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Feasibility and preliminary efficacy of an art-making program to manage fear of cancer recurrence (AM-I-FCR) in lung cancer patients: a randomized controlled pilot study

Jialing Lin^{1†}, Zhixuan Kang^{1†}, Chenxing Zhang¹, Rachel Arbing², Wei-Ti Chen² and Feifei Huang^{1*} 

Abstract

Background Fear of cancer recurrence (FCR) imposes a significant psychological and physical burden on cancer patients. Art-making interventions may offer a novel approach to alleviating FCR. This study aimed to develop an art-making program (AM-I-FCR) and assess its feasibility and preliminary effects on FCR in lung cancer patients.

Methods The AM7-I-FCR was developed and evaluated via intervention mapping from March to December 2023. Step 1 (needs assessment) involved qualitative interviews. Step 2 (setting objectives) included translation and matrix creation. Step 3 (program design) involved a theoretical framework and a systematic review. Step 4 (program production) conducted expert meetings and collected patient feedback. Step 5 (implementation) and Step 6 (program evaluation) involved a pilot-randomized controlled trial (RCT) from August to December 2023 at a tertiary hospital in Fuzhou, China. The participants were randomized to receive either standard care or AM-I-FCR plus standard care. Data were collected at baseline, midpoint, and post-intervention and analyzed using intention-to-treat analysis and generalized linear mixed models. Feasibility was assessed by participation rates, satisfaction, and adverse events. Fidelity was evaluated via standardized checklist, supervision meetings, audio recordings, and qualitative interviews.

Results Based on the first four steps, AM-I-FCR was developed successfully. The pilot-RCT including 60 patients (30 per group), with 28 valid cases per group, revealed significantly lower FCR severity (95% CI, 0.606 ~ 2.994, $p < 0.001$), anxiety (95% CI, -2.888 ~ -0.712, $p < 0.05$), depression (95% CI -3.587 to -1.147, $p < 0.05$), and illness perceptions (95% CI, 0.079 ~ 4.654, $p < 0.001$), along with improved confrontation (95% CI, -3.908 ~ -1.425, $p < 0.001$) and emotional quality of life (QOL) (95% CI, -2.674 ~ -0.859, $p < 0.001$) in the intervention group. No significant differences were noted in avoidance or other QOL dimensions ($p > 0.05$). The intervention was feasible, with no adverse events. The interviews emphasized emotional release and self-exploration, demonstrating high fidelity.

Conclusions This study successfully developed the AM-I-FCR, which showed encouraging feasibility and acceptability and preliminarily reduced FCR severity, anxiety, and depression while improving confrontation, illness perceptions, and emotional well-being.

Trial registration ChiCTR2300069395. Registered on 15 March 2023.

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Keywords Lung neoplasms, Art therapy, Feasibility studies, Fear of cancer recurrence, Intervention mapping

Background

Lung cancer is a leading global health challenge, with China reporting the highest incidence and mortality rates worldwide. In 2022, more than 1.06 million new cases (22% of global cases) and more than 730,000 deaths (28% of global deaths) from lung cancer were recorded in China [1]. Despite significant advancements in medical technology, which have notably improved survival and cure rates, lung cancer remains a major concern because of its high recurrence and metastasis rates [2]. These rates, ranging from 30 to 75%, are substantially higher than those of most other cancers, contributing to substantial distress among survivors [2–4]. One of the most prevalent and persistent psychological challenges faced by lung cancer survivors is the fear of cancer recurrence (FCR), which is defined as a persistent concern about the return or progression of cancer [2].

FCR has emerged as a significant unmet need in oncology care [2]. Globally, 57.5% of lung cancer survivors report experiencing FCR [5], with even higher rates in China (77.9% to 97.74%) [6, 7]. The psychological, cognitive, and emotional responses triggered by FCR, such as heightened anxiety, rumination, and hypervigilance to bodily sensations [8], can lead to dysfunctional behaviors [9, 10], including excessive health checks, avoidance of medical resources, and overuse of healthcare services [11]. These disruptions can distort illness perceptions, negatively affect coping strategies, and impair quality of life (QOL) [12]. In the long term, FCR can hinder future planning, reduce adherence to surveillance, and increase healthcare costs due to excessive reassurance-seeking behaviors [12]. Studies suggest that the effects of FCR can persist for up to 10 years following cancer diagnosis [13], highlighting the need for effective, theory-driven interventions to address this issue and improve the survivorship experience.

Psychological interventions, such as cognitive-behavioral therapy (CBT), mindfulness-based interventions, and narrative therapy, have shown small but consistent effects in reducing FCR [14, 15]. However, these interventions often face methodological limitations, including issues related to the intervention format, participant characteristics, ease of implementation, cultural adaptability, and theoretical grounding. For example, recent digital interventions, such as web-based CBT and mobile self-help applications, have shown promise but are often hindered by reduced adherence, limited personalization, and a lack of emotional engagement [15, 16]. To address these limitations, hybrid intervention

models that combine online and offline elements have been proposed, leveraging the accessibility of digital tools while maintaining the relational depth and empathy of in-person interactions [17].

Although much research has focused on breast [14] or female cancer survivors [18], lung cancer survivors, who face increased recurrence and metastasis risks, remain underrepresented in the literature. Furthermore, many studies lack interventions tailored to participants' clinical FCR levels, that is, the severity or degree of FCR reaching a clinically significant threshold [19, 20], limiting their impact. Additionally, many interventions fail to incorporate explicit theoretical frameworks, which would improve the understanding of the mechanisms underlying psychological change [21, 22]. Collectively, these gaps underscore the need for targeted, theory-driven research addressing FCR in underrepresented populations such as lung cancer survivors.

Cultural factors, particularly in Chinese contexts, also present challenges for psychological interventions. In China, the cultural concept of *mianzi* (saving face) and a tendency to avoid emotional disclosure [23] can inhibit patient engagement in interventions that require openly confronting personal fears. Furthermore, practical challenges such as poor patient compliance, heterogeneity in intervention quality, the need for intensive professional training, and high resource consumption have been highlighted in previous studies [14]. Future interventions must focus on cognitive processes, such as worry, rumination, and attentional bias, to alter how individuals relate to their inner experiences, rather than solely focusing on the content of fears [15].

Art-making interventions, which engage participants in nonverbal forms of expression such as painting, clay modeling, and coloring, offer promising solutions to these challenges [24]. Art-making allows participants to externalize and reframe their fears symbolically, facilitating cognitive restructuring and emotional regulation [24]. According to Czamanski-Cohen and Weihs's bodymind model [25], therapists provide high-quality materials and create a safe, supportive environment, fostering a harmonious relationship between the patient, artwork, and therapist. This environment enhances creativity, promotes mind–body integration, and facilitates self-expression through sensory stimulation, visual impact, and memory activation [25]. Unlike conventional talk therapies, art-making integrates both physiological and psychological processes,

fostering emotional regulation, self-activation, and personal growth [26]. By engaging in creative expression, patients can disrupt rigid cognitive patterns related to FCR—such as rumination, attentional bias, and catastrophic thinking—ultimately promoting more adaptive cognition [27].

For patients with lung cancer, art-making offers a nonverbal, symbolic channel to safely express fear [25], reducing the cultural barriers of saving face that often inhibit emotional disclosure, particularly in Chinese contexts [23]. By externalizing fear into visual form, patients can observe their emotions with greater psychological distance, reinterpret fear-related cues, and gain a sense of mastery over distressing experiences [25]. This process supports cognitive integration, emotional desensitization, and adaptive meaning-making—mechanisms aligned with both the bodymind model and contemporary cognitive-emotional theories of FCR [25]. Together, these theoretical foundations underscore art-making as a promising and culturally sensitive intervention for reducing FCR and promoting emotional well-being among lung cancer survivors.

Unlike traditional art therapy, art-making interventions are simple to perform, offer a wide range of materials, and require minimal space and personnel qualifications, promoting high participant autonomy [24]. Leveraging these advantages, scholars have applied art-making interventions such as collage, clay modeling, and mandala coloring to several cancer populations, including those with breast [28], oral [29], liver [30], and esophageal cancers [31]. The results revealed significant improvements in psychological health (e.g., anxiety, depression, illness perception, and coping) and physical symptoms (e.g., fatigue, sleep disorders, and nausea/vomiting). However, research on art-making interventions for FCR is limited [32]. Only one study on young breast cancer survivors who used collage reported significant improvements in FCR and QOL [33]. These findings suggest that art-making interventions hold promise as a new approach for improving FCR in cancer survivors, but their application in lung cancer remains unexplored.

Therefore, this study aimed to develop a tailored, theory-driven art-making intervention (AM-I-FCR) to reduce FCR in lung cancer survivors, via an intervention mapping (IM) framework. Intervention mapping is a systematic approach to designing, implementing, and evaluating interventions for complex health issues [34]. It integrates theory, evidence, and stakeholder input to create scientifically effective and sustainable strategies. By following this framework, interventions can be specifically tailored to meet the needs of lung cancer survivors and achieve the desired health outcomes [34].

The primary objective of this study was to assess the feasibility of the AM-I-FCR during the peri-chemotherapy period by evaluating participation rates, patient satisfaction, adverse events, and qualitative feedback. The secondary objectives included assessing the intervention's potential efficacy in reducing FCR, as well as improving anxiety, depression, coping, illness perception, and QOL. A pilot randomized controlled trial (RCT) was used to compare the AM-I-FCR group with standard care, hypothesizing that the intervention would result in significantly lower FCR, anxiety, and depression, along with enhanced coping, illness perception, and QOL, with effects evident at both the intervention midpoint and post-intervention.

