tertiary hospitals and five secondary hospitals in Chongqing, China between September 2018 and August 2019. Sample size was estimated based on the principle of minimum numbers needed to perform structural equation modelling (SEM) (Tinsley & Tinsley, 1987). We designed the following inclusion criteria to enrol eligible patients: (a) adult patients diagnosed with lung cancer with pathologic or histologic investigation; (b) have healthy listening and ability of independently reading, understanding and writing; (c) did not include in other studies which have similar study aims with the current study; (d) made a effective response about informed consent. Patients with serious physical diseases, mental disorder and consciousness disorder were excluded from the scope of the current study. A total of 450 lung cancer patients were recruited in the survey, and eventually 441 valid questionnaires were used in the final analysis, with a valid response rate of 98.0%.

3.4 | Data collection

The leading investigator in the current study determined targeted patients with convenience sampling. The investigator informed all patients about the details of the study aims, specified process, and patients' rights to decline and to withdraw from the study at any time with no negative consequences. Meanwhile, all patients were also informed that all data we collected from them will be protected strictly and only academic use of collected data. Before initiating the formal survey, we performed a pilot survey to test the feasibility of the questionnaire survey. Patients were required to independently answer all questionnaires.

3.5 | Instruments

3.5.1 | Demographic information sheet

The demographic information sheet was developed by the leading investigator (X.T.). Potential demographic variables which may have impact on psychological distress were identified from published literature and the consensus of the panel discussion. A total of 12 demographic variables were eventually identified in this study, including age, gender, educational level, work status, marital status, residence, home income, family history (yes or no), smoking history (yes or no), drinking history (yes or no), surgery history (yes or no), pain and TNM stage.

3.5.2 | Psychological distress

Psychological distress was measured with Chinese version of Distress Thermometer (DT) in the current study. The DT is a single item with an 11-point scale (0 and 10 represents no distress and extreme distress, respectively) in a thermometer format (Riba et al., 2019). The psychometric properties of DT have been extensively tested in several studies and all confirmed the value of DT to measure the level of psychological distress (Bui et al., 2005; Hong et al., 2015; Kornblith et al., 2001). Patients will be treated to have clinically significant distress when reported a score of 4 or above (Donovan et al., 2014; Tang et al., 2011). The optimal cut-off point of Chinese version of DT was also to be 4 (Hong et al., 2015).

3.5.3 | Social support

Social support was measured with the Chinese version of 12-item Multidimensional Scale of Perceived Social Support (MSPSS) in the current study (Yang et al., 2009), in which social support was divided into the following three aspects: support from family, friends

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

and others (Zimet et al., 1988). This instrument was answered with a 7-point Likert scale (1 = very strongly disagree to 7 = very strongly agree). Total score of the perceived social support ranges from 12–84 points. Psychological properties of MSPSS have been tested, with a coefficient alpha value of 0.81–0.98 for each subscale (Zimet et al., 1990). Reliability Cronbach alpha was 0.90 in this study.

3.5.4 | Self-esteem

In this study, we measured self-esteem with the Chinese version of the 10 items Rosenberg Self-Esteem Scale (RSES), which has been validated and reported to have a Cronbach's alpha of 0.88. The RSES is the most widely applied self-report instrument designed to measure global self-esteem, which should be understood as an individual's overall evaluation of worthiness as a human being (Rosenberg, 1986). Patients were requested to answer the instrument with a four-point Likert scale. A higher score indicates a higher level of self-esteem (Rosenberg, 1989). In this study, the Cronbach's alpha of the Chinese version of RSES was 0.937. Self-esteem was parcelled to produce two categories with item parcelling method (Yang et al., 2010) for the final analysis because common method bias resulted from method effects may negatively affect the model fit (Tomas & Oliver, 1999).

3.6 | Data analysis

We completed all statistical analyses with the Statistical Package for Social Sciences (Chicago, Illinois) and IBM AMOS 21.0 (Chicago, Illinois). Descriptive statistics were used to summarize patients' characteristics and scores of psychological distress, social support and self-esteem. The Kolmogorov–Smirnov test indicated a skew distribution about the score of psychological distress, social support and self-esteem, and thus Spearman rank correlation was conducted to investigate the associations among psychological distress, social support and self-esteem. Bootstrap test was conducted to test a mediating effect of self-esteem in the relation of social support and psychological distress. The criteria of fit index used in testing of how well the structural equation model should fit for recommendation. According to Schreiber (2017) (Schreiber, 2017), the chi-square (χ^2) test value should not be statistically significant ($p > .05$), $1 < \chi^2/$ degrees of freedom (df) < 3, goodness of fit index (GFI) > 0.90, adjusted goodness of fit index (AGFI) > 0.90, comparative fit index (CFI) ≥ 0.90, incremental fit index (IFI) > 0.90, normed fit index (NFI) > 0.90 and root mean square error of approximation (RMSEA) < 0.05. A p value of .05 was considered to be statistical significance (two-tailed).

4 | RESULTS

4.1 | Demographic characteristics

441 study participants had an average age of 59.48 years (SD = 9.93, range = 33–84). The majority of patients (N = 315, 71.4%) were male. One hundred and sixty-eight patients (38.1%) had undergone surgery. The majority of patients (N = 330, 74.8%) were diagnosed at the IV stage. The demographic disease characteristics are shown in Table 1.

4.2 | Relationships between psychological distress, social support and self-esteem

Overall, median score of psychological distress was 2 with an interquartile range of from 2–3. Medium score of social support and self-esteem was 66 (61–70) and 28 (26–29), respectively. Table 2 documented the results of correlation analyses of psychological distress, social support and self-esteem. The results of the Spearman rank correlation analyses showed social support (r = −0.444) and self-esteem (r = −0.112) were all negatively related to psychological distress, and social support was positively associated with self-esteem (r = 0.178).

4.3 | The mediating effect of self-esteem on the relationship between social support and psychological distress

Structural equation modelling (*SEM*) with maximum likelihood was used to analyse the path correlations which were presented in Table 3 and Figure 1. The results showed a better fitness between construct model and the data (χ^2 = 37.489, df = 7, GFI = 0.974, AGFI = 0.923, CFI = 0.974, IFI = 0.966, NFI = 0.958, RMSEA = 0.099 [90% CI, 0.000–0.075]).

As illustrated, social support had significant direct effects on psychological distress (β = −0.710, p = .001) and self-esteem (β = −0.510, p = .002) among Chinese lung cancer patients. Meanwhile, self-esteem had significant direct effects on psychological distress (β = −0.273, p = .004). The results of the bias-corrected bootstrap method indicated that the indirect pathways between social support and psychological distress through self-esteem were also significant. The results from bootstrap test for significance of indirect pathways were summarized in Table 3. The results indicated that self-esteem plays a partial mediator in the relationship between social support and psychological distress among Chinese lung cancer patients.

5 | DISCUSSION

5.1 | Main findings

The aim of the present study is to examine the influence of social support on psychological distress among Chinese lung cancer patients and determine whether self-esteem mediating the association between social support and psychological distress. Our current study stemmed from a fact that the mechanism by which social

TABLE 1 Characteristics of participants (N = 441)

Characteristics	Frequency	Per cent (%)	Mean rank of psychological distress score
Gender			
Male	315	71.4	219.51
Female	126	28.6	224.71
Age (years)			
18–39	12	2.7	266.00
40–49	57	12.9	249.26
50–59	141	32.0	218.64
≥60	231	52.4	213.13
Nationality			
Han nationality	435	98.6	220.44
Minority nationality	6	1.4	261.75
Educational level			
Primary	120	27.2	215.34
Junior high	180	40.8	208.43
Senior high	84	19.1	243.55
University	57	12.9	228.42
Work status			
Not working	198	44.9	217.48
Working	54	12.2	254.50
Retired	189	42.9	215.12
Marital status			
Married	438	99.3	220.21
Divorced/Widowed	3	0.7	336.50
Payment Method			
Medical insurance	429	97.3	221.58
Self-payment	12	2.7	200.38
Residence			
Urban	306	69.4	216.96
Rural	135	30.6	230.17
Household income			
<20,000	39	8.8	259.77
20,000–50,000	123	27.9	204.87
50,000–100,000	192	43.5	207.38
>100,000	87	19.8	256.48
Family history			
No	387	87.8	224.99
Yes	54	12.2	192.42
Smoking history			
No	159	36.1	218.00
Yes	282	63.9	222.69
Drinking history			
No	237	53.7	211.18
Yes	204	46.3	232.40
Surgery			

(Continues)

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

TABLE 1 (Continued)

Characteristics	Frequency	Per cent (%)	Mean rank of psychological distress score
No	273	61.9	216.76
Yes	168	38.1	227.89
Pain			
No pain	183	41.5	207.33
Mild	174	39.5	233.41
Moderate	81	18.4	227.67
Severe	3	0.06	155.00
TNM stage			
I	42	9.5	247.79
II	21	4.8	387.07
III	48	10.9	212.38
IV	330	74.8	208.28

support influences psychosocial distress among lung cancer patients is not yet clear.

In the current study, we found a directly negative correlation between social support and psychological distress among Chinese lung cancer patients, which was consistent with findings from previous studies (Burnette et al., 2017; Matzka et al., 2016). Social support has been identified as a protective source on distress and psychosocial adjustment (Schulz & Schwarzer, 2004). A great deal of studies has established the importance of involving social support sources such as caregivers, spouses, or partners in educational and psychosocial intervention regimes (Keefe et al., 2005). Studies which were performed to investigate the influencing factors on psychological distress also consistently indicated that social support is one of the most important factors of reducing the severity of psychological distress (Shen et al., 2018; Wang et al., 2018). One study focusing on breast cancer patients also suggested that a higher level of social support was associated with higher benefit when a critical threshold of social support was reached (Mallinckrodt et al., 2012). Therefore, intervention programmes involving professional and non-professional social supports such as health coaching and a web-based programme (Yun et al., 2020) should be adapted for lung cancer patients for the purpose of relieving the unfavourable consequences resulted from psychological distress and then improve the quality of life.

Meanwhile, our current study based on correlation analysis and structural equation modelling suggested a negative association between self-esteem and psychological distress in Chinese lung cancer patients, which was consistent with previous findings in other cancer patients (den Heijer et al., 2011; Kobayashi et al., 2008; McAteer & Gillanders, 2019; Rodin et al., 2009; Xiaoyun & Fenglan, 2020). For example, McAteer and colleagues found that self-esteem negatively predicted outcomes of distress in prostate cancer patients (McAteer & Gillanders, 2019). Self-esteem is defined as satisfaction with oneself or as the attitudes and feelings one has towards oneself (Tuinman et al., 2006). In fact, self-esteem plays a protective role through relieving negative emotions and improving psychological status (Neel et al., 2015). Patients with higher self-esteem will experience lower psychological distress; however, one with lower self-esteem will face significantly higher psychological distress due to more negative self-awareness (Baer et al., 2006). Study focused on Chinese male nursing students also established that self-esteem was a negative predictor of psychological distress (Feng et al., 2019). Therefore, it is critically important to enhance self-esteem of lung cancer patients in order to further enhance the patients' ability of coping adverse conditions and eventually relieve the negative effects of psychological distress on quality of life.

Additionally, in this study, we also found that self-esteem partially mediated the relationship between social support and psychological distress, with a negative correlation between perceived stress and psychological distress. Unfortunately, there is still no published study to investigate the mediating role of self-esteem between social support and psychological distress. Nevertheless, Feng

TABLE 2 Spearman correlation coefficient of study variables ($N = 441$)

Variables	Score (Median ± Quartile)	Psychological distress	Social support	Self-esteem
Psychological distress	2 (2–3)	1.000		
Social support	66 (61–70)	−0.444**	1.000	
Self-esteem	28 (26–29)	−0.112*	0.178*	1.000

*$p < .05$.
**$p < .01$.

TABLE 3 Bias-corrected bootstrap test for all indirect pathways

Pathway	Direct effects	Indirect effects	Total effects	Risk-corrected Bootstrap test	*p* value
psychological distress ← social support	−0.710	0.139	−0.571	−0.404 (−0.725, −0.298)	.001
psychological distress ← self-esteem	−0.273	0.000	−0.273	−0.861 (−4.160, −0.274)	.004
self-esteem ← social support	−0.510	0.000	−0.510	−0.092 (−0.166, −0.018)	.002

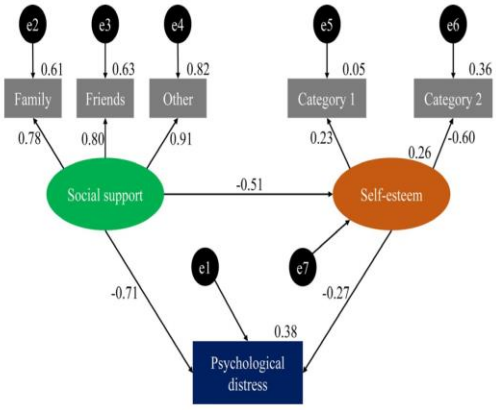

FIGURE 1 A path diagram of direct and indirect influences of social support and self-esteem on psychological distress among Chinese lung cancer patients ($N = 441$)

and colleagues found an indirect effect of self-esteem on psychological distress through perceived social support in Chinese nursing students (Feng et al., 2018), which was consistent with our finding. Higher perceived social support can enhance the level of self-esteem through improving self-awareness, and as a positive psychological source of coping negative conditions (Wang et al., 2014), self-esteem can inspire patients to seek external positive support for the purpose of enhancing self-awareness, and eventually relieve the level of psychological distress (Routledge, 2012). So, it is essential to emphasize the role of enhancing the level of self-esteem when interpreting the positive effects of social support on psychological distress. Moreover, psychological intervention programmes for involving elements of enhancing self-esteem should be developed in order to enhance the protective effects of social support on psychological distress.

5.2 | Limitations

Despite the fact that the current study identified several valuable findings, several limitations must be further interpreted. First and foremost is that the causal relationship between the proposed variables cannot be established due to the nature of cross-sectional survey design. We therefore suggested future longitudinal study to prospectively clarify the association among social support, self-esteem, and psychological distress and then determine the mechanism of social support relieves the negative consequences resulted from psychological distress. Second, convenience sampling was used to recruit eligible patients in the current study rather than random sampling method, which causes our sample is not representative. Third, social support, self-esteem and psychological distress were all measured with self-reported questionnaires in the current study, which made our results to be inflated due to subjective bias from participants and investigators. Additional studies considering physiological assessment and ecological momentary assessment should be conducted.

6 | CONCLUSIONS

Social support and self-esteem had direct negative effects on psychological distress among Chinese lung cancer patients, and self-esteem partially mediating the positive effect of social support on psychological distress.

7 | RELEVANCE TO CLINICAL PRACTICE

This study enhanced our understanding on the association among social support, self-esteem and psychological distress in lung cancer patients. From our current findings, practitioners can enhance the benefits of social support programmes through improving the level of self-esteem of lung cancer patients and eventually reduce the adverse consequences caused by psychological distress.

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CONFLICT OF INTEREST

The authors state that they have no conflict of interests.

AUTHOR CONTRIBUTIONS

Xu Tian, Yanfei Jin, Hui Chen, Ling Tang and Maria F. Jiménez-Herrera involved in substantial contributions to conception, design and acquisition of data. Xu Tian and Maria F. Jiménez-Herrera involved in analysis and interpretation of data. Xu Tian, Yanfei Jin and Maria F. Jiménez-Herrera involved in drafting the manuscript or revising it critically for important intellectual content. All authors finally approved the version to be submitted.

ETHICAL APPROVAL

The protocol of the current study has been approved by the ethics commission of the Chongqing University Cancer Hospital with an identifier of CUCH_P20180225. Oral informed consent has been obtained from all patients before performing the formal survey and all questionnaires were answered anonymously.

DATA AVAILABILITY STATEMENT

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

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Article 4

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ORIGINAL ARTICLE

The chain mediating role of social support and stigma in the relationship between mindfulness and psychological distress among Chinese lung cancer patients

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Abstract

Purpose Psychological distress greatly impaired the psychological and physical well-being of lung cancer patients. Identification of protective and risk factors is a prerequisite of developing effective psychological treatment protocol. The study aims to determine the relationship of mindfulness and psychological distress and further clarify the mechanism of mindfulness against psychological distress through perceived stigma and social support among Chinese lung cancer patients.

Method A cross-sectional survey study involving 441 valid Chinese lung cancer patients was conducted from September 2018 to August 2019. After all validated questionnaires that measured psychological distress, level of mindfulness, social support, and perceived stigma were returned by patients, we firstly performed correlation analysis to assess the associations between mindfulness, social support, perceived stigma, and psychological distress. Then structural equation modelling analysis was conducted to further clarify the mediating effects of perceived stigma and social support on the relationship between mindfulness and psychological distress.

Results According to our hypothesis and further modification, our revised model adequately fits to data. Mindfulness ($\beta = -0.107$, $p = 0.008$) and social support ($\beta = -0.513$, $p < 0.001$) had a direct effect on psychological distress. Meanwhile, mindfulness had a direct effect on perceived stigma ($\beta = -0.185$, $p < 0.001$), and perceived stigma had a direct effect on social support ($\beta = -0.373$, $p < 0.001$). Furthermore, mindfulness had also the indirect effect on psychological distress through the chain mediating role of stigma and social support among lung cancer patients.

Conclusions Mindfulness has direct negative effect on psychological distress and has also indirectly negative psychological distress through impacting social support and perceived stigma.

Keywords Lung cancer · Psychological distress · Mindfulness · Social support · Perceived stigma · Structural equation model

Introduction

According to the latest data, lung cancer was at the second rank for the incidence and the first rank for mortality, accounting for 11.4% of new cancer cases and 18.0% cancer-related deaths in 2020 worldwide, respectively [1]. Lung cancer patients have been reported to suffer from clinically significant psychological distress because of several factors such as a definitive diagnosis of lung cancer [2] and poor prognosis [3]. Meanwhile, compared to other types of cancers, lung cancer patients were even found to have the highest detection rate of psychological distress [4], with an empirical incidence of 17.0% to 73.0% [5–7].

Substantial evidence investigating the adverse consequences of psychological distress had been accumulated to

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

date. For example, studies demonstrated that psychological distress deeply decreased patients' compliance with cancer treatment and increased the risk of somatic symptoms [8]. Moreover, evidence published recently even suggested that psychological distress may accelerate the growth of tumor cells and decrease therapeutic effects [9], which may significantly reduce the quality of life [7] and even increase mortality [10]. Considering these negative results, it is critically important to identify potential protective and risk factors and further clarify potential relationships of all factors in order to develop precise psychological treatment protocol for psychological distress among lung cancer patients.

Background

Mindfulness refers to meditation practice cultivating present moment nonjudgmental awareness [11]. As a positive psychological trait, the role of mindfulness in psychological and mental well-being has been extensively investigated, indicating a negative association between mindfulness and psychological distress [12], even among general population [13]. Meanwhile, mindfulness-based interventions such as mindfulness-based stress reduction (MBSR) have also been demonstrated to improve psychological outcomes [14]. It is noted that the specific role of mindfulness in affecting psychological outcomes among different populations may be changed [15]. What is exhilarating is that, however, a handful of studies revealed that mindfulness was negatively related to psychological distress among lung cancer patients [16], and a scatter of clinical trials also suggested a promising role of MBSR intervention in lung cancer patients for the alleviation of psychological distress [17, 18]. To date, there are restricted data on the relationship between mindfulness and psychological distress in lung cancer patients. More importantly, the mechanism of mindfulness in buffering psychological distress has not yet been adequately clarified in lung cancer patients.

As a positive external source, the protective effects of social support on psychological distress have been extensively demonstrated in previous studies [19, 20]. Meanwhile, a negative association between social support and psychological distress among lung cancer patients has also been shown in our previous study [21]. Moreover, some studies also indicated that social support was positively associated with mindfulness [22, 23], and mindfulness-based interventions significantly improved social support [24]. However, the associations between mindfulness, social support, and psychological distress among lung cancer patients were not investigated, and therefore it's unclear whether mindfulness can indirectly alleviate psychological distress through strengthening social support among lung cancer patients.

Stigma refers to a negative emotional experience involving isolation, rejection, degradation, and criticism owing to patients suffer from some undesirable diseases such as lung cancer [25], which has been found to negatively impact many outcomes in cancer patients. For example, evidence demonstrated stigma was positively related to poorer quality of life (QoL) and psychological distress in lung cancer patients [26]. Meanwhile, stigma has also been found to significantly decrease the level of social support of advanced lung cancer patients [27] and mindfulness of youth with inflammatory bowel disease [28]. It is noteworthy that the relationship of mindfulness, social support, and stigma in lung cancer patients had not been empirically tested.

As discussed above, in this study, we firstly determined the relationship of mindfulness, social support, or perceived stigma and psychological distress, and then we further clarified whether perceived stigma and social support played mediators in the relationship between mindfulness and psychological distress among lung cancer patients.

Methods

Study design

The present study was a cross-sectional, correlational, descriptive survey design.

Participants

We designed inclusion criteria according to the previous studies [5]: (a) adult patients with definitive diagnosis of lung cancer and (b) having ability to clearly and accurately read and write. We excluded those patients who were identified to have the psychiatric disorder which was confirmed based on the medical information extracted from electronic medical record system or other types of cancer or participated in studies investigating the effects of psychological treatment or other survey studies with similar study aims. Sample size was calculated using the formula for cross-sectional survey design: $N = \left[\mu^2_{\alpha/2}\pi(1-\pi)\right]/\delta^2$. In this formula, π and δ represent the incidence and tolerance error, respectively. Theoretical sample size of 384 was determined eventually after α of 0.05, π of 0.5, and δ of 0.5 were defined, respectively. Eligible lung cancer patients were recruited from 7 hospitals in Chongqing, China from September 2018 to August 2019. All questionnaires were independently and anonymously completed by patients. At the end of study, total 450 eligible lung cancer patients were surveyed, and 441 validated questionnaires were collected eventually, with a validate response rate of 98.0%.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Procedure

This study is strictly in accordance with the provisions of the Declaration of Helsinki. Moreover, the protocol of the current study has been approved by the Institutional Review Board with an approval number of CUCH_P20180225. All eligible patients were enrolled based on convenience sampling, and all participants fully understood aims and procedure of this study and patients' rights before participating in the survey. The principal investigator orally informed all eligible patients about the aims and procedures of this study based on written research protocol before conducting the formal survey. More importantly, the formal survey was conducted after all patients gave informed consent orally. STROBE guideline (Strengthening the Reporting of Observational Studies in Epidemiology) was utilized to guide us to report all data [29].

Study variables

Demographic information

In this study, the following sociodemographic and clinical variables were collected with self-designed standard demographic information collection sheet including gender, age, educational level, occupational status, marital status, family history of lung cancer, smoking history, and alcohol consumption, time from diagnosis, surgical history, metastasis, comorbidity, pain degree, and TNM stage.

Psychological distress

In the current survey study, distress thermometer (DT) was utilized to measure psychological distress at 11-point thermometer scale from 0 to 10, and 0 and 10 indicates no distress and extreme distress, respectively [30]. DT was established to have satisfactory reliability and validity, and its psychometric characteristics have also been tested across diverse settings [31]. Studies indicates that patients reporting a cut-off of 4 would be considered to be clinically significant level of psychological distress [31, 32]. The cut-off value of 4 was also extensively accepted for Chinese cancer populations, with an area under the receiver operating characteristic curve of 0.885 in an empirical study [31].

Mindfulness

We used the Five Facet Mindfulness Questionnaire (FFMQ), which was designed by Baer and colleagues in 2006 [33], to measure the level of mindfulness. In the original version, total 39 items were effectively pooled to assess mindfulness from five facets including observing, describing, acting with awareness, nonjudging, and nonreacting at 5-point Likert scale, with a total score of ranging 39 to 195 [33]. In this study, we used Chinese version of original FFMQ, which was translated and then validated by Deng and colleagues in 2011 indicating an acceptable psychometric properties [34], to measure the level of mindfulness among lung cancer patients.

Social support

In the present study, we used the 12-item Multidimensional Scale of Perceived Social Support (MSPSS) to measure social support from three aspects including family, friends, and significant others [35]. Eligible lung cancer patients were asked to rate each item at a 7-point Likert scale (1 = very strongly disagree to 7 = very strongly agree), with an overall scores from 12 to 84. Previous study has tested the psychological properties of MSPSS and reported that the coefficient alpha values of subscales were ranging from 0.81 to 0.98 [35]. The reliability of the Chinese version of MSPSS was established to be 0.90 [36].

Perceived stigma

Lung cancer stigma was measured with the Cataldo lung cancer stigma scale (CLCSS) [25]. In the original version, a total of 31 items were pooled to measure four aspects including stigma and shame, social isolation, discrimination, and smoking. All items should be rated at 4-point Likert scale, with a total score from 31 to 124 and a higher score indicating a higher level of perceived stigma. In 2017, the Chinese version of CLCSS was translated by Yu and colleagues, reporting a Cronbach alpha of 0.932 for an overall scale and 0.799, 0.922, 0.863, and 0.803 for individual 4 subscales, respectively [37].

Statistical analysis

For patients' sociodemographic and clinical variables, we used descriptive statistics to express all. Numerical variables including age, the score of psychological distress, mindfulness, social support, and perceived stigma were expressed as median with interquartile rang (IQR) because of all did not follow normal distribution according to the results from Kolmogorov–Smirnov test. Meanwhile, Spearman rank correlation analysis was conducted to determine the correlation matrix among psychological distress, mindfulness, social support, and perceived stigma. The following indices were calculated in order to evaluate the fitness of the overall model: the ratio of Chi-square ($\chi 2$) to degrees of freedom (df), comparative fit index (CFI), goodness of fit index (GFI), adjusted GFI (AGFI), Tucker-Lewis index (TLI), incremental fit index (IFI), and root-mean-square error of approximation

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

(RMSEA). Model fit was regarded as good when a ratio of $\chi 2$/df was equal to or less than 3. For GFI and AGFI, a value of more than 0.90 indicates a good model fit. Moreover, CFI of ≥ 0.90 and RMSEA of < 0.05 were also suggesting a good model fit. Moreover, bootstrap test was also used to test a mediating effect of social support and perceived stigma in the relationship between mindfulness and psychological distress. A $p < 0.05$ indicated significance for all analyses. Dada was analyzed with the Statistical Package for the Social Sciences (Chicago, Illinois, USA) and IBM AMOS 21.0 (Chicago, Illinois, USA).

Results

Sample characteristics

Total 450 questionnaires were distributed during survey, and 441 valid questionnaires were received finally, with an effective response rate of 98.0%. Details of 441 Chinese lung cancer patients' sociodemographic and clinical were presented in Table 1. The participants had a median age of 60.0 (IQR: 52.0–67.0), and most were male (71.4%). Most participants did not get adequate education (68.0%), and a significant number of participants were unemployed (44.9%). Most participants were married (99.3%) and had medical insurance (97.3%), and more than half of them had no drinking history (53.7%) and diagnosis duration of less than 6 months (53.1%). In addition, most participants had no family history of lung cancer (87.8%) and no comorbidity (74.1%). However, most of these participants were at the advanced stage (85.7%) and most experienced metastasis (62.6%). Moreover, a minority of these participants experienced moderate to severe pain (19.0%), but most participants did not receive surgery (61.9%).

Correlation matrix of psychological distress, mindfulness, social support, and perceived stigma

The score of psychological distress, mindfulness, social support, and perceived stigma was 2 (2–3), 117 (111–123), 66 (61–70), and 98 (84–107), respectively. Among 441 lung cancer patients who returned valid questionnaires, 78 patients were confirmed to achieve a clinically significant level of psychological distress, indicating an incidence of 17.7%. Table 2 documented the results of correlation analyses of psychological distress, mindfulness, social support, and perceived stigma. The results of the Spearman rank correlation analyses showed all variables were significantly correlated with one another.

Structural equation modeling of the association of psychological distress, mindfulness, social support, and perceived stigma

Structural equation modeling (SEM) with maximum likelihood was used to analyze the route correlations. We firstly constructed the structure of all variables according to the results of correlation analyses. However, the relationship between perceived stigma and psychological distress did not get statistically significant. We therefore eliminated the direct route to good fit the structural model which was presented in Fig. 1 (χ^2/df = 1.201, CFI = 0.999, GFI = 0.999, AGFI = 0.986, TLI = 0.995, IFI = 0.999, RMSEA = 0.021 [0.000 to 0.130]). Corresponding numerical results were summarized in Table 3.

As illustrated, mindfulness ($\beta = -0.107$, $p = 0.008$) and social support ($\beta = -0.513$, $p < 0.001$) had direct negative effects on psychological distress. The direct pathway from mindfulness to perceived stigma ($\beta = -0.185$, $p < 0.001$) was statistically significant. Meanwhile, the direct pathway from perceived stigma to social support ($\beta = -0.373$, $p < 0.001$) was also statistically significant. The results from bootstrap test for significance of indirect pathways are summarized in Table 4. The results indicated that the indirect pathways between mindfulness and psychological distress through chain mediating effect of perceived stigma and social support were statistically significant ($B = -0.048$, 95% CI [−0.102 to 0.000], $p = 0.048$). Overall, the total effect of mindfulness in againsting psychological distress was −0.155. Furthermore, mindfulness had only an indirect positive effect on social support through route of perceived stigma ($B = 0.069$, 95% CI [0.037 to 0.105], $p = 0.001$). Meanwhile, perceived stigma had only indirect positive effect on psychological distress through social support ($B = 0.191$, 95% CI [0.240 to 0.149], $p < 0.001$). The results suggested that perceived stigma and social support play a chain mediating role in the relationship between mindfulness and psychological distress among Chinese lung cancer patients.

