Original Article Efficacy of behavioral activation in reducing fear of cancer recurrence in non-small cell lung cancer patients: a randomized controlled trial

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Abstract: Fear of cancer recurrence (FCR) is a significant risk factor affecting treatment outcomes and prognosis in non-small cell lung cancer (NSCLC) survivors. Behavioral activation (BA), a structured therapeutic approach based on cognitive-behavioral therapy (CBT) principles, has demonstrated efficacy in alleviating psychological distress among cancer patients. This study aims to investigate the effect of BA on FCR in patients with NSCLC and explore the underlying mechanisms. A total of 82 eligible patients were randomly assigned to either the intervention group (BA) (n = 41) or the usual care group (CAU) (n = 41). Assessments were conducted at baseline (TO), week 4 (T1), and week 8 (T2) using the Cancer Recurrence Fear Scale-Brief Form (FCRI-SF), the Hospital Anxiety and Depression Scale (HADS), the Brief Resilient Coping Scale (BRCS), and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC OLO-C30) version 3.0. Negative emotions (depression and anxiety), as well as resilient coping, were identified as potential mediators. The intervention effect and its potential mediating effects were analyzed using generalized estimating equations (GEE). GEE analysis revealed significantly lower FCR scores in the BA group at weeks 4 and 8 (Group T1: Wald $X^2 = 25.79$, P < 0.001; Group*T2: Wald X^2 = 59.59, P < 0.001). Depression and anxiety scores decreased over time in the BA group and remained consistently lower than those in the usual care group (depression: Group*T1 Wald $X^2 = 34.67$. P < 0.001; Group*T2 Wald X^2 = 56.05, P < 0.001; anxiety: Group*T1 Wald X^2 = 36.22, P < 0.001; Group*T2 Wald X^2 = 64.85, P < 0.001). Scores for resilient coping and quality of life increased over time in the BA group and were significantly higher than those in the usual care group (resilient coping: Group*T1 Wald X^2 = 19.49, P < 0.001; Group*T2 Wald X^2 = 66.19, P < 0.001; quality of life: Group*T1 Wald X^2 = 19.86, P < 0.001; Group*T2 Wald X^2 = 64.46, P < 0.001). Furthermore, negative emotions (depression and anxiety), as well as resilient coping, were found to mediate the effect of BA on changes in FCR. The BA intervention can alleviate FCR symptoms and improve the quality of life in NSCLC patients by reducing negative emotions (depression and anxiety) and enhancing resilient coping.

Keywords: Anxiety, behavior activation, depression, fear of cancer recurrence, non-small cell lung cancer, quality of life, resilient coping

Introduction

Lung cancer is the leading cause of malignant tumor-related deaths in China. In 2020, new cases and deaths from lung cancer accounted for 22% and 28.5% of all malignant tumors, making it the most fatal cancer in the country [1]. Non-small cell lung cancer (NSCLC), which constitutes approximately 85% of lung cancer cases, is characterized by subtle symptoms, rapid spread, and treatment challenges [2]. It is managed through surgery, chemotherapy, radiotherapy, immunotherapy, and targeted therapy. Despite medical advances, NSCLC exhibits high rates of metastasis and recurrence [3]. Studies indicate that recurrence and metastasis rates can reach up to 80% within two years of diagnosis, signi-ficantly impacting patients' well-being [4].

FCR is defined as "any fear, worry, or anxiety about the possibility of cancer recurrence or progression" [5]. A meta-analysis revealed that 59% of cancer patients experienced moderate FCR, while 19% had high levels [6]. In NSCLC patients, the proportion of high FCR levels reached up to 57.5%. Moderate FCR can motivate health-promoting behaviors and improved treatment adherence [6]. However, when FCR surpasses a certain threshold, it transforms into a pathological condition, imposing a significant psychological burden on patients, disrupting their social functioning, and markedly decreasing their quality of life [7, 8]. FCR is a pressing yet under-addressed supportive care need among cancer survivors, necessitating effective management strategies.

Lebel et al. described five core dimensions of clinical FCR [5]: (1) heightened concentration, worry, rumination, or intrusive thoughts; (2) adoption of passive and helpless coping strategies; (3) significant disturbance in daily functioning; (4) excessive disease monitoring behaviors; and (5) significant barriers to future planning. FCR severity positively correlates with depression and anxiety intensity, wherein cancer survivors with clinically significant FCR manifest disproportionately severe psychopathological profiles [9]. Poor emotional functioning has been identified as an independent predictor of elevated FCR in patients with NSCLC [10]. Anxiety symptoms driven by FCR frequently result in avoidance behaviors, such as reduced social engagement, postponement of medical examinations, and reluctance to discuss cancer-related topics [11]. Carver et al. emphasized that resilient coping is critical in mitigating FCR [12]. Individuals with higher psychological resilience are more capable of managing the uncertainty and stress associated with cancer recurrence and are less likely to experience elevated FCR. These factors are interrelated and mutually reinforcing, creating a vicious cycle that intensifies anxiety, fear, and avoidance behaviors, ultimately increasing the psychological burden on patients.