Methods

The study was conducted from March 2023 to December 2023, following the IM framework with six stages: needs assessment, setting objectives, program design, program production, and planning for implementation and evaluation [34]. The research group included one psychology researcher, two oncological nursing researchers, one researcher specializing in art therapy, and three master's candidates. The protocol was registered with the Chinese Clinical Trial Registry (ChiCTR2300069395). This study was approved by the ethics committee of the relevant hospital (LSK no. 2023–027) and adhered to the TIDieR checklist [35], the GUIDED checklist [36], and the CONSORT 2010 statement: extension to randomized pilot and feasibility trials [37] (see Additional Files 1, 2, and 3). All study participants provided written informed consent. Figure 1 provides an overview of the steps involved in the IM framework, with details of the methods employed in steps 1 to 6 provided below.

Step 1: Needs assessment

In the IM framework [38], the aims of step 1 were to assess the cognition and coping strategies of FCR, and the need for psychological intervention in lung cancer patients, combining both qualitative and quantitative methods. In this study, these goals were achieved through the integration of the results of our previously published longitudinal survey on FCR and QOL in 310 lung cancer survivors [6], the FCR model for lung cancer survivors [39], and semi-structured interviews with survivors and healthcare providers between March and April 2023. Moreover, it is necessary to understand the views of healthcare providers regarding patients' FCR, as well as the obstacles and challenges they face when dealing with patients' negative mental health issues. As such, the mixed-method results guided the development of a logic model to outline the FCR problem and identify the target population.

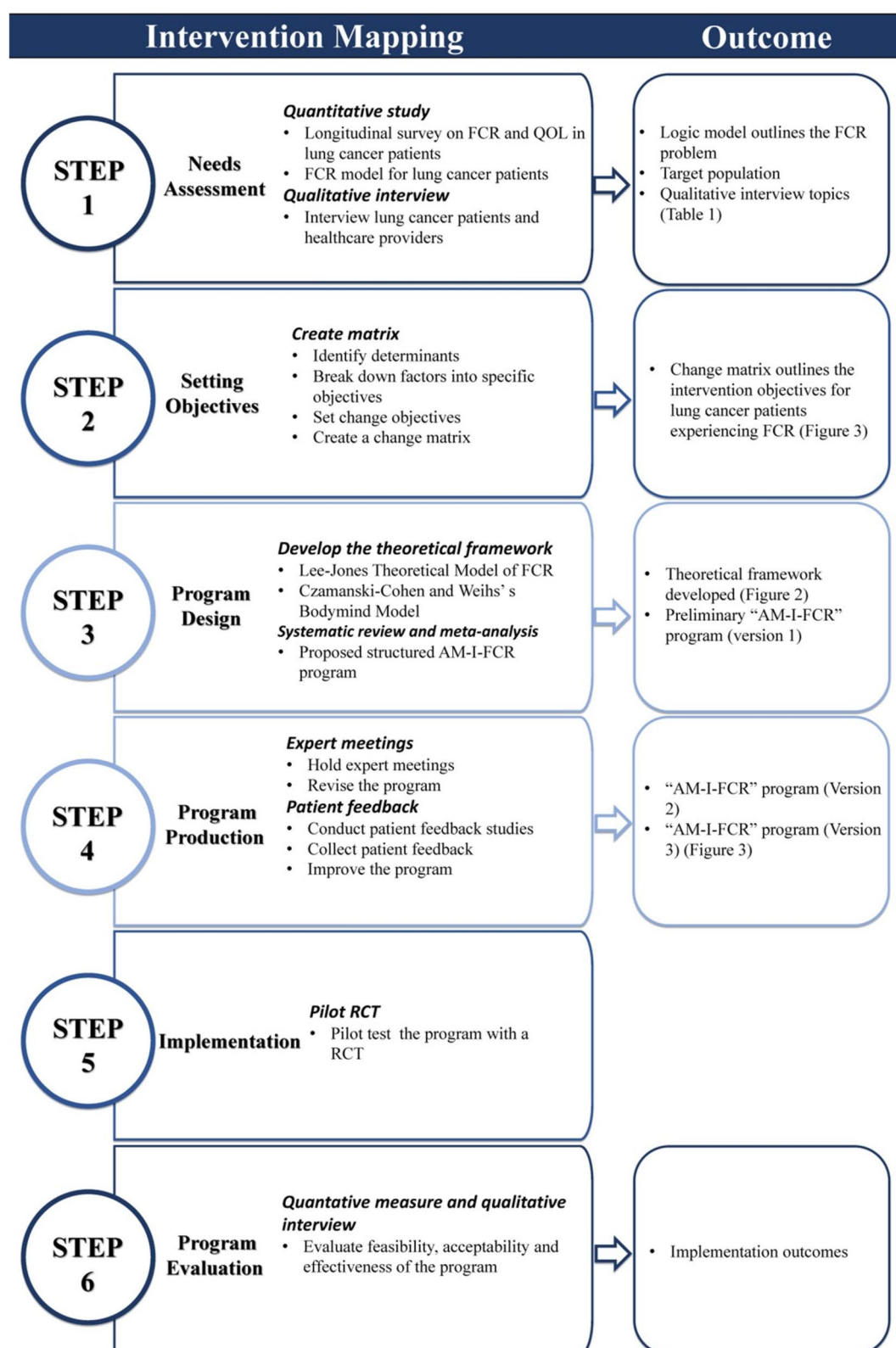


Fig. 1 The overview of steps involved in the IM framework

The participants were purposively sampled from the Department of Thoracic Surgery and Oncology at a tertiary hospital in Fuzhou, Fujian Province, China. The inclusion and exclusion criteria for patients with lung cancer are detailed in the section “Participants and setting” and in Additional File 4: Table 4a. The eligibility criteria for healthcare provider participants can be also found in Additional File 4: Table 4a. Data saturation was used to determine the sample size. The interviews were conducted privately in a hospital consultation room by an experienced qualitative researcher (LJL, female, master’s level) using a guide refined through pilot testing (see Additional File 4: Table 4b). Each session lasted 45–60 min and was digitally recorded. The interview data were transcribed within 24 h, anonymized, and reviewed by team members. Survivors were labeled P1–P13, and healthcare providers were labeled H1–H7. Two additional interviews confirmed saturation. The data were analyzed via traditional content analysis with Atlas.ti software [40], adhering to COREQ guidelines [21].

The demographic details of the participants can be found in Additional File 5, while the qualitative study findings are summarized in Additional File 6. By integrating the results of the authors’ previous survey with the qualitative data referenced above, a logic model of the problem was developed. This step assesses the key factors involved in the intervention program from

the perspective of multiple stakeholders. It is crucial to ensure the effectiveness and feasibility of the program, enabling more accurate formulation of intervention goals that meet the needs of patients and enhancing the targeted nature of the intervention program.

Step 2: Setting objectives

On the basis of the IM framework [34], Step 2 was used to determine the changes that should occur as a result of the intervention. In this study, on the basis of the findings of Step 1, five key modifiable determinants were identified: illness perceptions, negative emotions, coping, resilience, and FCR triggers. These determinants informed specific performance objectives: reducing anxiety and depression, promoting positive coping and resilience, changing illness perceptions, and decreasing FCR triggers. These objectives were translated into change goals, summarized in the change matrix (Additional File 7: Fig. S1). Finally, the aims of this program were to test the feasibility and acceptability of the AM-I-FCR and explore the preliminary effects of the program in reducing FCR levels in lung cancer survivors to improve their QOL, which could guide interventions for lung cancer survivors with FCR.

Step 3: Program design

Step 3 focused on identifying theoretical approaches that support the achievement of change objectives, as