Discussion

Psychological distress was extensively regarded as an important negative psychological consequence of diagnosis of cancer and anti-cancer, which has been demonstrated to be negatively related to poor treatment effectiveness, increased risk of morbidity and mortality, and poor quality of life [30]. The incidence of psychological distress among lung cancer patients was detected to be highest compared to other types of cancer [4]. Therefore, it is imperative to identify protective and risk factors in order to further develop precise psychological treatment protocol for psychological distress

Table 1 Socio-demographic and clinical characteristics of 441 Chinese lung cancer patients

Characteristic	Percentage, %
Age: Median (IQR)	60.0 (52.0–67.0) yrs
Gender	
Male	71.4%
Female	28.6%
Educational level	
Primary	27.2%
Junior high	40.8%
Senior high	19.1%
University	12.9%
Occupational status	
Not working	44.9%
Working	12.2%
Retired	42.9%
Marital status	
Married	99.3%
Divorced/Widowed	0.7%
Time from diagnosis, month	
< 1	11.6%
1–6	41.5%
7–12	19.0%
> 12	27.9%
Family history of lung cancer	
No	87.8%
Yes	12.2%
Smoking history	
No	36.1%
Yes	63.9%
Alcohol consumption	
No	53.7%
Yes	46.3%
Surgery	
No	61.9%
Yes	38.1%
Metastasis	
No	37.4%
Yes	62.6%
Co-morbidity	
No	74.1%
Yes	25.9%
Pain	
No pain	41.5%
Mild	39.5%
Moderate	18.4%
Severe	0.06%
TNM stage	
I	9.5%
II	4.8%
III	10.9%
IV	74.8%

IQR, interquartile rang; yrs, years

Table 2 Spearman correlation coefficient of study variables ($n=441$)

Variables	Score, median (IQR)	Psychological distress	Perceived stigma	Social support	Mindfulness
Psychological distress	2 (2 – 3)	1			
Perceived stigma	98 (84 – 107)	0.340**	1		
Social support	66 (61 – 70)	-0.444**	-0.392**	1	
Mindfulness	117 (111 – 123)	-0.152**	-0.237**	0.122*	1

*$P<0.05$, **$P<0.01$. IQR, interquartile rang

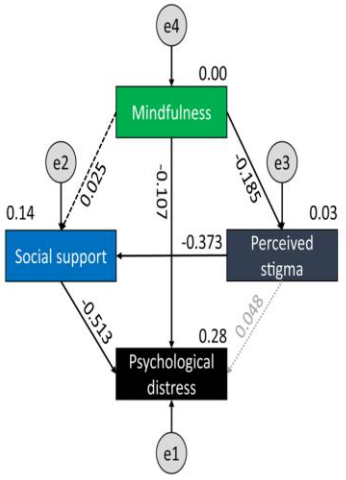

Fig. 1 Structural routes of mindfulness, social support, perceived stigma, and psychological distress among 441 Chinese lung cancer patients. Grey dotted arrow indicates the unconnected direct route between perceived stigma and psychological distress resulted from no statistical significance. Black solid arrow indicates statistically significant direct route, and black dotted arrow represents no statistical significance. Values are standardized coefficients for direct paths

among lung cancer patients. In this cross-sectional descriptive study, we revealed a relatively lower detection rate of psychological distress among lung cancer (17.7%); possible reasons such as higher proportion of advanced lung cancer patients and usage of DT have been deeply discussed in our previous study [21]. Meanwhile, we determined mindfulness and social support had direct positive effects on psychological distress as protective factors among lung cancer patients. Meanwhile, perceived stigma indirectly and negatively impacted psychological distress through reducing social support. Furthermore, mindfulness also alleviated psychological distress via the only chain mediating route between perceived stigma and social support due to the direct route between mindfulness and social support was not statistically significant.

Mindfulness is a positive psychological trait of regulating awareness and attention through meditation practice in which thoughts, feelings, and physical sensations are observed and then accepted at present moment non-judgmentally[38]. Mindfulness has been found to be beneficial for improving adverse psychological outcomes through effective self-designed regulation and keeping positive emotional status [14]. For example, studies revealed that self-reported mindfulness skills were related to less psychological distress in cancer patients [39] and less perceived stigma in other populations [28], which were further demonstrated in our current study.

Table 3 Decomposition of standardized effects from the path model

Variables	Mindfulness			Perceived stigma		Social support
	Perceived stigma	Social support	Psychological distress	Social support	Psychological distress	Psychological distress
Total effects	-0.185**	0.094	-0.155*	-0.373**	n.a	-0.513**
Direct effects	-0.185**	0.025	-0.107*	-0.373**	n.a	-0.513**
Indirect effects	0.000	0.069**	-0.048*	0.000	0.191**	0.000

*$P<0.05$, **$P<0.01$. n.a., not applicable

Table 4 Bias-corrected bootstrap test for all analyzed direct and indirect pathways

Direct pathway	**Bootstrap estimate (95% CI)**	***P* value**
psychological distress ← mindfulness	-0.107 (-0.195 to -0.017)	0.022
perceived stigma ← mindfulness	-0.185 (-0.098 to -0.272)	0.001
social support ← perceived stigma	-0.373 (-0.302 to -0.439)	0.001
psychological distress ← social support	-0.513 (-0.588 to -0.437)	0.001
social support ← mindfulness	0.025 (-0.004 to 0.192)	0.061
Indirect pathway	**Bootstrap estimate (95% CI)**	***P* value**
psychological distress ← mindfulness	-0.048 (-0.102 to 0.000)	0.048
social support ← mindfulness	0.069 (0.037 to 0.105)	0.001
psychological distress ← perceived stigma	0.191 (0.240 to 0.149)	< 0.001

CI, confidence interval

Social support was also listed as an important variable in this study. As one of the most common positive external sources coping with negative psychological events, social support has been extensively cited as a protective source on psychosocial adjustment [40]. Previous studies have demonstrated that social support plays a curial role in predicting psychological distress [41]. One study focusing on breast cancer patients also suggested that a higher level of social support was the association with higher benefit when a critical threshold of social support was reached [41]. In this study, we also demonstrated the direct negative correlation between social support and psychological distress, which were consistent with previous studies [41]. However, in this study, the role of social support in the relationship between mindfulness and psychological distress was not determined due to the direct effect of mindfulness on social support was not significant. Nevertheless, mindfulness was demonstrated to have an indirect effect on social support via mediating route of perceived stigma and further negatively influence psychological distress. Cancer stigma has been extensively regarded as a stressor [42, 43]. Previous studies consistently suggested that lung cancer stigma impeded patients to seek external supports [44], such as medical help-seeking behavior [45]. Therefore, nursing practitioners should design more support elements into mindfulness-based intervention protocols in order to significantly reduce the impact of perceived stigma on social support and further enhance the protective effect of mindfulness on psychological distress.

A few limitations in the current study must be further interpreted. First, the nature of the cross-sectional, observational, descriptive design limits the ability of interpreting causal interference between the mindfulness, social support, and perceived stigma. Although we proposed the theoretical model according to previous studies, the findings in our study should also be interpreted cautiously. Additional studies with longitudinal or experimental designs should be conducted to establish our findings. Second, all eligible lung cancer patients were enrolled based on convenience sampling, which impaired the representativeness of the sample. Therefore, we suggest future studies with random sampling method to further demonstrate the relationships of all variables. Third, the level of psychological distress, mindfulness, social support, and perceived stigma was measured with self-reported questionnaires, and thus inflation in results cannot be neglected due to subjective bias from patients. We therefore suggest designing more studies with physiological assessment and ecological momentary assessment. Forth, the relationships revealed in the current study may be specific to all lung cancer patients regardless of cancer treatment modalities and the level of symptom burden and not applicable to other populations. Additional studies with samples of greater diversity should be performed to determine these relationships. Fifth, DT was selected to measure the level of psychological distress in the present study; however as a self-answered scale at grade evaluation, it cannot separate the risk of psychological distress and the accumulated level of psychological distress. Therefore, further study should be designed to develop an instrument of measuring the risk of psychological distress based on objective variables. Sixth, demographic characteristics such as marital status may have an impact on the levels of social support and perceived stigma; the generalizability of our findings may be limited because of we did not further investigate the role of demographic characteristics on targeted variables such as social support.

Conclusion

In conclusion, to our knowledge, this is the first study that investigated the associations between mindfulness, social support, perceived stigma, and psychological distress among lung cancer patients. As expected, through conducting investigation among 441 lung cancer patients, this study showed that mindfulness have direct negative impact on psychological distress, and social support and perceived stigma mediated the relationship between mindfulness and psychological distress. It suggested that clinicians and

nursing professionals may enhance the positive effects of mindfulness-based intervention protocol through involving more social support elements on perceived stigma in psychological treatments, and further lessen psychological distress finally.

Clinical implications

This study enhanced our understanding on the associations between mindfulness, social support, perceived stigma, and psychological distress in lung cancer patients. From our current findings, practitioners may enhance the benefits of mindfulness-based intervention protocol involving social support elements through alleviating the level of perceived stigma of lung cancer patients and eventually reduce the adverse consequences caused by psychological distress.

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Author contribution Xu Tian had full access to all of the data in the study and held responsible for the integrity of the data and accuracy of the data analysis. Concept and design: Hui Lei, Xu Tian and Maria F. Jiménez-Herrera. Acquisition, analysis, or interpretation of data: Hui Lei, Xu Tian, Yan-Fei Jin, and Ling Tang. Drafting of the manuscript: Hui Lei, Xu Tian, and Hui Chen. Critical revision of the manuscript for important intellectual content: Wei-Qing Chen and Maria F. Jiménez-Herrera. Statistical analysis: Lei Hui and Xu Tian. Obtaining funding: Xu Tian. Administrative, technical, or material support: Wei-Qing Chen. Supervision: Maria F. Jiménez-Herrera.

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Declarations

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Article 5

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BRIEF RESEARCH REPORT
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Mindfulness Affects the Level of Psychological Distress in Patients With Lung Cancer *via* Illness Perception and Perceived Stress: A Cross-Sectional Survey Study

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Purpose: The aims of the study were first to investigate the association between illness perception and psychological distress and second to determine whether mindfulness affects psychological distress *via* illness perception and perceived stress in patients with lung cancer.

Methods: Among 300 patients with lung cancer who participated in this cross-sectional study, 295 patients made valid responses to distress thermometer (DT), the Five Facet Mindfulness Questionnaire (FFMQ), the Brief Illness Perception Questionnaire (B-IPQ), and the Perceived Stress Scale (PSS) between January and July 2021. The possible pathways of mindfulness affecting psychological distress were analyzed based on the structural equation modeling analysis.

Results: A total of 24.4% patients with lung cancer had DT > 4. Illness perception ($\beta = 0.17$, $p = 0.002$) and perceived stress ($\beta = 0.23$, $p < 0.001$) had a direct effect on psychological distress. Mindfulness had a direct effect on illness perception ($\beta = -0.16$, $p = 0.006$) and mindfulness indirectly influenced psychological distress ($\beta = -0.04$, $p = 0.009$) through affecting illness perception alone or simultaneously affecting both the illness perception and perceived stress in patients with lung cancer.

Conclusion: Lung cancer suffered from varying levels of psychological distress. Mindfulness may alleviate psychological distress by reducing the level of illness perception and perceived stress. We suggest developing a comprehensive factor model to clarify potential mechanisms of mindfulness on psychological distress due to the very low effect of mindfulness on psychological distress *via* illness perception and perceived stress.

Keywords: lung cancer, psychological distress, mindfulness, illness perception, perceived stress, structural equation model

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

INTRODUCTION

According to the National Comprehensive Cancer Network (NCCN) guideline, psychological distress is a multifactorial and unpleasant emotional experience, involving changes in psychological, social, spiritual, and physical aspects (Riba et al., 2019). Psychological distress can be detected at any stage in patients with cancer and even remain throughout the cancer trajectory (Gao et al., 2010). Overall, studies reported a prevalence of 20–52% for psychological distress [distress thermometer (DT) > 4] among patients with cancer (Funk et al., 2016; Mehnert et al., 2018). However, compared to patients with other types of cancers, patients with lung cancer reported the highest incidence of psychological distress (Zabora et al., 2001), with a detection rate of 17.0–73.0% (Lynch et al., 2010; Chambers et al., 2015; Tian et al., 2021a). It is noted that approximately 220 million new lung cancer cases were estimated in 2020, ranking second place among all the cancers (Sung et al., 2021). Therefore, the anticipated prevalence of psychological distress among patients with lung cancer should be especially emphasized.

Psychological distress has become a major psychological problem faced by patients with cancer because it has been demonstrated to be associated with the occurrence of several adverse consequences (Riba et al., 2019). As an example, psychological distress was found to be the contributor to the interruption of anticancer treatment (Mausbach et al., 2015; Lin et al., 2017; Yee et al., 2017). Meanwhile, psychological distress has also been found to be associated with longer hospital stays (Nipp et al., 2017), poor quality of life (Chambers et al., 2015), and increased risk of mortality (Batty et al., 2017; Hamer et al., 2009). Moreover, psychological distress was evidenced to accelerate the growth of tumor cells (Zhang et al., 2020a). Therefore, to develop effective intervention protocols to address psychological distress among patients with lung cancer, it is critically important to clarify the potential mechanisms involved in the development and progress of psychological distress (Riba et al., 2019).

BACKGROUND

Mindfulness refers to an individual's focused attention on the present moment and non-judgmental awareness (Kabat-Zinn, 2003). As a protective source of negative psychological outcomes, several studies have suggested the positive effects of mindfulness among different populations (Kashiwazaki et al., 2020), even in the general population (Freudenthaler et al., 2017). At present, several meta-analyses have demonstrated that interventions involving mindfulness elements (Cillessen et al., 2019; Zhang et al., 2019; Nnate et al., 2021; Rieger et al., 2021), such as mindfulness-based cognitive therapy (MCT), mindfulness-based art intervention, and mindfulness-based stress reduction (MBSR), significantly improved the psychological wellbeing of patients with cancer. It should be noted that, moreover, our previous study consistently determined the negative association between mindfulness and psychological distress among patients with lung cancer and further clarified the influence of mindfulness on psychological distress through the mediating role of social support and perceived stigma, with a slight total effect of 0.048 (Lei et al., 2021). However, are there other potential mechanisms else in the association between mindfulness and psychological distress among patients with lung cancer to be discovered and elucidated?

Illness perception refers to an individual's reflection in both the cognitive and emotional aspects and coping styles through personal knowledge and experiences when one confronts symptoms or illness threats, which have been revealed to have an impact on health outcomes (Leventhal et al., 2016). In a prospective, longitudinal, and observational study, illness perceptions were demonstrated as a potential predictor of psychological distress in patients with non-muscle-invasive bladder cancer (Zhang et al., 2020b). Meanwhile, illness perception has been found to predict psychological distress in head and neck cancer survivors (Zhang et al., 2018), esophageal cancer survivors (Dempster et al., 2011), and breast cancer survivors (Zhang et al., 2017). However, it is not yet known whether the same association holds for patients with lung cancer. Moreover, no study has investigated the association between mindfulness and illness perception; however, mindfulness-based interventions have been found to reduce the level of negative illness perceptions in patients with rheumatoid arthritis (Dalili and Bayazi, 2019) or acute coronary syndrome (Nasiri et al., 2020). We, therefore, assume that the association between mindfulness and illness perception also holds among patients with lung cancer.

Perceived stress refers to an individual's subjective perception of stress and assessment of the ability of processing stress (Kim and Jang, 2020), which was positively related to psychological distress among patients with lung cancer in our previous study (Tian et al., 2021a). Meanwhile, perceived stress was also speculated to be associated with mindfulness because mindfulness-based intervention protocols had generally been shown to reduce stress (Lengacher et al., 2021). Interestingly, the negative association between mindfulness and perceived stress has been detected in patients with digestive tract cancer (Zhong et al., 2019). Moreover, some studies have also investigated the relationship between illness perception and perceived stress and found that individuals will experience greater levels of perceived stress if they negatively perceived their illness (Miceli et al., 2019). Unfortunately, these relationships of variables introduced above have not yet been determined in patients with lung cancer.

In the light of the above, we performed this study to examine three hypotheses as follow: (a) illness perception is positively associated with perceived stress and psychological distress, (b) mindfulness can influence psychological distress through illness perception, and (c) mindfulness has an impact on psychological distress through simultaneously influencing illness perception and perceived stress among patients with lung cancer.

METHODS

Study Design

This study was a cross-sectional descriptive survey design.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Participants

We recruited eligible patients with convenience sampling method from a tertiary hospital in Chongqing between January and July 2021 according to the inclusion criteria which was designed according to our previous studies (Tian et al., 2021a,b): adult patients were diagnosed with lung cancer based on definitive and route methods and confirmed to have ability to clearly and accurately read and write. Patients who were confirmed to have a mental disorder or received psychological treatment before eligibility evaluation or participated in those studies with similar study aims were excluded from this study.

Sample Size

In this study, we used structural equation modeling technique with maximum likelihood to examine all the paths between variables, the *N*:*q* rule with a ratio of 10/1 was, therefore, used to calculate the theoretical sample size, in which *N* and *q* indicate required cases and the number of parameters that require statistical estimates, respectively (McDonald and Ho, 2002). In this study, *q* was identified to be 10 and, thus, a minimum sample size of 120 was calculated under the consideration of 20% invalid questionnaires.

Study Variables

Demographic information was collected using a self-designed questionnaire and other variables, namely, psychological distress, illness perception, and perceived stress were measured using validated instruments, which have been translated into Chinese and published publicly in academic journals.

Demographic Information

In this study, we collected the following sociodemographic and clinical variables by the self-designed information collection form, namely, gender, age, educational degree, marital status, place of residence, occupational status, family history, pain, cancer metastasis, and tumor's TNM stage.

Psychological Distress

We used DT to measure psychological distress at an 11-point thermometer scale from 0 to 10 in this study and 0 and 10 indicate no distress and extreme distress, respectively (Riba et al., 2019). The reliability and validity of DT have been extensively tested across different settings (Hong et al., 2015). According to several empirical studies, an individual with a score of 4 was defined to have clinically significant psychological distress (Donovan et al., 2014; Hong et al., 2015). There was no exception in China, a score of 4 was also demonstrated as the cutoff value of defining clinically significant psychological distress in Chinese cancer populations (Hong et al., 2015).

Mindfulness

We used the Five Facet Mindfulness Questionnaire (FFMQ), which was developed by Baer and colleagues in 2006 (Baer et al., 2006), to measure the level of mindfulness at a 5-point Likert scale. In the original version, total of 39 items were effectively pooled to assess mindfulness from five facets as follows: observing, describing, acting with awareness, non-judging, and non-reacting (Baer et al., 2006). The original FFMQ has been translated into Chinese by Deng et al. (2011), with acceptable psychometric propertiesDeng et al., 2011.

Illness Perception

We used the Brief Illness Perception Questionnaire (B-IPQ), which was developed by Weinman et al. (1996), to measure emotional and cognitive representations of illness at an 8-item continuous linear scale from 0 to 10. Higher scores represent more negative illness perceptions. Broadbent et al. (2006) have shown the B-IPQ to have good test-retest reliability and predictive and discriminant validityBroadbent et al., 2006. The B-IPQ has been translated into Chinese (Xue and Lin, 0000) and has been widely used as a screening tool for assessing illness perceptions in China (Broadbent et al., 2006).

Perceived Stress

We used the 10-item Perceived Stress Scale (PSS), which was developed by Cohen et al. (1983), to measure the level of perceived stress at a 5-point Likert scale from 0 to 4. A higher score represents a greater stress level. The Cronbach's alpha was 0.84 at the instrument development stage. The Chinese version of the 10-item PSS has been found to have the Cronbach's alpha of 0.619 (Yuan and Lin, 2009).

Procedure

We strictly performed this study following the provision of the Declaration of Helsinki. The Institutional Review Board (IRB) approved our protocol and assigned an ethical identifier of CZLS2021183-A to this protocol before enrollment commenced. Before conducting the formal survey, all eligible patients were informed about objectives and the risks and benefits of the study and required to sign informed consent. Study questionnaires were independently and anonymously completed by patients. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were utilized to guide us to report all the data (von Elm et al., 2014).

Statistical Analysis

All the valid questionnaires were completely written by responders. Descriptive statistics for all the variables were calculated using Statistical Package for the Social Sciences (SPSS) version 22.0 (Chicago, IL, United States). Age, the score of psychological distress, mindfulness, social support, and perceived stigma were expressed as median with interquartile range (IQR) because all did not follow normal distribution according to the results from the Kolmogorov–Smirnov test. The Spearman's rank correlation analysis was conducted using SPSS version 22.0 to examine the relations between mindfulness, illness perception, perceived stress, and psychological distress. The mediation model was tested using AMOS version 21.0 (Chicago, IL, United States). In these analyses, we used 2,000 bootstrap resamples and focused on the bias-corrected and accelerated CI. The following indices were calculated to evaluate the fitness of the overall model: the ratio of the chi-squared (χ^2) to degrees of freedom (*df*), comparative fit index (CFI), goodness-of-fit

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

index (GFI), adjusted GFI (AGFI), Tucker–Lewis index (TLI), incremental fit index (IFI), and root mean square error of approximation (RMSEA) with 90% CI. Model fit was regarded as good when a ratio of χ^2/df was equal to or less than 3. For GFI and AGFI, a value of $p < 0.90$ indicates a good model fit. Moreover, CFI of ≥ 0.90 and RMSEA of < 0.05 were also suggesting a good model fit. A $p < 0.05$ indicated significance for all the analyses.

RESULTS

Sample Characteristics

A total of 300 eligible patients with lung cancer were recruited to participate in this survey study eventually, of which 295 patients returned valid questionnaires, representing a valid response rate of 98.3%. Among these 295 patients, 72 patients were defined to have clinically significant psychological distress, with a detection rate of 24.4%. Sociodemographic and clinical variables of 295 patients are shown in **Table 1**. Most patients were men (71.2%) and did not get adequate education (67.1%) and a significant number of patients were married (97.6%). Most patients lived in urban (71.5%) and balanced medical expenditure with medical insurance (96.9%), and more than half of them suffered from cancer metastasis (64.1%). Although most patients had no family history (92.2%), a significant number of patients were at the advanced stage (81.0%) and had no or mild pain (99.0%).

TABLE 1 | Psychological distress among patients with different sample characteristics ($N = 295$).

Characteristics	Frequency (%)	Mean rank	Z/χ^2	P
Gender			−1.197	0.231[a]
Male	210 (71.2)	144.65		
Female	85 (28.8)	156.26		
Age, years			0.567	0.753[b]
18–40	4 (1.4)	164.00		
41–60	144 (48.8)	150.55		
>60	147 (49.8)	145.06		
Education			1.650	0.648[b]
Illiterate or elementary school	88 (29.8)	142.61		
Junior school	110 (37.3)	146.97		
Senior high school	57 (19.3)	149.27		
College or above	40 (13.6)	160.88		
Marital status			2.535	0.282[b]
Married	288 (97.6)	146.91		
Unmarried	1 (0.4)	199.50		
Widowed or divorced	6 (2.0)	191.67		
Residence			−0.120	0.905[a]
Urban	211 (71.5)	148.33		
Rural	84 (28.5)	147.17		
Occupation status			3.616	0.164[b]
Unemployed	112 (38.0)	145.60		
Employed	40 (13.6)	169.01		
Retired	143 (48.4)	144.00		
Medical insurance			0.502	0.478[a]
Self-paying	9 (3.1)	130.44		
Medicare	286 (96.9)	148.55		
Family history			−1.860	0.063[a]
No	272 (92.2)	150.38		
Yes	23 (7.8)	119.89		
Pain			27.307	<0.001[b]
No	190 (64.4)	131.84		
Mild	102 (34.6)	176.74		
Moderate	2 (0.7)	143.75		
Severe	1 (0.3)	295.00		
Cancer metastasis			−3.181	0.001[a]
No	106 (35.9)	166.66		
Yes	189 (64.1)	137.53		
Tumor stage			7.687	0.053[b]
I	30 (10.2)	159.30		
II	26 (8.8)	183.69		
III	38 (12.9)	141.16		
IV	201 (68.1)	142.99		

[a] *Mann–Whitney U test.*
[b] *Kruskal–Wallis H test.*

Relationships of Psychological Distress, Mindfulness, Illness Perception, and Perceived Stress

Overall, the median score of psychological distress was 0 with an IQR of from 0 to 3. The score of mindfulness, illness perception, and perceived stress was 115 (109 to 119), 43 (39 to 47), and 20 (17 to 23), respectively. We designed **Table 2** to display the relationships of psychological distress, mindfulness, illness perception, and perceived stress. The results of the Spearman's rank correlation analyses suggested that all the variables were significantly correlated with one another.

Structural Equation Modeling of the Association of Psychological Distress, Mindfulness, Illness Perception, and Perceived Stress

We first constructed the relationship structure of all variables according to the results of the correlation matrix. After conducting model fit analysis, we found that the direct path from mindfulness to psychological distress or perceived stress was not statistically significant (**Figure 1A**). We therefore eliminated those two paths to good fit the structural model ($\chi^2/df = 0.867$, CFI = 0.999, GFI = 1.000, CFI = 1.000, TLI = 1.019, and RMSEA = 0.000 [0.000 to 0.111]).

As illustrated in **Figure 1A**, illness perception ($\beta = 0.18$ and $p = 0.002$) and perceived stress ($\beta = 0.23$ and $p < 0.001$) had direct positive effects on psychological distress. The direct pathways from mindfulness to illness perception ($\beta = -0.16$ and $p = 0.006$) and from illness perception to perceived stress ($\beta = 0.17$ and $p = 0.003$) were all statistically significant.

The results from the bootstrap test for the significance of all pathways are shown in **Table 3**. Results for indirect pathways indicated that the indirect pathways between illness perception and psychological distress through perceived stress were statistically significant ($B = 0.04$, 95% CI [0.02–0.07], and $p = 0.009$). Overall, the total effect of illness perception on psychological distress was 0.22 [95% CI (0.12–0.30) and $p = 0.007$]. Furthermore, mindfulness had only an indirect

TABLE 2 | Spearman correlations for mindfulness, illness perception, perceived stress, and psychological distress.

Variable	Median (P_{25}, P_{75})	Psychological distress	Mindfulness	Illness perception	Perceived stress
Psychological distress	0 (0, 3)	1			
Mindfulness	115 (109, 119)	−0.143*	1		
Illness perception	43 (39, 47)	0.233**	−0.181**	1	
Perceived stress	20 (17, 23)	0.235**	−0.116*	0.143*	1

*$P < 0.05$, **$P < 0.01$.

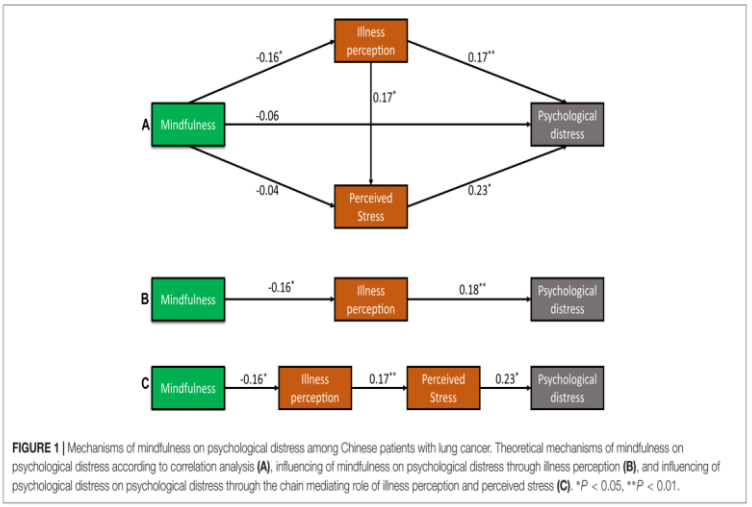

FIGURE 1 | Mechanisms of mindfulness on psychological distress among Chinese patients with lung cancer. Theoretical mechanisms of mindfulness on psychological distress according to correlation analysis **(A)**, influencing of mindfulness on psychological distress through illness perception **(B)**, and influencing of psychological distress on psychological distress through the chain mediating role of illness perception and perceived stress **(C)**. *$P < 0.05$, **$P < 0.01$.

TABLE 3 | Effect estimates of mindfulness to psychological distress through illness perception and perceived stress.

	Direct effect (95% CI)	Indirect effect (95% CI)	Total effect (95% CI)
Direct path			
Mindfulness → Illness perception	−0.16 (−0.27, −0.07)	n.a.	−0.16 (−0.27, 0.07)
Illness perception → Perceived stress	0.17 (0.08, 0.26)	n.a.	0.17 (0.08, 0.26)
Illness perception → Psychological distress	0.18 (0.09, 0.26)	n.a.	0.18 (0.09, 0.26)
Perceived stress → Psychological distress	0.23 (0.10, 0.30)	n.a.	0.23 (0.10, 0.30)
Indirect path			
Illness perception → Psychological distress	0.18 (0.09, 0.26)	0.04 (0.02, 0.07)	0.22 (0.12, 0.30)
Mindfulness → Perceived stress	n.a.	−0.03 (−0.07, −0.01)	−0.03 (−0.07, −0.01)
Mindfulness → Psychological distress	n.a.	−0.04 (−0.07, −0.02)	−0.04 (−0.07, −0.02)

CI, confidence interval; n.a., not available.

negative effect on perceived stress through illness perception, with an indirect effect of −0.03 [95% CI (−0.07 to −0.01) and $p = 0.009$]. However, mindfulness had an impact on psychological distress through influencing only illness perception (**Figure 1B**) or influencing simultaneously illness perception and perceived stress (**Figure 1C**). Specifically, the indirect effect of mindfulness on psychological distress was −0.03 through mediating effect of illness perception alone, and the indirect effect of mindfulness on psychological distress was −0.01 through the chain mediating effect of illness perception and perceived stress. Overall, the total effect of mindfulness on psychological distress was −0.04 through two indirect pathways. The results suggested that illness perception and perceived stress play a chain mediating role in the relationship between mindfulness and psychological distress among patients with lung cancer.