In patients with NSCLC, studies have indicated that survivors exposed to low levels of FCRtriggering factors exhibit higher cognitive disease perception enhanced coping strategies. These individuals are more likely to experience lower levels of FCR and report improved quality of life [13]. These findings provide a theoretical foundation for the management of FCR symptoms in NSCLC patients.

In recent years, psycho-oncology interventions has emerged as an effective approach to alleviating the negative emotions and treatment-related symptoms experienced by cancer survivors [14]. BA, as a psychological intervention, aims to identify and eliminate avoidance patterns that contribute to negative emotions while encouraging patients to engage in activities aligned with their personal values [15]. Studies have demonstrated that BA is effective in reducing depression and anxiety among cancer patients [16-18]. Furthermore, some studies have combined BA with problem-solving therapy, reporting positive effects on FCR in breast cancer patients [19]. This evidence provides a foundation for exploring the role of BA in FCR management. The core principles of BA - reducing avoidance behaviors and rumination - may alleviate FCR by decreasing cancer-related vigilance, improving emotional regulation, and fostering adaptive coping strategies. Additionally, BA interventions promote behavior change by identifying and minimizing negative behaviors (e.g., compulsive symptom monitoring) and enhancing positive behaviors related to life goa-Is or personal values. Therefore, BA is highly aligned with the core dimensions of FCR and holds potential as a treatment for FCR symptoms. However, direct evidence supporting this hypothesis is currently lacking. The present study aims to address this gap and investigate the mechanisms by which BA may influence FCR symptoms.

The primary objective of this randomized controlled trial was to assess the effectiveness of BA in reducing FCR levels in patients with NSCLC. The secondary objective was to examine whether changes in negative affect (depression, anxiety) and resilience mediate the effects of the intervention on FCR.

Method

Study design

The study was designed as a single-blind, twoarm randomized controlled trial (RCT). Participants were randomly allocated to either the intervention or control group. Evaluators and data analysts were blinded to the participants' group assignments to ensure objective assessment and analysis.

Participants

Upon agency approval, we enrolled NSCLC patients from March 1, 2023 to October 1, 2023, in four wards of the Oncology Department of the Second Affiliated Hospital of Anhui Medical University. The patients in these four wards were in similar treatment environments and nursing routines. Subjects must meet the following inclusion criteria: (1) Meet the diagnostic criteria for primary NSCLC through clinical, pathological, and imaging examinations and are aware of their diagnosis. (2) Have not received any prior psychological intervention. (3) Have a FCRI-SF score of \geq 13 points. (4) Are 18 years of age or older at the time of diagnosis and have sufficient auditory and visual abilities to complete the questionnaire tests and intervention procedures. Exclusion criteria include: (1) Individuals with severe cognitive impairments or other communication difficulties. (2) Patients with an estimated survival time of less than 4 months. (3) Patients with fractures, severe cardiac insufficiency, or other serious comorbidities. Termination criteria include: (1) Serious adverse events or adverse reactions that make it difficult to continue the intervention. (2) Patient requests to discontinue the intervention. (3) At least three weeks elapsed between sessions. (4) Regular use of psychotropic medications, as determined by the attending physician, during the implementation of the program or the waiting period. (5) Meeting the exclusion criteria during the waiting period. (6) Other reasons deemed necessary by the attending physician to discontinue the intervention.

Sample size

Due to the absence of previous relevant studies, we conducted a pilot study with 20 participants. Using the data from this this pilot study, we estimated the required sample size with G*Power 3.1 software. We set an expected effect size of 0.25, a significance level of 0.05, and aimed for 90% power. The software calculated a minimum sample size requirement of 43 participants. To account for a 20% dropout rate, we increased the sample size to 54 participants. Considering our resources, research team capacity, and the need for comprehensive research, we decided to expand the final sample size to 100 participants to enhance representativeness and reliability. No interim analyses or stopping guidelines were established for this trial.

Sample size considerations: The current sample of 82 participants achieves 95% power to detect effects. While sufficient for preliminary exploration, this limitation necessitates caution in generalizing findings to the broader NSCLC population. Large, multicenter, randomized controlled trials are needed for validation.