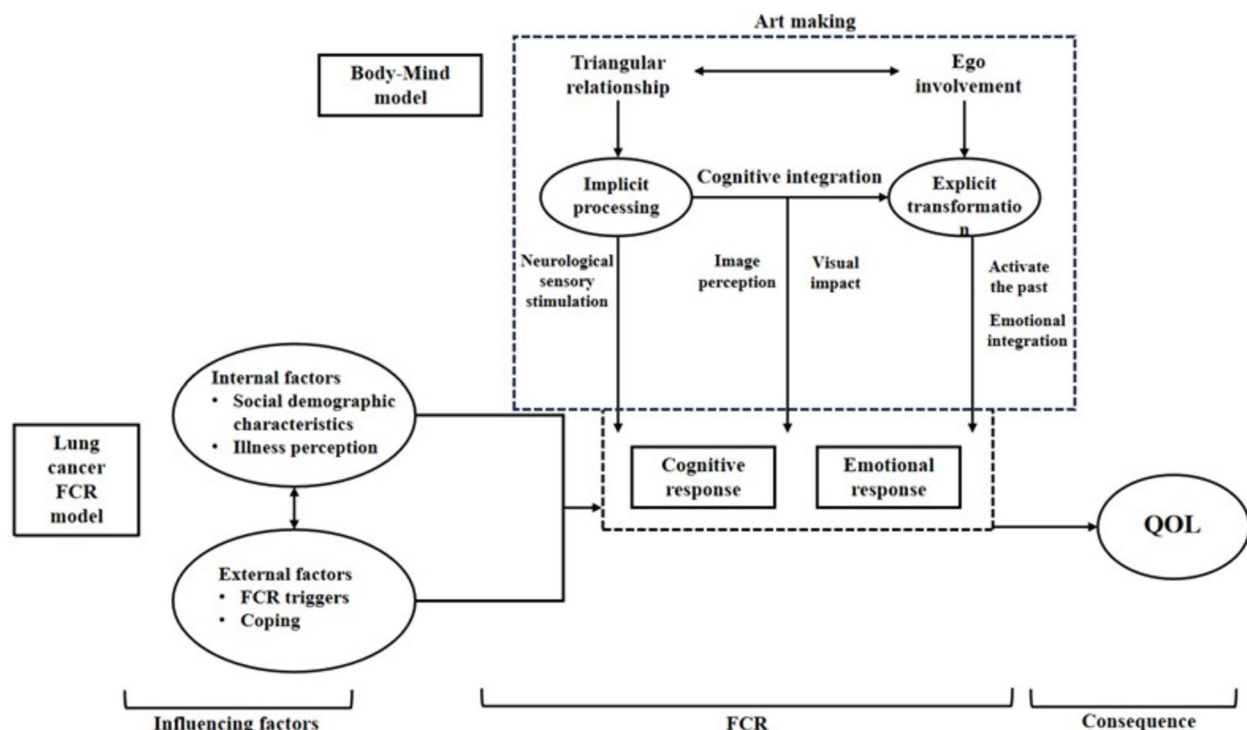


Fig. 2 The theoretical framework of the intervention

well as practical tools that facilitate the operationalization of these approaches [34]. We developed the theoretical framework for this study (see Fig. 2) in May 2023, integrating the Lee-Jones theoretical model of FCR [11] and Czamanski-Cohen and Weihs's bodymind model [25]. This framework addresses misconceptions about FCR, including attention bias and negative beliefs, while accounting for factors such as awareness of disease and coping mechanisms. In the same period, a systematic review and meta-analysis were conducted to evaluate the effectiveness of art-making interventions in cancer care, identify intervention characteristics, and assess their efficacy in alleviating physical and psychological distress [32]. Finally, insights from step 1 and step 2 were synthesized (see Additional File 8: Table 7) to develop the preliminary AM-I-FCR (version 1), outlining intervention targets, potential mechanisms, content, and methods.

Step 4: Program production

In line with the IM framework [34], step 4 involved developing the intervention protocol and supporting materials. This step involved revising and improving version 1 of the AM-I-FCR, generated in step 3 on the basis of feedback from the expert meeting and the patients, to create the final AM-I-FCR version 1.

Expert meetings

Two rounds of expert meetings were held to evaluate AM-I-FCR version 1, with 12 experts participating. The group, with an average age of 36.92 ± 6.68 years and 12.67 ± 8.29 years of experience, included specialists in nursing psychology (6), applied psychology (3), oncology nursing (2), and art therapy (1). All the experts held advanced degrees (equivalent to an M.D.), with service years ranging from 5 to 30. The expert response rate was 100%, with judgment, familiarity, and authority coefficients of 0.958, 0.866, and 0.912, respectively. Scores for the overall plan (4.25–5.00), content (4.08–5.00), design (4.42–5.00), and theme evaluations (4.00–4.83) indicated strong consensus. Based on expert feedback (see Additional File 9: Table 8a), the program was refined, resulting in AM-I-FCR version 2.

Survivors' feedback

To assess the acceptability and feasibility of AM-I-FCR version 2 in lung cancer survivors and identify potential challenges, five lung cancer survivors undergoing chemotherapy in the thoracic surgery department of a tertiary hospital in Fuzhou, Fujian Province, in June 2023 were selected through convenience sampling. These participants received AM-I-FCR alongside routine care. After

the intervention, a satisfaction survey was administered, which rated various aspects from "very satisfied" to "very dissatisfied" on a 5–1 scale. Open-ended questions were included to gather suggestions on areas of dissatisfaction, which are summarized in Additional File 9: Table 8b.

Researchers also documented challenges encountered during the intervention to refine and improve its feasibility. On the basis of this feedback, the third version of the AM-I-FCR was developed (see Fig. 3).

Step 5: Implementation

Study design

In this study, step 5 was conducted as a single-blind, two-arm parallel-group pilot RCT, with blinding applied only to the data collectors.

Participants and setting

Lung cancer patients admitted to the thoracic surgery inpatient departments of a tertiary hospital in Fuzhou, Fujian Province, between August and December 2023 were recruited for this study. The inclusion criteria were as follows: (1) Confirmed diagnosis of primary lung cancer on the basis of clinical endoscopy and pathology, with the patient scheduled for first-time chemotherapy; (2) age ≥ 18 years; (3) FCRI-SF score > 13 , indicating moderate to severe FCR (assessed at recruitment); (4) Karnofsky performance status (KPS) score ≥ 60 ; and (5) at least an elementary school education.

The exclusion criteria included the following: (1) Mental disorders or current mental health treatment; (2) personality disorders, intellectual disabilities, brain injuries, or neurological diseases; (3) other malignant tumors; (4) communication difficulties; (5) expected survival time < 1 year, as determined by the attending physician; (6) fractures or ongoing limb surgery; and (7) prior participation in similar art-based interventions.

The trial termination criteria were as follows: (1) Severe adverse complications preventing continuation or (2) voluntary withdrawal.

The study was approved by the department, and the lung cancer patients were enrolled by the referral of the doctor in charge and secondary screening. After admission and trust building, the informed consent was signed, and baseline data were collected by the research assistant at the same time.

Sample size calculation

For the experimental and control groups that met the inclusion criteria, the sample size was allocated at a 1:1 ratio. G*Power 3.1 software was used to calculate the required sample size, and based on an estimated effect

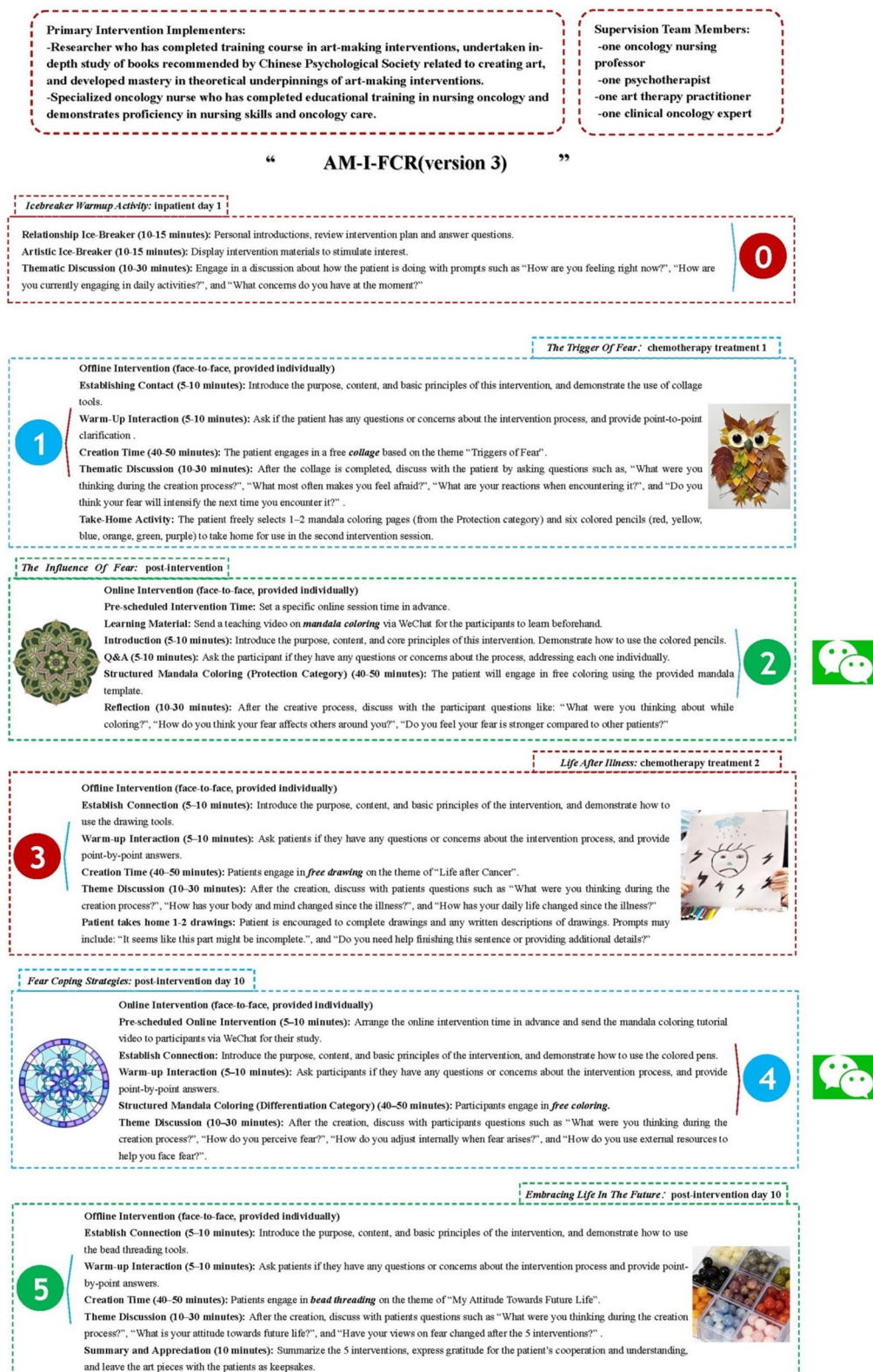


Fig. 3 A visual summary of the art-making intervention for fear of cancer recurrence in lung cancer patients (AM-I-FCR) (version 3)

size from previous research ($f=0.21$) [33], with a statistical power of $1-\beta=0.90$ and a significance level of $\alpha=0.05$, a minimum of 50 participants was needed. Accounting for a 20% dropout rate, the total sample size was 60 participants, with 30 participants in each group (see Additional File 10: Fig. S2).