DISCUSSION

Psychological distress has been demonstrated to be associated with several negative clinical outcomes such as interruption of anticancer treatment, poor quality of life, and higher morbidity

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

and mortality (Riba et al., 2019). It is imperative to clarify the potential mechanisms of the development and progress of psychological distress among patients with lung cancer to develop a more effective intervention protocol (Lei et al., 2021; Riba et al., 2019). The major aim of this study is to determine whether negative illness perception is positively related to be psychological distress and whether mindfulness may have a protective effect on psychological distress through negatively influencing illness perception and perceived stress among patients with lung cancer.

After completing this study, we found that 24.4% of patients experienced clinically significant psychological distress, which was consistent with previous findings (Tian et al., 2021a) although there also are some studies that reported a higher detection rate (Hong et al., 2015; Carlson et al., 2004). It is possible that the relatively lower detection rate of psychological distress in our study can be explained by the fact that patients experience significantly serious stigma after confirming the diagnosis of advanced lung cancer (Maguire et al., 2019), which has an impact on the tendency of patients to deliberately conceal their psychological distress. Moreover, as stated in our previous study (Lei et al., 2021), DT is not specific to patients with cancer (Hong et al., 2015) and cannot differentiate the risk of initial psychological distress from the accumulated risk of psychological distress, which may be an explanation for our findings.

Leventhal's commonsense model of illness representations proposes that individuals' illness perceptions are the major determinants of their health outcomes (Diefenbach and Leventhal, 1996). The individual will concurrently construct or elaborate both cognitive and emotional representations of their symptoms and illness to relieve the adverse impacts resulting from the symptom or an illness (Dempster et al., 2011). Some studies have revealed the association between illness perception and psychological distress among different populations (Zhang et al., 2017, 2018, 2020b). In this study, we first investigated the association between illness perception and psychological distress among patients with lung cancer and determined that illness perception was positively related to psychological distress.

As a positive psychological trait, mindfulness was found to be beneficial for improving adverse psychological outcomes through effective self-designed regulation and keeping positive emotional status (Ludwig and Kabat-Zinn, 2008). We have previously determined the direct association between mindfulness and psychological distress in patients with lung cancer; however, this specific association was not held in this study, which may be explained by the relatively mild severity of psychological distress compared with our finding (Lei et al., 2021). Moreover, we did not separately investigate the relationships of facets in mindfulness scale and psychological distress (Burger et al., 2021). Interestingly, we first determined the negative association between mindfulness and illness perception and revealed that mindfulness has an indirect impact on psychological distress through correcting negative illness perception. Illness perceptions refer to the attitudes, beliefs, and expectations of patients about symptoms or illnesses (Dalili and Bayazi, 2019), which are related to health information behavior practices and coping strategies (Katavic et al., 2016). Several studies have established that mindfulness-based interventions were associated with increased positive health perceptions and health behaviors (Roberts and Danoff-Burg, 2010), which provide theoretical support for our findings.

This study also revealed another novel finding that mindfulness indirectly influenced psychological distress among patients with lung cancer through the mediating effect of illness perception and perceived stress. As we introduced earlier, a higher negative perception of symptoms or illness represented worse psychological outcomes (Weinman et al., 1996). As one of the most common psychosocial risk factors, perceived stress has been suggested as a precursor state of adverse psychological outcomes because it has a negative impact on individual psychological adjustment (Kim and Jang, 2020). Previous studies also revealed the predictive effect of illness perception on perceived stress (Miceli et al., 2019; Sadeghi et al., 2019), which was further demonstrated in this study.

This study has some potential limitations that should be further interpreted. First, we used a convenience sample to investigate the associations between variables, which may introduce bias. Second, we calculated the theoretical sample size according to the number of variables, rather than performing an estimation based on acceptable statistical power. Third, all the patients were recruited from a single hospital in a single city and the sample size was relatively small; therefore, the generalizability of the study is questionable. Fourth, the level of mindfulness, illness perception, perceived street, and psychological distress were measured by using the self-report instruments, which may introduce subjective bias from patients. Definitively speaking, the prevalence of psychological distress and the type of scale could have some effects on the results.

CONCLUSION

This study first shows that illness perception is positively related to the perceived stress and psychological distress in patients with lung cancer and negatively related to mindfulness. This study provided some evidence for the hypothesis that mindfulness can relieve the severity of psychological distress by decreasing the level of negative illness perception alone or decreasing the level of negative illness perception and perceived stress simultaneously. Based on these findings, illness perception and perceived stress screening should be enrolled in mindfulness-based intervention strategies for patients with lung cancer. Certainly, the total effect of mindfulness on psychological distress through the two targeted pathways in this study was very low; we, therefore, suggest continuing to explore other potential mechanisms.

CLINICAL IMPLICATIONS

This study further clarified the potential mechanism of mindfulness on psychological distress through influencing illness perception and perceived stress in patients with lung cancer. From our current findings, mindfulness-based

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

intervention protocol focusing on the correction of illness perception and reduction of perceived stress may be feasible and effective in improving psychological distress among patients with lung cancer.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Institutional Review Board of Chongqing University Cancer Hospital. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

LT and XT: had full access to all of the data in the study and are held responsible for the integrity of the data and accuracy of the data analysis. X-PQ, LT, XT, and MJ-H: concept and design. X-PQ, LT, XT, and L-JY: acquisition, analysis, or interpretation of data. X-PQ, XT, and MJ-H: drafting of the manuscript. XT, G-HC, and MJ-H: critical revision of the manuscript for important intellectual content. X-PQ and XT: statistical analysis. XT: obtaining funding, administrative, technical, or material support. MJ-H: supervision. All authors contributed to the article and approved the submitted version.

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Article 6

Tian X, Zhang ZL, Jin YF, Chen H, Jiménez-Herrera MF. The use of mindfulness-based stress reduction (MBSR) for lung cancer patients: protocol for a systematic review and meta-analysis. Ann Palliat Med. 2021 Jul;10(7):8276-8282. doi: 10.21037/apm-21-194.

Study Protocol

The use of mindfulness-based stress reduction (MBSR) for lung cancer patients: protocol for a systematic review and meta-analysis

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Background: Mindfulness-based stress reduction (MBSR) intervention has been extensively applied in cancer patients for relieving symptom burden and its effectiveness has also been demonstrated. However, the effectiveness of MBSR on psychological and physical functions in lung cancer patients has not yet been determined. The aim of the present systematic review and meta-analysis seeks to determine the role of MBSR in lung cancer patients.

Methods: A systematic search of PubMed, EMBASE, Cochrane Library, and China National Knowledgement Infrastructure (CNKI) will be carried out from their inception until to December 30, 2020. Studies investigating the comparative effects between MBSR and control groups on psychological and physical outcomes will be documented. Data concerning studies, patient characteristics, and outcomes will be extracted. Methodological quality of each eligible randomized controlled trial (RCT) will be assessed individually by two investigators independently using criteria recommended in the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0. Meanwhile, Newcastle-Ottawa Quality Assessment Scale (NOS) will be used to assess methodological quality of non-randomized studies. All statistical analyses will be performed with RevMan and STATA softwares.

Discussion: The role of MBSR in lung cancer patients has not yet been demonstrated. This systematic review and meta-analysis will further determine the effectiveness of MBSR on psychological and physical outcomes and QoL among lung cancer patients, which will provide golden references for developing psychological interventions in order to improve patient care and designing future studies to bridge the gap between research findings and clinical practice.

Trial registration: We registered the protocol of this systematic review and meta-analysis in Open Science Framework (OSF) platform with a registration DOI of 10.17605/OSF.IO/MWVBQ (available from: https://osf.io/mwvbq).

Keywords: Lung cancer; psychological function; physical function; protocol; systematic review

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Introduction

Lung cancer is the second most common type of cancer worldwide and also the first-rank reason of causing cancer-related death (1). The increasing incidence of lung cancer can be attributed to numerous aspects, such as aging of population and environmental pollution (2). It is reported that the new cases of lung cancer have been more than 2.20 million, and approximately 1.80 million deaths in 2020 have been estimated (1).

Although a series of treatment modalities such as surgical operation, chemotherapy, radiotherapy, immuno-biological cancer therapy, and complementary and alternative therapy have been used for treating lung cancer (3-5), patients remain experiencing many serious symptoms such as fatigue (6) and symptom distress (7) because all treatments have also destructive effects on both cancer and normal cells (8). Moreover, cancer self also play a critical role in the development of symptoms (9,10). Previous studies revealed that lung cancer patients experienced more symptom burden than patients who were diagnosed with other types of cancer (7,9,11). It is acknowledged that these all symptoms are significantly associated with reduced psychosocial and physical functions among lung cancer patients (8,12). Additionally, the negative association between symptoms and quality of life (QoL) has also been established by several studies (13-15).

Previous findings have evidently established the effects of psychosocial interventions in improving psychological and physical wellbeing and QoL of cancer patients (16-18). As one of the most common psychosocial interventions, mindfulness-based stress reduction (MBSR) has been extensively applied in cancer patients (18,19). MBSR program was initially developed by Kabat-Zinn to consist of an 8-week psycho-educational program and four meditative techniques including sitting meditation, body scan, gentle Hatha yoga, and walking meditation (20-22). Training of MBSR will make participants gradually to be out of dysfunctional thoughts and directly perceive the emotions and bodily sensations at the present moment via repeatedly bring participants' attention back to the present moment (23). As a result, MBSR program enable participants to step back from ruminating about the past or worrying about the future and simply unfold experiences of the present moment (21). MBSR has been demonstrated to be effective in relieving symptom burden and improving psychosocial adjustment to disease and QoL to date (18,19,24,25). Some studies also tried to investigate the effects of MBSR in lung cancer patients (26,27) and other lung diseases such as interstitial lung diseases (28,29). However, the systematic review and meta-analysis specifically for lung cancer patients is greatly limited except for one meta-analysis which investigated the effects of MBSR on fatigue among lung cancer with subgroup analysis (24).

Therefore, we conduct the current systematic review and meta-analysis to comprehensively evaluate the benefits of MBSR on psychological and physical functions and QoL in patients with lung cancer. We present the following article in accordance with the PRISMA reporting checklist (available at http://dx.doi.org/10.21037/apm-21-194) (30).

Methods

We designed the methodological framework of this systematic review and meta-analysis protocol in accordance with the methodology recommended by the Cochrane handbook (31). Additionally, we will report our findings in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (32). No ethics approval and informed consent will be required because all statistical analysis will be performed based on published studies without involvement of patients. The protocol of this systematic review and meta-analysis has been registered in Open Science Framework (OSF) platform on 22 January, 2021. A registration DOI of 10.17605/OSF.IO/MWVBQ has been approved (available from: https://osf.io/mwvbq).

Search strategy

We will electronically search PubMed, EMBASE, Cochrane Library, and China National Knowledgement Infrastructure (CNKI) for potentially eligible studies from their inception to December 30, 2020. We will construct the search strategy with the combination of medical subject heading (MeSH) terms and text words. We will verify the systematic review and meta-analysis which also focused our topic and the bibliographies of eligible studies in order to add any additionally eligible study. As an example, we summarized the search strategy of PubMed in *Table 1*. The process of identification and selection of literature will be displayed in *Figure 1*. Any disagreement about retrieval of eligible studies will be settled through consulting a third senior author.

Study selection

One study will be included in the current systematic review

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Table 1 Search strategy of PubMed

Search number	Query
7	#3 AND #6
6	#4 OR #5
5	((((((Pulmonary Neoplasms[Title/Abstract]) OR (Lung Neoplasm[Title/Abstract])) OR (Pulmonary Neoplasm[Title/Abstract])) OR (Lung Cancer[Title/Abstract])) OR (Lung Cancers[Title/Abstract])) OR (Pulmonary Cancer[Title/Abstract])) OR (Pulmonary Cancers[Title/Abstract])
4	"Lung Neoplasms"[Mesh]
3	#1 OR #2
2	((((mindfulness[Title/Abstract]) OR (mindfulness meditation[Title/Abstract])) OR (mindfulness-based stress reduction[Title/Abstract])) OR (mindfulness based stress reduction[Title/Abstract])) OR (MBSR[Title/Abstract])
1	"Mindfulness"[Mesh]

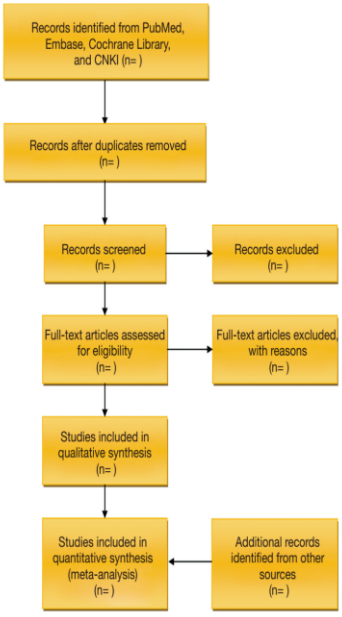

Figure 1 The process of identification and selection of literature.

and meta-analysis if the following criteria were covered: (I) patients, with the age of 18 years or older and irrespective of gender, were diagnosed with lung cancer; (II) MBSR in research group; (III) usual care (UC) or no intervention in control group; (IV) psychological and physical outcomes such as self-designed efficacy and cancer-related fatigue which were defined as primary outcomes and QOL which was defined as secondary outcome; (V) clinical controlled trial (CCT) and randomized clinical trial (RCT); (VI) only full text published in English and Chinese language will be eligible for our inclusion criteria.

One study will be excluded if it covered at least one of the following criteria: (I) MBSR was not used in research group; (II) included mixed patients; and (III) protocol, unpublished or duplicate without adequate information or poor quality.

Data extraction

Two authors will be assigned to independently extract essential data with designed information extraction form (*Table 2*). The following information will be extracted from eligible studies: basic information eligible study including author, publication year and country, basic information of patients including sample size, age and tumor staging such as TNM stage, basic information of regimes including details of interventions, outcomes and study design, and information of methodological quality. Quantitative data will be extracted to estimate effect sizes. Data on effect size that could not be obtained directly will be recalculated when possible. Qualitative information will also be summarized to systematically describe the effects and safety of MBSR. Any disagreement about data extraction will be resolved through consulting a third senior author.

Methodological quality assessment

Two authors will be assigned to independently assess the methodological quality of eligible studies. Methodological quality of individual RCT will be appraised with the

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Table 2 Basic characteristics of all eligible studies

Study	Country	Sample size	Age, year	Interventions		Follow-up	Outcomes	Instruments	Study design
				RG	CG				
Study 1									
Study 2									
Study 3									
.....									

Cochrane risk of bias tool as following six domains including (33): (I) random sequence generation; (II) allocation concealment; (III) blinding of personnel, participants, and assessors; (IV) incomplete outcome data; (V) selective reporting; and (VI) other bias. Additionally, methodological quality of nonrandomized studies will be assessed with Newcastle-Ottawa Quality Assessment Scale (NOS) from three aspects: selection of study groups, comparability of study groups and ascertainment of either the exposure or outcome of interest (34). Any disagreement about the methodological quality assessment will be resolved through consulting a third senior author.

Statistical analysis

For continuous outcomes, we will calculate the differences between two groups as the standard mean difference (SMD) or mean difference (MD) with 95% confidence interval (CI). For categorical outcomes, we will use risk ratio (RR) with 95% CI to express pooled estimates. In this meta-analysis, we only extract immediate, post-intervention data (after a 6–16 week course) to estimate the effect size in order on achieve uniformity according to the methods used in previous meta-analysis (17). Meanwhile, we also extract the data at the first time point which is defined as immediately post-intervention for statistical analysis if a study reported data on a series of time points. Before performing statistical analysis, we will use Cochrane's Q test and the I^2 statistic to qualitatively and quantitatively evaluate the heterogeneity across studies accordingly (35,36). Nevertheless, we will only perform a random-effects model to calculate all pooled results regardless of actual level of heterogeneity across studies because substantial variations in population, interventions, and outcome measures are inevitable. A $P<0.05$ will be considered to be the criteria of statistical significance. All statistical analyses will be conducted using Review Manager (RevMan) version 5.3 (Cochrane Collaboration, Oxford, United Kingdom).

Publication bias

For individual outcome, we will draw funnel plot and perform Egger's tests respectively to test the possibility of publication bias when accumulated number of 10 were achieved (37-39). STATA 14.0 software (StataCorp, Texas, USA) will be utilized to complete Egger's tests.

Quality of evidence assessment

We will use the Grading of Recommendations Assessment, Development and Evaluation method (40) to grade the overall quality of evidence of quantitative pooled results as high, moderate, low, or very low after completing all statistical analyses. With the GRADE system, the level of RCT will be initially rated as high, and the level can be downgraded according to five aspects including risk of bias, inconsistency, indirectness, imprecision, and publication bias. Two authors will independently rate the level of evidence and any disagreement will be resolved based on the consensus principle.

Discussion

As one of the most common malignant tumors around the world, lung cancer was estimated to account for 11.4% new cancer cases and 18.0% cancer deaths in 2020 (41). Evidence suggested lung cancer patients will experience a series of serious symptoms due to the negative impact of definitive diagnosis of cancer and anticancer treatments (7,9). As a result, lung cancer patients will also suffer from poor psychological and physical functions and QoL (6,7). As one of the most common psychological intervention programs, MBSR have been extensively investigated and also established to improve symptoms of cancer patients

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

(19,24,26). However, there was no systematic review and meta-analysis specifically focused on the impacts of MBSR intervention on psychological and physical functions and QoL of lung cancer patients has been reported to date. As a result, it remains unclear whether MBSR should be preferentially prescribed for the treatment of psychological and physical conditions among lung cancer patients. The present systematic review and meta-analysis will provide a comprehensive summary of studies exploring the effectiveness of MBSR on psychological and physical outcomes and QoL in lung cancer patients.

To our knowledge, this is the first systematic review and meta-analysis of RCTs and CCTs that will investigate the effects of MBSR on psychological and physical outcomes and QoL for lung cancer patients. However, we also must further interpret the limitations in this systematic review and meta-analysis. First, we will only search four databases including PubMed, EMBASE, Cochrane Library and CNKI, and thus some potentially eligible studies included in other databases such as Web of Science and SCOPUS may be missed. Second, the substantial variations in intensity, frequency, and duration of MBSR across studies may introduce heterogeneity, we thus use a random-effects model to perform all statistical analyses, which will result in wider 95% CI. Third, definitions of usual care in individual study are different, however subgroup analysis will not be designed because details of usual care were not introduced.

Conclusions

The systematic review and meta-analysis will investigate the effectiveness of MBSR intervention on psychological and physical functions and QoL in patients with lung cancer. The results from the current study will demonstrate the effects of MBSR on specific outcomes and then provide evidence for developing psychological interventions in clinical practice. Meanwhile, this study also determines the gap between research findings and clinical practice, and then provides references for designing further studies.

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Footnote

Reporting Checklist: The authors have completed the PRISMA reporting checklist. Available at http://dx.doi.org/10.21037/apm-21-194

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

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Article 7

Tian X, Yi LJ, Liang CS, Gu L, Peng C, Chen GH, Jiménez-Herrera MF. The Impact of Mindfulness-Based Stress Reduction (MBSR) on Psychological Outcomes and Quality of Life in Patients With Lung Cancer: A Meta-Analysis. Front Psychol. 2022 Jun 28;13:901247. doi: 10.3389/fpsyg.2022.901247.

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The Impact of Mindfulness-Based Stress Reduction (MBSR) on Psychological Outcomes and Quality of Life in Patients With Lung Cancer: A Meta-Analysis

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Objective: The impact of the mindfulness-based stress reduction (MBSR) program on psychological outcomes and quality of life (QoL) in lung cancer patients remains unclear. This meta-analysis aimed to evaluate the effectiveness of the MBSR program on psychological states and QoL in lung cancer patients.

Methods: Eligible studies published before November 2021 were systematically searched from PubMed, EMBASE, Cochrane Library, PsycINFO, China National Knowledge Infrastructure (CNKI), and Wanfang databases. The risk of bias in eligible studies was assessed using the Cochrane tool. Psychological variables and QoL were evaluated as outcomes. We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to grade the levels of evidence. Statistical analysis was conducted using RevMan 5.4 and STATA 14.0.

Results: A total of 17 studies involving 1,680 patients were included for meta-analysis eventually. MBSR program significantly relieved cancer-related fatigue (standard mean difference [SMD], −1.26; 95% confidence interval [CI], −1.69 to −0.82; moderate evidence) and negative psychological states (SMD, −1.35; 95% CI, −1.69 to −1.02; low evidence), enhanced positive psychological states (SMD, 0.91; 95% CI, 0.56–1.27; moderate evidence), and improved quality of sleep (MD, −2.79; 95% CI, −3.03 to −2.56; high evidence). Evidence on MBSR programs' overall treatment effect for QoL revealed a trend toward statistical significance ($p = 0.06$, low evidence).

Conclusion: Based on our findings, the MBSR program shows positive effects on psychological states in lung cancer patients. This approach should be recommended as a part of the rehabilitation program for lung cancer patients.

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Keywords: lung cancer, mindfulness-based stress reduction, physical and psychological wellbeing, quality of life, meta-analysis

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

INTRODUCTION

According to the Global Cancer Statistics 2020, lung cancer ranked second for incidence and first for mortality among all types of cancers worldwide (Sung et al., 2021). Currently, several treatment modalities are available for lung cancer patients, such as surgery, chemotherapy, radiotherapy, immunotherapy, biotherapy, and complementary and alternative therapy (Gadgeel et al., 2012; Jurisevic and Bolevich, 2020; Yang and Luan, 2020); however, patients continue to suffer from serious psychological symptoms (Iyer et al., 2013; Morrison et al., 2017) because most treatment modalities simultaneously destroy both tumor and normal cells (Yang et al., 2020). Meanwhile, except for the adverse effects resulting from treatment modalities, cancer diagnosis also contributes to the development and progression of distressing symptoms (Iyer et al., 2014; Sung et al., 2017).

Patients with lung cancer have more symptom burdens than patients diagnosed with other types of cancer (Chan et al., 2009; Iyer et al., 2014; Morrison et al., 2017). Distressing symptoms can negatively affect the psychosocial wellbeing of patients with lung cancer (Yang et al., 2020; Lee, 2021). A recent study indicated that psychological stress accumulated tumor growth and increased the risk of radio-resistance associated with the activation of epithelial-mesenchymal transition by stress hormone-stimulated adrenergic receptors (Zhang et al., 2020). Moreover, several studies also demonstrated the association between high-level distressing symptoms and poor quality of life (QoL) (Möller and Sartipy, 2012; Park et al., 2016; Choi and Ryu, 2018). Fortunately, psychological interventions have been demonstrated to significantly improve the psychological wellbeing of patients with cancer (Galway et al., 2012; Huang et al., 2016; Cillessen et al., 2019).

Among the currently available psychological interventions, mindfulness-based stress reduction (MBSR), initially developed by Kabat-Zinn et al., 1998, has been widely applied in cancer settings (Lee et al., 2017; Cillessen et al., 2019). The standard MBSR program comprises an 8-week psycho-educational program and four meditative techniques, including sitting meditation, body scan, gentle Hatha yoga, and walking meditation (Kabat-Zinn et al., 1985, 1992, 1998). The exact mechanisms of the MBSR program in improving psychological wellbeing have not been fully clarified, although some studies revealed that it could affect cancer patients' neuroendocrine and immune regulation functions (Davidson et al., 2003; Robinson et al., 2003; Carlson et al., 2004; Hölzel et al., 2011). According to the previously published evidence (Kabat-Zinn et al., 1985; Kabat-Zinn and Santorelli, 2002; Kabat-Zinn, 2003), the practice of mindfulness can guide participants purposefully pay attention to the present moment and non-judgmentally monitor the unfolding of experiences moment by moment, and therefore, having a profound benefit *via* the mind-body connection.

Nevertheless, Garland et al. (2009) proposed a causal model helping to explain the mechanism of mindfulness, named as "Mindful Coping Model." In this model, mindfulness plays a critically important role in the positive reappraisal process (Shapiro et al., 2006). Specifically, if a threat, harm, or loss exceeds one's coping capabilities, then an individual's attention may be transferred from contents to the dynamic process of consciousness by distracting stress appraisal into the model of mindfulness and then increasing individual's attentional flexibility and broadens awareness. From the vantage point of this expanded, metacognitive awareness, one can reconstrue appraisal of the given event as positive by attributing to it a new meaning, which may arise either through a conscious process of reflection or a more automatic process based on spontaneous insight. The reappraisal of the given event then triggers positive emotions to reduce stress and influences subsequent appraisal processes. According to this model and empirical evidence, destructive effects resulting from external and internal stressors (given events) may break an individual's psychosomatic balance (one's coping capabilities) and impair an individual's health status. However, mindfulness can trigger positive emotions by imitating the positive reappraisal (psychological adjustment) to restore psychosomatic balance and improve clinical outcomes.

Currently, studies have demonstrated the effectiveness and safety of the MBSR program on psychosocial wellbeing and QoL (Lee et al., 2017; Cillessen et al., 2019; Xie et al., 2020; Xunlin et al., 2020). Some studies also initially investigated the role of the MBSR program in patients diagnosed with lung diseases, such as lung cancer (van den Hurk et al., 2015; Schellekens et al., 2017) and interstitial lung diseases (Arefnasab et al., 2013; Sgalla et al., 2015). However, the benefits of the MBSR program on psychological wellbeing and QoL of lung cancer patients remain unclear because published studies reported conflicting results. More importantly, the sample size of published studies regarding lung cancer was extremely small, significantly increasing the risk of generating false results. Therefore, we performed this meta-analysis to comprehensively evaluate the effectiveness of the MBSR program on psychological outcomes and QoL of lung cancer patients.

METHODS

Study Design

We reported all results according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Page et al., 2021). We registered the protocol of this meta-analysis at the Open Science Framework (OSF) (registration number: 10.17605/OSF.IO/MWVBQ) and publicly published it in an academic journal (Tian et al., 2021). This study did not need ethical approval and patients' informed consent because it was a meta-analysis of published data.

Information Sources

Two reviewers independently searched PubMed, EMBASE, Cochrane Library, PsycINFO, China National Knowledge Infrastructure (CNKI), and Wanfang database for relevant randomized controlled trials (RCTs) investigating the effectiveness of the MBSR program on psychological outcomes and QoL among patients with lung cancer. The literature search was limited from its inception until November 2021. The search strategy was constructed by using both the medical subject heading (MeSH) and text words, which were logically connected using Boolean operators. We also checked reference lists of

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

previous systematic reviews with a similar topic and eligible studies to add additional studies. The consensus principle was imposed to resolve any disagreement between the two reviewers. Details of search strategies of English databases are shown in **Supplementary Table 1**.

Study Selection

After removing duplicate studies, two independent reviewers conducted study selection based on the title, abstract, and full-text screening. Studies were included in the meta-analysis if they met the following criteria: (a) adult patients were cytologically or histologically diagnosed with lung cancer; (b) patients in the intervention group received both the MBSR program and usual care (UC), and patients in the control group received UC program alone, which contained at least five elements, including dietary instruction, health education, rehabilitation excise, emotional counseling, and medication instruction; (c) at least one of psychological outcomes and QoL was reported, and corresponding data were suitable for statistical analysis; (d) RCTs published in full-texts; and (e) publication language was restricted into English and Chinese because an extensive range of related research is published in English and Chinese, and no translator of other languages is available in our team. Studies were excluded if they covered at least one of the following criteria: (a) the MBSR program was designed as the part of a comprehensive strategy; (b) mixed patients were enrolled but patients with lung cancer were not separately analyzed; (c) duplicate reports of same data published by the same group; and (d) conference abstract without sufficient data.

Data Extraction

Two reviewers independently extracted essential data from eligible studies using a predesigned standard information extraction sheet, including the first author's name, publication year, country, condition of patients, tumor stage, sample size, mean age, details of the MBSR program, outcomes, and measurements. We extracted the data at the end of the intervention or the last follow-up for statistical analysis. We contacted the corresponding author to obtain the essential data if necessary. The consensus principle was introduced to resolve the disagreement between the two reviewers.

Risk of Bias Assessment

Two reviewers independently assessed the risk of bias in eligible studies using the Cochrane risk of bias assessment tool from seven items (Higgins et al., 2011): random sequence generation, allocation concealment, blinding of personnel and participants, blinding of outcome assessor, incomplete outcome data, selective outcome reporting, and other bias sources. Each item was rated as "low," "unclear," or "high" risk according to the matching level between actual information and assessment criteria. The level of overall methodological quality was judged as "high" if all items were rated as "low" risk of bias, as "low" if at least one item was rated as "high" risk of bias, and "moderate" if at least one item was rated as "unclear" risk of bias, but no item was rated as "high" risk of bias. The consensus principle was introduced to resolve the disagreement between the two reviewers.

Statistical Analysis

Statistical analysis was conducted using Review Manager (RevMan) 5.4 (Cochrane Collaboration, Oxford, United Kingdom) and STATA 14.0 (StataCorp, Texas, USA). All outcomes were continuous variables in this meta-analysis. We, therefore, used mean difference (MD) or standard mean difference (SMD) with a 95% confidence interval (CI) to express all pooled results. We comprehensively evaluated statistical heterogeneity using the Chi-square test (Cochrane Q) and I^2 statistic (Higgins and Thompson, 2002; Higgins et al., 2003). Substantial statistical heterogeneity was considered if the p-value was <0.1 and I^2 was more than 50%. Nevertheless, we used the random-effects model to conduct a meta-analysis because variations across studies are inevitable in real settings. We also designed a series of subgroup analyses to investigate the influence of the MBSR program on different functional dimensions. We did not perform a publication bias test because the number of eligible studies for individual outcomes did not exceed 10 (Egger et al., 1997; Sterne and Egger, 2001; Page et al., 2018). Statistical significance was judged based on two-tail, and a p-value of <0.05 was regarded as the cutoff value of statistical significance.