Recruitment, randomization, and blinding

Recruitment notices will be posted in four inpatient and high-traffic outpatient areas of the Oncology Department at the Second Affiliated Hospital of Anhui Medical University. Medical personnel involved in the study actively review patients' medical records, identify eligible participants, and issue invitations. After obtaining informed consent from all participants, the eligibility of the invited patients was assessed by the lead researcher, and the eligible individuals were then coded by an independent statistician. Using the PROC PLAN procedure of SAS 9.2 software, the expert implemented a random allocation algorithm and upload the results online through a centralized randomization system, following pre-established standard operating procedures (SOPs). The statistical expert handled randomization independently, and researchers collecting data not be involved in the intervention delivery.

Intervention group

Patients in the behavioral activation (BA) group received an 8-week BA intervention in addition to the routine care and health education provided to the control group. Weekly sessions, lasting 30-60 minutes, were held both offline and online (Annex I) and conducted by the same therapist in a quiet conference room for consistency.

Researchers (practicing psychologists) underwent two weeks of BA training and practical exercises. Their competency to deliver BA interventions was approved by senior therapists and attending physicians. Therapists will sub-

mit weekly case reports and audio-record interviews to maintain quality and consistency; all online sessions were recorded for later evaluation. If a participant missed a session due to medical or logistical reasons, the session would be rescheduled within 3-5 days. Assessments were primarily conducted in the conference room, with online options available when necessary. To ensure data integrity, a dual-verification protocol was implemented during data collection phases, wherein two independent researchers cross-validated questionnaire entries prior to database entry. Participants demonstrating incomplete responses were systematically contacted within 24 hours to request supplementary information through standardized follow-up procedures.

The experimental protocol was formulated in strict accordance with the Ten-year Revised Edition of Brief Behavioral Activation Therapy for Depression [20]. The intervention framework comprises five systematically structured modules: (1) Therapeutic Orientation & Baseline Assessment: Introduce behavior activation concepts, link positive behavior to mood improvement, and evaluate emotional state, activity patterns, and quality of life through questionnaires and interviews. Patients identify negative emotions and develop a correct understanding of their condition. (2) Environmental Contingency Analysis & Behavioral Planning: Identify and analyze positive and negative environmental stimuli. Develop individualized activity plans to increase positive, goal-directed behaviors and reduce negative activities. (3) Implementation & Progress Monitoring: Teach activity scheduling, goal setting, action planning, and coping with challenges. Track and evaluate activities using logs and self-monitoring, adjusting plans as needed. (4) Cognitive-Affective Integration: Manage emotions through positive activities, identify emotional triggers, apply regulation strategies, and change negative thinking patterns to establish positive self-cognition. (5) Social Reinforcement System Development: Highlight the importance of social support, encourage connections with family, friends, or professionals, and instruct on using resources like community events and interest groups to expand social circles and active opportunities.

Control group

Participants in the control group received the same routine care and health education as the BA group, identical in planning and implementation. The session duration was consistent with the intervention group, ranging between 30 to 60 minutes, to ensure a balance of nonspecific intervention content between the two groups. The health education content for both groups includes basic disease knowledge, nutritional and dietary recommendations, nursing guidance during radiotherapy and chemotherapy, and emphasis on the importance of regular follow-up. It is important to note that during this study, the therapist and medical team members avoid introducing any ideas or techniques related to behavioral activation to the control group members in order to maintain the purity of the experiment. The control group was not provided with psychotherapy or structured psychological support in addition to routine symptom management. Patients added to the control group will have their activities of daily living monitored, but no active intervention or attempts to adjust their daily living patterns will be made.

Measures

Enrolled patients completed all questionnaires at three key time points: at baseline (TO), immediately after the fourth intervention (T1), and immediately after the eighth intervention (T2). For patients who found it inconvenient to return to the hospital during the prescribed time of intervention, the questionnaire survey was conducted online. Importantly, the primary and secondary outcomes of this study were pre-specified and remained unchanged throughout the trial, ensuring the integrity and reliability of the research findings.

Sociodemographic and clinical data were collected only at baseline: Eligible patients completed the questionnaire under the guidance of the designated investigator. This included general demographic information such as sex, age, education level, primary caregiver, marital status, occupation, and smoking status. Patients' disease-related data were collected from clinical records, including their Karnofsky Performance Status (KPS) score, pathological type, disease stage, and treatment plan. The Cancer Recurrence Fear Scale-Brief Form (FCRI-SF): FCRI-SF is a nine-item Likert scale derived from the original 42-item Fear of Cancer Recurrence Inventory. The FCRI-SF aims to quantify the presence and severity of intrusive thoughts associated with cancer recurrence. The scale ranges from 0 to 36 points, with higher scores indicating a greater fear of cancer recurrence. Given its optimal sensitivity (88%) and specificity (75%), a cutoff value of \geq 13 was selected as the primary outcome [21]. Additionally, FCRI-SF has demonstrated high internal consistency (Cronbach's α = 0.95), good temporal stability (r = 0.89), and satisfactory structural validity [22].