Randomization, concealment, and masking

- (1) *Randomization*: The random allocation sequence was generated by a research team member who was not involved in the implementation or data analysis via R software (version 4.3.3). A variable block randomization method was applied, with randomly varying block sizes of 4 and 6 and an allocation ratio of 1:1, to ensure balanced group sizes between the intervention and control groups while maintaining allocation unpredictability. A fixed random seed was set before sequence generation to ensure reproducibility of the randomization results.
- (2) *Allocation concealment*: To ensure rigorous allocation concealment, a system of sequentially numbered, opaque, sealed envelopes with multiple security layers was adopted. The randomization table generated in R (containing participant IDs and corresponding group assignments) was printed and sealed in tamper-evident inner envelopes that permanently displayed an “open” mark once unsealed. Each inner envelope was then placed into an outer envelope labeled only with the participant’s enrollment number, forming a double-envelope system. All envelopes were stored by an independent researcher who was not involved in participant recruitment or assessment. After the participants met the eligibility criteria and provided written informed consent, the investigator requested the corresponding numbered envelope from the custodian. The research assistant opened the outer envelope on site and handed the still-sealed inner envelope to the investigator, who then opened it in the presence of the research team to reveal the group assignment and implement the corresponding intervention. All opened envelopes were securely retained for audit purposes.
- (3) *Blinding*: Due to the nature of the psychological intervention, blinding of the interventionists and participants was not feasible. Therefore, blinding was implemented only for the data collectors. During the allocation disclosure process, data collectors were not present and remained unaware of group assignments. They had access only to participants’ identification numbers and were blinded to group allocation information.

Control group (CG)

Patients in the CG received standard care, including chemotherapy education on treatment goals, side effects (e.g., nausea, fatigue), and relief strategies. They were advised to have a light pre-chemotherapy meal, increase protein and fluids afterward, and practice hygiene measures such as handwashing and mask-wearing to prevent infections. A follow-up call within 1 week post-discharge reminded patients about blood tests and monitored them for adverse effects. Nutritional counseling supported immunity, and patients were encouraged to contact the healthcare team for assistance with discomfort or side effects.

Intervention group (IG)

In addition to standard care, patients in the IG participated in the AM-I-FCR for lung cancer patients, which consists of six components: (1) icebreaker warm-up activity, (2) the trigger of fear, (3) the influence of fear, (4) life after illness, (5) fear coping strategies, and (6) embracing life in the future. The intervention was delivered by the researcher and an oncology specialist nurse, both of whom completed a one-week (21-h) standardized training program in art-based intervention and successfully passed a competency assessment, thereby ensuring intervention consistency.

Over three chemotherapy cycles, the intervention included ice breaking activity at admission, three face-to-face sessions during hospitalization, and two online sessions approximately 10 days post-discharge. Each session lasted 4–60 min and was tailored to the patient’s progress. A detailed intervention plan is outlined in Fig. 3.

Step 6: Program evaluation

In the IM framework [34], the aim of step 6 is to assess the feasibility, acceptability, and preliminary efficacy of the intervention program through a qualitative and quantitative approach. Therefore, in this study, we assessed the AM-I-FCR by collecting questionnaires and conducting qualitative interviews.

Outcome measures of feasibility and acceptability

- (1) *Participants’ satisfaction*: Satisfaction with the intervention was assessed via a self-reported 5-point Likert scale ranging from very satisfied (5) to very unsatisfied (1) from November to December 2023.
- (2) *Safety of the intervention*: Adverse events were recorded during the intervention via a customized form, documenting causes, actions taken, and follow-up results.

- (3) *Participants' experience and suggestions*: Semi-structured interviews were conducted from November to December 2023, with an interview guide developed through team brainstorming and refined by an experienced nursing professor. Following the principle of maximum variation, factors such as gender, residential area, education level, and cancer stage were considered. The sample size continued to increase until no new themes emerged, and data saturation was reached [41].

Outcome measures of preliminary efficacy

All participants completed validated questionnaires at three time points: before the intervention (T0), at the midpoint (T1), and immediately after the intervention (T2). The primary outcome was FCR severity, measured by the 9-item Fear of Cancer Recurrence Inventory (FCRI) severity subscale (Cronbach's $\alpha=0.89$) [19]. The secondary outcomes included FCR triggers (8-item FCRI triggers subscale, Cronbach's $\alpha=0.89$) [19], anxiety and depression (14-item Hospital Anxiety and Depression Scale, Cronbach's $\alpha=0.82$) [42], illness perception (19-item Medical Coping Modes Questionnaire, Cronbach's $\alpha=0.71$) [43], coping behaviors (8-item Brief Illness Perception Questionnaire, Cronbach's $\alpha=0.77$) [44], and QOL (36-item Functional Assessment of Cancer Therapy-Lung Scale, Cronbach's $\alpha=0.79$) [45].

Data analysis

Analyses were conducted via IBM SPSS Statistics 27.0, with a two-sided p -value <0.05 considered statistically significant [46]. Baseline demographic and clinical differences between the intervention and CGs were assessed via chi-square tests and independent t -tests. The effects of the AM-I-FCR were evaluated via linear mixed models with fixed effects for group, time, and group-by-time interactions and a random intercept for the subjects. The analyses adhered to the intention-to-treat (ITT) and per-protocol (PP) principles to verify the consistency of the conclusions, thereby enhancing the credibility of the research results [47]. The missing data were imputed using the last observation carried forward [48]. Covariance structure selection used likelihood ratio tests, AIC, and BIC, which compare unstructured (UN), compound symmetry (CS), and first-order autoregressive (AR1) models [49–51]. Sensitivity analyses for the PP sample and all time points were used to assess robustness. Effect sizes (Cohen's d) were calculated for each time point (0.2 =small, 0.5 =medium, 0.8 =large) [52].

Qualitative data from interviews were analyzed using NVivo 12.0 and Hsieh and Shannon's conventional content analysis [40]. Two researchers independently coded transcripts through three steps: (1) Line-by-line coding of

key statements, (2) refining codes into themes until saturation, and (3) defining themes with supporting excerpts. Discrepancies were resolved through team discussions and reviewed by a third expert.

Intervention fidelity

Intervention fidelity was ensured using multiple strategies. First, a standardized fidelity checklist was developed and completed for each session, covering intervention duration, frequency, and delivery procedures. Weekly supervision meetings were held during which interventionists reported participant feedback and practical challenges encountered during implementation. Supervisors proposed necessary modifications based on relevant literature and clinical experience and monitored their subsequent implementation. Second, with participants' informed consent, all intervention sessions were audio-recorded. A licensed psychologist conducted random fidelity assessments by reviewing one out of every three recorded sessions to evaluate adherence to the intervention protocol. Third, qualitative interviews were conducted with participants to explore their perceptions of and experiences with the intervention, providing additional evidence regarding the consistency and integrity of intervention delivery.

Results

Participant flow and baseline characteristics

We screened 72 eligible lung cancer patients, excluding those with FCRI-SF scores <13 ($n=4$) and those who declined to participate ($n=8$). The remaining 60 patients were randomly assigned equally to the IG or CG. The follow-up rate at T2 was 93.33% (56/60). As shown in Table 1 baseline demographic and clinical characteristics, along with measures of FCR severity, triggers, QOL, anxiety, depression, coping behaviors, and illness perception, were comparable between the groups. Both groups experienced a 6.67% dropout rate due to physical discomfort or refusal to continue. Dropout and completion characteristics did not differ significantly ($p>0.05$). Figure 4 displays the CONSORT flowchart of the study.

Preliminary efficacy estimate

Primary outcomes based on the intention-to-treat sample

The covariance model with scale identity was used for model fitting (see Additional File 11: Table 9). A significant group-by-time interaction was observed for FCR severity (mean difference = -3.30 ; Cohen's $d=0.378$; 95% CI, $1.432 \sim 3.968$; $p<0.001$) (Tables 2 & 3). The mean FCR severity scores in both groups tended to increase over time; however, the increase in the IG was minimal and stabilized ($F=23.945$, $p<0.001$) (Fig. 5 & Table 4).