Quality of Evidence Assessment

Two independent reviewers used the Grading of Recommendations Assessment, Development and Evaluation system (Guyatt et al., 2008) to rate the level of evidence as "high," "moderate," "low," or "very low." With the GRADE system, the level of RCT was initially rated as high, and 5 factors could downgrade the level, including the risk of bias, inconsistency, indirectness, imprecision, and publication bias. Certainly, some factors could also upgrade the level of evidence, such as large effects. The consensus principle was introduced to resolve the disagreement between the two reviewers.

RESULTS

Study Selection

Figure 1 shows the process of study retrieval and selection. We identified 123 records from the database. Notably, 43 duplicate records were first removed. Then, 50 studies were excluded after checking their titles and abstracts. Thirty studies were further assessed for eligibility, while 13 studies were excluded due to: (a) non-RCT design ($n = 3$), (b) lack of essential data ($n = 1$), and (c) unrelated topic ($n = 9$). Finally, 17 studies were included in this meta-analysis (Ning et al., 2017; Schellekens et al., 2017; Wang et al., 2017; Guan and Zhou, 2018; Liu, 2018; Tang et al., 2018; Chen et al., 2019; Liu J. L. et al., 2019; Liu T. et al., 2019; Tian et al., 2019; Wang, 2019; Xu et al., 2019; Ding and Chu, 2020; Feng and Gong, 2020; Wu, 2020; Xi et al., 2020; You, 2020).

Characteristics of Included Studies

All studies (Ning et al., 2017; Wang et al., 2017; Guan and Zhou, 2018; Liu, 2018; Tang et al., 2018; Chen et al., 2019; Liu J. L. et al., 2019; Liu T. et al., 2019; Tian et al., 2019; Wang, 2019; Xu et al., 2019; Ding and Chu, 2020; Feng and Gong, 2020; Wu, 2020; Xi et al., 2020; You, 2020) were conducted in China except for

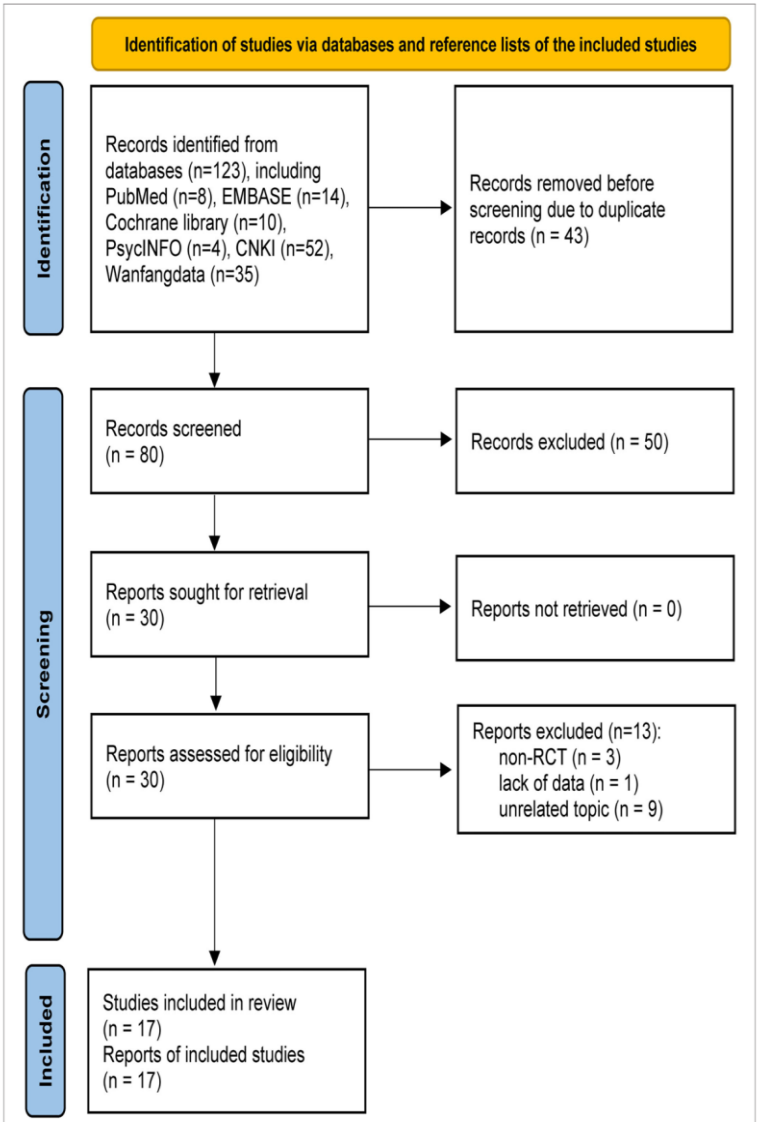

FIGURE 1 | PRISMA flowchart of study retrieval and selection process. CNKI, China National Knowledge Infrastructure.

one study, which was conducted in the Netherlands (Schellekens et al., 2017). All studies were published between 2017 and 2020. The sample size of individual study ranged from 36 to 378, with a total number of 1,680. A total of 13 studies (Ning et al., 2017; Schellekens et al., 2017; Wang et al., 2017; Guan and Zhou, 2018; Liu, 2018; Tang et al., 2018; Chen et al., 2019; Tian et al., 2019;

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Xu et al., 2019; Ding and Chu, 2020; Feng and Gong, 2020; Wu, 2020; Xi et al., 2020) used standard 8-week MBSR program, but four studies used modified MBSR protocols, including 3-week program (Liu T. et al., 2019), 4-week program (Liu J. L. et al., 2019; Wang, 2019), and 6-week program (You, 2020). The remaining characteristics of eligible studies are shown in **Table 1**.

Risk of Bias

The risk of bias assessment of included studies is displayed in **Supplementary Figure 1**. Overall, more than half of the studies (52.94%) (Ning et al., 2017; Schellekens et al., 2017; Wang et al., 2017; Chen et al., 2019; Liu J. L. et al., 2019; Tian et al., 2019; Feng and Gong, 2020; Wu, 2020; You, 2020) were judged as "low" risk of bias due to the attrition bias. Generally, the majority of studies (Ning et al., 2017; Wang et al., 2017; Guan and Zhou, 2018; Liu, 2018; Tang et al., 2018; Chen et al., 2019; Liu J. L. et al., 2019; Liu T. et al., 2019; Tian et al., 2019; Wang, 2019; Xu et al., 2019; Ding and Chu, 2020; Feng and Gong, 2020; Wu, 2020; Xi et al., 2020; You, 2020) did not report details of allocation concealment and blinding of personnel, participants, and outcome assessors.

Cancer-Related Fatigue

A total of seven studies reported the overall level of cancer-related fatigue (Wang et al., 2017; Guan and Zhou, 2018; Liu, 2018; Tang et al., 2018; Chen et al., 2019; Wang, 2019; Wu, 2020); however, five (Wang et al., 2017; Liu, 2018; Tang et al., 2018; Wang, 2019; Wu, 2020) and three studies (Guan and Zhou, 2018; Chen et al., 2019) used the Revised Piper Fatigue Scale (R-PFS) and Cancer Fatigue Scale (CFS) to measure this outcome, respectively. Therefore, SMD was used to express the pooled results. Meta-analysis revealed a significant improvement in patients receiving MBSR program (514 patients; $I^2 = 80\%$; SMD, −1.26; 95% CI: −1.69 to −0.82; $p < 0.001$; **Figure 2A**), which was supported by moderate evidence (**Table 2**).

Negative Psychological Status

A total of eight studies (Ning et al., 2017; Chen et al., 2019; Liu J. L. et al., 2019; Tian et al., 2019; Xu et al., 2019; Ding and Chu, 2020; Wu, 2020; You, 2020) reported the changes of negative psychological states, including anxiety, depression, and psychological distress. It is noted that the level of anxiety was measured by using the Self-rating Anxiety Scale (SAS) and Hamilton Anxiety Scale (HAMA), and the level of depression was measured by using the Self-rating Depression Scale (SDS) and Hamilton Depression Scale (HAMD), and the level of psychological distress was measured using Distress Thermometer (DT). Therefore, SMD was selected as the measurement to express the pooled result of negative psychological states. Meta-analysis suggested that patients receiving the MBSR program had a significantly lower level of negative psychological outcomes compared with patients receiving UC alone (1,029 patients; $I^2 = 92\%$; SMD, −1.35; 95% CI, −1.69 to −1.02; $p < 0.001$; **Figure 2B**), which was only supported by low evidence (**Table 2**). It is noted that the level of anxiety (1,029 patients; $I^2 = 88\%$; SMD, −1.48; 95% CI, −1.91 to −1.05; $p < 0.001$), depression (765 patients; $I^2 = 52\%$; SMD, −0.98; 95% CI, −1.21 to −0.76; $p < 0.001$), and psychological distress (470 patients; $I^2 = 97\%$; SMD, −2.05; 95% CI, −3.64 to −0.45; $p = 0.01$) were all significantly lower in the MBSR group.

Positive Psychological Status

Among the 17 included studies, four studies reported changes in positive psychological states, including self-efficacy and mindfulness. We selected SMD to express the pooled result because self-efficacy and mindfulness were combined as an individual outcome. For self-efficacy, the "strategies used by people to promote health (SUPPH)" was used as the measurement; however, the level of mindfulness was measured by using the Mindful Attention Awareness Scale (MASS) and Five Facet Mindfulness Questionnaire (FFMQ). Meta-analysis suggested that the MBSR program significantly improved the positive psychological states (292 patients; $I^2 = 62\%$; SMD, 0.91; 95% CI, 0.56–1.27; $p < 0.001$; **Figure 3**), which was only supported by moderate evidence (**Table 2**). It is noted that the level of self-efficacy (253 patients; $I^2 = 76\%$; SMD, 0.97; 95% CI, 0.42–1.52; $p < 0.001$) and mindfulness (139 patients; $I^2 = 28\%$; SMD, 0.82; 95% CI, 0.39–1.25; $p < 0.001$) were all significantly improved in the MBSR group.

Quality of Sleep

Four studies (Xu et al., 2019; Feng and Gong, 2020; Xi et al., 2020; You, 2020) reported the quality of sleep, but the total score of the Pittsburgh sleep quality index (PSQI) was available in two studies (Xu et al., 2019; You, 2020). Meta-analysis suggested that the MBSR program significantly improved the quality of sleep compared with UC alone (546 patients; $I^2 = 0\%$; MD, −2.79; 95% CI, −3.03 to −2.56; $p < 0.001$; **Figure 4A**), which was supported by high evidence (**Table 2**). Subgroup analysis was conducted to investigate the impact of the MBSR program on different dimensions, including sleep quality, sleep duration, sleep disturbance, habitual sleep efficiency, sleep latency, use of sleeping medication, and daytime dysfunction, and pooled results revealed that the MBSR program only significantly influences sleep latency, use of sleeping medication, and daytime dysfunction (**Figure 4A**).

Quality of Life

Four studies (Schellekens et al., 2017; Liu J. L. et al., 2019; Wang, 2019; Wu, 2020) reported QoL, but only 3 (Schellekens et al., 2017; Liu J. L. et al., 2019; Wu, 2020) provided total EORTC QLQ-C30 score. Meta-analysis on MBSR programs' overall treatment effect for QoL revealed a trend toward statistical significance (241 patients; $I^2 = 97\%$; MD, 9.55; 95% CI, −0.47–19.58; $p = 0.06$; **Figure 4B**), which was only supported by low evidence (**Table 2**). However, subgroup analysis revealed that MBSR had considerable influence on all dimensions, including emotional, physical, role, social, and cognitive aspects (**Figure 4B**).

DISCUSSION

Lung cancer remains the leading type of cancer worldwide, accounting for ∼11.4% of new cancer cases and 18.0% of cancer-related deaths in 2020 (Sung et al., 2021). Patients with

TABLE 1 | Basic characteristics of the included studies (n = 17).

References	Country	Patients	Stage	Sample for analysis		Mean age, years		Details of MBSR	Follow-up	Outcomes	Instrument
				MBSR	UC	MBSR	UC				
Wang et al. (2017)	China	Lung cancer underwent surgery and chemotherapy	0, I–III	33	34	n.a.	n.a.	8-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 8 weekly group-based 2-h sessions and once-daily 30-min self-training. Patients were supervised to daily practice after discharge by a nurse using telephone or WeChat.	8 weeks	CRF	RPFS
Liu (2018)	China	Lung cancer	n.a.	31	31	62.5	62.3	8-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 8 weekly group-based 2-h sessions and once-daily self-training. Patients were supervised to daily practice after discharge by a nurse using telephone or WeChat.	8 weeks	CRF	RPFS
Wang (2019)	China	Lung cancer	0, I–III	45	45	45	56.02	4-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 10-min explanation and meditation in the first week, 10-min walking meditation in the second week, 10-min breathing meditation in the third week, and 20-min experience sharing in the fourth week. Patients were supervised to daily practice after discharge by a nurse twice weekly using telephone or WeChat.	4 weeks	CRF; QoL	RPFS; EORTC QLQ-C30
Ding and Chu (2020)	China	Lung cancer underwent chemotherapy	III, IV	45	45	55.26	53.59	8-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 8 weekly group-based 2-h sessions and once-daily self-exercise. Patients were supervised to daily train after discharge by a nurse using telephone or WeChat.	8 weeks	Anxiety, depression, CRF; self-efficacy	SAS, SDS, CFS; SUPPH
Xi et al. (2020)	China	NSCLC underwent chemotherapy	III, IV	34	34	62	62	8-week MBSR protocol training under the guidance and supervision of a nurse with qualification, consisting of 8 weekly group-based 30-min sessions. Patients were supervised to train after discharge was implemented by nurses using the telephone twice per week.	8 weeks	CRF; quality of sleep	RPFS, PSQI
Guan and Zhou (2018)	China	Lung cancer underwent chemotherapy	I–IV	23	23	54.4	51.8	8-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 6 weekly group-based 30-min sessions. Patients were supervised to daily practice after discharge by a nurse using telephone or WeChat.	8 weeks	CRF; self-efficacy	CFS; SUPPH
Xu et al. (2019)	China	Lung cancer underwent chemotherapy	II–IV	84	84	n.a.	n.a.	8-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 6 weekly 30–45-min self-practice at 9:00–10:00 a.m. and 17:00–18:00 p.m. Patients were supervised to practice MBSR for 30–45 min daily by a nurse using the telephone after discharge.	8 weeks	Anxiety, depression, quality of sleep	SAS, SDS, PSQI
Liu T. et al. (2019)	China	Lung cancer underwent chemotherapy	II, III	50	50	54.49	57.65	3-week MBSR program practice under the guidance and supervision of a qualified nurse, consisting of 3 weekly group-based 30–40-min sessions including a 15-min explanation from a trainer and 20–30-min training. Patients were supervised to practice MBSR for 30–45 min daily by a nurse using the telephone after discharge.	12 weeks	Self-efficacy, mindfulness	SUPPH; MAAS

(Continued)

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

TABLE 1 | Continued

References	Country	Patients	Stage	Sample for analysis		Mean age, years		Details of MBSR	Follow-up	Outcomes	Instrument
				MBSR	UC	MBSR	UC				
Liu J. L. et al. (2019)	China	Lung cancer underwent chemotherapy	n.a.	44	44	56	55	4-week MBSR program under the guidance and supervision of a qualified nurse, consisting of 4 weekly group-based 2-h sessions and 30-min self-practice daily.	10 weeks	Anxiety, depression, QoL	SAS, SDS, EORTC QLQ-C30
Ning et al. (2017)	China	Lung cancer	n.a.	18	18	39.81	40.76	Standard 8-week MBSR program, which was accessed from www.mbsy.com, under the guidance and supervision of a qualified nurse.	8 weeks	Anxiety, depression	SAS, SDS
Tang et al. (2018)	China	Lung cancer underwent surgery and chemotherapy	I–III	36	36	53.22	50.55	8-week MBSR program under the guidance and supervision of a qualified nurse, consisting of 8 weekly group-based 2-h sessions including a 30-min explanation from a trainer, 30-min practice, 30-min question, and 30-min experience-sharing. Patients were supervised to practice MBSR daily by a nurse using the telephone after discharge.	8 weeks	CRF	RPFS
Tian et al. (2019)	China	Lung cancer underwent concurrent chemoradiotherapy	n.a.	46	46	53.51	54.12	8-week MBSR program, consisting of 8 weekly group-based 30–40-min sessions and self-practice daily. Patients were supervised to practice MBSR daily by a nurse using the telephone after discharge.	8 weeks	Psychological distress, anxiety, depression, the activity of daily living	DT, SAS, SDS, ADL
Wu (2020)	China	Lung cancer underwent chemotherapy	0, I–III	57	57	67.49	67.51	8-week MBSR program training under the guidance and supervision of a qualified nurse, consisting of 8 weekly group-based 30-min sessions and self-practice every day.	8 weeks	CRF, anxiety, depression, QoL	RPFS, HAMA, HAMD, EORTC QLQ-C30
You (2020)	China	Early lung cancer underwent surgery	n.a.	189	189	57.73	58.43	6-week MBSR program under the guidance and supervision of a nurse with qualification, consisting of 6 weekly group-based 2-h sessions, including 30-min explanation, 60-min self-practice, and 30-min experience-sharing.	6 weeks	Psychological distress, anxiety, depression, quality of sleep, quality of life	DT, HAMA, HAMD, PSQI, KPS
Schellekens et al. (2017)	Netherlands	Lung cancer	I–IV	21	18	60.6	57	8-week MBSR program, consisting of 1 weekly 2.5-h group training, a silent day between sessions 6 and 7, and home practice assignments of about 45 min, 6 days per week.	3 months	Anxiety, depression, QoL, mindfulness	HADS, EORTC QLQ-C30, FFMQ
Chen et al. (2019)	China	NSCLC underwent chemotherapy	n.a.	31	32	57.83	59.11	8-week MBSR program under the guidance and supervision of a qualified nurse, consisting of 1 weekly 2-h group training and self-practice daily. Patients were supervised to daily practice MBSR by a nurse using the telephone after discharge.	8 weeks	CRF, anxiety, depression	CFS, SAS, SDS
Feng and Gong (2020)	China	Lung cancer underwent chemotherapy	n.a.	54	53	57.69	57.34	8-week MBSR program under the guidance and supervision of a qualified nurse, consisting of 1 weekly 2-h group practice at 9:00–10:00 a.m. or 17:00–18:00 and 30-min self-practice at home.	8 weeks	CRF, self-efficacy, quality of sleep	RPFS, SUPPH, PSQI

NSCLC, non-small-cell lung cancer; CRF, cancer-related fatigue; QoL, quality of life; Ri-PFS, Revised Piper Fatigue Scale; CFS, Cancer Fatigue Scale; SAS, Self-rating Anxiety Scale; SDS, Self-rating Depression Scale; HAMA, Hamilton Anxiety Scale; HAMD, Hamilton Depression Scale; HADS, Hospital Anxiety and Depression Scale; DT, distress thermometer; SUPPH, strategies used by people to promote health; MAAS, Mindful Attention Awareness Scale; ADL, Activity of Daily Living Scale; PSQI, Pittsburgh sleep quality index; EORTC QLQ-C30, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; FFMQ, Five Facet Mindfulness Questionnaire; KPS, Karnofsky performance status; MBSR, mindfulness-based stress reduction; US, usual care; n.a., not applicable.

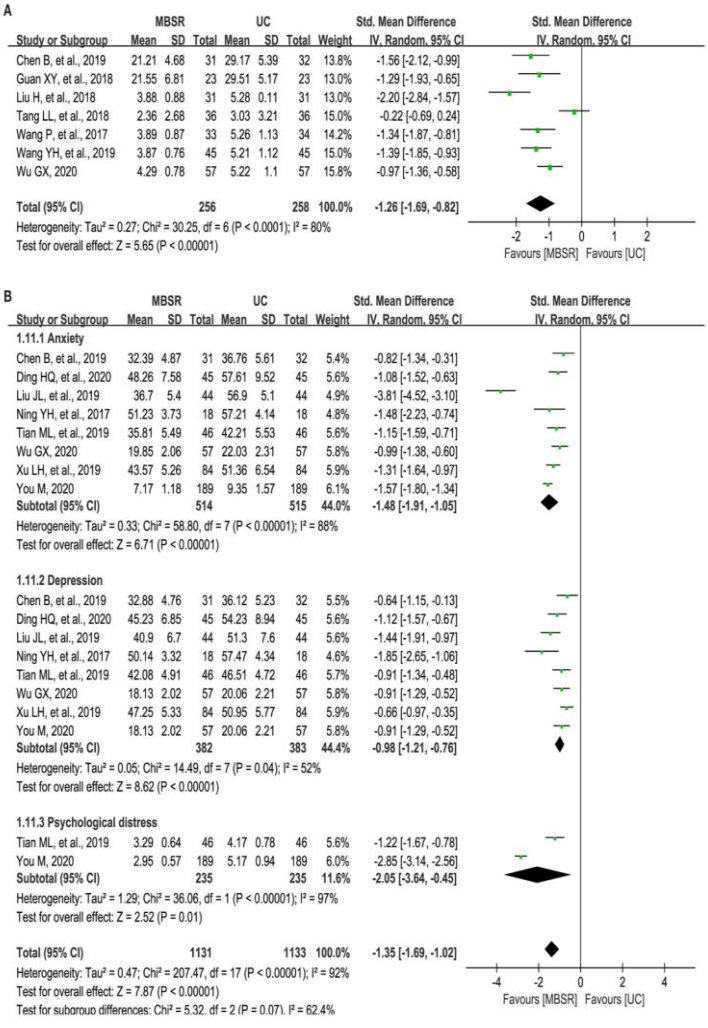

FIGURE 2 | Forest plot of comparative effectiveness between mindfulness-based stress reduction (MBSR) program and UC in terms of cancer-related fatigue **(A)** and negative psychological states **(B)**. MBSR, mindfulness-based stress reduction; UC, usual care; R-PFS, Revised Piper Fatigue Scale; CFS, Cancer Fatigue Scale; SAS, Self-rating Anxiety Scale; SDS, Self-rating Depression Scale; HAMA, Hamilton Anxiety Scale; HAMD, Hamilton Depression Scale; SD, standard deviation.

lung cancer suffer from a significant psychological symptom burden resulting from the destructive effects of anticancer treatment and cancer diagnosis (Iyer et al., 2014; Morrison et al., 2017), which greatly impair an individual's psychological wellbeing and reduce QoL (Iyer et al., 2013; Morrison et al., 2017). Psychological interventions have a positive impact on psychological outcomes among patients with cancer, and as a common type of psychological intervention, MBSR has also been extensively demonstrated to have a positive role in improving psychological outcomes among patients with cancer (van den Hurk et al., 2015; Lee et al., 2017; Xie et al., 2020). However, the role of the MBSR program in

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

TABLE 2 | The level of evidence based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

No. of studies	Study design	Certainty assessment					No. of patients		Effect	Certainty	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBSR	UC	Absolute (95% CI)		
Cancer-related fatigue											
5	Randomized trials	Serious[a]	Not serious	Not serious	Not serious	None	256	258	SMD **−1.26 lower** (−1.69 lower to −0.82 lower)	⊕⊕⊕◯ Moderate	CRITICAL
Negative psychological status											
8	Randomized trials	Serious[b]	Not serious	Not serious	Serious[c]	Strong association	514	515	SMD **−1.35 lower** (−1.69 lower to −1.02 lower)	⊕⊕◯◯ Low	IMPORTANT
Positive psychological status											
4	Randomized trials	Not serious	Not serious	Not serious	Very serious[c]	None	148	144	SMD **0.91 SD higher** (0.56 higher to 1.27 higher)	⊕⊕⊕◯ Moderate	IMPORTANT
Quality of sleep											
2	Randomized trials	Serious[b]	Not serious	Not serious	Not serious	Strong association	273	273	MD **2.79 lower** (3.03 lower to 2.56 lower)	⊕⊕⊕⊕ High	IMPORTANT
Quality of life											
3	Randomized trials	Serious[d]	Not serious	Not serious	Serious[c]	None	122	119	MD **9.55 lower** (0.47 lower to 19.58 higher)	⊕⊕◯◯ Low	IMPORTANT

CI, confidence interval; MBSR, mindfulness-based stress reduction; MD, mean difference; US, usual care; SMD, standardized mean difference.
[a]Two eligible studies were judged to be at high risk of bias.
[b]One eligible study was judged to be at high risk of bias.
[c]Inadequate sample size was accumulated.
[d]Most eligible studies were judged to be at high risk of bias.

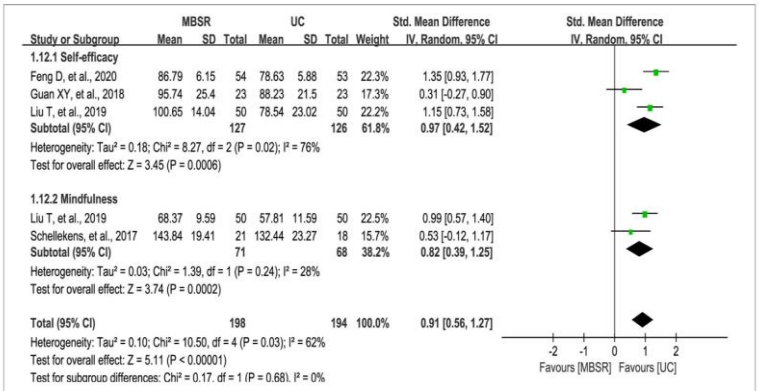

FIGURE 3 | Forest plot of comparative effectiveness between the MBSR program and UC in terms of positive psychological status. MBSR, mindfulness-based stress reduction; UC, usual care; SUPPH, strategies used by people to promote health.

the treatment of patients with lung cancer has not yet been fully investigated.

In this meta-analysis, we obtained a comprehensive summary of studies investigating the effectiveness of the MBSR program on psychological outcomes (negative vs. positive aspects), quality of sleep, and QoL in lung cancer patients. Findings of this meta-analysis suggest that the MBSR program significantly relieves cancer-related fatigue, improves negative psychological states, including anxiety, depression, and psychological distress, enhances positive psychological states, including self-efficacy and mindfulness, and improves the quality of sleep. Unfortunately, meta-analysis does not reveal a statistical difference in QoL between the MBSR program and UC alone. However, the MBSR program tends to have a beneficial influence on QoL. Meanwhile, subgroup analysis suggests that the MBSR program significantly improved all dimensions of QoL compared with UC alone.

Till present, only one meta-analysis (Xie et al., 2020) investigated the effects of the MBSR program on cancer-related fatigue of patients with lung cancer based on subgroup analysis. In this meta-analysis, 3 eligible studies involving 185 patients with lung cancer were included to evaluate the effects of the MBSR program on cancer-related fatigue, and the result suggested that the MBSR program was significantly associated with a decreased level of cancer-related fatigue compared with UC alone (SMD, −0.95; 95% CI, −1.74 to −0.15; $p = 0.02$). Although the previous meta-analysis reported a consistent result with our meta-analysis in terms of cancer-related fatigue, our meta-analysis has more strengths than the previous meta-analysis. First and foremost, apart from cancer-related fatigue, the current meta-analysis also evaluated psychological variables, quality of sleep, and QoL. Moreover, we categorized psychological status into negative and positive aspects, which let us fully know that MBSR improves an individual's health status by simultaneously improving positive psychological states (i.e., the level of mindfulness and self-efficacy) and relieving negative psychological states (i.e., the level of anxiety, depression, and psychological distress). Second, this meta-analysis also used the GRADE system to rate the levels of evidence, which greatly facilitated clinical decision-making. Third, more eligible studies were included in our meta-analysis to greatly increase the statistical power. Although most included studies reported beneficial results to the MBSR program, the insufficient sample size greatly decreased the statistical power of the findings. Specifically, the sample size of individual studies ranged from 36 to 378, and more than 94% of eligible studies involved a sample size of <200. As stated previously, a total of 1,680 patients were accumulated to significantly increase the statistical power of this meta-analysis. Therefore, more reliable and robust results could be generated from the current meta-analysis compared with previous individual studies. Fourth, distress has been regarded as the sixth vital sign in the care of cancer persons (Stapleton et al., 2017; Fitch et al., 2018); however, the current meta-analysis found that limited studies evaluated the effect of the MBSR program on psychological distress of patients with lung cancer, which provides valuable implications for designing the future study. More importantly, this meta-analysis revealed that most studies were dedicated to evaluating the effectiveness of the MBSR program in physical and psychological wellbeing, but few studies tried to elucidate the potential mechanisms of the MBSR program in improving physical and psychological wellbeing. Therefore, future studies should be designed to clarify the possible mechanisms of the MBSR on different clinical outcomes from multiple perspectives.

Generally, the psychosomatic balance may be a moderator of psychological well-being adjustment in patients with cancer (Bărbuș et al., 2017). As a result, people may suffer from significant symptom burden, such as cancer-related fatigue

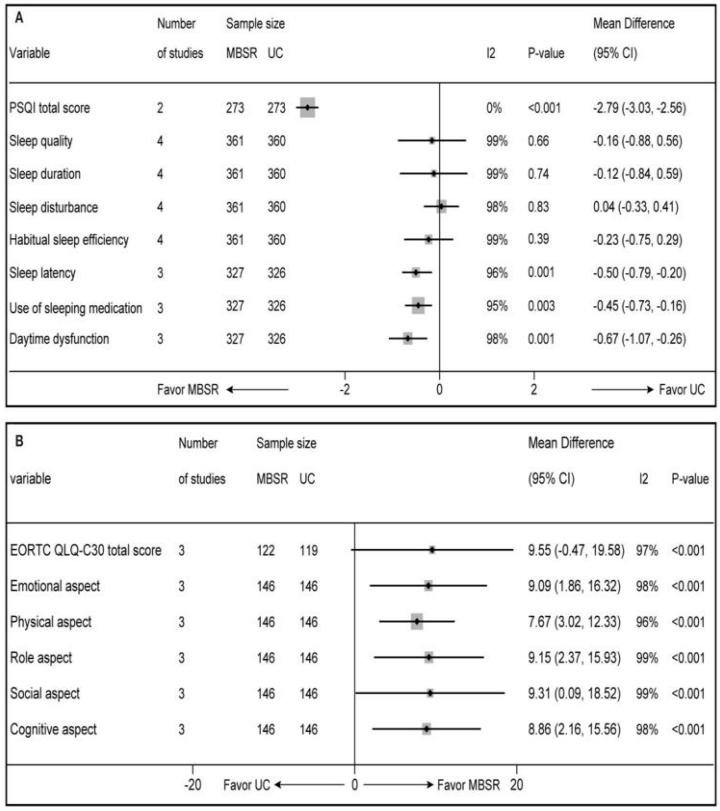

FIGURE 4 | Forest plot of comparative effectiveness between MBSR program and UC in terms of quality of sleep **(A)** and QoL **(B)**. MBSR, mindfulness-based stress reduction; UC, usual care; PSQI, Pittsburgh sleep quality index; EORTC QLQ-C30, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire.