The Hospital Anxiety and Depression Scale (HADS) [23]: HADS, developed by Zigmond AS and Snaith RP in 1983, is primarily used for the screening of depression and anxiety symptoms in hospital inpatients. This scale consists of 14 items, with 7 items each for depression and anxiety. Each item is scored on a 4-point scale. Scores for anxiety and depression are categorized as follows: 0-7 indicates no or minimal symptoms; 8-10 suggests mild symptoms; 11-14 indicates moderate symptoms; and 15-21 indicates severe symptoms. The higher the score, the higher the level of anxiety and depression. The HADS has been proven to have good reliability and validity, with a total Cronbach's α coefficient of 0.785.

The Brief Resilient Coping Scale (BRCS): BRCS, developed by Smith et al. (2008), evaluates an individual's ability to adapt to adversity and maintain psychological well-being during challenging life events [24]. The BRCS consists of four items designed to measure the capacity to recover quickly from stress and sustain a positive outlook in difficult situations. Each item is rated on a 5-point Likert scale, ranging from "not at all like me" to "very like me". Total scores range from 4 to 20, with higher scores reflecting greater resilience. A score of 13 or less indicates low resilience, while a score of 17 or higher represents high resilience. The BRCS demonstrates good internal consistency (α = 0.78) and test-retest reliability (r = 0.71).

The EORTC QLQ-C30 (Version 3.0) assesses the physical, psychological, and social functioning of cancer patients: It includes 30 items across 15 fields, with items 29 and 30 rated on a 7-point scale and the others on a 4-point scale [25]. Functional and global health status scores are positively correlated with quality of life, while symptom scores are negatively correlated. This widely used scale has demonstrated good reliability and validity in Chinese cancer patients since its introduction in 1995.

Data analysis

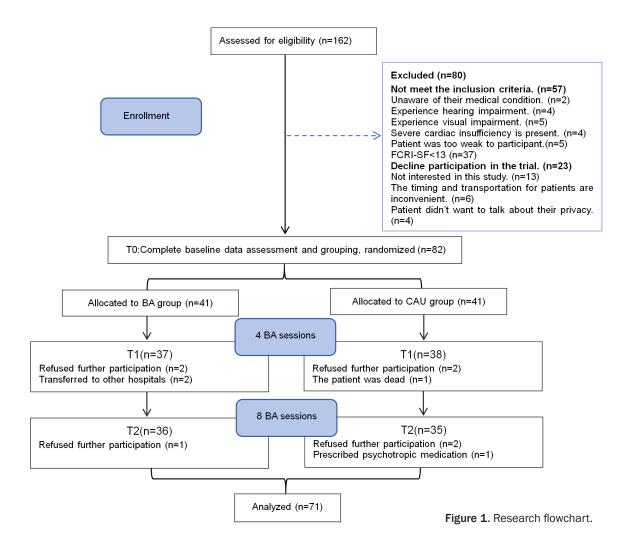
IBM SPSS Statistics 25.0 was used for all statistical analyses. A two-sided test principle was applied, with a p-value less than 0.05 indicating statistical significance. Baseline demographic characteristics were described using means, standard deviations, and frequency distributions. To assess baseline balance between groups, the chi-square test or Fisher's exact test was employed. Comparisons of average predicted values at different time points were performed using the independent sample t-test or the Mann-Whitney U test, depending on the distribution of the data. Generalized Estimating Equations (GEE) analyzed outcome indicators such as FCR, depression, anxiety, resilient coping and quality of life. The GEE model used a linear function and a non-structural working correlation matrix. The Least Significant Difference (LSD) method was used for post-hoc testing.

Results

Recruitment and characteristics of participants

A total of 162 patients were enrolled in the trial. Among them, 57 failed the screening process, and 23 declined to participate. Ultimately, 82 patients met the eligibility qualified and agreed to participate, being randomly assigned to the control group (n = 41) and the intervention group (n = 41). The dropout rates were 14.63% for the control group and 12.2% for the intervention group, resulting in a total dropout rate of 13.41%. Consequently, 35 patients remained in the control group and 36 in the intervention group. Statistical analysis was conducted on the data from 71 patients. **Figure 1** illustrates the recruitment flowchart, detailing the reasons for participant dropout.