Table 1 Comparison of characteristics and baseline outcome variables between the two groups of patients

Variable	IG (n = 30)	CG (n = 30)	T/ χ^2 /Z	P
Age	56.63 ± 6.88	56.70 ± 4.56	− 0.044	0.965
Medical investment to date (per 10,000) ^a	2.30 (1.87, 5.95)	1.75 (1.30, 3.90)	− 1.821	0.069
Gender			0.341	0.559
Male	23	21		
Female	7	9		
Religion			0.800	0.371
No	21	24		
Yes ^b	9	6		
Residence location			0.798	0.670
Township	4	6		
Town	12	13		
City	14	11		
Level of education			0.596	0.940
Primary school	2	3		
Junior high school	21	21		
High school	4	4		
University and above	3	2		
Number of children			0.111	0.739
1–2	24	25		
> 2	6	5		
Living with children			0.373	0.542
No	6	8		
Yes	24	22		
Employment			1.199	0.918
Self-employed	12	10		
Company employee	6	6		
Laborer	4	3		
Homemaker	1	1		
Retired	7	10		
Medical insurance type			0.218	0.640
Urban and rural residents	27	28		
Employee health insurance	3	2		
Main source of income for family			0.067	0.795
Yes	16	17		
No	14	13		
How does your family's financial situation compare to those around you?			0.363	0.956
Poor	1	1		
Similar	21	22		
Better	8	7		
Cancer type			0.373	0.542
NSCLC	22	24		
SCLC	8	6		
TNM stage ^e			0.642	0.934
I	1	1		
II	10	9		
III	15	17		
IV	4	3		
Surgery			0.073	0.787
Yes	11	10		

Table 1 (continued)

Variable	IG (n = 30)	CG (n = 30)	$T/\chi^2/Z$	P
No	19	20		
Surgical site			0.535	0.864
No surgery	19	20		
Left	7	5		
Right	4	5		
Comorbidities			0.010	0.920
No	18	19		
Yes ^d	12	11		
Cancer regimen			0.458	0.855
Chemotherapeutics only	20	18		
Chemotherapeutics + immunotherapy	8	9		
Chemotherapeutics + immunotherapy + targeting drug	2	3		
Smoking status			0.156	1.000
Nonsmoker	9	9		
Former smoker	19	19		
Smoker	2	2		
Baseline outcome variable				
FCR severity	25.23 ± 2.31	24.33 ± 2.45	0.650	0.518
QOL (physical condition)	19.80 ± 2.79	20.77 ± 1.99	− 1.550	0.126
QOL (social/family condition)	13.23 ± 1.45	13.47 ± 1.57	− 0.597	0.553
QOL (specific symptom condition)	19.17 ± 3.91	18.63 ± 3.74	0.540	0.591
QOL (total)	66.27 ± 7.30	66.97 ± 7.51	− 0.366	0.716
Anxiety	12.33 ± 2.34	12.37 ± 2.59	− 0.052	0.958
Confrontation	21.33 ± 2.58	20.97 ± 1.90	0.627	0.533
Acceptance of resignation	14.00 ± 1.87	14.10 ± 1.92	− 0.204	0.839
Illness perception	52.20 ± 3.97	53.10 ± 3.91	− 0.885	0.380
FCR triggering factors	25 (24.75, 27)	25 (24, 27)	− 0.767	0.448
QL (emotional condition)	5 (4, 8)	5 (4, 7)	− 0.226	0.825
QOL (functional condition)	8 (6, 11)	7.5 (5, 12)	− 0.423	0.677
Depression	12 (10, 14)	12 (11, 14)	− 0.097	0.926
Fear avoidance	18 (16, 19)	17 (16, 18.25)	− 0.698	0.490

^a Analyzed via the Mann–Whitney test^b Involving Buddhism or Christianity^c Referencing the TNM staging criteria for lung cancer according to the AJCC (8th edition, 2018)^d Comorbidities include hypertension, diabetes mellitus, and gout

Random effects analysis revealed significant individual differences in FCR severity scores ($Z = 4.260$, $p < 0.001$).

Secondary outcomes based on the intention-to-treat sample

- (1) *FCR severity triggers*: A covariance model with AR1 fitting was used for model fitting (Additional File 11: Table 9). A significant group-by-time interaction was observed for FCR triggers (mean difference = − 2.46; 95% CI, 0.606 ~ 2.994, $p < 0.001$) (Tables 2 & 3). The mean FCR trigger scores in both

groups tended to increase over time; however, the increasing trend was slower in the IG ($F = 12.462$, $p < 0.001$) (Fig. 5 & Table 4).

- (2) *Anxiety and depression*: Covariance models with diagonal and scalar structures were used for model fitting (see Additional File 11: Table 9). Although no significant group-by-time interactions were observed for anxiety and depression, the measurement time points had statistically significant effects on the changes in anxiety and depression scores ($F = 13.326$ & 5.434 , $p < 0.01$). Both groups of lung cancer patients exhibited an overall upward trend

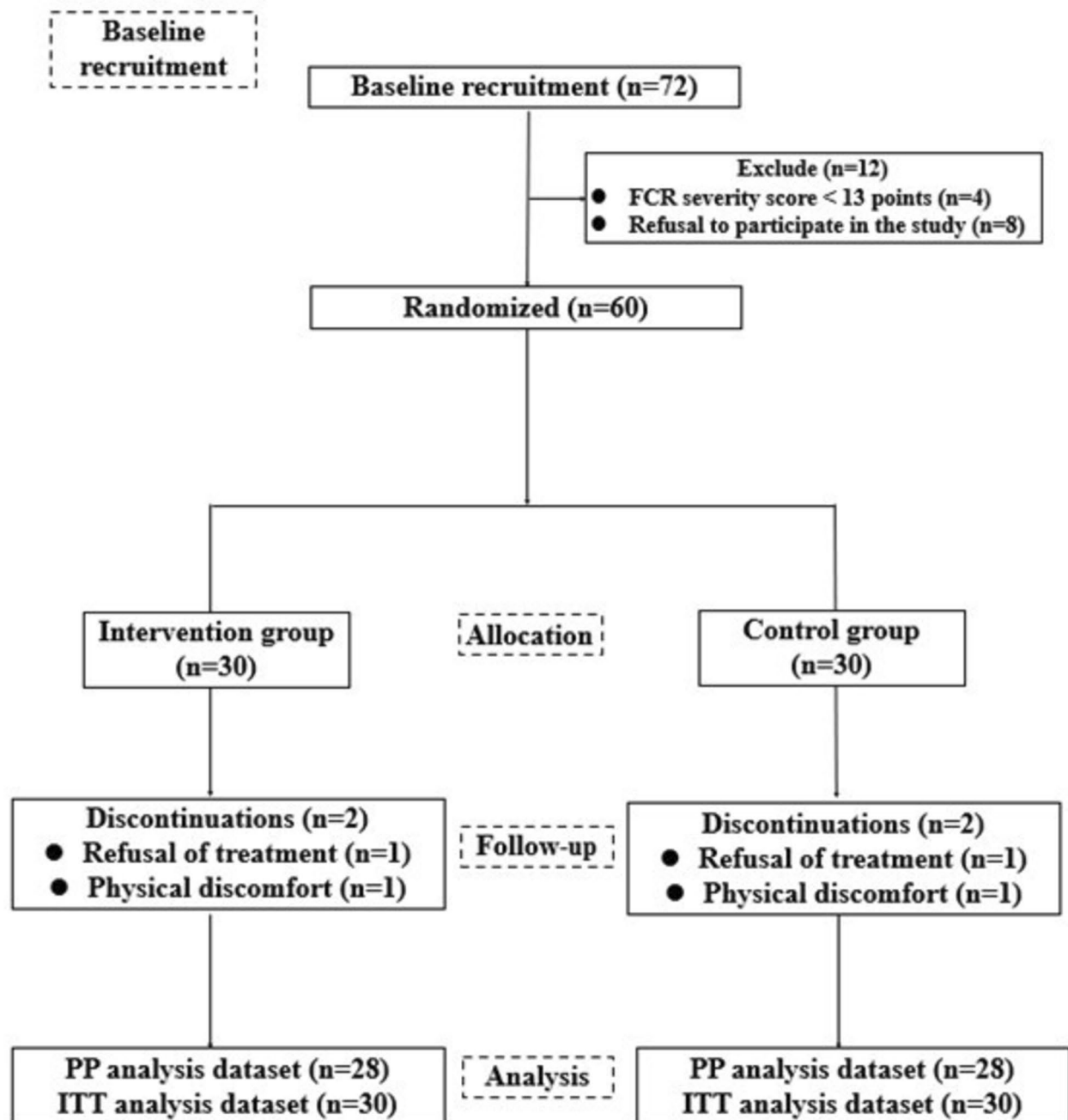


Fig. 4 The CONSORT flowchart

in anxiety and depression scores over time. However, the increasing trend was slower in the IG than in the CG (see Fig. 5 & Table 4). Post-intervention, anxiety, and depression scores in the IG were significantly lower than those in the CG (mean difference = -0.97 & -1.28 ; 95% CI, -2.888 ~ -0.712 & -3.587 to -1.147 ; Cohen's $d = -0.016$, $p < 0.05$),

with statistically significant differences observed ($F = 4.552$ & $F = 9.567$, $p < 0.05$) (Tables 2, 3, & 4).

- (3) *Coping behaviors*: A covariance model with AR1 fitting was used for model fitting (see Additional File 11: Table 9). A significant group-by-time interaction was observed for both confrontation and resignation coping. The confrontation coping scores in the IG were significantly higher than those in the CG

Table 2 Pairwise comparison results of groups and interaction terms for outcome variables between two groups (ITT)

Variable	Program	D	P
Time = T2, G1–G2	FCR severity	− 3.30	< 0.001
	FCR triggering factors	− 2.46	< 0.001
	QOL (physical condition)	− 0.50	0.458
	QOL (social/family condition)	0.13	0.833
	QOL (emotional condition)	2.63	< 0.001
	QOL (functional condition)	− 0.10	0.917
	QOL (specific symptom condition)	− 0.23	0.822
	QOL (total)	1.83	0.413
	Anxiety	− 1.80	0.001
	Depression	− 2.36	< 0.001
	Confrontation	2.73	< 0.001
	Fear avoidance	− 0.46	0.325
	Acceptance of resignation	− 3.40	< 0.001
	Illness perception	− 3.46	< 0.001
	Anxiety	− 0.97	0.034
	Depression	− 1.28	0.002

G1, control group; G2, intervention group

(mean difference = 2.73; 95% CI, − 3.908 ~ − 1.425; Cohen's $d = 0.159$; $p < 0.001$). In contrast, the resignation coping scores in the IG were significantly lower than those in the CG (mean difference = − 3.40; 95% CI, 0.778 ~ 2.488; Cohen's $d = -0.026$; $p < 0.001$) (Tables 2 & 3). With respect to trends across measurement time points, only resignation coping demonstrated a statistically significant

change over time ($F = 18.726$, $p < 0.001$). This finding indicates that resignation coping levels in lung cancer patients in the IG decreased over time, whereas an increasing trend was observed in those in the CG (see Fig. 5 & Table 4). However, no significant group-by-time interaction was found for avoidance coping ($F = -0.46$; 95% CI, − 0.369 ~ 1.502; $p > 0.05$).