(Besika et al., 2021) when internal (e.g., confirmation of the diagnosis of cancer) or external (e.g., anticancer treatment) stressors destructed psychosomatic balance. Then, people may suffer from a great reduction in psychological wellbeing and QoL (Zhang et al., 2019). According to the Mindful Coping Model (Garland et al., 2009), it is not surprising to the benefits of the MBSR program on psychological wellbeing, quality of sleep, and QoL. Studies have revealed that mindfulness-based interventions have a positive impact on symptom burden and psychological outcomes in patients with cancer (Rouleau et al., 2015). Specifically speaking, when patients suffer from destructive effects resulting from both external and internal stressors, the MBSR program initiates psychological adjustment to trigger positive psychological sources (positive reappraisal) (Jeffers et al., 2019), which may greatly dilute the destructive effects of stressors (Galante et al., 2021) and then restore patient's psychosomatic balance. As a result, patients' health outcomes would be significantly improved. As an example, studies have suggested that the MBSR program greatly decreased patients' symptom burden (physical wellbeing) and improved patients' psychological wellbeing and QoL (Zimmaro et al., 2020; Kim et al., 2021). Moreover, empirical studies suggested that the MBSR program also improved patients' treatment adherence and then enhanced the anticancer treatment effects, as well as improved physical status, psychological wellbeing, and QoL (Cillessen et al., 2020). According to the "Mindful Coping Model" and findings from empirical studies, we, therefore,

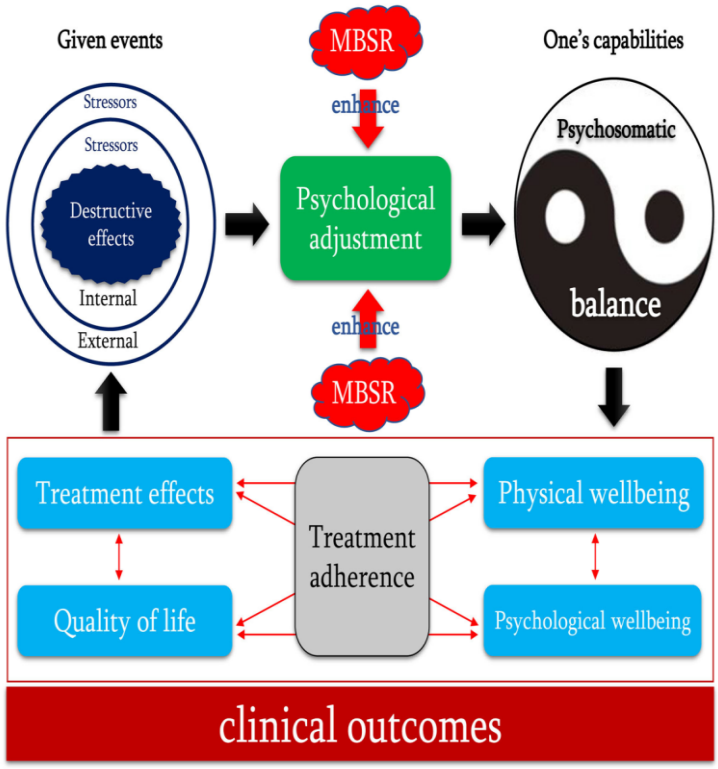

FIGURE 5 | The hypothetical causal pathway of the MSBR program for improving psychological outcomes and QoL of lung cancer patients. MBSR, mindfulness-based stress reduction; QoL, quality of life. In this hypothetical causal pathway, the black unidirectional arrow indicated the causal relationship between two elements, and the red bidirectional arrow indicated the interrelationship of two elements. Destructive effects of stressors break a patient's psychosomatic balance by initiating negative psychological adjustment and then harming clinical outcomes. In contrast, implementation of the MBSR program may enhance positive psychological adjustment by triggering positive psychological sources (e.g., self-efficacy) to gradually restore the patient's psychosomatic balance and then improve clinical outcomes.

proposed the hypothetical causal pathway that argues for the role of the MBSR program in regulating lung cancer patients' psychological wellbeing (**Figure 5**). It is noted that these potential influence pathways of the MBSR program on the adjustment in psychological status are speculated from previously published studies. Therefore, definitive mechanisms of the MBSR program from different aspects should be further clarified in patients with lung cancer because this meta-analysis has revealed the effectiveness of the MBSR program on psychological outcomes.

To our knowledge, this is the first study that investigated the effectiveness of the MBSR program on psychological outcomes, quality of sleep, and QoL in patients with lung cancer with a meta-analysis technique, and several promising findings provide a valuable reference for developing the socio-psychological rehabilitation program of patients with lung cancer. However, we must acknowledge that several limitations may impair the robustness and reliability of our findings. First, we systematically searched several electronic databases, including PubMed, EMBASE, PsycINFO, Cochrane Library, CNKI, and Wanfang, to identify relevant studies; however, some potentially eligible studies may be missed from our literature retrieval because other databases, such as Web of Science and SCOPUS, were not searched. Second, the substantial variations in the intensity, frequency, and duration of the MBSR program across eligible studies may introduce heterogeneity, which also

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

may reduce the robustness of the pooled results. However, we utilized the random-effects model to conservatively estimate the effects of the MBSR program on psychological outcomes, quality of sleep, and QoL. Nevertheless, we still believe that it is essential to apply for a standard MBSR program in clinical practice to ensure interventional efficacy. Third, details of UC across studies were different, which also a potential source of introducing statistical heterogeneity. However, we defined five essential elements of UC protocol to ensure the similarity of various strategies, including dietary instruction, health education, rehabilitation excise, emotional counseling, and medication instruction. Fourth, the baseline status of patients with lung cancer was also different from one to another; however, subgroup analysis was not imposed due to limited data. Fifth, we could not quantitatively evaluate the impact of the MBSR program on the physical status because only one study reported this outcome. Sixth, most results of this meta-analysis were only supported by low to moderate evidence except for the quality of sleep. Therefore, attention should be specially paid to the interpretation of our findings. Seventh, we used the first version of the Cochrane risk of bias assessment tool for methodological quality assessment in this meta-analysis. However, a second version is being published, which should be cited in the future study.

CONCLUSION

The results of this meta-analysis suggest that the MBSR program is an effective psychological approach to relieve cancer-related fatigue, and negative emotional states, including anxiety and depression, psychological stress, and improving self-efficacy, mindfulness, and quality of sleep among patients with lung cancer. Therefore, it is worthy of being recommended to patients with lung cancer as part of their rehabilitation protocol. Certainly, future studies are warranted to further investigate the effects of the MBSR program on psychological distress, level of mindfulness, and QoL because these three outcomes are only supported by low evidence. Moreover, the impact of the MBSR program on the psychological states should also be investigated in future studies because it was evaluated by only one study.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding authors.

AUTHOR CONTRIBUTIONS

Conception and design: XT and MJ-H. Administrative support: XT, G-HC, and MJ-H. Provision of study materials or patients: XT and L-JY. Collection and assembly of data: XT, L-JY, and C-S-SL. Data analysis and interpretation: XT, L-JY, LG, CP, and G-HC. Manuscript writing and final approval of manuscript: All authors. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2022.901247/full#supplementary-material

Supplementary Figure 1 | Risk of bias of each eligible study. Green (+), yellow (?), and red (–) circle represents "low," "unclear," and "high" risk of bias, respectively.

Supplementary Table 1 | Search strategies of targeted English databases.

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

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Article 8

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Original Article

Efficacy and mechanisms of 4-week MBSR on psychological distress in lung cancer patients: A single-center, single-blind, longitudinal, randomized controlled trial

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ABSTRACT

Objective: This study aimed to evaluate the efficacy of a 4-week mindfulness-based stress reduction (MBSR) program on psychological distress in patients with lung cancer and elucidate its mechanisms.
Methods: This single-center, single-blinded, longitudinal, randomized controlled trial was conducted on 175 patients with lung cancer randomly allocated to a 4-week MBSR or a waiting-list group. The efficacy and mechanisms of the 4-week MBSR program were evaluated by outcome measures at preintervention (T0), the immediate postintervention (T1), 1 month (T2), and 3 months (T3). We analyzed the collected data using the per-protocol set principle, independent sample t-test, repeated measure analysis of variance, and structural equation modeling.
Results: The 4-week MBSR program significantly alleviated psychological distress ($F = 15.05$, $P < 0.001$), decreased perceived stigma ($F = 8.260$, $P = 0.005$), improved social support ($F = 16.465$, $P < 0.001$), and enhanced mindfulness ($F = 17.207$, $P < 0.001$) compared with usual care at T1, T2, and T3. All variables significantly changed over time except for copying style ($P = 0.250$). The changes in social support, mindfulness, and perceived stigma mediated the efficacy of the 4-week MBSR program on psychological distress ($\beta = -0.292$, $P = 0.005$; $\beta = -0.358$, $P = 0.005$).
Conclusions: This study shows the benefits of the MBSR program for psychological distress, social support, mindfulness, and perceived stigma in patients with lung cancer. Also, it elucidates the mechanisms by which the MBSR program alleviates psychological distress by improving social support, enhancing mindfulness, and decreasing perceived stigma. The findings provide insights into applying the MBSR program to reduce psychological distress among patients with lung cancer.

Introduction

Lung cancer remains the first reason of cancer-related death worldwide, accounting for approximately 18% of all cancer deaths.[1] In China, according to the statistics published in 2022, lung cancer ranked first in incidence and cancer-related mortality, with new cases of 828,100 and cancer-related deaths of 657,000.[2] Patients with cancer will suffer from various psychological problems except for various physical symptoms (eg, fatigue and shortness of breath) due to cancer diagnosis and anticancer treatment, especially psychological distress.[3,4] Psychological distress will exist throughout the cancer trajectory,[5] having different prevalence across studies, cancers, and countries,[6] with a range from 20% to 58%.[7–10] Compared with other cancers, lung cancer was associated with the highest psychological distress prevalence,[11,12] varying from 17.0% to 73.0%.[13–15] In addition, a recent meta-analysis reported a mean prevalence of 48.3% of psychological distress in Chinese patients with lung cancer .[16]

Distress refers to "a multifactorial and unpleasant emotional experience, involving changes in psychological, social, spiritual, and physical aspects," according to the definition given out by the National

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UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Comprehensive Cancer Network (NCCN) guideline.[17] Patients and oncologists prefer the term "distress" because it is less stigmatizing; therefore, the NCCN guideline panel used "distress" rather than "psychological distress."[18] However, both terms are used interchangeably in the literature. Clinically significant psychological distress is associated with a range of adverse consequences,[17] such as interruption of anticancer treatment[19–21], prolonged hospital stay,[22] higher suicidal risk,[23] poor quality of life,[14,24] and higher risk of mortality.[25,26] Moreover, a previous study also evidenced that psychological distress can accelerate the growth of tumor cells.[27] Therefore, regular and timely screening of psychological distress among patients with cancer is critical because it has been recognized as the sixth vital sign.[17,28] Indeed,it is critical to alleviate it after early and precise detection of psychological distress.

Currently, psychological interventions have been demonstrated efficacy in improving the psychological well-being of patients with cancer.[29–31] Among the available psychological interventions, mindfulness-based stress reduction (MBSR), initially developed by Kabat-Zinn et al,[32] has been widely applied in cancer settings[31,33] and might also the best psychological intervention to relieve cancer-related fatigue.[34] Based on previously published evidence,[35–37] the practice of mindfulness can guide participants purposefully pay attention to the present moment and nonjudgmentally monitor the unfolding of experiences moment by moment, thus having profound benefit via the mind–body connection. The standard MBSR program comprises an 8-week psychoeducational course and four meditative techniques, including sitting meditation, body scan, gentle Hatha yoga, and walking meditation.[32,36,38] Studies have demonstrated the effectiveness and safety of MBSR program on psychosocial well-being and quality of life.[31,33,39,40] Currently, several studies have initially investigated the role of MBSR program in patients diagnosed with lung diseases, such as lung cancer[41,42] and interstitial lung diseases.[43,44] Furthermore, our meta-analysis further demonstrated the positive impact of the MBSR program on psychological states in patients with lung cancer.[45] However, a definitive conclusion regarding the efficacy of the MBSR program for psychological distress has not obtained and should be further investigated in future studies with larger sample sizes.

Although a previous study attempted to explore the efficacy of MBSR program on psychological distress from three perspectives, including mindfulness skills, self-compassion, and rumination,[42] the exact psychosocial mechanisms by which MBSR program alleviates psychological distress remain unclear. Previous studies have revealed that several psychosocial factors in patients with cancer are associated with psychological distress, such as social support,[46] perceived stigma,[47] perceived stress,[48] intrusive thoughts,[49] symptom burden,[49] type D personality,[49] coping style,[50] self-esteem,[51] mindfulness,[52,53] and illness perception.[54,55] In addition, our previous studies explicitly investigated the roles of social support, perceived stigma, perceived stress, coping styles, self-esteem, mindfulness, and illness perception in the development of psychological distress in patients with lung cancer.[15,56–58] However, it remains unclear which pathways may mediate the interventional effects of the MBSR program on psychological distress in patients with lung cancer.

Therefore, based on currently available evidence, we hypothesized that (a) a 4-week MBSR program could alleviate psychological distress in patients with lung cancer and (b) by affecting social support, coping style, self-esteem, mindfulness, perceived stress, perceived stigma, and illness perception.

Methods

Study design

The present study was a single-center, single-blinded, longitudinal, randomized, controlled, parallel trial, including a 4-week MBSR program group and a waiting-list group. We recruited eligible participants from a hospital in southwest China between January 1 and September 30, 2021.

Data collection

We designed a face-to-face questionnaire survey to collect data, administered by a trained research nurse at three time points (Fig. 1): baseline (T0), the immediate postintervention (T1), 1 month postintervention (T2), and 3 months postintervention (T3).

Sample size

We estimated the sample size using psychological distress as the main effect indicator for this study. According to our previous meta-analysis,[45] the MBSR program was associated with an effect size of 0.418, which was estimated based on the pooled result of psychological distress. Therefore, we estimated a theoretical sample size of 75 cases to ensure a statistical power of 80.0%. After considering a 20% dropout rate, 90 patients were calculated and then randomized to the 4-week MBSR or the waiting-list group. We used the G*Power software (version 3.1) to estimate the sample size.

Participant criteria

We selected potential participants according to the following inclusion criteria: (a) cytological or histological diagnosis of lung cancer; (b) age ≥18 years; (c) patients with proven clinically significant psychological distress or at high risk of suffering from psychological distress; (d) known their diagnosis and were willing to participate in this study; and (e) able to read, write, and speak Chinese.

Exclusion criteria included: (a) a concurrent diagnosis of other cancers or psychiatric disorders; (b) a history of suicide attempts; (c) participation in any other psychosocial interventions within 3 months before enrollment; (d) prior experience with mindfulness-based interventions (MBIs); and (e) physical or cognitive (< 26 on the Mini-Mental State Examination) impairments hampering participation in the 4-week MBSR program or completion of questionnaires. Dropout criteria included: (a) unable to complete the intervention and (b) loss to follow-up.

Recruitment

The trained research nurses enrolled participants from the respiratory and medical oncology inpatient departments of a general hospital in southwest China at patient visits. Trained research nurses assessed their eligibility, introduced the purpose of the study, and explained research content to potential participants and ensured that participants voluntarily participated in this study.

Randomization, allocation concealment, and blinding

After signing a written informed consent, eligible participants formally participated in this study. We first conducted a baseline survey of all participants in this study. Then, we randomly assigned participants to a 4-week MBSR or waiting-list group using random numbers generated by SPSS software (version 22.0). An independent research nurse used sealed and opaque envelopes for assignments. We invited independent psychologists qualified in the MBSR program to conduct a 4-week MBSR program for participants in the experimental group. Since all participants have been informed of the detailed processes of this study, it is not possible to blind participants. However, outcome assessments were blinded because independent staff analyzed all outcomes.

Interventions

Experimental group

Participants in the experimental group received both usual care and a 4-week MBSR program. In this study, we selected a 4-week MBSR program as an intervention according to our meta-analysis[45] because

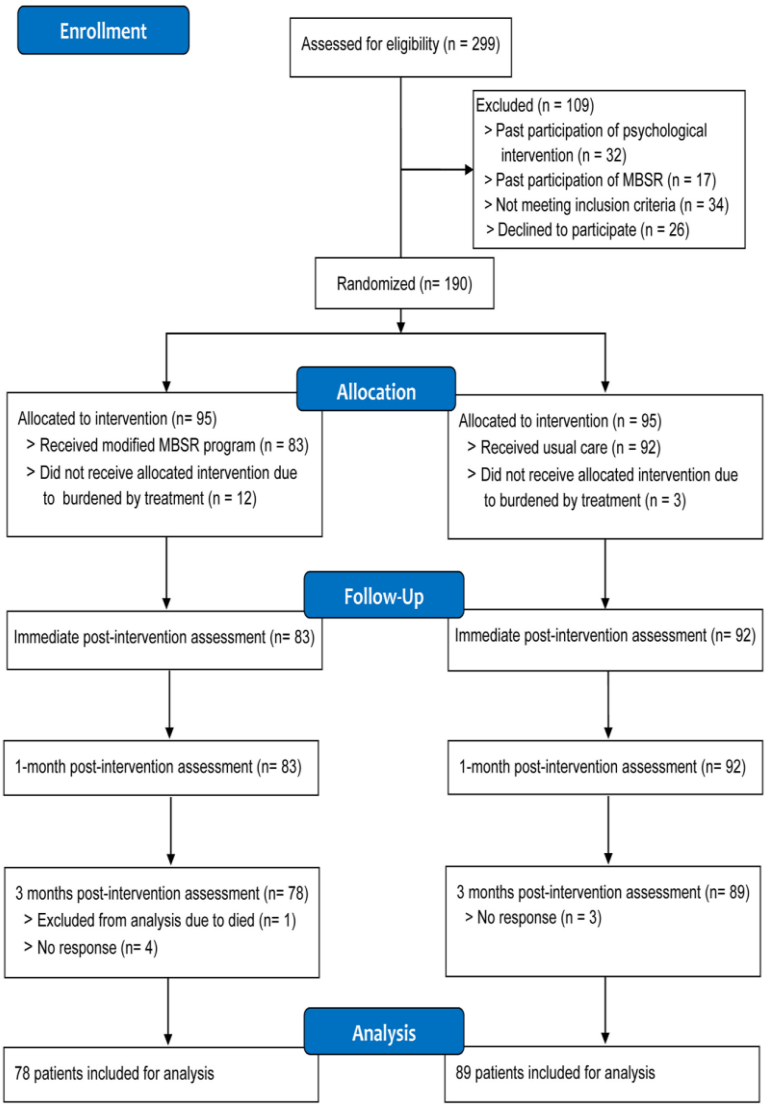

Fig. 1. The Consolidated Standards for Reporting Trials (CONSORT) flow diagram of participant recruitment.

patients with lung cancer usually have a relatively short median survival time and fast deterioration in physical health.[59] During this 4-week MBSR program, all participants in the experimental group practiced MBSR under the guidance and supervision of a psychologists qualified as mindfulness trainer. The details of this 4-week program were as follows: 10-min explanation and meditation in the first week, 10-min walking meditation in the second week, 10-min breathing meditation in the third week, and 20-min experience sharing in the fourth week. Details of each session in this 4-week MBSR program are summarized in Table S1. Participants were supervised to daily practice at home by psychologists twice weekly using telephone or WeChat (a popular social media in China).

Waiting-list group

Participants in the waiting list group first received usual care, including dietary instruction, health education, rehabilitation excise, emotional counseling, and medication instruction. Following the conclusion of this study, these participants were invited to voluntarily

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Table 1
Demographic and clinical characteristics of the patients ($N = 175$).

Variable	Experimental ($n = 83$)	Control ($n = 92$)	t/χ^2	*P*-value
Gender			0.059*	0.809
Male	52	56		
Female	31	36		
Age, years	58.98 ± 9.72	59.90 ± 8.72	0.664#	0.507
Education			3.086*	0.214
Primary school or below	15	26		
Middle and high school	57	52		
College and above	11	14		
Occupation			6.726*	0.081
No work	42	38		
Working	8	17		
Retire	30	37		
Marital status			1.128*	0.569
Single	1	0		
Married	80	90		
Divorced/widowed	2	2		
Residence			0.938*	0.333
City	52	51		
Rural areas	31	41		
Medical insurance			1.248*	0.264
Self-payment	3	1		
Residents' basic health insurance	80	91		
Yearly income, yuan			5.080*	0.166
< 20,000	3	9		
20,001-50000	25	17		
50,001-100,0000	38	46		
> 100,000	17	20		
Family history of LC			1.040*	0.308
Yes	2	5		
No	81	87		
Smoking history			0.217*	0.641
Yes	39	40		
No	44	52		
TNM tumor stage			3.055*	0.383
I	10	15		
II	22	15		
III	18	20		
IV	33	42		
Metastases			1.361*	0.506
Yes	48	48		
No	35	43		
Comorbidities			2.525*	0.112
Yes	15	26		
No	68	66		
Pain degree			4.102*	0.251
No pain	54	65		
Mild	15	13		
Moderate	13	9		
Severe	1	5		

LC, lung cancer; TNM, tumor-node-metastasis. *χ^2, #*t*.

receive a 4-week MBSR program and were provided with videos and materials for the intervention.

Demographics

At baseline, we used a self-designed data collection sheet to collect the demographic and clinical characteristics, including demographic information (gender, age, education level, occupation, marital status, residence, medical insurance, yearly income, family history of lung cancer, and smoking history) and clinical characteristics (TNM tumor stage, metastases, comorbidities, and pain degree).

Outcome measures

Psychological distress

We used the distress thermometer (DT) to measure psychological distress on an 11-point thermometer scale from 0 to 10 in this study, and 0 and 10 indicate no distress and extreme distress, respectively.[17] The reliability and validity of DT across different settings have been extensively tested.[60] Previous empirical studies indicated a score of ≥ 4 effectively confirms clinically significant psychological distress.[60,61] A score of 4 was also demonstrated as the cut-off value for defining clinically significant psychological distress in Chinese cancer populations.[60] Meanwhile, we used the predictive algorithm, which was previously developed by our team,[62] to identify those patients at high risk of psychological distress. In this predictive algorithm, a score of ≥ 66 indicates that patients have a high risk of suffering from psychological distress. We selected patients with lung cancer who scored ≥4 in DT or ≥ 66 in the predictive algorithm to participate in this study.

Social support

The 12-item Multidimensional Scale of Perceived Social Support was used to measure social support from three aspects, including family, friends, and significant others, on a 7-point Likert scale (1 indicates very strongly disagree but 7 represents very strongly agree).[63] A previous study tested the psychological properties of Multidimensional Scale of Perceived Social Support and reported coefficient alpha values of subscales ranging from 0.81 to 0.98.[63] The Chinese version had a reliability of 0.90.[64] We used the Chinese version in this study, which had an overall Cronbach's alpha coefficient of 0.818, 0.785, 0.835, and 0.701 at T0, T1, T2, and T3, respectively, to measure social support.

Coping style

The 20-item Medical Coping Modes Questionnaire was used to evaluate the coping styles, including confrontation, avoidance, and giving up coping, on a linear 4-point Likert scale from 1 to 3.[65] Shen et al[66] validated the Chinese version of the Medical Coping Modes Questionnaire, reporting a Cronbach's alpha coefficient of more than 0.60 for three subscales. We used the Chinese version in this study, which had an overall Cronbach's alpha of 0.561, 0.542, 0.753, and 0.537 at T0, T1, T2, and T3, respectively, to measure coping style.

Self-esteem

The 10-item Rosenberg Self–Esteem Scale was developed to measure global self-esteem, having a Cronbach's alpha of 0.88.[67] A higher score indicated a higher level of self-esteem.[67] The Chinese version of the Rosenberg Self-esteem Scale has been validated by Wu et al[68] and has been extensively used in China.[69–71] We used the Chinese version in this study, which had an overall Cronbach's alpha coefficient of 0.809, 0.774, 0.750, and 0.775 at T0, T1, T2, and T3, respectively, to measure self-esteem.

Mindfulness

The 39-item Five Facet Mindfulness Questionnaire was first developed by Baer et al[72] to assess mindfulness from five facets on a 5-point Likert scale: observing, describing, acting with awareness, non-judging, and non-reacting.[72] The original Five Facet Mindfulness Questionnaire has been translated into Chinese[73] with good psychometric properties. In addition, a recent study continued to confirm the psychometric properties of the Chinese version in patients with cancer using a Bayesian structural equation modeling approach.[74] We used the Chinese version in this study, which had an overall Cronbach's alpha coefficient of 0.644, 0.704, 0.731, and 0.749 at T0, T1, T2, and T3, respectively, to measure mindfulness.

Perceived stress

The 10-item Perceived Stress Scale was used to measure perceived stress on a linear 5-point Likert scale from 0 to 4.[75] A higher score represents a greater stress level. The 10-item Chinese version has been validated and got a Cronbach's alpha of 0.619.[76] We used the Chinese version in this study, which had an overall Cronbach's alpha coefficient of 0.614, 0.608, 0.699, and 0.682 at T0, T1, T2, and T3, respectively, to measure perceived stress.

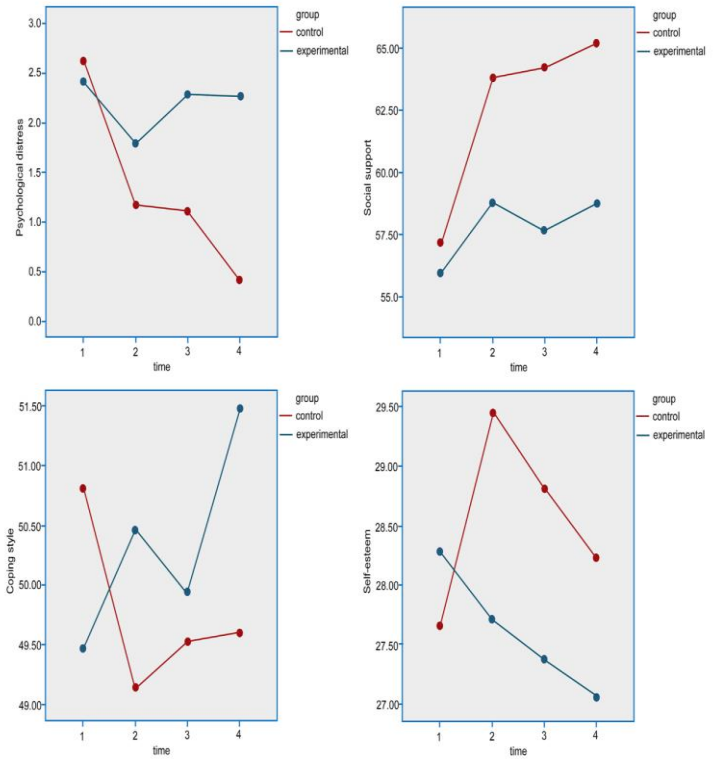

Fig. 2. The changes of scores in psychological distress, social support, coping style, and self-esteem before and after intervention between the two groups.

Perceived stigma

The 31-item Cataldo lung cancer stigma scale was used to measure perceived stigma, categorized into stigma and shame, social isolation, discrimination, and smoking, on a linear 0- to 4-point.[77] A higher score indicates a higher level of perceived stigma. Yu et al[78] translated the original version to Chinese and reported an overall Cronbach's alpha of 0.932. In addition, four subscales had a Cronbach's alpha of 0.799, 0.922, 0.863, and 0.803, respectively. This study used the Chinese version of the Cataldo lung cancer stigma scale, which had an overall Cronbach's alpha coefficient of 0.863, 0.717, 0.709, and 0.730 at T0, T1, T2, and T3, respectively, to measure perceived stigma.

Illness perception

Weinman et al[79] first developed the Brief Illness Perception Questionnaire to measure illness's emotional and cognitive representations on a continuous linear 0 to 10 point. A higher score represents a more negative illness perception. Broadbent et al[80] have shown a good test–retest reliability and predictive and discriminant validity of the Brief Illness Perception Questionnaire. Xue et al[81] translated the original version to Chinese, and it has been widely used in China.[82,83] We used the Chinese version in this study, which had an overall Cronbach's alpha coefficient of 0.657, 0.676, 0.643, and 0.630 at T0, T1, T2, and T3, respectively, to measure illness perception.

Statistical analysis

We used descriptive statistics to present participants' demographics. The Kolmogorov–Smirnov tests showed that, in addition to age and risk scores in the prediction algorithm, the distribution of scores for psychological distress, social support, coping style, self-esteem, mindfulness, perceived stress, perceived stigma, and illness perception was abnormal at most time points. However, we preferred to use mean ± standard deviation (SD) for all continuous variables because (a) parametric tests are more powerful than nonparametric tests, (b) the results of the Kolmogorov–Smirnov test are not necessarily true, especially for relatively large sample size,[84] and (c) according to kurtosis and skewness values, our data followed a normal distribution.[85] Therefore, we used the Chi-square test and independent-sample t-test to compare the variables between the two groups. However, repeated measure analysis of variance was used to analyze changes or differences of variables between the groups (experimental vs. waiting-list groups), within-group (time), and interaction (group*time) effects.