Table 1 presents the socio-demographic andclinical characteristics of participants in thecontrol group (CAU) and intervention group(BA). No statistically significant differences



were observed between the two groups for the following variables: age (Z = -0.109, P = 0.913), gender (χ^2 = 0.018, P = 0.893), KPS score (Z = -0.159, P = 0.873), marital status (χ^2 = 0.248, P = 0.674), occupation (χ^2 = 3.966, P = 0.142), education level (χ^2 = 1.349, P = 0.531), primary caregiver (χ^2 = 5.913, P = 0.089), smoking status (χ^2 = 1.986, P = 0.370), tumor histology (χ^2 = 0.359, P = 0.926), tumor stage (χ^2 = 4.466, P = 0.188), and treatment method (χ^2 = 3.716, P = 0.631). These findings indicate that the two groups were well-matched at baseline.

Baseline data characteristics

FCR Scores: Control group: 18.09 ± 3.97 , Intervention group: 19.42 ± 5.36 , P = 0.240; BRCS Scores: Control group: 13.34 ± 3.12 , Intervention group: 13.92 ± 2.71 , P = 0.479; Depression Scores: Control group: 8.34 ± 5.49 , Intervention group: 8.75 ± 5.22 P = 0.750; Anxiety Scores: Control group: 6.63 ± 4.45 , Intervention group: 7.22 \pm 4.91, P = 0.596; Quality of Life Scores: Control group: 75.66 \pm 15.00, Intervention group: 73.89 \pm 15.42, P = 0.625. There was no statistical difference in baseline data between the two groups, and the distribution was balanced (**Table 2**).

Effects of intervention on FCR

Table 2 presents the results for each indicator, while **Figure 2** illustrates the trends of these indicators over time. Comparisons between the two groups revealed that FCR scores in the intervention group were significantly lower than those in the control group at both T1 (t = 3.246, P = 0.002) and T2 (Z = -5.767, P < 0.001). The above results were further verified using GEE (**Table 3**). The GEE results showed that: During the baseline to T1 period: There was no significant difference in FCR between the two groups (Wald χ^2 = 0.41, P = 0.523). During the T1 to T2

Variable	Experimental group (n = 36)	Comparison group (n = 35)	X^2/Z	Р
Age (y)	64.5 (55.25, 69.00)	62 (52.00, 70.00)	-0.109°	0.913
KPS	90 (80.00, 90.00)	90 (80.00, 90.00)	-0.159°	0.873
Sex			0.018ª	0.893
Male	20 (50%)	20 (50%)		
Female	16 (51.6%)	15 (48.4%)		
Marital status			0.248 ^b	0.674
Be married	34 (51.5%)	32 (48.5%)		
Other	2 (40.0%)	3 (60.0%)		
Occupation			3.966⁵	0.142
Working	5 (35.7%)	9 (64.3%)		
Retired	1 (20.0%)	4 (80.0%)		
Unemployed	30 (57.7%)	22 (42.3%)		
Educational level			1.349 ^b	0.531
Less than high school	31 (53.4%)	27 (46.6%)		
High school and above	1 (25.0%)	3 (75.0%)		
Above high school	4 (44.4%)	5 (55.6%)		
Family care-givers			5.913 ^b	0.089
Offspring	13 (39.4%)	20 (60.6%)		
Mate	17 (65.4%)	9 (34.6%)		
Unattended	4 (40.0%)	6 (60%)		
Other	2 (100%)	0 (0.00%)		
Smoking status			1.986ª	0.370
Smoker	5 (50.0%)	5 (50.0%)		
Nonsmoker	21 (58.3%)	15 (41.7%)		
Quit smoking	10 (40%)	5 (60%)		
Tumor histology				
Adenocarcinoma	24 (49.0%)	25 (51.0%)	0.359 ^b	0.926
Squamous carcinoma	9 (56.3%)	7 (43.8%)		
Other	3 (50%)	3 (50.0%)		
Stage			4.466 ^b	0.188
I	2 (66.7%)	1 (33.3%)		
I	0 (0.00%)	3 (100.0%)		
III	4 (36.4%)	7 (63.6%)		
IV	30 (55.6%)	24 (44.4%)		
Treatment mode			3.716 ^b	0.631
Not in progress	1 (25.0%)	3 (75.0%)		
chemotherapy	8 (66.7%)	4 (33.3%)		
radiotherapy	2 (40.0%)	3 (60.0%)		
Targeted therapy	7 (43.8%)	9 (56.3%)		
immunotherapy	1 (100.0%)	0 (0.00%)		
Combination therapy	17 (51.5%)	16 (48.5%)		

Table 1. Comparison of demographic and baseline characteristics

^aChi-square test; ^bFisher's exact test; ^cMann-Whitney U-test. Data are expressed as M (P25, P75) for continuous variables, and as frequency (percentage) for categorical variables.

period: Both groups exhibited an upward trend in FCR scores (Wald χ^2 = 10.88, P = 0.001). However, compared to the control group, FCR scores in the intervention group decreased significantly during the T1 and T2 periods (T1: B = -5.63, P < 0.001; T2: B = -9.23, P < 0.001). These findings indicate that the intervention can effectively reduce FCR over time.