(4) *Illness perceptions*: A covariance model with scalar invariance was used for model fitting (see Additional File 11: Table 9). A significant group-by-time interaction was observed for illness perceptions, with illness perception scores in the IG being lower than those in the CG (mean difference = − 3.46; 95% CI, 0.079 ~ 4.654; Cohen's $d = -0.053$; $p < 0.001$) (Tables 2 & 3). However, the time points of measurement had no statistically significant effect on the trend of changes in illness perception scores ($F = 1.774$, $p > 0.05$).

(5) *QOL*: A significant group-by-time interaction was observed for the emotional dimension of QOL, with emotional dimension scores in the IG being higher than those in the CG (mean difference = 2.63; 95% CI, − 2.674 ~ − 0.859; $p < 0.001$) (Tables 2 & 3). However, no significant group-by-time interactions were found for the physical, functional, or lung cancer-specific dimensions or the overall QOL score. Random effects analysis revealed significant inter-individual differences in the emotional dimension of QOL scores ($Z = 4.537$, $p < 0.001$). With respect to trends across measurement time points, only the physical dimension of QOL demonstrated a sta-

Table 3 Fixed effects analysis results of time points and groups for outcome variables between the two groups

Variable	Outcome	Coefficient (β)	95% CI	P
Time × group	FCR severity	2.700	(1.432, 3.968)	< 0.001
	FCR triggering factors	1.800	(0.606, 2.994)	0.003
	QOL (physical condition)	0.033	(− 1.098, 1.164)	0.954
	QOL (social/family condition)	0.033	(− 1.410, 1.477)	0.963
	QOL (emotional condition)	− 1.767	(− 2.674, − 0.859)	< 0.001
	QOL (functional condition)	− 0.033	(− 1.121, 1.054)	0.952
	QOL (specific symptom condition)	0.067	(− 1.892, 2.05)	0.947
	QOL (total)	− 1.567	(− 4.633, 1.499)	0.315
	Anxiety	0.700	(− 0.663, 2.063)	0.312
	Depression	0.967	(− 0.591, 2.524)	0.222
	Confrontation	− 2.667	(− 3.908, − 1.425)	< 0.001
	Fear avoidance	0.567	(− 0.369, 1.502)	0.233
	Acceptance of resignation	1.633	(0.778, 2.488)	< 0.001
	Illness perception	2.370	(0.079, 4.654)	0.043
Group	Anxiety	− 1.800	(− 2.888, − 0.712)	< 0.001
	Depression	− 2.367	(− 3.587, − 1.147)	< 0.001

G1, intervention group; G2, control group

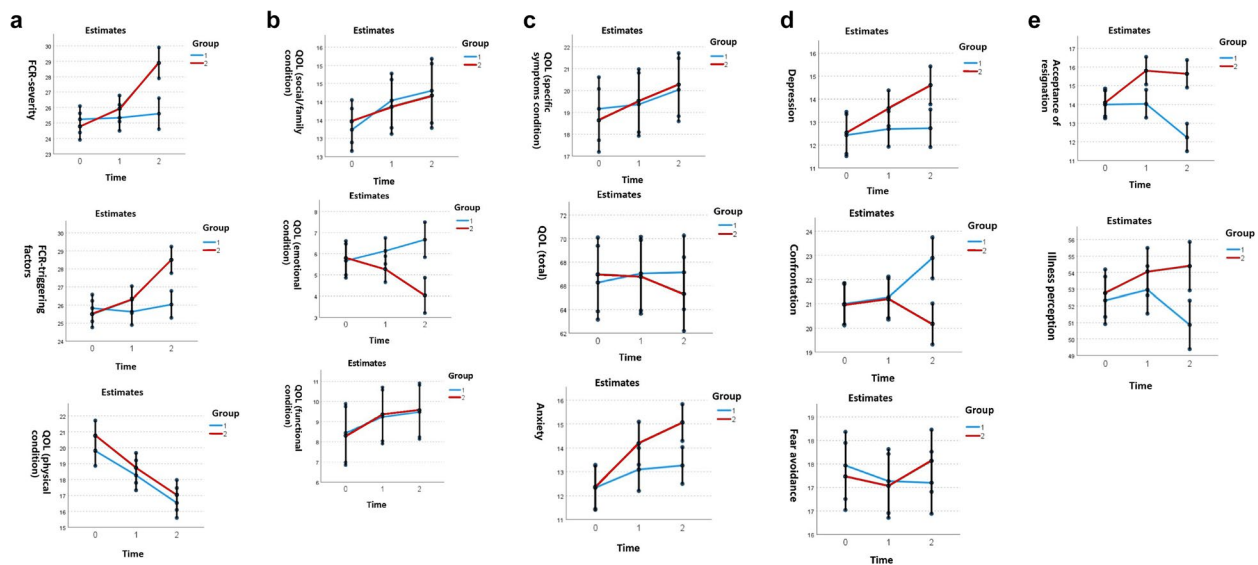


Fig. 5 **a** Outcome trends over time in control group versus intervention group. Note: Group 1, intervention group; Group 2, control group. **b** Outcome trends over time in control group versus intervention group. Note: Group 1, intervention group; Group 2, control group. **c** Outcome trends over time in control group versus intervention group. Note: Group 1, intervention group; Group 2, control group. **d** Outcome trends over time in control group versus intervention group. Note: Group 1, intervention group; Group 2, control group. **e** Outcome trends over time in control group versus intervention group. Note: Group 1, intervention group; Group 2, control group

tistically significant change over time ($F=50.965$, $p<0.001$), indicating that the physical health levels of lung cancer patients in both groups significantly declined over time.

Sensitivity analysis

Similar to findings based on the intention-to-treat sample, the analysis based on the per-protocol sample revealed that post-intervention, the IG had significantly lower scores than did the CG in several domains, including severity of FCR (mean difference = -1.14 , $F=4.479$, $p<0.05$), FCR triggers (mean difference = -0.93 , $F=6.174$, $p<0.05$), anxiety (mean difference = -0.99 , $F=5.213$, $p<0.05$), depression (mean difference = -1.15 , $F=8.568$, $p<0.01$), resignation coping (mean difference = -1.82 , $F=13.683$, $p<0.001$), and illness perception (mean difference = -1.73 , $F=4.849$, $p<0.05$). The IG also had significantly higher scores for the emotional dimension of QOL (mean difference = 1.13 , $F=6.084$, $p<0.05$) and confrontation coping (mean difference = 1.00 , $F=4.602$, $p<0.05$), with statistically significant differences.

Participants' satisfaction with and safety of the intervention

A total of 28 lung cancer patients who fully participated in the intervention rated their satisfaction with the AM-I-FCR. Among them, 20 patients (71.43%) rated the intervention as 5 (very satisfied), 5 patients (17.8%) rated it as

3 (satisfied), and 2 patients (10.7%) rated it as 3 (somewhat satisfied). No patients rated it as 2 (dissatisfied) or 1 (very dissatisfied). No adverse events were reported in this study.

Participants' experience and suggestions

The analysis of interview data from patients participating in the AM-I-FCR for FCR in lung cancer patients identified four themes: "Immersive emotional release," where patients were able to focus on the present and express their inner thoughts; "relief of physical and mental suffering," as the intervention alleviated pain and promoted well-being; "self-exploration journey," where patients experienced cognitive growth and self-discovery; and "evaluation and suggestions for the intervention program," with positive feedback on the artistic process, although patients highlighted challenges with the online format and the need for consistent practice to improve artistic proficiency. The detailed themes, categories, and illustrative quotes are shown in Table 5.

Discussion

In this study, the IM framework was used to guide the development and implementation of an art-making intervention program (AM-I-FCR), and a pilot RCT was used to evaluate the feasibility and initial efficacy of the AM-I-FCR. The AM-I-FCR intervention aimed to alleviate FCR in lung cancer patients undergoing chemotherapy, expand the role of art-making in the psychological rehabilitation

Table 4 Generalized linear mixed model analysis results of quantitative data confrontation between two groups (ITT)

Program	Group	T ₀	T ₁	T ₂	F _{Group}	F _{Time}	F _{Group × Time}	Z
FCR severity	G1	25.23	25.33	25.60	4.479*	23.945***	16.770***	4.260***
	G2	24.76	25.93	28.90				
FCR trigger factors	G1	25.83	25.63	26.03	6.076*	12.462***	8.294***	-
	G2	25.50	26.30	28.50				
QOL (physical condition)	G1	19.80	18.26	16.53	1.275	50.965***	0.397	0.954
	G2	20.76	18.73	17.03				
QOL (social/family condition)	G1	13.23	14.03	14.30	0.003	4.821	0.335	2.986*
	G2	13.46	13.86	14.16				
QOL (emotional condition)	G1	5.66	6.13	6.66	5.978*	1.223	11.372***	4.537***
	G2	5.80	5.26	4.03				
QOL (functional condition)	G1	8.43	9.23	9.46	0.001	5.764**	0.081	4.862***
	G2	8.30	9.36	9.56				
QOL (specific symptom condition)	G1	19.16	19.36	20.03	0.002	2.081	0.277	-
	G2	18.63	19.53	20.26				
QOL (total)	G1	66.26	67.03	67.13	0.816	0.657	0.455	0.016
	G2	66.96	66.76	65.30				
Anxiety	G1	12.33	13.10	13.26	4.552*	13.326***	3.130	2.996**
	G2	12.36	14.20	15.06				
Depression	G1	12.43	12.56	12.60	9.567**	5.434**	4.102*	1.357
	G2	12.53	13.96	14.97				
Confrontation	G1	21.00	21.26	22.90	4.069*	1.049	9.7468***	0.015
	G2	20.96	21.20	20.13				
Fear avoidance	G1	17.46	17.13	17.10	0.012	0.737	1.186	3.927***
	G2	17.23	17.03	17.56				
Acceptance of resignation	G1	14.00	14.03	12.23	12.135***	18.726***	27.443***	-
	G2	14.10	15.80	15.63				
Illness perception	G1	52.20	52.96	50.96	4.814*	1.774	3.854*	3.400***
	G2	52.76	54.06	54.43				