Furthermore, we used structural equation modeling to elucidate the mediating role of significant variables that showed significant differences in the efficacy of a 4-week MBSR program on psychological distress between the two groups after intervention We first defined the interventions used in the experimental and waiting-list groups as dummy variables using 1 (experimental group) and 0 (waiting-list group),

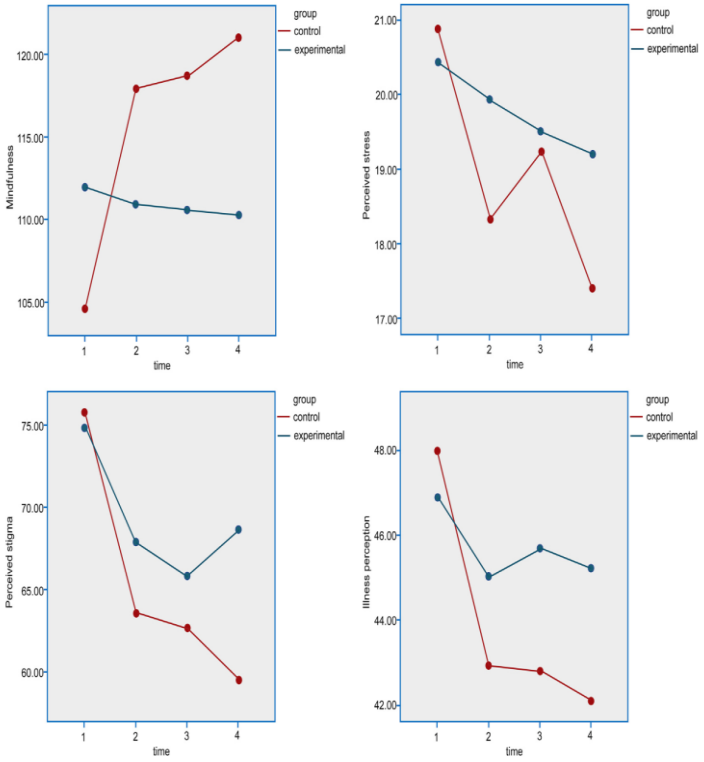

Fig. 3. The change of scores in mindfulness, perceived stress, perceived stigma, and illness perception before and after intervention between the two groups.

respectively. In addition, we adjusted all variables obtained from post-intervention using the baseline value.[86]

We employed IBM Statistical Package for Social Sciences (SPSS) version 22.0 and Amos version 21.0 for statistical analysis.

Ethical consideration

This study strictly followed the statement of the Declaration of Helsinki. The ethical institutional board of the hospital approved this trial (Approval No. CZLS2021183-A), and we also registered the study protocol at the Chinese Clinical Trials Registry (Registration No. ChiCTR2100041899). Before participating in this study, all eligible participants signed informed consent and were freely allowed to withdraw from this study.

Results

Recruitment

As depicted in the CONSORT flowchart (Fig. 1), 299 patients with lung cancer were eligible for evaluation, but 190 patients who were eligible agreed to participate in this study. Of the 190 patients, 95 were randomly assigned to the experimental or waiting-list groups. However, 12 and 3 patients received no interventions in the experimental and waiting-list groups, respectively. One hundred seventy-five patients completed the study and underwent T1 and T2 assessments; however, at the T3 assessment, 5 and 3 patients were missed from the experimental and waiting-list groups, respectively. There was no statistically significant difference in the lost participants between the two groups at T3 ($P = 0.480$).

Participants' characteristics

The mean age of the participants in the experimental and waiting-list groups was 58.98 (SD = 9.72) and 59.90 (SD = 8.72), respectively, without significant difference ($P = 0.507$). Of the 175 patients analyzed, most patients were male (61.7%) and lived in the urban areas (58.9%). Most patients were married (97.1%) and had low education (85.7% with a middle-high school education or less). Most of the patients paid medical costs using resident basic health insurance (97.7%) and had no family history of lung cancer (96.0%). Still, most patients were pain free (68.0%), had no comorbidity (76.6%), and were at stage III or IV. There remaining demographic and clinical data of the two groups were no significantly different ($P > 0.05$), as presented in Table 1.

The effect of the intervention on outcomes

The scores of seven variables between the two groups were not significantly different ($P > 0.05$) at the baseline except for the score in the mindfulness, which was significantly higher in patients in the waiting-list group than patients in the 4-week MBSR program group ($t = 4.746$, $P < 0.001$). After the intervention, as shown in Figs. 2 and 3, apart from the coping style ($F = 1.386$, $P = 0.250$), the remaining variables changed significantly over time ($P < 0.05$). As presented in Table 2, the 4-

Table 2
A comparison of the outcome variables between the two groups before and after the intervention.

Variable	T0 (mean ± *SD*)		T1 (mean ± *SD*)		T2 (mean ± *SD*)		T3 (mean ± *SD*)		F1 (*P*)	F2 (*P*)	F3 (*P*)
	Experimental (n = 83)	Control (n = 92)	Experimental (n = 83)	Control (n = 92)	Experimental (n = 92)	Control (n = 83)	Experimental (n = 78)	Control (n = 89)			
Risk score	67.84 ± 24.42 *t* = −0.350 *P* = 0.727	66.39 ± 29.90	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.	n.a. n.a. n.a.
Psychological distress	2.70 ± 2.13 *t* = −0.617 *P* = 0.537	2.45 ± 2.21	1.16 ± 1.57 *t* = −2.519 *P* = 0.012	1.78 ± 1.74	1.07 ± 1.53 *t* = −6.278 *P*=<0.001	2.27 ± 1.27	0.43 ± 1.08 *t* = −9.580 *P*=<0.001	2.26 ± 1.25	56.245 (< 0.001)	15.051 (< 0.001)	37.762 (< 0.001)
Social support	57.31 ± 7.17 *t* = −0.170 *P* = 0.865	55.66 ± 12.32	64.02 ± 7.34 *t* = −3.752 *P* < 0.001	58.80 ± 9.38	64.48 ± 8.35 *t* = −4.865 *P* < 0.001	57.73 ± 9.50	65.30 ± 6.42 *t* = −4.769 *P* < 0.001	58.81 ± 9.11	33.911 (< 0.001)	16.465 (< 0.001)	8.598 (< 0.001)
Coping style	50.77 ± 4.89 *t* = −1.702 *P* = 0.091	49.54 ± 4.50	49.10 ± 3.51 *t* = −1.486 *P* = 0.137	50.48 ± 4.93	49.47 ± 3.73 *t* = −0.203 *P* = 0.839	50.02 ± 5.23	49.56 ± 5.25 *t* = −2.372 *P* = 0.018	51.60 ± 4.15	1.386 (0.250)	1.515 (0.220)	4.995 (0.005)
Self-esteem	27.72 ± 4.04 *t* = −0.754 *P* = 0.451	28.17 ± 5.00	29.59 ± 4.34 *t* = −3.018 *P* = 0.003	27.67 ± 4.00	29.00 ± 4.53 *t* = −2.765 *P* = 0.006	27.44 ± 3.91	28.30 ± 4.70 *t* = −2.419 *P* = 0.016	27.14 ± 4.19	4.894 (0.006)	2.425 (0.121)	9.181 (< 0.001)
Mindfulness	104.57 ± 10.87 *t* = −4.746 *P* < 0.001	111.97 ± 9.03	117.54 ± 9.78 *t* = −4.540 *P* < 0.001	110.88 ± 7.71	118.30 ± 10.05 *t* = −5.138 *P* < 0.001	110.59 ± 6.98	120.90 ± 11.20 *t* = −6.568 *P* < 0.001	110.31 ± 6.60	43.216 (< 0.001)	17.207 (< 0.001)	64.963 (< 0.001)
Perceived stress	20.95 ± 4.64 *t* = −1.099 *P* = 0.272	20.48 ± 4.65	18.35 ± 3.86 *t* = 3.106 *P* = 0.002	19.97 ± 2.95	19.23 ± 3.62 *t* = −1.206 *P* = 0.228	19.55 ± 3.06	17.49 ± 3.61 *t* = 3.498 *P* = 0.001	19.26 ± 3.03	17.365 (< 0.001)	3.755 (0.054)	5.405 (0.002)
Perceived stigma	75.83 ± 15.14 *t* = −0.571 *P* = 0.568	75.22 ± 16.06	63.57 ± 8.27 *t* = −4.309 *P*=<0.001	67.79 ± 8.87	62.55 ± 7.51 *t* = −2.436 *P* = 0.016	59.50 ± 7.70	68.58 ± 9.10 *t* = 6.995 *P*=<0.001	86.42 ± 9.10	87.520 (< 0.001)	8.260 (0.005)	12.988 (< 0.001)
Illness perception	48.19 ± 7.81 *t* = −0.762 *P* = 0.434	46.98 ± 4.63	43.20 ± 7.00 *t* = 1.571 *P* = 0.118	45.00 ± 7.69	43.00 ± 7.49 *t* = −1.080 *P* = 0.280	45.62 ± 12.17	42.21 ± 7.20 *t* = −1.539 *P* = 0.124	45.13 ± 12.20	15.240 (< 0.001)	2.365 (0.126)	4.760 (0.009)

T0, baseline; T1, the immediate postintervention; T2, 1-month postintervention; T3, 3 months postintervention; *F1*, time effect; *F2*, group effect; *F3*, group*time effect; *SD*, standard deviation.

UNIVERSITAT ROVIRA I VIRGILI
PSYCHOLOGICAL DISTRESS IN CHINESE LUNG CANCER PATIENTS: PREDICTION, PSYCHOSOCIAL MECHANISMS, AND INTERVENTION
Xu Tian

Table 3
Path coefficient of variables in intervention mechanism analysis.

Pathway	*B*	95% *CI*	*P*
Total effects	−0.924		
Psychological distress (T1)	−0.274	−0.461 to −0.144	0.005
Psychological distress (T2)	−0.292	−0.434 to −0.715	0.005
Psychological distress (T3)	−0.358	−0.530 to −0.237	0.005
Direct effects	−0.274	−0.461 to −0.144	0.005
Psychological distress (T1)	−0.274		
Indirect effects	−0.650		
Psychological distress (T2)	−0.292	−0.434 to −0.175	0.005
Intervention → Psychological distress (T1) → Psychological distress (T2)	−0.274*0.886 = −0.243		
Intervention → Mindfulness (T1) → Mindfulness (T2) →Psychological distress (T2)	−0.141*0.415*0.844 = −0.049		
Psychological distress (T3)	−0.358	−0.401 to −0.236	0.005
Intervention → Psychological distress (T1) → Psychological distress (T2) → Psychological distress (T3)	−0.274*0.886*0.816 = −0.198		
Intervention → Mindfulness (T1) → Mindfulness (T2) → Perceived stigma (T3) → Psychological distress (T3)	−0.129*0.415*0.844**0.160 = −0.007		
Intervention → Mindfulness (T1) → Mindfulness (T2) → Psychological distress (T2) → Psychological distress (T3)	−0.141*0.415*0.844*0.816 = −0.040		
Intervention → Perceived stigma (T1) → Perceived stigma (T2) →Perceived stigma (T3) → Psychological distress (T3)	−0.403*0.768*1.639*0.160 = −0.081		
Intervention → Social support (T1) → Social support (T2) → Psychological distress (T3)	−0.132*0.264*0.827* = −0.029		
Intervention → Social support (T1) → Social support (T2) → Perceived stigma (T2) → Perceived stigma (T3) → Psychological distress (T3)	−0.052*0.264*0.827*1.639*0.160 = −0.003		

T1, immediate postintervention; T2, 1-month postintervention; T3, 3 months postintervention; *β*, standardized regression coefficients; *CI*, confidence interval.

week MBSR program significantly alleviated psychological distress ($F = 15.051$, $P < 0.001$), improved social support ($F = 16.465$, $P < 0.001$), enhanced mindfulness ($F = 17.207$, $P < 0.001$), and reduced perceived stigma ($F = 8.260$, $P = 0.005$) at immediate postintervention, 1-month postintervention, and 3 months postintervention. In addition, the difference in interventional effects between the two groups was statistically significant over time ($P < 0.05$).

Results of the mediating analysis

We only included three variables in the mediation analysis, including social support, mindfulness, and perceived stigma, according to predesigned criteria. After structural equation modeling and appropriate adjustment of the pathways between variables according to the modification index and empirical evidence, the model fitted our data better ($\chi 2/df = 3.451$, CFI = 0.893, TLI = 0.855, RMSEA = 0.122 [95% CI: 0.108–0.136]).

Overall, the effects of the 4-week MBSR program on psychological distress at T1, T2, and T3 were −0.274, −0.292, and −0.358, respectively. At the immediate postintervention (T1), the 4-week MBSR program alleviated psychological distress directly (β = −0.274, P = 0.005), not mediated by other variables. The effect of the 4-week MBSR program on mindfulness at T1 and T2 continued to help alleviate psychological distress at T2 (β = −0.049). The effects of the 4-week MBSR program on social support and mindfulness at T1 and T2 also continued to alleviate psychological distress at T3 by reducing perceived stigma at T2 and T3 (β = −0.039). The effect of the 4-week MBSR program on perceived stigma at T1, T2, and T3 also influenced psychological distress at T3 (β = −0.081). Moreover, there was a continuous effect between psychological distress from T1 to T3 (β = 0.886 from T1 to T2, β = 0.816 from T2 to T3), indicating that the 4-week MBSR program had a persistent effect on psychological distress (β = −0.198). The results of mediation analysis are summarized in Table 3, and the mechanism pathways are depicted in Fig. 4.

Discussion

In this study, we aimed to validate the interventional effects of a 4-week MBSR program on psychological distress in patients with lung cancer and to further elucidate the psychosocial mechanisms by which the program alleviates psychological distress. Our findings suggest that the 4-week MBSR program, as an effective psychological intervention, significantly alleviates the psychological distress. The 4-week MBSR program also improved patients' social support considerably, enhanced mindfulness, and reduced perceived stigma. Furthermore, the results of the structural equation modeling suggest that the 4-week MBSR program can exert an interventional effect by directly targeting psychological distress. Meanwhile, the 4-week MBSR program supports continuous interventional effects on psychological distress by indirectly affecting social support, mindfulness, and perceived stigma.

MBSR has been extensively used in cancer settings.[31,33] Currently, many meta-analyses[30,31,40,87,88] have demonstrated the benefits of MBSR program in improving the psychological well-being of patients with cancer. Furthermore, our recent meta-analysis confirmed that the MBSR program significantly diluted negative psychological states and enhanced positive psychological states. In this study, we further validated the beneficial role of the MBSR program in alleviating psychological distress in patients with lung cancer. Although it remains not entirely unclear why and how the MBSR program improves psychological well-being, previous studies[35–37] suggest that the practice of mindfulness instructs participants to deliberately focus on the present moment and monitor the unfolding of experiences all the time without passing judgment. As a result, participants experience profound benefits through the mind-body connection. Thus, it is plausible that patients with lung cancer experience significant alleviation in psychological distress, improvement in social support, enhancement in mindfulness, and reduction in perceived stigma following a 4-week MBSR program.

This study also showed that the MBSR program had a retained effect on psychological distress after ending the intervention through indirect

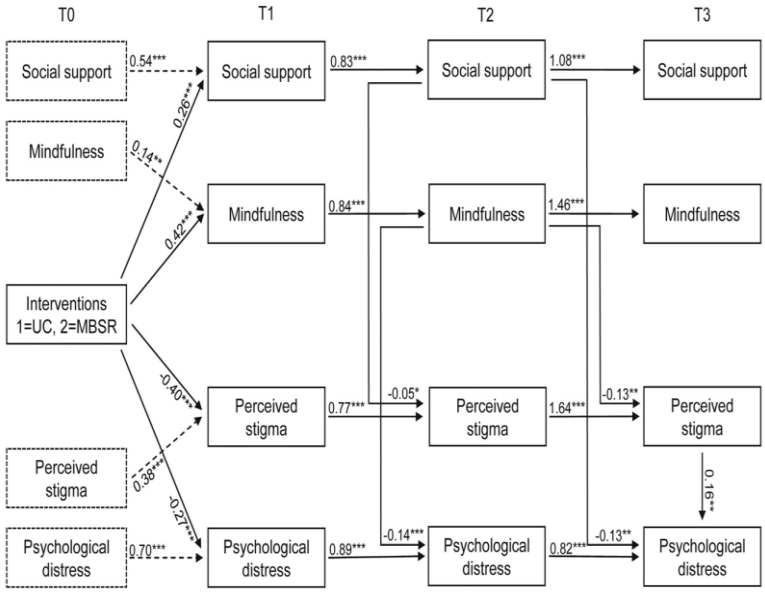

Fig. 4. Mechanism model of the 4-week MBSR program to alleviate psychological distress in patients with lung cancer. MBSR, mindfulness-based stress reduction.

effects of social support, mindfulness, and perceived stigma. Both mindfulness[89] and social support[90] are positive sources for copying with negative psychological states, and our previous studies have demonstrated the inverse association between mindfulness and social support and psychological distress.[15,56,58] In contrast, stigma, a negative emotional experience that includes isolation, rejection, degradation, and criticism due to undesirable conditions,[77] has been demonstrated to be a predictor of psychological distress in patients with lung cancer.[47] In general, psychosomatic balance plays a vital role in regulating the psychological well-being of patients with cancer.[91] Therefore, patients would suffer from significant physical and psychological problems when specific events (eg, cancer diagnosis) destroyed psychosomatic balance.[87]

According to the Mindful Coping Model,[92] we can easily explain why MBSR program can consistently affect psychological distress through social support, mindfulness, and perceived stigma. Specifically, the destructive effects of internal and external stressors (eg, cancer diagnosis, anticancer treatment, and symptom burden) can cause psychological distress in patients; however, the implementation of an MBSR program can initiate psychological adjustment to trigger or enhance the protective effects of positive sources (improvement in social support and enhancement in mindfulness) and weaken the harmful effects of negative sources (reduction in perceived stigma)[93] and may then significantly dilute the destructive impacts of stressors (alleviation in psychological distress).[94]

Strengths and limitations

Overall, our study obtained these valuable findings due to several strengths. First, we enrolled both patients with clinically significant psychological distress and those at high risk of psychological distress by applying both DT and the risk prediction algorithm we developed, which significantly expanded the applicability of our findings in clinical practice. Second, we estimated the theoretical sample size from our meta-analysis, which ensured the statistical power of our results. Third, we explored the intervention mechanisms of the 4-week MBSR program by determining the role of significant variables after the intervention, which benefited more simply revealing the active ingredients of the 4-week MBSR program. Fourth, all potential mediating variables included in the intervention mechanism analysis have been previously investigated for their role in the development of psychological distress, increasing the reliability of theoretical evidence. Finally, our study was also rated as high in methodological quality because it met the six Cochrane collaboration criteria for high-quality trials,[95] except that blinding participants due to the nature of the psychological intervention.

We cannot deny the fact that our study has several limitations. First and foremost, we used self-reported instruments to collect data, which may affect the accuracy of the results. Therefore, more objective tools need to be developed to measure these variables. Second, we recruited potentially eligible participants from only one hospital in southwest China due to the limited time. Therefore, we are unable to eliminate the adverse impact of selection bias and time constraints on our findings. As a result, adequately powered studies with more extended intervention and follow-up duration are warranted to demonstrate our findings. Third, we selected only those variables tested in our previous studies to explore possible mechanisms of the MBSR program on psychological distress. However, we did not consider those factors that we did not investigate previously. Therefore, more intervention mechanism analysis is needed to fully reveal the nature of MBSR program in alleviating psychological distress in patients with lung cancer. Fourth, we used a 4-week MBSR program with abbreviated sessions instead of a standard 8-week MBSR program in this study, which may have underestimated the intervention effect of the MBSR program due to inadequate duration of intervention. Therefore, future studies should further balance the interventional effects and applicability of the MBSR program in patients with lung cancer. More importantly, it is necessary to further investigate the interventional effects of the enhanced protocol with adequate sessions in future studies. Fifth, the mechanism model fitted our data relatively when we explored the intervention mechanism of the MBSR program to alleviate psychological distress, which limited the generalization of our results. Therefore, considering that limited participants were enrolled in our study, we

suggest future studies with larger sample sizes to further elucidate the intervention mechanism of the MBSR program in alleviating psychological distress. Sixth, we chose brief versions of the scales to ensure the quality of the data collection process in this study; however, the average time for a patient to complete all scales was still up to 45 min. Although no patients were excluded for failing to complete scales, we could not eliminate the psychological burden caused by the need to complete multiple scales. Finally, in this study, we did not consider the impacts of sleep, fatigue, and exercise on the psychological status of patients with lung cancer. Therefore, we suggest future studies to address this limitation.

Conclusions

In summary, the present study validated the intervention effect of the MBSR program in alleviating psychological distress, and provided relatively robust and reliable evidence for clinical practitioners to integrate the MBSR program into usual care to improve psychological well-being of patients with lung cancer. Meanwhile, this study also suggested the positive effects of MBSR program on social support, mindfulness, and perceived stigma, which provided a reference for the application of MBSR program to improve clinical outcomes. Furthermore, this study revealed the direct impact of the MBSR program on short-term psychological distress. Additionally, it indicated the continuous effect of the MBSR program on psychological distress through social support, mindfulness, and perceived stigma.

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Author contributions

Conceived and designed the analysis: Xu Tian, Guihua Chen, María F. Jiménez Herrera.

Collected the data: Xu Tian, Zhongli Liao, Ling Tang.

Contributed data or analysis tools: Xu Tian, María F. Jiménez Herrera.

Performed the analysis: Xu Tian, Zhongli Liao, Lijuan Yi.

Wrote the paper: Xu Tian, Zhongli Liao, Guihua Chen, María F. Jiménez Herrera.

Declaration of competing interest

None declared.

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Ethics statement

This study was approved by the Clinical Research Ethics Board of the Chongqing University Cancer Hospital (Approval No. CZLS2021183-A).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2022.100151.

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Conclusions

In the current thesis, a total of 7 separate studies including 8 articles were performed to achieve two major goals. We therefore drawn a series of conclusions from these various studies, which are summarized below in order of (i) development and validation of screening tool, (ii) elucidation of possible psychosocial mechanisms of psychological distress, (iii) evidence-based evaluation of the efficacy of MBSR on psychological outcomes in lung cancer patients, and (iv) empirical evaluation of efficacy a 4-weeks MBSR on psychological distress in lung cancer patients.

i. In the first study, based on pre-selected sociodemographic and clinical variables, 6 independent variables are identified to be associated with clinically significant psychological distress in lung cancer patients, including educational level, residence, metastasis, pain degree, family history, and tumor, node, and metastasis stage. After combining these 6 independent variables into a prediction algorithm, an easy-to-use prediction tool with moderate accuracy is developed for early and accurately screening lung cancer patients at high risk of psychological distress.

ii. The second and third studies mainly aim to explore the association between social support and psychological distress in lung cancer patients, and these two studies consistently reveal that social support has significantly direct negative association with psychological distress. The second study further suggests that social support ameliorate psychological distress by enhancing confrontation

coping with cancer and enhancing perceived stress, while the third study further unfold that social support also affects psychological distress by indirectly affecting self-esteem. Furthermore, the third and fourth studies aim to unfold the association between mindfulness and psychological distress in lung cancer patients. Specifically, the third study reveals a significant direct association between mindfulness and psychological distress, and mindfulness also indirectly affects psychological distress through the chain mediating role of stigma and social support among lung cancer patients. However, the fourth study dose not support the significant direct association between mindfulness and psychological distress, but reveals that mindfulness can significantly affect psychological distress by indirectly affecting illness perception and perceived stress.

iii. In the sixth study, meta-analysis suggests that the MBSR program is an effective psychological approach to relieve cancer-related fatigue, and negative emotional states including anxiety and depression, psychological stress, and improving self-efficacy, mindfulness, and quality of sleep among lung cancer patients. Therefore, it's worthy of being recommended to lung cancer patients as part of their rehabilitation protocol. Certainly, future studies are warranted to further investigate the effects of the MBSR program on psychological distress, level of mindfulness, and QoL because these three outcomes are only supported by low evidence. Moreover, the impact of the MBSR program on the psychical state should also be investigated in future studies because it was evaluated by

only one study.

iv. The seventh study suggests that the 4-week MBSR program is effective in alleviating psychological distress, and provides relatively robust and reliable evidence for clinical practitioners to integrate the MBSR program into usual care to improve psychological well-being of lung cancer patients. Meanwhile, this study also suggests the positive effects of MBSR program on social support, mindfulness, and perceived stigma, which provides a reference for the application of MBSR program to improve clinical outcomes. Furthermore, this study reveals the direct impact of the MBSR program on short-term psychological distress. Additionally, it indicates the continuous effect of the MBSR program on psychological distress through social support, mindfulness, and perceived stigma.

Limitations

As introduced previously, this thesis performed a total of 7 separate studies to yield additional knowledge, with the aim of bridging the gaps between currently available evidence and clinical practice. Although after completing these studies, a series of positive findings have been obtained, it must be pointed out that the current thesis also has some limitations, which are summarized below according to the order of drawing four major conclusions.

i. In the first study, two main limitations must be further interpreted. First, psychosocial factors were not included even though 19 sociodemographic and clinical factors have been considered. However, it remains an issue that inclusion of psychological factors may greatly decrease the feasibility of predictive algorithm because psychological states will be assessed with various complex questionnaires. Second, external validation was not performed after developing the predictive algorithm. However, we further evaluated the accuracy of our predictive algorithm through calculating the coincidence rate.

ii. In these four studies exploring possible psychosocial mechanisms of psychological distress in lung cancer patients, the first and foremost limitation is that the nature of cross-sectional, observational, descriptive design limits the ability of establishing causality between the proposed variables. We therefore suggested future longitudinal study to prospectively clarify the association of these

variables. Second, we used convenience sampling method to enroll potentially eligible patients, which impaired the representativeness of the sample. Therefore, we suggest future studies with random sampling method to further demonstrate the relationships of all variables. Third, we assessed these psychosocial outcomes using self-reported questionnaires in the present study. So, the results may be inflated due to subjective bias from participants and investigators. Additional studies considering physiological assessment and ecological momentary assessment should be performed. Fourth, we estimated the theoretical sample size according to the number of variables, rather than performing an estimation based on acceptable statistical power. Fifth, the relationships revealed in the four studies may be specific to all lung cancer patients regardless of cancer treatment modalities and the level of symptom burden and not applicable to other populations. Additional studies with samples of greater diversity should be performed to determine these relationships. Sixth, all patients were recruited from a single hospital at a single city and the sample size was relatively small, therefore the generalizability of the study is questionable.

iii. We must acknowledge that several limitations may impair the robustness and reliability of pooled results in this meta-analysis. First, we systematically searched several electronic databases including PubMed, EMBASE, PsycINFO, Cochrane Library, CNKI, and Wanfang to identify relevant studies; however, some potentially eligible studies may be missed from our literature retrieval because

other databases such as Web of Science and SCOPUS were not searched. Second, the substantial variations in the intensity, frequency, and duration of the MBSR program across eligible studies may introduce heterogeneity, which also may reduce the robustness of the pooled results. However, we utilized the random-effects model to conservatively estimate the effects of the MBSR program on psychological outcomes, quality of sleep, and QoL. Nevertheless, we still believe that it is essential to apply for a standard MBSR program in clinical practice to ensure interventional efficacy. Third, details of UC across studies were different, which also a potential source of introducing statistical heterogeneity. However, we defined five essential elements of UC protocol to ensure the similarity of various strategies, including dietary instruction, health education, rehabilitation excise, emotional counseling, and medication instruction. Fourth, the baseline status of lung cancer patients was also different from one to another; however, subgroup analysis was not imposed due to limited data. Fifth, we could not quantitatively evaluate the impact of the MBSR program on the physical status because only one study reported this outcome. Sixth, most results of the current meta-analysis were only supported by low to moderate evidence except for the quality of sleep. Therefore, attention should be specially paid to the interpretation of our findings. Seventh, we used the first version of the Cochrane risk of bias assessment tool for methodological quality assessment in this meta-analysis. However, a second version is

being published, which should be cited in the future study.

iv. In the seventh study, we cannot deny the fact that several limitations may negatively affect the reliability and robustness of results. First and foremost, we used self-reported instruments to collect data, which may affect the accuracy of the results. Therefore, more objective tools need to be developed to measure these variables. Second, we recruited potentially eligible participants from only one hospital in southwest China due to the limited time. Therefore, we unable to eliminate the adverse impact of selection bias and time constraints on our findings. As a result, adequately powered studies with more extended intervention and follow-up duration are warranted to demonstrate our findings. Third, we selected only those variables tested in our previous studies to explore possible mechanisms of the MBSR program on psychological distress. However, we did not consider those factors that we did not investigate previously. Therefore, more intervention mechanisms analysis is needed to fully reveal the nature of MBSR program in alleviating psychological distress in lung cancer patients. Fourth, we used a four-week MBSR program with abbreviated sessions instead of a standard eight-week MBSR program in this study, which may have underestimated the intervention effect of the MBSR program due to inadequate duration of intervention. Therefore, future studies should further balance the interventional effects and applicability of the MBSR program in lung cancer patients. More importantly, it is necessary to further investigate the interventional

effects of the enhanced protocol with adequate sessions in future studies. Fifth, the mechanism model fitted our data relatively when we explored the intervention mechanism of the MBSR program to alleviate psychological distress, which limited the generalization of our results. Therefore, considering that limited participants were enrolled in our study, we suggest future studies with larger sample sizes to further elucidate the intervention mechanism of the MBSR program in alleviating psychological distress. Sixth, we chose brief versions of the scales to ensure the quality of the data collection process in this study; however, the average time for a patient to complete all scales was still up to 45 minutes. Although no patients were excluded for failing to complete scales, we could not eliminate the psychological burden caused by the need to complete multiple scales. Finally, in this study, we did not consider the impacts of sleep, fatigue, and exercise on the psychological status of lung cancer patients. Therefore, we suggest future studies to address this.