Variable	Time	Comparison Group (n = 36)	Experimental Group (n = 35)	t/Z	р
FCRI-SF					
	то	18.09 (3.97)	19.42 (5.36)	-1.186 ^b	0.240
	T1	18.63 (6.28)	14.33 (4.79)	3.246 ^b	0.002
	T2	20.26 (3.74)	12.36 (4.51)	-5.767ª	0.000
Depressed					
	то	8.34 (5.49)	8.75 (5.22)	-0.320 ^b	0.750
	T1	10.14 (5.84)	5.44 (4.87)	3.686 ^b	0.000
	T2	11.34 (4.82)	2.86 (3.24)	-6.274ª	0.000
Anxiety					
	то	6.63 (4.45)	7.22 (4.91)	-0.533 ^b	0.596
	T1	9 (5.07)	4.25 (4.00)	-3.949ª	0.000
	T2	10.94 (4.80)	2.08 (2.99)	-6.540ª	0.000
BRCS					
	то	13.34 (3.12)	13.92 (2.71)	-0.071ª	0.479
	T1	12.06 (3.31)	14.81 (2.89)	-3.505ª	0.000
	T2	10.40 (3.89)	16.64 (2.92)	-5.901ª	0.000
QOL					
	то	75.66 (15.00)	73.89 (15.45)	0.491 ^b	0.625
	T1	69.11 (20.33)	80.74 (16.25)	-2.622ª	0.009
	T2	64.28 (19.79)	91.51 (10.03)	-6.090ª	0.000

Table 2. All variable values changes over time in two groups

Data are expressed as mean (SD); ^aMann-Whitney U-test; ^bT-test. The scores of depression and anxiety were derived from the two subscales of the Hospital Anxiety and Depression Scale (HADS). Each subscale comprises 7 items, with a total of 14 items for the entire scale.

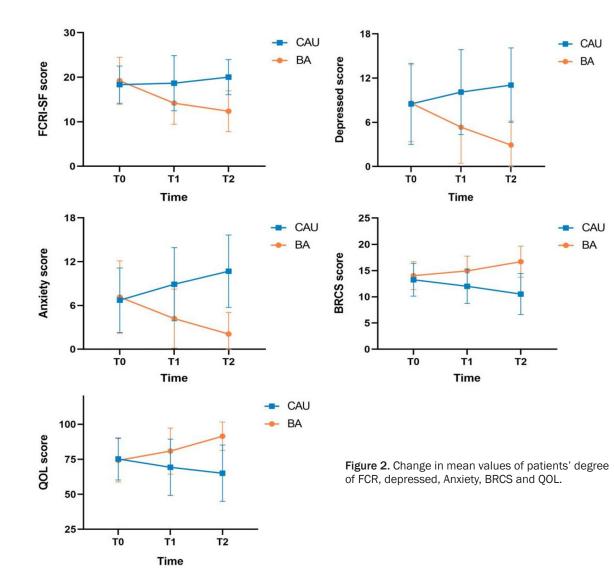
Effect on mediators

To investigate the effects of negative emotions (depression and anxiety) and psychological resilience on the outcome variables, GEE were employed, with results presented in **Table 3**. Compared to the control group, the intervention group exhibited significant reductions in depression at both T1 (B = -5.11, P < 0.001) and T2 (B = -8.89, P < 0.001). Similarly, anxiety levels also decreased significantly in the intervention group at both time points (T1: B = -5.34, P < 0.001; T2: B = -9.45, P < 0.001). Furthermore, the BRCS score demonstrated a notable upward trend in the intervention group, with significant increases at T1 (B = 2.18, P < 0.001) and T2 (B = 5.67, P < 0.001).

To explore potential mediation effects, the causal step model proposed by Baron and Kenny was utilized. Initially, the significance of the intervention's impact on both the primary outcome (FCR) and the mediating variables (depression, anxiety, and psychological resilience) was assessed individually. Subsequent-

ly, both the intervention and mediating variables were incorporated simultaneously into the model to determine whether the intervention's effect on the outcome variable remained significant after accounting for the mediators.

The GEE results (Table 4) demonstrated that the intervention effectively reduced FCR symptoms, alleviated negative emotions (depression and anxiety), and improved psychological resilience. By including time, group, their interaction, and the mediating variables in the model, a significant interaction effect was observed (χ^2 = 16.318, df = 2, P = 0.000), indicating a difference in FCR changes over time between the two groups. Mediation analysis further revealed that depression ($\chi^2 = 5.164$, df = 1, P = 0.023), anxiety (χ^2 = 5.544, df = 1, P = 0.019), and resilience (χ^2 = 4.192, df = 1, P = 0.041) significantly influenced FCR. In summary, the findings highlight the multifaceted impact of the intervention, not only directly improving functional capacity recovery but also indirectly influencing mental health outcomes through the mediation of emotional and psychological factors.