Dependent variables: total score of FCR severity, FCR triggering factors, QOL for each item and total, anxiety, depression, confrontation, fear avoidance, acceptance of resignation, and illness perception

Fixed effects: group, time, group × time interaction. Random effects, participants

Numerical values are reported with three decimal places

G1, control group; G2, intervention group; T₀, baseline; T₁, third intervention; T₂, fifth intervention

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$

Table 5 Qualitative interview topic extraction results

Theme	Subcategory	Illustrative quote
Immersive emotional release	Immersive investment	"It's just that you feel that in the process of painting, you will be involved and only focus on what you are doing now... For example, if you tell me paper cuttings, then I will be involved to choose some suitable pictures so that I will not think about other things." N1 "I think that in the process of doing a work, I can be fully involved, what is called in the present words, immersion." N12
	Express freely	"For example, during the process of painting, you can calm down and choose the color you want. What color needs to be painted to match it, how the color distribution will look better, and whether to paint the dark color inside or outside, you need to think carefully. One theme is influence or something else, I really forgot, I painted the dark color inside and the light color outside because I think this disease has the deepest impact on myself. I am the most afraid of it, so I painted the deepest color inside, which represents the impact on myself." N3 "After chemotherapy, I have been worried about my body all along. I searched around and couldn't find anything suitable. When I saw this glass bottle later, because it is easy to break, I felt that it represents my current body, which is very fragile and not like before." N2
Relieving physical and mental pain	Relieve physical symptoms	"... And I feel like after cutting and moving my hands like this, the numbness on my hands decreases." N5 "I feel like applying your color can help me move my hands around and be seen as a form of exercise." N12
	Remove negative emotions	"During the process of painting, coloring, and other manual labor, you tend to focus more on what you are about to do, and only think about what you are doing. If you are too busy with something, you won't have time to think about unpleasant things, such as diseases. As long as you don't want this disease, you will naturally relax." N4 "It means that every time you do it, you are quite happy and feel fully invested, without thinking about other things... it's just about diseases." N1
	Generate positive thinking	"I feel quite happy too. I can choose the picture and shape I want, it's quite happy and relaxed, especially the beaded ones. The colorful colors look very hopeful." N2 "I think my emotion may become more stable, for example, the last time I didn't tie the knot of that bead, and then it fell out completely. If it were me before, I would have been angry, but now it seems like I'm not so angry anymore, my mentality has become more stable." N7
Self-discovery journey	Perceived self-worth	"I always take photos of my works and send them to my friends and family. They all say they are very beautiful, and I feel very happy. It's a feeling of recognition, and I feel like you don't feel like a patient. You suddenly feel better." N5 "I feel quite accomplished because I never thought I could do something in this area before. Especially after watching this, I think there are areas where the colors can be improved to make the whole picture look better. Next time, I will use this again in the picture, so I can feel like I have made some progress. I am very proud." N1
	Cognitive growth	"I have a better understanding of this disease, especially after discussing it. It makes me feel that mentality is also very important. This kind of thing is not just a physical problem, a good mentality is also crucial." N2 "I also know that some of my sadness and fear can affect my family. Sometimes it's not easy for my family, and they may even be more afraid and fearful than you are. In fact, it's a debt to them. I feel like I will gradually change my mentality and may be more positive than before." N4

Table 5 (continued)

Theme	Subcategory	Illustrative quote
Evaluation and suggestions for intervention program	Overall evaluation of artistic creation	"I have never tried drawing before, but it is very fresh." N9 "The biggest feeling is that it is very relaxed and fresh. During this process, I feel very calm and magical. I feel like time is slowing down, and I am slowly choosing and completing the entire work." N10
	Strengthen operability of online intervention	"I feel like it's a bit troublesome online. Every time I lose that pencil, I have to ask you to send it to me again. It's quite troublesome, and every time I have to open a video, it's also quite troublesome." N2 "It's just that the pen colors I brought back are too few, the choices are too few, and there should be more colors. Sometimes it's not easy to match, and sometimes the pen tip breaks when I bring it back, so I can't use it. Then I have to find a way to solve this problem." N4
	Art creation requires practice to make perfect	"At the beginning, I may not be very good at drawing and don't know how to start, but the later times it's much better. Practice makes perfect." N1 "At the beginning, it was quite difficult because I didn't have much exposure to this thing... but after a while, I found it quite interesting." N11

of cancer patients, and, by taking into account theory and evidence, ensure its standardization and scientific basis for future use. The results revealed a 93.33% participation rate and positive feedback from both groups, indicating the intervention's feasibility and acceptability. ITT and PP analyses preliminarily confirmed its positive psychosocial effects, reducing FCR, anxiety, and depression while also lowering FCR triggers, providing coping strategies, and improving illness perception. The intervention aims to enhance emotional well-being and help patients develop more positive coping strategies, suggesting that art-making is a promising tool for promoting psychological health of lung cancer patients.

In the process of program development, the two theories [11, 25] were combined with a systematic review [32] to form the theoretical framework, thus constituting the basis of the intervention program and ensuring its scientific foundation. In addition, through the combination of qualitative and quantitative methods, stakeholder interests were incorporated into the process of program development to ensure the suitability and feasibility of the intervention program. The use of consensus workshops and feedback collection allowed prompt adjustments and optimization of intervention measures, fully considering stakeholders' needs and perspectives. This exchange and collaboration ensured the effectiveness and clinical practicality of the intervention measures. Subsequently, a theory-driven, tailored intervention program was successfully developed and preliminarily applied to lung cancer survivors in China.

The intervention demonstrated high feasibility, with 93.33% participation rate in the pre-experiment and

positive feedback from both the intervention and control groups. Approximately, 90% of patients expressed satisfaction, indicating strong acceptability. These results were consistent with those of De Feudis et al.'s study, which carried out group art interventions for cancer patients before chemotherapy and achieved a 100% participation rate and a satisfaction rate of 89.93% [53]. These results suggest the feasibility and acceptability of art-making in different treatment stages and for cancer patients with various needs. Qualitative interviews revealed that nearly all participants felt relaxed and happy during the intervention, describing it as novel and interesting, and many suggested its broader promotion in clinical settings. The art-making process allows patients to immerse themselves fully in creative expression [54], with 90% reporting full engagement. This facilitates emotional release and detachment from negative emotions such as FCR and fostered a positive mindset toward the disease [25, 55]. By providing space for self-expression through freely chosen materials, patients experience a sense of calmness and achievement [54]. The intervention also promoted cognitive growth and self-reflection, helping patients discover their inner values and enhancing self-awareness. By combining emotional release with cognitive development, the intervention improved coping mechanisms and emotional well-being and helped patients manage the psychological burden of cancer, underscoring the potential of art-making as a therapeutic tool for FCR in lung cancer survivors.

In line with previous findings of visual art therapy applied in breast cancer, liver cancer, and other cancer populations [33, 56, 57], our findings indicated that

art-making interventions tended to initially alleviate FCR in lung cancer patients and reduce triggering factors. Possible reasons for these findings may be rooted in Czamanski-Cohen and Weihs's bodymind model; that is, in this study, various forms of visual art creation were employed, including collage-making, mandala coloring, free drawing, and beadwork. Through direct contact with art materials, lung cancer patients experience positive tactile sensations that offer them a unique nonverbal outlet for emotional release. This process transforms their implicit fear-related emotional materials into explicit expressions [25, 58], facilitating the dissociation [55] of fear emotions and enhancing their confidence in coping with the disease.

Additionally, influenced by Confucian values, many lung cancer patients in China tend to restrain the expression of fear-related emotions in order to preserve dignity and maintain social harmony, which may exacerbate their internal psychological burden [23]. Art-making interventions, as nonverbal modes of emotional expression, offer potential advantages in facilitating positive emotional experiences and emotional processing [25]. Through creative activities such as painting, clay modeling, and color filling, participants can engage in emotional expression without relying on direct verbal disclosure [24]. This symbolic and nonconfrontational approach allows individuals to externalize, reinterpret, and regulate their inner fears without explicit language-based emotional exposure [24]. In the present study, five themed art-making sessions were designed to help patients transcend cultural constraints, authentically express fear-related emotions, and visually explore the sources, impacts, and coping strategies associated with fear of cancer recurrence.