Implications for clinical practice

The current thesis mainly tried to develop a validate and easy-to-use screening tool to detect lung cancer patients who are at high-risk of psychological distress, clarify possible psychosocial mechanisms of psychological distress in lung cancer patients, and evaluate the therapeutic effectiveness and elucidate the possible psychosocial mechanisms of a 4-week MBSR program on psychological distress in lung cancer patients. Based on all findings from these studies, several implications are drawn for clinical practice, which are also summarized below according to the order of drawing four major conclusions.

i. The first study suggests that by applying this valid and easy-to-use predictive algorithm, a considerable number of subjects at the clinically significant level for psychological distress who will benefit more from psychological intervention programs can be early and precisely identified. Therefore, the predictive algorithm has great potential as a validated screening measure for use in research and clinical practice, evaluating the effects of intervention programs designed to decrease the level of psychological distress among lung cancer patients through measuring accumulation of psychological distress. In addition, the methodological framework used in developing and validating this predictive algorithm also provides reference for developing and validating prediction tool specific to other cancers, thereby facilitating early and accurate screening of various cancer patients at high risk of psychological

distress.

ii. In the part of the elucidation of possible psychosocial mechanisms of psychological distress in lung cancer patients, the second and third studies enhance our understanding on the association among social support, coping style, perceived stress, self-esteem, perceived stigma, illness perception, perceived stress, and psychological distress in lung cancer patients. Based on these findings from the second and third studies, practitioners can enhance the benefits of social support programs through strengthening confrontation coping and perceived stress, and then reduce the adverse consequences resulted from psychological distress. Meanwhile, practitioners can also enhance the benefits of social support programs through improving the level of self-esteem of lung cancer patients, and eventually reduce the adverse consequences caused by psychological distress. Based on the findings from the fourth and fifth studies, practitioners may enhance the benefits of mindfulness-based intervention protocol involving social support elements through alleviating the level of perceived stigma of lung cancer patients and eventually reduce the adverse consequences caused by psychological distress. In addition, mindfulness-based intervention protocol focusing on the correction of illness perception and reduction of perceived stress may be feasible and effective in improving psychological distress among patients with lung cancer.

iii. Studies have revealed that lung cancer patients suffer from several psychological issues through the whole disease duration. Given the fact that lung cancer ranks second for incidence among all types of cancers and first for cancer-related death, it is crucial to effectively manage the psychological issues of lung cancer patients. The current meta-analysis demonstrates the therapeutic advantages of MBSR program in reducing negative psychological states, enhancing positive psychological states, and improving QoL. These promising results indicate that it is reasonable to select MBSR program for managing psychological issues of lung cancer patients in routine practice. Furthermore, based on the fact that various MBSR programs with varying durations in the currently available studies, practitioners should select the most appropriate MBSR for target patients according to the actual condition of patients rather than selecting an undifferentiated program for different patients with significant difference in clinical practice.

iv. While various psychosocial interventions are available to manage psychological distress in patients with lung cancer, most of these interventions are difficult to use successfully in patients with lung cancer due to weak patient health and heavy treatment-related burdens. Therefore, it is essential to select those interventions with relatively short intervention duration for lung cancer patients. Four-week MBSR program has been revealed to effectively alleviate psychological distress in this study, indicating that this type of MBSR programs may be an appropriate option for

managing psychological distress in lung cancer. In addition, the possible psychosocial mechanisms of four-week MBSR program on alleviating psychological distress have also been elucidated in this study, providing alternative consideration for practitioners to manage psychological issues shared similar psychosocial mechanisms with psychological distress.

Dissemination of investigation

Oral presentation and poster

2022 World Cancer Congress, "*Meta-analysis of benefits of MBSR on physical and psychological outcomes in lung cancer patients*", as part of the session "Rapid Fire/RF 15 - Cancer care; access and quality of care" held on "18 October 2022" at "13:00 - 14:00" in the Room S09, Geneva, Switzerland, 2022. (Invitation letter is attached in Appendix 8)

5th Asian Oncology Nursing Society Conference (AONS 2021), "*The positive effect of social support on psychological distress among Chinese lung cancer patients: the mediating role of self-esteem*", 17 to 19 November, Taipei, China, 2021. (Invitation letter is attached in Appendix 9)

2021 Chinese Conference on Oncology (2021 CCO), "*The chain mediating role of social support and stigma in the relationship between mindfulness and psychological distress among Chinese lung cancer patients*", 14 to 17 April, Henan, China, 2022. (Invitation letter is attached in Appendix 10)

2021 Chinese Conference on Oncology (2021 CCO), "肺癌患者社会支持及自尊与心理困扰结构方程模型的构建 (*The structural equation modeling the relationship between psychological distress, social support and self-esteem*)", 14 to 17 April, Henan, China, 2022. (Invitation letter is attached in Appendix 11)

2021 Chinese Conference on Oncology (2021 CCO), "*Predicting the risk of psychological distress among lung cancer patients: development of*

predictive algorithm based on sociodemographic and clinical factors", 14 to 17 April, Henan, China, 2022. (Invitation letter is attached in Appendix 12)

Workshop

Public-entry lecture for Mindfulness, "*Intervention for Psychological Distress in Lung Cancer Patients by Implementing Mindfulness-based Stress Reduction*", Online Workshop, Chiangmai, Thailand, 2022. (PPT for this lecture is attached in Appendix 13)

Seminar for Training Clinical Nurses' Research Skills of Peking University School and Hospital of Stomatology, "*How to determine research question and correctly design a nursing research plan: from the perspective of psychological distress in lung cancer*", 16 May, Peiking, China, 2021. (One picture for this seminar is attached in Appendix 14)

Seminar for Training Clinical Nurses' Research Skills of Peking University School and Hospital of Stomatology, "*How to design a nursing research plan: from the perspective of psychological distress in lung cancer*", 28 July, Guizhou, China, 2021. (Picture for this seminar is attached in Appendix 14)

Seminar for Nursing Research Training, "*Cultivation of Nursing Academic Thinking: from the perspective of a series study of studies on psychological distress in lung cancer*", 8 June, Chongqing, China, 2021. (One picture for this seminar is attached in Appendix 14)

Research collection

Tian X, Chen GH, Jimenez-Herrera MF, and Shuai T. Research Topic of "*Psychosocial Rehabilitation for Cancer Patients*" launched in Frontiers in Psychology, Frontiers Media S.A., 2022. (available at https://www.frontiersin.org/research-topics/31133/psychosocial-rehabilitation-for-cancer-patients) (Screenshot is attached in Appendix 15)

Software

Software of Screening Tool for Psychological Distress in Lung Cancer Patients, Chongqing Science and Technology Bureau, Chongqing, China, 2021.

Appendix

Appendix 1

Certificate of Research Stay

天津医院
TIANJIN HOSPITAL

September 30, 2021

To Whom It May Concern:

As the Director of Department of Tianjin Hospital, I hereby certify that Xu Tian has carried out research activities at the Institute from January 20 to April 30, 2021.

Xu Tian has been working on part of his doctoral project, in particular designing the clinical trial plan of the research project, and conducting a pilot study to validate the trial, in collaboration with our team.

Sincerely,

Guomin Song (宋国敏)

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Tianjin Hospital

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Appendix 2

Registration of study

今天是: 2022-12-29 星期四

网站首页 | ChiCTR简介 | 检索入口 | 重要文件 | 注册指南 | 常见问题 简体中文 | English

检索试验 按国家、省（市）统计 按疾病代码统计 按试验实施单位统计 按试验主办单位统计 按经费或物资来源统计 按征募研究对象情况统计 按注册状态统计 按干预措施统计 按伦理委员会统计 按研究类型统计

该研究尚未获得伦理委员会批准，请于批准后再开始纳入参试者，并与我们联系上传批件。 基于随机对照试验探讨改良正念减压方案对肺癌患者心理困扰的干预效应及潜在社会心理学机制

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注册号: Registration number:	ChiCTR2100041899
最近更新日期: Date of Last Refreshed on:	2021-03-27
注册时间: Date of Registration:	2021-01-09
注册号状态:	预注册
Registration Status:	Prospective registration
注册题目:	该研究尚未获得伦理委员会批准，请于批准后再开始纳入参试者，并与我们联系上传批件。 基于随机对照试验探讨改良正念减压方案对肺癌患者心理困扰的干预效应及潜在社会心理学机制
Public title:	The efficacy and potential underlying psycho-social mechanisms of a modified mindfulness-based stress program in lung cancer patients with psychological distress: a randomized controlled trial
注册题目简写:	
English Acronym:	
研究课题的正式科学名称:	正念减压疗法对肺癌患者心理困扰的干预研究
Scientific title:	Research of mindfulness-based stress reduction on psychological distress in lung cancer patients
研究课题代号(代码): Study subject ID:	
在二级注册机构或其它机构的注册号: The registration number of the Partner Registry or other register:	

申请注册联系人:	田旭	研究负责人:	唐玲
Applicant:	Xu Tian	Study leader:	Ling Tang
申请注册联系人电话: Applicant telephone:	+86 18222275023	研究负责人电话: Study leader's telephone:	+86 18222275023
申请注册联系人传真: Applicant Fax:		研究负责人传真: Study leader's fax:	
申请注册联系人电子邮件: Applicant E-mail:	yxtx880919@hotmail.com	研究负责人电子邮件: Study leader's E-mail:	CQCH_TangL@163.com
申请单位网址(自愿提供): Applicant website(voluntary supply):		研究负责人网址(自愿提供): Study leader's website(voluntary supply):	
申请注册联系人通讯地址:	重庆市沙坪坝区汉渝路181号	研究负责人通讯地址:	重庆市沙坪坝区汉渝路181号
Applicant address:	181 Hanyu Road, Shapingba District, Chongqing	Study leader's address:	181 Hanyu Road, Shapingba District, Chongqing
申请注册联系人邮政编码: Applicant postcode:	400030	研究负责人邮政编码: Study leader's postcode:	400030
申请人所在单位:	罗维拉威尔吉利大学护理学院		
Applicant's institution:	Universitat Rovira i Virgili		

是否获伦理委员会批准:	否
Approved by ethic committee:	NO
伦理委员会批件文号: Approved No. of ethic committee:	
伦理委员会批件附件: Approved file of Ethical Committee:	

批准本研究的伦理委员会名称:	
Name of the ethic committee:	
伦理委员会批准日期: Date of approved by ethic committee:	2013-08-26
伦理委员会联系人:	
Contact Name of the ethic committee:	
伦理委员会联系地址:	
Contact Address of the ethic committee:	
伦理委员会联系人电话: Contact phone of the ethic committee:	伦理委员会联系人邮箱: Contact email of the ethic committee:
研究实施负责（组长）单位:	重庆大学附属肿瘤医院
Primary sponsor:	Chongqing University Cancer Hospital
研究实施负责（组长）单位地址:	重庆市沙坪坝区汉渝路181号
Primary sponsor's address:	181 Hanyu Road, Shapingba District, Chongqing

试验主办单位(项目批准或申办者): Secondary sponsor:	国家:	中国	省(直辖市):	重庆	市(区县):
	Country:	China	Province:	Chongqing	City:
	单位(医院):	重庆大学附属肿瘤医院	具体地址:	汉渝路181号	
	Institution hospital:	Chongqing University Cancer Hospital	Address:	181 Hanyu Road, Shapingba District	

经费或物资来源:	重庆市科技局
Source(s) of funding:	Chongqing Science and Technology Bureau
研究疾病:	肺癌
Target disease:	Lung cancer
研究疾病代码:	
Target disease code:	
研究类型:	干预性研究
Study type:	Interventional study
研究所处阶段:	其它
Study phase:	N/A
研究目的:	明确正念减压疗法对肺癌患者心理困扰的干预效应及潜在社会心理学机制。
Objectives of Study:	To determine the efficacy and potential underlying psychosocial mechanisms of mindfulness-based stress reduction on psychological distress in lung cancer patients.
药物成份或治疗方案详述:	
Description for medicine or protocol of treatment in detail:	
研究设计:	随机平行对照
Study design:	Parallel
纳入标准:	①经病理学确诊为肺癌（包括小细胞肺癌和非小细胞肺癌）； ②年满18周岁； ③明确自身病情和癌症诊断； ④具有一定的理解和语言表达能力并同意参加本研究者。
Inclusion criteria	1) Diagnosed with stage I through IV lung cancer; 2) aged >= 18 years; 3) known their diagnosis; and 4) able to read, write, and speak Chinese.
排除标准:	①共患其他肿瘤或精神疾病； ②有自杀史；合并有其它严重威胁生命的疾病； ③三月内参加了其他身心干预类研究； ④有正念干预经验。
Exclusion criteria:	1) A concurrent diagnosis of other tumor types or psychiatric disorders; 2) a history of suicide attempts; 3) participation in any other psychosocial interventions within 3 months before enrollment, and 4) prior experience with MBIs.
研究实施时间: Study execute time:	从From2021-01-01至To 2022-12-31
征募观察对象时间: Recruiting time:	从From2021-02-01至To 2022-07-31
干预措施:	

Interventions:	组别:	正念减压	样本量:	100
	Group:	MBSR	Sample size:	
	干预措施:	改良正念减压干预	干预措施代码:	
	Intervention:	modified MBSR	Intervention code:	
	组别:	等待组	样本量:	100
	Group:	wait-list group	Sample size:	
	干预措施:	常规照护	干预措施代码:	
	Intervention:	controversial care program	Intervention code:	

研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市):	重庆	市(区县):
	Country:	China	Province:	Chongqing	City:
	单位(医院):	重庆大学附属肿瘤医院	单位级别:	三级甲等	
	Institution hospital:	Chongqing University Cancer Hospital	Level of the institution:	Tertiary A	

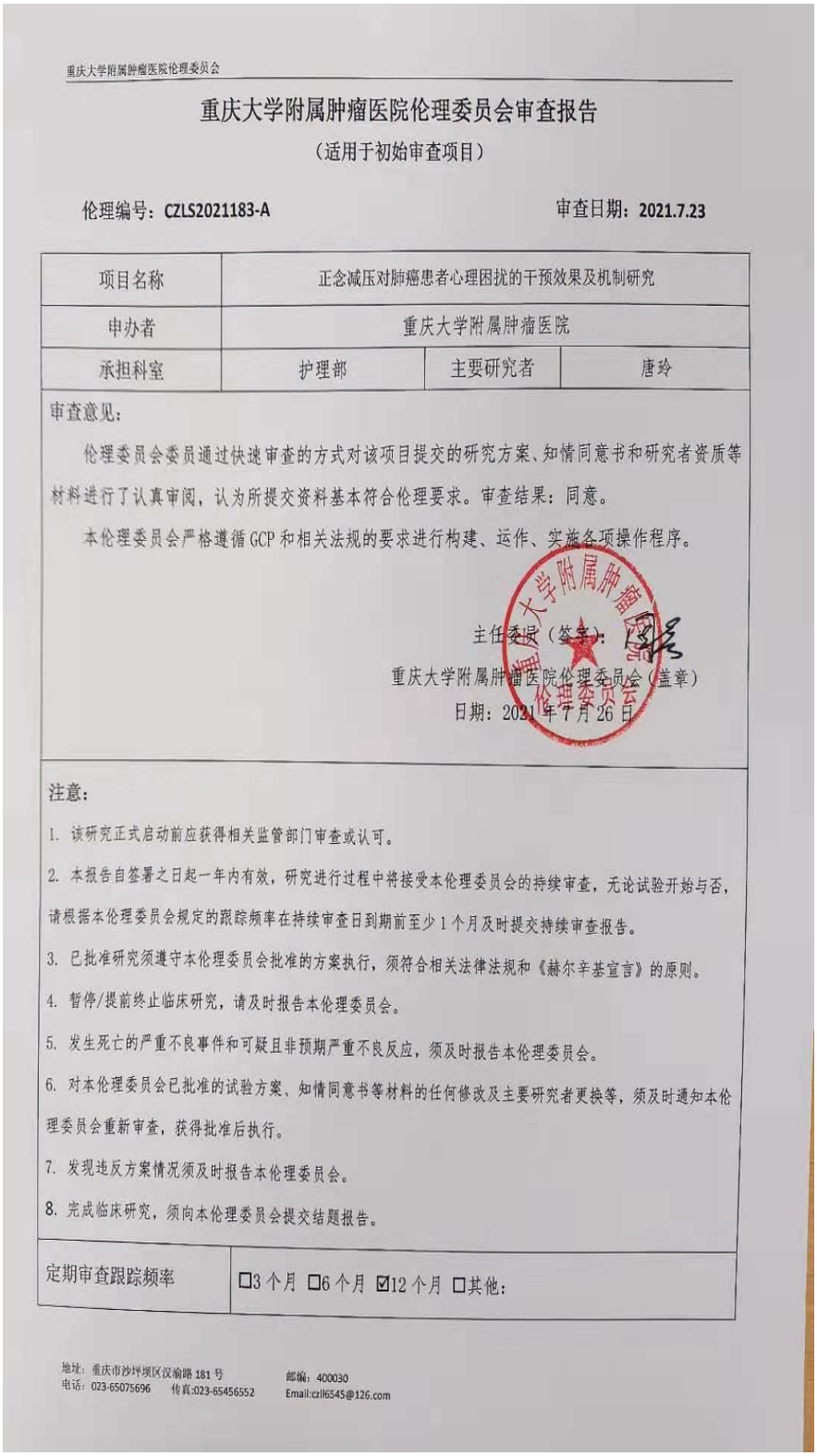
测量指标: Outcomes:	指标中文名:	心理困扰	指标类型:	主要指标
	Outcome:	psychological distress	Type:	Primary indicator
	测量时间点:		测量方法:	DT
	Measure time point of outcome:		Measure method:	

采集人体标本: Collecting sample(s) from participants:	标本中文名:	无	组织:	
	Sample Name:	N/A	Tissue:	
	人体标本去向	其它	说明	
	Fate of sample:	Others	Note:	

征募研究对象情况: Recruiting status:	正在进行 Recruiting	年龄范围: Participant age:	最小 Min age 18 岁 years 最大 Max age 75 岁 years
性别:	男女均可	Gender:	Both
随机方法（请说明由何人用什么方法产生随机序列）:	电脑随机化数字表		
Randomization Procedure (please state who generates the random number sequence and by what method):	computer-based random table		
盲法:	未说明		
Blinding:	Not stated		
试验完成后的统计结果（上传文件）:	点击下载		
Calculated Results after the Study Completed(upload file):	download		
是否共享原始数据: IPD sharing	否No		
共享原始数据的方式（说明：请填入公开原始数据日期和方式，如采用网络平台，需填该网络平台名称和网址）:	所有原始数据由研究执行单位保存		
The way of sharing IPD"(include metadata and protocol, If use web-based public database, please provide the url):	All data will be stored at hospital where the trial will be performed		
数据采集和管理（说明：数据采集和管理由两部分组成，一为病例记录表(Case Record Form, CRF)，二为电子采集和管理系统(Electronic Data Capture, EDC)，如ResMan即为一种基于互联网的EDC:	问卷		
Data collection and Management (A standard data collection and management system include a	questionnaires		

Appendix 3

Ethical Approval for Studies



重庆大学附属肿瘤医院伦理委员会

重庆大学附属肿瘤医院伦理委员会审查报告

（适用于初始审查项目）

伦理编号：CZLS2021183-A　　审查日期：2021.7.23

项目名称	正念减压对肺癌患者心理困扰的干预效果及机制研究		
申办者	重庆大学附属肿瘤医院		
承担科室	护理部	主要研究者	唐玲

审查意见：

伦理委员会委员通过快速审查的方式对该项目提交的研究方案、知情同意书和研究者资质等材料进行了认真审阅，认为所提交资料基本符合伦理要求。审查结果：同意。

本伦理委员会严格遵循 GCP 和相关法规的要求进行构建、运作、实施各项操作程序。

主任委员（签字）：

重庆大学附属肿瘤医院伦理委员会（盖章）

日期：2021 年 7 月 26 日

注意：

1. 该研究正式启动前应获得相关监管部门审查或认可。
2. 本报告自签署之日起一年内有效，研究进行过程中将接受本伦理委员会的持续审查，无论试验开始与否，请根据本伦理委员会规定的跟踪频率在持续审查日到期前至少 1 个月及时提交持续审查报告。
3. 已批准研究须遵守本伦理委员会批准的方案执行，须符合相关法律法规和《赫尔辛基宣言》的原则。
4. 暂停/提前终止临床研究，请及时报告本伦理委员会。
5. 发生死亡的严重不良事件和可疑且非预期严重不良反应，须及时报告本伦理委员会。
6. 对本伦理委员会已批准的试验方案、知情同意书等材料的任何修改及主要研究者更换等，须及时通知本伦理委员会重新审查，获得批准后执行。
7. 发现违反方案情况须及时报告本伦理委员会。
8. 完成临床研究，须向本伦理委员会提交结题报告。

定期审查跟踪频率	☐3 个月 ☐6 个月 ☑12 个月 ☐其他：

地址：重庆市沙坪坝区汉渝路 181 号　　邮编：400030
电话：023-65075696　　传真:023-65456552　　Email:czll6545@126.com

Appendix 4

Patient's Informed Consent Template

知情同意书

受试者须知页

方案名称：正念减压疗法对肺癌患者心理困扰的干预效应及机制研究
主要研究者：唐玲
申办者：重庆大学附属肿瘤医院

尊敬的受试者：

您被邀请参加 正念减压疗法对肺癌患者心理困扰的干预效应及机制研究 研究，该项研究由重庆大学附属肿瘤医院提供支持。请仔细阅读本知情同意书并慎重做出是否参加本项研究的决定。参加这项研究完全是您自主的选择。作为受试者，您必须在加入临床研究前给出您的书面同意书。当您的研究医生或者研究人员和您讨论知情同意书的时候，您可以让他/她给您解释您看不明白的地方。我们鼓励您在做出参与此项研究的决定之前，和您的家人及朋友进行充分讨论。您有权拒绝参加本研究，也可随时退出研究，且不会受到处罚，也不会失去您应有的权利。若您正在参加别的研究，请告知您的研究医生或者研究人员。本研究的背景、目的、研究过程及其他重要信息如下：

一、 研究背景

心理困扰已成为癌症患者面临的极为重要的心理健康问题，有效的干预肺癌患者的心理困扰以降低其危害尤为重要。正念减压对癌症患者（尤其是乳腺癌和前列腺癌）心理痛苦困扰的改善效果已得到广泛验证，但有关其对癌症患者心理困扰产生作用的机制研究却极为缺乏。

二、 研究目的

本研究的目的是在我们前期研究的基础上，利用我院作为重庆市抗癌协会、重庆市肿瘤研究所及重庆市“一网一链”肿瘤防治服务体系牵头单位的优势，对我院及“一网一链”覆盖的区域级与区县级肿瘤规范化诊疗基地收治住院的合格肺癌患者，运用横断面调查设计，开展肺癌患者心理困扰发生现状及影响因素的调查；然后以我院收治的合格肺癌患者为受试，基于随机临床对照框架，开展为期八周的正念减压干预，进一步研究正念减压干预对肺癌患者心理困扰的干预效果；最后基于临床研究后的量表调查结果，采用结构方程建模技术，从假定的路径出发，阐明正念减压干预对肺癌患者心理困扰发挥作用的机制，从而为真实了解肺癌患者心理困扰的流行现状、构建肺癌患者心理困扰预测模型、制定肺癌患者心理困扰标准化干预方案、拓展正念减压干预的应用范畴提供资料，进而在从根本上降低或阻止癌症患者心理困扰的发生与危害、改善癌症患者的心理健康状况、提高抗癌治疗效果、改善癌症患者生活质量方面具有重大意义，将产生广泛

的社会效益和经济效益。

三、研究过程

1. 多少人将参与这项研究?

大约 200 人将参与本项研究。

2. 研究步骤

如果您同意参加本研究，请您签署这份知情同意书。

1. 在您入选研究前，医生和护士将询问、记录您的病史，并进行心理困扰等问卷筛查。

确定您可以参加本研究后，您将参与为期 8 周的正念减压干预，并分别在干预前、干预结束时、干预结束后 3 月和 6 月接受相同的问卷评估。

3. 这项研究会持续多久?

本项研究拟持续 1 年，您可以在任何时间选择退出研究而不会失去您本应获得的任何利益。然而，如果在研究途中您决定退出本研究，我们鼓励您先和您的医生商议。如果您出现严重的不良事件，或者您的研究医生觉得继续参加研究不符合您的最佳利益，他/她会决定让您退出研究。申办者或者监管机构也可能在研究期间终止研究。但您的退出不会影响您的正常医疗待遇与权益不受影响。

如果您因为任何原因从研究中退出，您可能被询问有关您参加研究的情况。如果医生认为需要，您也可能被要求进行实验室检查和体格检查。

四、风险与受益

1. 参加本研究的风险是什么?

参加本研究可能给您带来的风险如下：疲乏、眩晕等。您应该和您的研究医生，或者您愿意，与您平日照看您的医生讨论一下这些风险。

如果在研究期间您出现任何不适，或病情发生新的变化，或任何意外情况，不管是否与研究有关，均应及时通知您的医生，他/她将对此作出判断并给与适当的医疗处理。

您在研究期间需要按时到医院随访，这将会占用您的一些时间，也可能给您造成麻烦或带来不方便。

2. 参加研究有什么受益?

直接受益：如果您同意参加本研究，您将有可能获得直接的医疗受益。

潜在受益：本研究可能会治愈疾病或阻止/减缓疾病的进展。我们希望从您参与的本研究中得到的信息在将来能够使您或与您病情相同的病人获益。

五、研究结果的使用和个人信息的保密

在您和其他受试者的理解和协助下，通过本项目研究的结果可能会在医学杂志

上发表，但是我们会按照法律的要求为您的研究记录保密。研究受试者的个人信息将受到严格保密，除非应相关法律要求，您个人信息不会被泄露。必要时，政府管理部门和医院伦理委员会及其它相关研究人员可以按规定查阅您的资料。

六、受试者的权利和相关注意事项

1. 您的权利

在参加研究的整个过程中，您都是自愿的。如果您决定不参加本研究，也不会影响您应该得到的其他治疗。如果您决定参加，会要求您在这份书面知情同意书上签字。您有权在试验的任何阶段随时退出试验而不会遭到歧视或受到不公平的待遇，您相应医疗待遇与权益不受影响。

2. 注意事项

作为受试者，您需要提供有关自身病史和当前身体状况的真实情况；告诉研究医生自己在本次研究期间所发现的任何不适；不得服用医生已告知的受限制药物、食物等；告诉研究医生自己最近是否参与其他研究，或目前正参与其他研究。

七、获知信息的相关联系方式

如果在研究过程中有任何重要的新信息，可能影响您继续参加研究的意愿时，您的医生将会及时通知您。如果您对自己的研究数据，或研究结束后您希望知道本研究的发现。您可以在任何时间提出有关本项研究的任何问题，并得到相应的解答，请通过电话 18222275023 与 田旭联系。

受试者签字页

知情同意声明：

我已被告知此项研究的目的、背景、过程、风险及获益等情况。我有足够的时间和机会进行提问，问题的答复我很满意。

我也被告知，当我有问题、想反映困难、顾虑、对研究的建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。

我已经阅读这份知情同意书，并且同意参加本研究。

我知道我可以选择不参加此项研究，或在研究期间的任何时候无需任何理由退出本研究。

我已知道如果我的状况更差了，或者我出现严重的不良事件，或者我的研究医生觉得继续参加研究不符合我的最佳利益，他/她会决定让我退出研究。无需征得我的同意，资助方或者监管机构也可能在研究期间终止研究。如果发生该情况，医生

将及时通知我，研究医生也会与我讨论我的其他选择。

我将得到这份知情同意书的副本，上面包含我和研究者的签名。

受试者签名：_____ 日期：_____

（注：如果受试者无行为能力/限制行为能力时，则需法定代理人签名和签署日期）

受试者联系方式：_____

法定代理人签字：_____ 日期：_____

（注：如果受试者不能阅读该知情同意书时，则需一名独立见证人证明研究者已将知情同意书的所有内容告知了受试者，独立见证人需签名和签署日期）

法定代理人联系方式：_____

独立见证人签字：_____ 日期：_____

独立见证人联系方式：_____

研究者签名：_____ 日期：_____

研究者联系方式：_____

Appendix 5

Supplementary Table 1 of Article 7

Supplementary Table 1: The level of evidence based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

No. of studies	Study design	Certainty assessment					No. of patients		Effect	Certainty	Importance
		A	B	C	D	E	MBSR	UC	Absolute (95% CI)		
Cancer-related fatigue											
5	randomised trials	serious[a]	not serious	not serious	not serious	none	256	258	SMD **-1.26 lower** (-1.69 lower to -0.82 lower)	⨁⨁⨁◯ Moderate	CRITICAL
Negative psychological status											
8	randomised trials	serious[b]	not serious	not serious	serious[c]	strong association	514	515	SMD **-1.35 lower** (-1.69 lower to -1.02 lower)	⨁⨁◯◯ Low	IMPORTANT
Positive psychological status											
4	randomised trials	not serious	not serious	not serious	very serious[c]	none	148	144	SMD **0.91 SD higher** (0.56 higher to 1.27 higher)	⨁⨁⨁◯ Moderate	IMPORTANT
Quality of sleep											
2	randomised trials	serious[b]	not serious	not serious	not serious	strong association	273	273	MD **2.79 lower** (3.03 lower to 2.56 lower)	⨁⨁⨁⨁ High	IMPORTANT
Quality of life											
3	randomised trials	serious[d]	not serious	not serious	serious[c]	none	122	119	MD **9.55 lower** (0.47 lower to 19.58 higher)	⨁⨁◯◯ Low	IMPORTANT

MBSR: mindfulness-based stress reduction; US: usual care; CI: confidence interval; MD: mean difference; SMD: standardized mean difference. A, B, C, D, and E represents risk of bias, inconsistency, indirectness, imprecision, and other considerations, respectively.