Harms

No important harms or unintended effects were observed in either the intervention or control groups during the trial.

Discussion

This study aimed at evaluating the effectiveness of BA in alleviating FCR in patients with NSCLC and exploring the mediating roles of psychological resilience, anxiety, and depression in this relationship. The results demonstrate that BA significantly reduced FCR levels in NSCLC patients, with this effect partially mediated by improvements in psychological resilience and reductions in anxiety and depression. Post-intervention, FCR symptoms in NS-CLC survivors were significantly improved, consistent with previous findings, which once again emphasizes the importance of psychosocial interventions in managing FCR symptoms and enhancing the quality of life for cancer patients [26, 27].

Psychological issues in cancer patients severely impact their quality of life and survival rates, highlighting the urgency of addressing the psychological health concerns of cancer survivors [28]. Pharmacological treatments for FCR primarily encompass antidepressants, anxiolytics, and antipsychotic drugs. However, due to side effects and the potential for long-term drug dependency, these are not typically recommended as first-line treatments. Consequently, psychological therapies are gained broader acceptance among patients [29]. The theoretical foundation of BA is rooted in behavior-

Variable	В	SE	[95% CI]	Wald X^2	P-value
FCRI-SF					
Intercept	18.09	0.66	16.79, 19.38	749.31	0.000
Group	1.33	1.10	-0.83, 3.49	1.46	0.227
T1	0.54	0.85	-1.12, 2.21	0.41	0.523
T2	2.17	0.66	0.88, 3.46	10.88	0.001
Group*T1	-5.63	1.11	-7.80, -3.45	25.79	0.000
Group*T2	-9.23	1.20	-11.57, -6.88	59.59	0.000
Depressed					
Intercept	8.34	0.91	6.55, 10.13	83.27	0.000
Group	0.41	1.25	-2.05, 2.86	0.11	0.745
T1	1.80	0.72	0.38, 3.22	6.21	0.013
T2	3.00	0.90	1.24, 4.76	11.16	0.001
Group*T1	-5.11	0.87	-6.80, -3.41	34.67	0.000
Group*T2	-8.89	1.19	-11.22, -6.56	56.05	0.000
Anxiety					
Intercept	6.63	0.74	5.17, 8.08	79.84	0.000
Group	0.59	1.10	-1.55, 2.74	0.29	0.588
T1	2.37	0.75	0.89, 3.85	9.87	0.002
T2	4.31	0.81	2.73, 5.89	28.66	0.000
Group*T1	-5.34	0.89	-7.08, -3.60	36.22	0.000
Group*T2	-9.45	1.17	-11.75, -7.15	64.85	0.000
BRCS					
Intercept	13.34	0.52	12.33, 14.36	661.11	0.000
Group	0.57	0.68	-0.77, 1.91	0.70	0.401
T1	-1.29	0.33	-1.93, -0.64	15.21	0.000
T2	-2.94	0.52	-3.96, -1.92	31.97	0.000
Group*T1	2.18	0.49	1.21, 3.14	19.49	0.000
Group*T2	5.67	0.70	4.30, 7.03	66.19	0.000
QOL					
Intercept	75.66	2.50	70.76, 80.56	916.94	0.000
Group	-1.77	3.56	-8.75, 5.20	0.25	0.618
T1	-6.55	2.05	-10.57, -2.53	10.21	0.001
T2	-11.38	2.60	-16.49, -6.28	19.11	0.000
Group*T1	13.40	3.01	7.51, 19.29	19.86	0.000
Group*T2	29.01	3.61	21.93, 36.09	64.46	0.000

Table 3. The between-group, within-group and interaction effects of FCR-SF score, depression score,anxiety score, BRCS score and quality of life score

Abbreviations: B = regression coefficient; T0 = baseline; T1 = Immediately after the fourth intervention; T2 = Immediately after the eighth intervention. For the GEE model, only model estimates of regression coefficients for the dummy variables of the group [group: 0 = control (reference); 1 = intervention], time points (T1 and T2, using T0 as reference), time points, and group interaction terms (group *T1 and group *T2) are shown.

ism and Cognitive Behavioral Therapy (CBT). Its core principles include: (1) reducing avoidance behaviors; (2) positive reinforcement; (3) evaluating and adjusting behavioral responses; and (4) goal-setting and incremental achievement [30]. These principles help disrupt the cycles of rumination and avoidance behaviors observed in FCR patients. Our study found that BA encourages patients to engage in daily activities that are meaningful to them, thereby fostering a sense of accomplishment, enhancing psychological resilience, and improving negative emotions, all of which are crucial for reducing FCR.