From an implementation perspective, the AM-I-FCR intervention was integrated into routine oncology care workflows in China. Hospital sessions were scheduled during pre-infusion waiting periods and posttreatment observation windows, utilizing patients' physiological and psychological downtime without disrupting standard medical procedures. Home-based sessions were delivered via online video and aligned with routine self-care, including symptom monitoring, medication management, and nutritional guidance. This delivery model supports structured integration of psychosocial support within existing biomedical treatment pathways. Importantly, these strategies were deliberately designed to address culturally rooted barriers, including patients' reluctance to openly express emotions to preserve "face," by providing a nonverbal, nonconfrontational pathway for emotional exploration. The findings suggest that AM-I-FCR may promote emotional integration among lung cancer patients and demonstrates preliminary benefits in

reducing fear of cancer recurrence-related triggers and enhancing psychological resilience.

Notably, after the intervention, the IG showed a gradual increase in FCR severity and trigger scores, likely due to the characteristics of the sample. The participants were predominantly young males, with over half being primary family breadwinners. Younger cancer patients often report higher FCR levels [59, 60], facing the dual pressures of supporting elderly parents and young children. A lung cancer diagnosis disrupts one's career, reduces income, and, coupled with the side effects of chemotherapy and declining health, may shift one's familial role to that of a dependent, exacerbating psychological stress. On the basis of the results from this pilot-RCT, these initial results suggest that art-making may have some potential in alleviating FCR. However, they also indicate that personalized strategies need to be developed for young male lung cancer patients to better support the enhancement of their emotional resilience and confidence in coping with the disease.

This study preliminarily confirmed the effectiveness of the AM-I-FCR in reducing anxiety and depression among lung cancer patients, which is consistent with findings in breast [61] and liver cancer [62] populations and meta-analysis results. Negative emotions in lung cancer patients often stem from intrusive rumination [61, 62], which is characterized by a repetitive focus on the impact of cancer, causing emotional isolation and heightened psychological distress [62, 63]. Compared with those of other cancers, the high recurrence and metastasis rates of lung cancer triple the risk of anxiety and depression, significantly affecting psychological health and QOL [64, 65]. The intervention's safe, supportive environment and engagement with art materials helped patients improve attention control, integrate cognitive and emotional responses, and transform negative emotions into positive experiences, enhancing emotional well-being. However, post-intervention, anxiety, and depression slightly increased, possibly because 75% of the participants had a smoking history. Smoking-related self-blame and stigma are strongly linked to increased anxiety and depression levels. Future research should focus on tailored interventions, particularly for patients with smoking histories, to better address individual needs, improve intervention efficacy, and promote psychological health [66]. Notably, the effectiveness of the AM-I-FCR for decreasing anxiety and depression levels still requires further verification through larger sample sizes and longer follow-up periods in future studies.

This study demonstrated that art-making interventions help lung cancer patients adopt active coping strategies, reduce illness perception, and improve the emotional dimension of QOL. Engaging with art materials such

as collage materials, paints, and beads provides tactile experiences that stimulate positive emotions and reduce physiological stress by activating brain regions associated with emotional processing and reward systems. From the initial observation, this kind of sensory interaction seems to have a certain positive effect on patients, helping them to transform negative emotions and enhancing their acceptance of life challenges [55]. Additionally, creating art around specific themes promotes self-reflection, enhancing cognitive growth and emotional awareness, as indicated by the participants' interview findings. These combined benefits help patients face cancer more proactively and reduce their reliance on resignation coping strategies.

However, unlike previous studies [57], this intervention did not significantly reduce avoidant coping in lung cancer patients. This may be attributed to the predominantly male sample (75%); as compared with females, male patients often adopt problem-focused or avoidant coping strategies. Additionally, over 50% of participants with advanced-stage (III/IV) lung cancer face greater psychological burdens and poor prognoses, which exacerbates avoidance tendencies [67]. The preliminary results of this pilot study suggest that future research should focus on the unique coping difficulties faced by male patients with advanced lung cancer, explore the formulation of more targeted personalized intervention programs, and provide a direction for improving the overall adaptability of art-making interventions.

Similarly, this pilot study revealed that art-making interventions had no significant impact on physical, social, or functional aspects, which is consistent with prior research on art therapy for postoperative breast cancer patients [68] and meta-analyses [32] on art therapy for cancer patients. A possible explanation is that the participants, mostly advanced-stage lung cancer patients undergoing chemotherapy, faced greater symptom burdens (e.g., shortness of breath, fatigue, physical decline) that negatively impacted their QOL [69]. Chemotherapy side effects (e.g., nausea, vomiting, and hair loss) may also disrupt their social activities [70]. These findings indicate that future studies with larger sample sizes are warranted to examine differences across patient subgroups and to further investigate the effects of art-making interventions on physical health outcomes, cancer-specific symptoms, and social functioning, thereby providing more targeted guidance for clinical practice.

Study limitations

This study has several limitations. First, as a pilot randomized controlled trial with a relatively small sample

size, the findings should be interpreted cautiously. Moreover, the sample was predominantly male and comprised mainly patients with stage III–IV disease, which may have limited the generalizability of the results. Future studies should aim for a more balanced distribution of demographic and clinical characteristics and employ larger, multicenter RCTs to confirm the effectiveness of the intervention. Second, outcomes were assessed only at baseline and immediately post-intervention, restricting conclusions regarding long-term effects. Extended follow-up periods are therefore required to evaluate the sustainability of intervention benefits. Third, the reliance on self-reported outcome measures may have introduced reporting or recall bias; the inclusion of objective or physiological indicators in future research could strengthen outcome assessment. Fourth, participant feedback indicated limitations in the online intervention component, highlighting the need for further refinement of intervention delivery and usability. Additionally, this study lacked quantitative fidelity assessments, which limited the reproducibility. Therefore, it is recommended for future studies to clarify the details of fidelity assessment and adopt quantitative methods. Finally, as this study was conducted exclusively among Chinese lung cancer survivors, the applicability of the findings to other populations and cultural contexts remains uncertain and should be examined in future studies.

Clinical implications

This study leverages an IM framework to develop and preliminarily evaluate an art-making intervention for FCR among lung cancer survivors, offering a novel, theory-based approach for standardized nursing interventions in psychological rehabilitation. As the first pilot study to explore the effectiveness of visual art-making interventions in alleviating FCR in this population, it expands the application of art therapy beyond its traditional focus on breast cancer survivors and integrates with the routine care workflow. Specifically, the intervention was carried out during the waiting periods of patients' hospitalization for chemotherapy, and the portable universal art materials were provided for patients to use. In different cultural contexts, more localized materials (such as collage materials) could be selected, and the intervention could be extended to multiple periods such as home follow-up visits during cancer treatment.

By introducing an innovative method to address FCR, this study broadens the scope of nursing interventions and provides a foundation for future research. This highlights the potential for adapting art interventions across cultural contexts and integrating them with other psychological therapies, paving the way for robust RCTs. Furthermore, this holistic approach aligns with the global

trend toward patient-centered care, addressing survivors' emotional needs, enhancing mental health, and reducing the societal burden of cancer-related challenges.

Conclusions

This study developed and evaluated a visual art-based intervention for managing FCR in lung cancer patients across the early stages of survival, which showed encouraging feasibility and acceptability. The results also preliminarily revealed significant reductions in FCR, anxiety, and depression, along with decreased FCR triggers and resignation coping. Additionally, the intervention preliminarily enhanced emotional well-being, improved illness perception, and fostered positive coping strategies. These findings underscore the potential of art-based interventions to facilitate emotional expression, alleviate distress, and promote self-exploration, providing a practical and effective approach for managing FCR. This work lays a foundation for integrating standardized art-based interventions into clinical practice to improve cancer-related FCR.

Abbreviations

ACT	Acceptance and commitment therapy
AIC	Akaike's information criterion
AM-I-FCR	Art-making program to manage fear of cancer recurrence
AR1	First-order autoregressive model
BIC	Bayesian information criterion
CG	Control group
FCR	Fear of cancer recurrence
FCRI-SF	Fear of Cancer Recurrence Inventory-Short Form
KPS	Karnofsky performance status
IG	Intervention group
IM	Intervention mapping
ITT	Intention to treat
PP	Per protocol
QOL	Quality of life
RCT	Randomized controlled trial
UN	Unstructured model

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12916-026-04722-1>.

Additional file 1: Table 1. The TIDieR checklist.

Additional file 2: Table 2. GUIDED checklist.

Additional file 3: Table 3. CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial.

Additional file 4: Table 4a. Inclusion criteria and exclusion criteria by participant group. Table 4b. Interview outline.

Additional file 5: Table 5a. Demographic and clinical characteristics of interviewed patients. Table 5b. Demographic characteristics of interviewed healthcare providers.

Additional file 6: Table 6. Qualitative research findings.

Additional file 7: Fig. 1. Change matrix of the intervention.

Additional file 8: Table 7. Insights from art-making intervention programs to reduce FCR in lung cancer patients.

Additional file 9: Table 8a. Suggested revisions to the program from expert meetings. Table 8b. Lung cancer patient and researcher feedback and explanation of subsequent program revisions.

Additional file 10: Fig. 2. Sample size calculation parameters.

Additional file 11: Table 9. Fit indicator results of the covariance model.

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Authors' contributions

All the authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors. The study concept and design were contributed by FFH. Data acquisition was performed by JLL, CXZ, and ZXK. Data analysis and interpretation were conducted by JLL and ZXK. The manuscript was drafted by JLL and ZXK. RA and WTC provided critical revisions of the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Data availability

The datasets analyzed during the current study are not publicly available due privacy reasons but are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees and with the Helsinki Declaration of 1975, as revised in 2008. The study design was approved by the ethics committee of the relevant hospital (LSK No. 2023–027).

Consent for publication

All study participants provided written informed consent.

Competing interests

The authors declare no competing interests.

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