Explanations

a. Two eligible studies were judged to be at high risk of bias.

b. One eligible study was judged to be at high risk of bias.

c. Inadequate sample size was accumulated.

d. Most eligible studies were judged to be at high risk of bias.

e. All studies were judged to be at high risk of bias.

Appendix 6

Supplementary Table 1 of Article 8

Session	Theme	Details
First week	Explanation and meditation (10 minutes)	During the first MBSR session, the qualified psychologists will first explain the MBSR program and the importance of home practice to participants. Then, the psychologists will conduct an automatic pilot activity to increase their awareness and response to situations by choice, which will show that people tend to be only dimly aware of what they are doing, following unhelpful thinking habits that lead to stress. The psychologists will conduct a "raisin exercise" to show how people's attention is not always entirely directed now. Then, the trainers will emphasize that when people become more aware of the present moment, including their thoughts, feelings, and bodily sensations, they can enjoy greater freedom and choice. The psychologists will explain that mindfulness does not aim for a specific result but somewhat increased awareness of where one is and how one allows themselves to be. At the end of this session, psychologists will introduce participants to the body-scan exercise, which aims to encourage participants to focus on

		the different parts of their bodies and use each part of their body to anchor their awareness of a moment. Then, the psychologists will ask participants to practice this body-scan exercise six times at home while watching a video explaining how to perform the activity.
Second week	Breathing meditation (10 minutes)	During the second MBSR session, the psychologists will review the previous session's lessons and home practices. The psychologists will discuss the body scan exercise, meditation techniques, and mindful breathing meditation with participants. The psychologists will practice ten-minute breathing mediation with participants and give participants home assignments regarding what was learned in this session.
Third week	Walking meditation (10 minutes)	During the third MBSR session, the psychologists will discuss the previous lesson and encourage participants to use their bodies to increase their awareness. By remaining aware of the present moment, they can mindfully respond instead of automatically reacting to stressors. However, such responses require that participants

		experience and accept stressors in the present moment. Then, the psychologists will practice a ten-minute walk mindfully with participants.
Fourth week	Experience sharing (20 minutes)	During the fourth and final MBSR session, the psychologists will summarize the previous sessions' content and encourage participants to continue regular mindfulness exercises. After reconnecting with expanded awareness, the psychologists will also encourage participants to undertake a considered action to deal with troubling feelings, such as performing a pleasurable activity or an activity that will instill a sense of satisfaction.

Appendix 7

Supplementary Table 2 of Article 8

Supplementary Table 2: A comparison of the outcome variables between the two groups before and after the intervention.

Variable	T0 (mean ± *SD*)		T1 (mean ± *SD*)		T2 (mean ± *SD*)		T3 (mean ± *SD*)		F1 (*P*)	F2 (*P*)	F3 (*P*)
	Experimental (n=83)	Control (n=92)	Experimental (n=83)	Control (n=92)	Experimental (n=92)	Control (n=83)	Experimental (n=78)	Control (n=89)			
Risk score	67.84±24.42	66.39±29.90	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	t=-0.350		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	P=0.727		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Psychological distress	2.70 ± 2.13	2.45 ± 2.21	1.16 ± 1.57	1.78 ± 1.74	1.07 ± 1.53	2.27 ± 1.27	0.43 ± 1.08	2.26 ± 1.25	56.245 (<0.001)	15.051 (<0.001)	37.762 (<0.001)
	t=-0.617		*t*=-2.519		*t*=-6.278		*t*=-9.580				
	P=0.537		*P*=0.012		*P*=<0.001		*P*=<0.001				
Social support	57.31±7.17	55.66±12.32	64.02±7.34	58.80±9.38	64.48±8.35	57.73±9.50	65.30±6.42	58.81±9.11	33.911 (<0.001)	16.465 (<0.001)	8.598 (<0.001)
	t=-0.170		*t*=-3.752		*t*=-4.865		*t*=-4.769				
	P=0.865		*P*<0.001		*P*<0.001		*P*<0.001				
Coping style	50.77±4.89	49.54±4.50	49.10±3.51	50.48±4.93	49.47±3.73	50.02±5.23	49.56±5.25	51.60±4.15	1.386 (0.250)	1.515 (0.220)	4.995 (0.005)
	t=-1.702		*t*=-1.486		*t*=-0.203		*t*=-2.372				
	P=0.091		*P*=0.137		*P*=0.839		*P*=0.018				
Self-esteem	27.72±4.04	28.17±5.00	29.59±4.34	27.67±4.00	29.00±4.53	27.44±3.91	28.30±4.70	27.14±4.19	4.894 (0.006)	2.425 (0.121)	9.181 (<0.001)
	t=-0.754		*t*=-3.018		*t*=-2.765		*t*=-2.419				
	P=0.451		*P*=0.003		*P*=0.006		*P*=0.016				
Mindfulness	104.57±10.87	111.97±9.03	117.54±9.78	110.88±7.71	118.30±10.05	110.59±6.98	120.90±11.20	110.31±6.60	43.216 (<0.001)	17.207 (<0.001)	64.963 (<0.001)
	t=-4.746		*t*=-4.540		*t*=-5.138		*t*=-6.568				
	P<0.001		*P*<0.001		*P*<0.001		*P*<0.001				

Supplementary Table 2 (*continued*).

Variable	T0 (mean ± *SD*)		T1 (mean ± *SD*)		T2 (mean ± *SD*)		T3 (mean ± *SD*)		F1 (*P*)	F2 (*P*)	F3 (*P*)
	Experimental (n=83)	Control (n=92)	Experimental (n=83)	Control (n=92)	Experimental (n=92)	Control (n=83)	Experimental (n=78)	Control (n=89)			
Perceived stress	20.95±4.64	20.48±4.65	18.35±3.86	19.97±2.95	19.23±3.62	19.55±3.06	17.49±3.61	19.26±3.03	17.365 (<0.001)	3.755 (0.054)	5.405 (0.002)
	t=-1.099		*t*=3.106		*t*=-1.206		*t*=3.498				
	P=0.272		*P*=0.002		*P*=0.228		*P*=0.001				
Perceived stigma	75.83±15.14	75.22±16.06	63.57±8.27	67.79±8.87	62.55±7.51	59.50±7.70	68.58±9.10	86.42 ± 9.10	87.520 (<0.001)	8.260 (0.005)	12.988 (<0.001)
	t=-0.571		*t*=-4.309		*t*=-2.436		*t*=6.995				
	P=0.568		*P*=<0.001		*P*=0.016		*P*=<0.001				
Illness perception	48.19±7.81	46.98±4.63	43.20±7.00	45.00±7.69	43.00±7.49	45.62±12.17	42.21±7.20	45.13 ± 12.20	15.240 (<0.001)	2.365 (0.126)	4.760 (0.009)
	t=-0.782		*t*=1.571		*t*=-1.080		*t*=-1.539				
	P=0.434		*P*=0.118		*P*=0.280		*P*=0.124				

T0, baseline; T1, the immediate post intervention; T2, 1-month post-intervention; T3, 3 months post intervention; *F1*, time effect; *F2*, group effect; *F3*, group*time effect; *SD*, standard deviation.

Appendix 8

Invitation letter for presentation in WCC 2022

2022 World Cancer Congress – Abstract Presentation in Geneva

WCC 2022 <2022wcc@kit-group.org>

Dj. 14/7/2022 11:37

Per a: Xu Tian <xu.tian@estudiants.urv.cat>

You have received this communication as your abstract has been accepted for the 2022 World Cancer Congress. If you will NOT be attending the Congress and have not yet notified us, please email us at 2022wcc@kit-group.org so that your abstract will be withdrawn accordingly.

Dear Xu Tian,

Congratulations! Your abstract **150** entitled **Meta-analysis of benefits of MBSR on physical and psychological outcomes in lung cancer patients has been accepted to be presented on-site in Geneva, as a Rapid-Fire presentation**, as part of the 2022 World Cancer Congress (18 October – 20 October 2022 in Geneva, Switzerland).

First, it is important you register and confirm your participation on-site (*if you have not done so yet*), **before 16 September.** If you fail to confirm your participation by registering before this deadline, your abstract will be withdrawn from the Programme and the abstract library.

Your Rapid Fire presentation will take place at the International Conference Centre Geneva (CICG) - and your presentation time should not exceed **3 minutes**, in front of an audience of 80 persons.

Your abstract will be presented as part of the session **"Rapid Fire / RF 15 - Cancer care; access and quality of care"** held on **"12:00:00 AM"** at **"13:00 - 14:00"** in **the Room S09.** You will be the **"11"** to present within this session.

Please note that the 3 best scored abstracts in each of the submission categories will be offered an Abstract oral (8mns presentation) and will be eligible to Awards that will be remitted during the Closing Ceremony of the Congress on 20 October 2022. The review of the shortlisted abstracts is currently ongoing and will be announced by mid-September 2022.

Thank you for reading carefully the following information:

1. YOUR PRESENTATION

The Rapid Fire (RF) format was launched in Montréal at the 2012 World Cancer Congress and it proved to be one of the highlights of many participants. It is especially designed to provide maximum visibility for selected high quality abstracts.

How will the Rapid Fire (RF) presentations work?

RF sessions will be scheduled within the programme and each session is organised by theme. There will be 2 lecterns on stage and you will only be on stage during the 3 minute-presentation of the presenter in front of you, then during your 3-minute presentation. The audience is typically about 50 people.

Each presenter will be allowed to screen **5 slides (1 title and closing slide + 3 content slides) and speak for 3 minutes**, after which time the sound system at your lectern will be switched off and the next speaker will commence from the other lectern. Presenters will use their time to introduce delegates to their material. Please ensure that within your slides you maximise using visuals (i.e. photos, graphics rather than heavy text).

Please prepare and rehearse carefully to ensure you complete the presentation within 3 minutes and that you have reached the conclusion / impact within your time limit. The session chair (to be announced) may allocate a few minutes for you to take one or two questions from the audience following your presentation at their discretion. Session chairs have been instructed to be strict on time limits and will invite the audience to connect with you after the session.

As well as speaking clearly in English, please be mindful not to speak rapidly, as this will create difficulties for many in the international audience.

Your presentation

All presentations must include the following elements on the first slide:

0. Abstract title and author name on all slides
1. Completed footer with:
    0. Abstract submission identifier 150
    1. Submission type name: 2
    2. Congress Theme: Theme 4 – Cancer treatment & palliative care
    3. Disclosure of interest
    4. Abstract previously published / presented: No
    5. Affiliated organisation: Universitat Rovira i Virgili

The format of the screens is 16/9 horizontal

Please click **here** if you would like to use a dedicated WCC power point template.

Once your presentation is ready, you will have to upload it through the **Speaker Service Centre**, either online through a dedicated platform ahead of the Congress from 10 September onwards, or onsite (at least 90 minutes before the start of your session)).

BONUS – your abstract will also be available for self-consultation by the delegates :

1. **On a eLibrary** available on the Congress online platform from 18 October until 31st December 2022. During that time, you will be able to connect with other Congress registered participants, propose or be proposed meetings to present your abstract directly on the Congress online platform.

2. **On dedicated e-poster screens** available in the Theme Pavilions of the Geneva venue, the International Conference Centre of Geneva. You can propose presentation meetings through the Congress online platform and present in one of the lounge areas or Theme Pavilions of the Congress venue.

2. YOUR REGISTRATION AND CONFIRMATION

Before 16 September, submitters and authors whom wish to have their accepted abstracts part of the abstract e-library will need **to either purchase an on-site registration ticket if they wish to attend the Congress in-person in Geneva, or a digital ticket if they cannot travel to Geneva**.

Should you wish to participate on-site, and present in the proposed Rapid Fire session, please use this code WCC 2022 to benefit from 20% on the current applicable price of on-site tickets.

Should you wish to only access the Congress online platform, and have your abstract included in the abstracts eLibrary, please use this code WCC 2022 to benefit from 20% off on the current applicable price of digital tickets.

Please **click here** to access the online registration system.

For any questions, or Ii you do not want to register and do not wish to have your abstract included in the abstracts eLibrary, please email 2022wcc@kit-group.org

Please note:

- The 20% code is non transferable and eligibility will be regularly verified
- If you have already registered for the Congress, you do not need to register again.
- **We regret that we will have to withdraw your abstract from the on-site Programme if you are not registered by September 16th .**

3. ACCOMMODATION

You are responsible for arranging and paying your own accommodation; if you have not already made a hotel booking, we kindly invite you to do so as soon as possible.

Appendix 9

Invitation letter for presentation in AONS 2021

AONS 2021: Your Abstract Is Accepted for Oral Presentation. 您的稿件已錄取口頭報告

aons2021.reg@elitepco.com.tw <aons2021.reg@elitepco.com.tw>
Dl. 24/5/2021 5:44
Per a: Xu Tian <xu.tian@estudiants.urv.cat>

2021 AONS
5th Asian Oncology Nursing Society Conference
Virtual Conference

ACCEPTANCE NOTICE OF
ORAL PRESENTATION

May 24, 2021

Dear Dr. Xu Tian,

On behalf of the Scientific Committee of the 5th Asian Oncology Nursing Society Conference (AONS 2021), we are glad to inform your abstract entitled "The positive effect of social support on psychological distress among Chinese lung cancer patients: the mediating role of self-esteem" is accepted for **Oral Presentation**.

Presenting Author is required to **complete below reply form in one week** and **complete registration of the main conference with payment before 31 July, 2021 (23:59:59, GMT+8)** to confirm your participation; otherwise, your abstract may be excluded from conference materials

> **Register Online:** https://www.aons2021.tw/en-us/Page/Index/17

Feel free to contact us if you have any further inquiry or assistance required.

Sincerely,

Shwn-Huey Shieh	**Woung-Ru Tang**	**Ming-Ying Hong**
Conference Chair, AONS 2021	Conference Chair, AONS 2021	Scientific Committee Chair, AONS 2021

REPLY FORM

Please reply and contact the Secretariat promptly if you wish to amend your abstract before **23:59:59 (GMT+8), 30 June 2021**. After the deadline, all the content will be finalized. The information you submitted will be published on AONS 2021 conference materials.	
Abstract No.	
Abstract Title	
Presenting Author	**First Name:**
	Last Name:
Acceptance Reply	□ Yes, I agree to present at AONS 2021. □ Sorry, I am unable to present at AONS 2021.

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Appendix 10

Invitation letter for presentation 1 in 2021 CCO

2021 中国肿瘤学大会（CCO）
论文录取通知

尊敬的田旭医生您好！

由中国抗癌协会主办，河南省肿瘤医院、河南省癌症基金会承办协会承办，国际抗癌联盟(UICC)、中国整合医学发展战略研究院协办的2021中国肿瘤学大会(CCO)将于2021年11月18日-21日在郑州隆重召开。我们诚挚地邀请您参加此次盛会。

经过专家审稿，您投的稿件评审结果如下

ID	论文编号	稿件题目	第一作者	评审结果
7579		The chain mediating role of social support and stigma in the relationship between mindfulness and psychological distress among Chinese lung cancer patients	田旭	壁报交流展示
	所有作者：田旭，张照莉			

您也可以直接登录大会网站http://www.cco2021.org 后点击“论文评审结果”按钮进行实时的网上查询。

温馨提示：

1. 如果您的论文被评为壁报交流，请您按照以下要求准备您的壁报：

壁报尺寸：竖版16:9 PPT/PPTX格式

大会为电子壁报，壁报上传截止日期为：2021年9月30日
壁报上传流程请登陆大会网站，点击壁报上传按钮进行流程查看并下载电子壁报模板。
壁报上传成功后，大会将在11月30日前发送大会壁报交流证书。

2. 如果您的论文被评为书面交流，不必准备壁报，欢迎积极参加会议讨论。

3. 对于已经安排壁报而无故不按时上传壁报的，组委会将做记录并在将来的会议上酌情严肃处理。

4. 提示：**会前注册第一次优惠将于2021年8月31日截止，请登录大会网站进行注册操作并交会议费**，以享受注册费优惠，凡没有事先交费的代表，无论是否进行网上注册，现场一律按照现场注册费率交费。由于住房比较紧张，请各位需要安排住房的代表务必在网上做住房预定。没有预定将无法保证安排住房。详情请参照大会网站。

期待与您在中国肿瘤学大会见面。

中国抗癌协会

2021年8月

Appendix 11

Invitation letter for presentation 2 in 2021 CCO

2021 中国肿瘤学大会（CCO）
论文录取通知

尊敬的陈慧医生您好！

由中国抗癌协会主办，河南省肿瘤医院、河南省癌症基金会承办协会承办，国际抗癌联盟(UICC)、中国整合医学发展战略研究院协办的2021中国肿瘤学大会(CCO)将于2021年11月18日-21日在郑州隆重召开。我们诚挚地邀请您参加此次盛会。

经过专家审稿，您投的稿件评审结果如下

ID	论文编号	稿件题目	第一作者	评审结果
6577		肺癌患者社会支持及自尊与心理困扰结构方程模型的构建	陈慧	壁报交流展示
	所有作者：陈慧，田旭			

您也可以直接登录大会网站http://www.cco2021.org 后点击“论文评审结果”按钮进行实时的网上查询。

温馨提示：

1. 如果您的论文被评为壁报交流，请您按照以下要求准备您的壁报：

壁报尺寸：竖版16:9 PPT/PPTX格式

大会为电子壁报，壁报上传截止日期为：2021年9月30日
壁报上传流程请登陆大会网站，点击壁报上传按钮进行流程查看并下载电子壁报模板。
壁报上传成功后，大会将在11月30日前发送大会壁报交流证书。

2. 如果您的论文被评为书面交流，不必准备壁报，欢迎积极参加会议讨论。

3. 对于已经安排壁报而无故不按时上传壁报的，组委会将做记录并在将来的会议上酌情严肃处理。

4. 提示：**会前注册第一次优惠将于2021年8月31日截止，请登录大会网站进行注册操作并交会议费**，以享受注册费优惠，凡没有事先交费的代表，无论是否进行网上注册，现场一律按照现场注册费率交费。由于住房比较紧张，请各位需要安排住房的代表务必在网上做住房预定。没有预定将无法保证安排住房。详情请参照大会网站。

期待与您在中国肿瘤学大会见面。

中国抗癌协会
2021年8月

Appendix 12

Invitation letter for presentation 3 in 2021 CCO

2021 中国肿瘤学大会（CCO）
论文录取通知

尊敬的田旭医生您好！

由中国抗癌协会主办，河南省肿瘤医院、河南省癌症基金会承办协会承办，国际抗癌联盟(UICC)、中国整合医学发展战略研究院协办的2021中国肿瘤学大会(CCO)将于2021年11月18日-21日在郑州隆重召开。我们诚挚地邀请您参加此次盛会。

经过专家审稿，您投的稿件评审结果如下

ID	论文编号	稿件题目	第一作者	评审结果
131		Predicting the risk of psychological distress among lung cancer patients: development of predictive algorithm based on sociodemographic and clinical factors	田旭	收录大会论文集
	所有作者：田旭			

您也可以直接登录大会网站http://www.cco2021.org 后点击“论文评审结果”按钮进行实时的网上查询。

温馨提示：

1. 如果您的论文被评为壁报交流，请您按照以下要求准备您的壁报：

壁报尺寸：竖版16:9 PPT/PPTX格式

大会为电子壁报，壁报上传截止日期为：2021年9月30日
壁报上传流程请登陆大会网站，点击壁报上传按钮进行流程查看并下载电子壁报模板。
壁报上传成功后，大会将在11月30日前发送大会壁报交流证书。

2. 如果您的论文被评为书面交流，不必准备壁报，欢迎积极参加会议讨论。

3. 对于已经安排壁报而无故不按时上传壁报的，组委会将做记录并在将来的会议上酌情严肃处理。

4. 提示：**会前注册第一次优惠将于2021年8月31日截止，请登录大会网站进行注册操作并交会议费**，以享受注册费优惠，凡没有事先交费的代表，无论是否进行网上注册，现场一律按照现场注册费率交费。由于住房比较紧张，请各位需要安排住房的代表务必在网上做住房预定。没有预定将无法保证安排住房。详情请参照大会网站。

期待与您在中国肿瘤学大会见面。

中国抗癌协会
2021年8月

Appendix 13

PPT for public-entry lecture

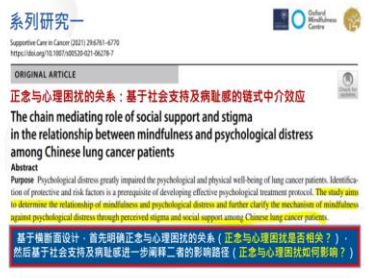
正念公益讲座
正念与肺癌患者社会心理康复
基于正念减压的肺癌心理困扰干预
分享者：田旭 时间：2022/11/11

肺癌流病学
肺癌仍位居新发及死亡首位

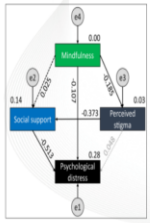
癌症心理困扰
JNCCN
Distress Management, Version 3.2019, NCCN Clinical Practice Guidelines in Oncology
癌症患者在疾病全周期均会遭受不同水平心理困扰的影响

肺癌心理困扰
Psychosocial Rehabilitation for Cancer Patients
肺癌患者心理困扰检出率位居各类癌症之首！！！

心理困扰的危害
临床显著的心理困扰将导致一系列不良后果
自杀风险
高死亡率
治疗中断
1
2
3
4
5
6
肿瘤生长
住院延长
生活质量


系列研究一
ORIGINAL ARTICLE
正念与心理困扰的关系：基于社会支持及病耻感的链式中介效应
The chain mediating role of social support and stigma in the relationship between mindfulness and psychological distress among Chinese lung cancer patients
Abstract
基于横断面设计，首先明确正念与心理困扰的关系（正念与心理困扰是否相关？），然后基于社会支持及病耻感进一步阐释二者的影响路径（正念与心理困扰如何影响？）

系列研究一



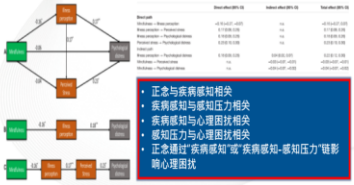
Direct pathway	Bootstrap estimate (95% CI)	P value
psychological distress←mindfulness	-0.107 (-0.195 to -0.017)	0.022
perceived stigma←mindfulness	-0.185 (-0.098 to -0.272)	0.001
social support←perceived stigma	-0.373 (-0.302 to -0.439)	0.001
psychological distress←social support	-0.512 (-0.588 to -0.437)	0.001
social support←mindfulness	0.025 (-0.004 to 0.192)	0.061
Indirect pathway	**Bootstrap estimate (95% CI)**	**P value**
psychological distress←mindfulness	-0.048 (-0.102 to 0.000)	0.048
social support←mindfulness	0.069 (0.037 to 0.105)	0.001
psychological distress←perceived stigma	0.191 (0.240 to 0.149)	<0.001

- 正念与心理困扰相关（直接效应）
- 正念与病耻感相关
- 病耻感与社会支持相关
- 社会支持与心理困扰相关
- 正念通过"病耻感-社会支持"链影响心理困扰（间接效应）

系列研究二

前面研究揭示，尽管正念可通过"社会支持-病耻感"链影响肺癌心理困扰，但其影响效力有限，显然其他路径可能也参与两者关系的调节，因此，基于横断面调查进一步阐释是否"疾病感知-感知压力"链可参与了正念对心理困扰的影响。

系列研究二



- 正念与疾病感知相关
- 疾病感知与感知压力相关
- 疾病感知与心理困扰相关
- 感知压力与心理困扰相关
- 正念通过"疾病感知"或"疾病感知-感知压力"链影响心理困扰

正念主题趋势

正念应用领域

正念国家热度

正念主题基金

系列研究三

系列研究三

系列研究四

系列研究四

系列研究四

注意事项
• 调试的正念干预方案需具备证据基础；
• 掌握正念相关干预技术是开展正念干预研究的前提；
• 正念干预实施者是否具备资质是评价研究信度的重要标准；
• 正念干预是否由具备资质的人员实施是伦理审核的关键。
MINDFULNESS
1 参加正念相关培训 掌握相关干预技术
2 跨学科多渠道合作 各司其职确保实施

正念公益讲座
感谢参与 期待交流
分享者：田旭 时间：2022/11/11
正念与肺癌患者社会心理康复
基于正念减压的肺癌心理困扰干预

Appendix 14

Sample pictures for seminars

临床问题如何结构化
1 提出问题
2 凝练问题
3 研究问题
肠道准备对肠镜检查和治疗至关重要，但如何提高肠道准备的质量亟待解决？
微信强化教育与常规教育（文字说明）相比，能否有效地提高肠道准备质量？
微信强化与常规教育用于结肠镜检查前肠道准备效果比较的随机对照试验
如何将临床问题结构化，形成可供开展研究的科学问题

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从肺癌心理困扰早期筛查及精准干预系列研究谈护理研究思路与思维
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TMR
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临床护理科研选题
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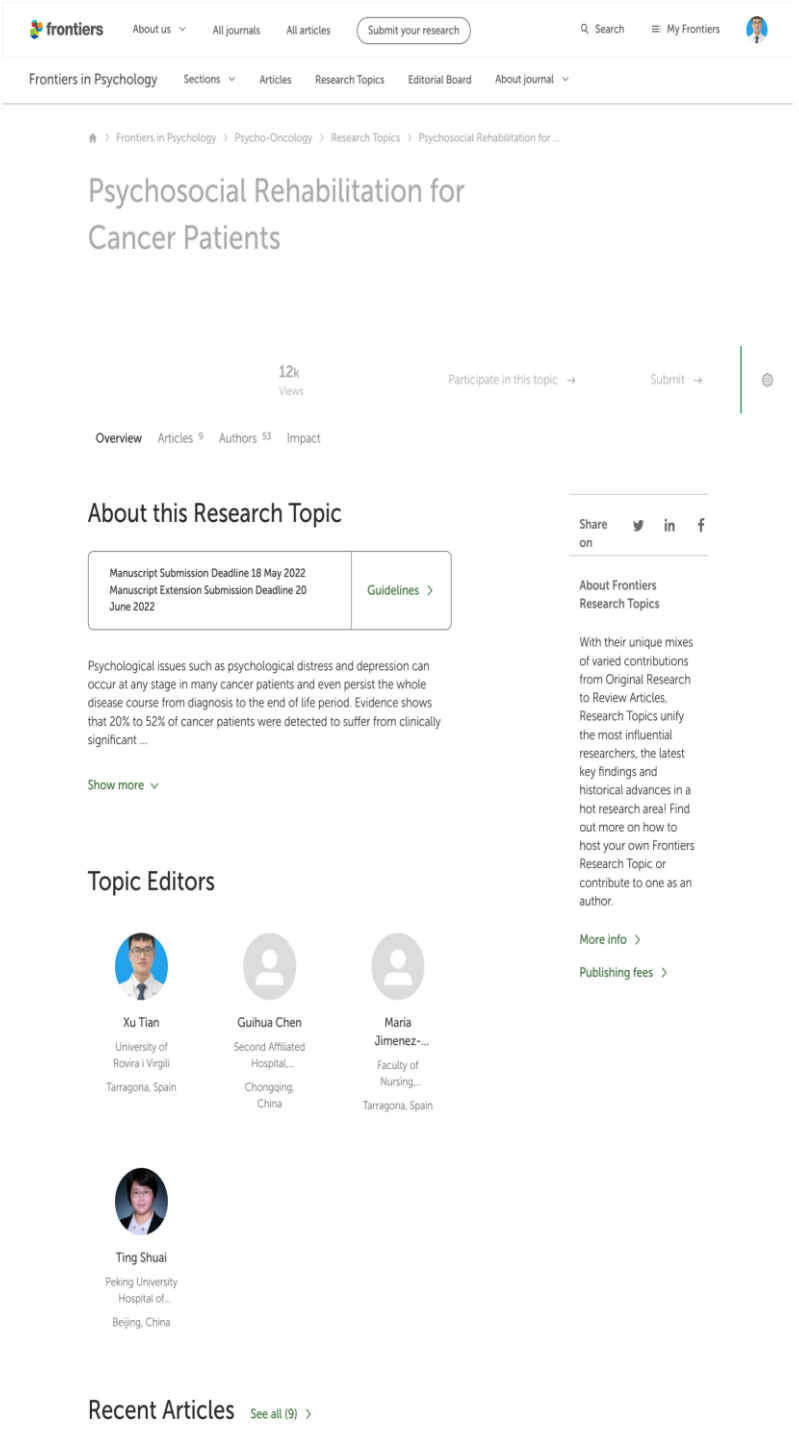
Xu Tian RN, BNSc, MSN, PhDs

Appendix 15

Screenshot for Research Topic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Impact
About this Research Topic
Manuscript Submission Deadline 18 May 2022
Manuscript Extension Submission Deadline 20 June 2022
Guidelines ›
Psychological issues such as psychological distress and depression can occur at any stage in many cancer patients and even persist the whole disease course from diagnosis to the end of life period. Evidence shows that 20% to 52% of cancer patients were detected to suffer from clinically significant ...
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Appendix 16

Screenshot for Software

医学计算
卡氏评分
体力评分
体质指数和体表面积计算
化疗毒性分级
下肢静脉栓塞风险评估
临床肺部感染评分
NYHA心功能分级
肝功能分级
肝昏迷分级
肌酐清除率
肺癌患者心理困扰风险测评
心理困扰风险评估
评测
欢迎使用
肺癌患者心理困扰风险预测
请认真填写如下信息
年龄段
文化程度
职业状态
家庭收入
饮酒史
肿瘤分期
心理困扰风险评估
评测
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请认真填写如下信息
测评结果
心理困扰得分: -18 高风险
知觉压力: 22 0-40
病耻感: 78 31-124
正念: 124 39-195
社会支持: 42 12-84
应对方式: 44 20-80
建议提供社会支持，培养积极的应对方式，从而降低病耻感，最终降低心理困扰水平。
确定

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