Negative emotions, such as depression and anxiety, are closely related to FCR [9]. In our

equations, N =	71		
Outcome	Wald Chi-Square Test	Degree of Freedom	Р
FCR			
Group	11.541	1	0.039
Time	14.033	2	< 0.001
Time × group	16.318	2	0.000
Depressed	5.164	1	0.023
Anxiety	5.544	1	0.019
BRCS	4.192	1	0.041

Table 4. Model effect estimation using generalized estimatedequations, N = 71

study, negative emotions (depression and anxiety) played a significant mediating role between BA and FCR. Depression and anxiety often cooccur and interact [31]. Excessive anxiety leads survivors to catastrophic thinking and overestimation of the risk of recurrence, while depression exacerbates these feelings, reinforcing avoidance behaviors and increasing FCR [32]. Previous studies have highlighted the role of BA in alleviating depression and anxiety symptoms across various populations [33, 34]. In recent years, several studies have applied BA to treat depressive symptoms in cancer patients, including those with breast, gastric, and esophageal cancers [19, 35]. Our findings extend these results to cancer survivors, demonstrating that BA not only effectively treats mood disorders but also addresses specific fears and anxieties related to cancer recurrence.

Psychological resilience refers to an individual's ability to effectively cope with and recover from stress, adversity, difficulties, or challenges in life. This ability includes maintaining emotional stability during adversity, actively adjusting one's mindset, adapting to the environment, and seeking solutions to problems, thereby facilitating psychological recovery and growth [36]. In our study, psychological resilience was identified as a key mediator through which BA exerts its influence on FCR. During the intervention, patients reported increased feelings of mastery and personal accomplishment after completing each important activity goal, which was associated with lower FCR levels. Previous research has demonstrated that higher resilience is associated with better mental health outcomes in cancer survivors, including lower levels of anxiety and depression [37]. Therefore, our study highlights that highly resilient patients are better able to cope with the threat of cancer recurrence, maintain a more positive mindset, and avoid excessive worry and the accumulation of negative emotions. Notably, no previous studies on BA have incorporated psychological resilience as a research variable. This finding suggests that resilience can be cultivated through behavioral therapy, thereby providing a protective factor for alleviating FCR symptoms.

In summary, BA therapy may facilitate effective management of FCR through the above multidimensional pathways, and these hypotheses provide a theoretical foundation for further research on the specific mechanisms of action of BA in FCR intervention.

Limitations

While this trial confirmed the effectiveness of BA in alleviatir FCR in NSCLC patients, it had several limitation. First, the sample size was relatively small, potentially limiting the generalizability of the findings. Larger multicenter randomized controlled trials are needed for validate these findings. Second, while we assessed the mediating roles of psychological resilience, anxiety, and depression, other potential mediators - such as coping strategies or social support - were not explored. Third, the trial only evaluated patient measures during the 8-week intervention period, precluding conclusions about the long-term durability of BA effects on FCR and psychological outcomes. The relatively short follow-up duration limits our ability to assess whether the observed benefits persist beyond the acute intervention phase or require booster sessions. Finally, while the study design included post-intervention assessments, the absence of longer-term follow-up evaluations (e.g., 6 or 12 months) prevents us from determining the trajectory of treatment effects over time. This limitation should be addressed in future research.

Clinical implications

FCR should attract the attention of medical staff, who should establish and improve the corresponding nursing intervention programs. Although this study has some limitations, it contributes to reducing FCR, depression, and

anxiety while enhancing psychological resilience in patients with non-small cell lung cancer. These findings provide strong evidence for FCR symptom management. Long-term followup studies are needed to evaluate this intervention's efficacy. Compared with other psychological treatments, BA offers more delivery methods, such as transmission by clinical health care professionals via phone and online [19, 38]. From a cost-effectiveness perspective, BA reduces clinical providers' financial burden by 21% compared to CBT, making it a cost-effective treatment [39]. Finally, while acknowledging BA's effectiveness in alleviating FCR and recognizing the simplicity of the intervention method, future clinical work could explore combining it with other psychological treatment methods to future enhance patients' quality of life.

Conclusion

BA demonstrates effectiveness in alleviating FCR symptoms in cancer patients and significantly improving their quality of life. Integrating BA into comprehensive cancer treatment enhances patients' physical and mental health and optimizes the cancer care model. These findings highlight the urgency and strategic importance of further research in this field.

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Disclosure of conflict of interest

None.

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