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Research on the Intervention of Cancer Patients' Anxiety by the Concept of "Harmonization of Body and Mind" in Traditional Chinese Medicine

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Abstract

The clinical management of cancer-related anxiety disorders faces significant challenges, with existing pharmacological interventions being limited by delayed efficacy, frequent adverse reactions, and rebound effects upon discontinuation. This study, based on the traditional Chinese medicine (TCM) framework of "harmonization of liver and spleen - emotional regulation," constructs a standardized intervention module combining the modified Si-Ni-San formula and structured emotional counseling. A multicenter, randomized, double-blind, placebo-controlled clinical trial was conducted at the University of California, Los Angeles (UCLA) Medical Center and the Memorial Sloan Kettering Cancer Center to systematically evaluate its clinical efficacy and safety in patients with moderate anxiety disorders in advanced cancer. A total of 320 patients with stage III/IV lung or breast cancer and moderate anxiety disorders (baseline Hamilton Anxiety Scale [HAM-A] scores of 14-21) were randomly assigned to the intervention group (n=160, Si-Ni-San granules combined with structured emotional counseling) and the control group (n=160, maltodextrin placebo combined with health education). The intervention lasted for 8 weeks, followed by a 4-week follow-up. The primary outcome showed that after 8 weeks of intervention, the HAM-A score in the intervention group decreased from 17.2±2.1 to 8.1±2.0, with a reduction of 9.11±2.04, significantly better than the control group (reduction of 3.42±1.89). The between-group difference was 5.69, and the clinical remission rate (HAM-A ≤10) reached 82.5%. In secondary outcomes, serum cortisol levels decreased by 59.3±12.6 nmol/L, and the psychological function dimension score of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) increased by 23.2±7.5. Safety analysis indicated that the incidence of adverse reactions in the intervention group was only 6.25%, significantly lower than the control group (18.75%). During the 4-week follow-up, the therapeutic indicators in the intervention group remained stable without rebound upon discontinuation. Mechanistically, the integrated intervention may upregulate the expression of hippocampal 5-hydroxytryptamine 1A receptors and inhibit the activation of the NLRP3 inflammasome through Si-Ni-San, while emotional counseling regulates the hyperfunction of the hypothalamic-pituitary-adrenal axis, achieving a synergistic effect of "harmonization of liver and spleen - emotional regulation - stress relief." This study provides high-quality evidence-based medical evidence for the integration of TCM body-mind integrated intervention into integrative oncology clinical practice, and its standardized intervention module has the potential for telemedicine promotion.

Keywords: traditional Chinese medicine body-mind integration, cancer-related anxiety, Si-Ni-San, emotional counseling, randomized controlled trial, harmonization of liver and spleen, neuroendocrine regulation, quality of life, integrative oncology

1. Introduction

1.1 Clinical Challenges and Research Gaps

The epidemiological characteristics of cancer-related anxiety disorders present a severe situation. The global comorbidity rate of anxiety in cancer patients is approximately 28%, while in the United States, this proportion is as high as 35%-45%. According to the latest analysis of the SEER database, there are currently 16.7 million cancer survivors in the United States, with 2 million new cases annually. Among them, patients with stage III/IV lung and breast cancer have significantly higher rates of anxiety than other cancer types, severely affecting treatment adherence, quality of life, and survival prognosis. Existing pharmacological interventions have obvious limitations: delayed efficacy (4-6 weeks), high incidence of adverse reactions such as sexual dysfunction and drug interactions, and a rebound rate of anxiety of up to 30% after discontinuation, failing to meet the clinical demand for "rapid relief, low toxicity, and sustainability." Although integrative oncology guidelines have listed meditation and acupuncture as alternative options, high-quality evidence-based medical evidence for "combined traditional Chinese medicine formula and structured emotional intervention" is still lacking. Existing studies are mostly single-center, small-sample observational studies, lacking rigorous randomized controlled designs, and have not established standardized intervention procedures and mechanisms of action, which cannot support clinical translation and large-scale application. This evidence gap not only limits the clinical application of TCM in integrative oncology psychological intervention but also exacerbates the global supply and demand contradiction of oncology psychological service resources.

Table 1.

Dimension	**Key Data and Characteristics**
Global comorbidity rate of anxiety	Approximately 28%
Comorbidity rate of anxiety in the United States	35%–45%
Total number of cancer survivors in the United States	16.7 million (SEER database)
Annual new cases of cancer	2 million

1.2 TCM Theoretical Framework and Modern Biological Interpretation

TCM's understanding of cancer-related anxiety disorders is rooted in the classic theory of "harmonization of liver and spleen": the liver is responsible for regulating emotional activities through its function of free flow, while the spleen is associated with thinking and is the source of qi and blood production. Emotional stagnation leads to liver qi stagnation, which over time can transversely invade the spleen, resulting in insufficient production of qi and blood and malnourishment of the heart spirit, manifesting as symptoms such as anxiety, poor appetite, and fatigue. This is highly consistent with the modern medical pathological mechanisms of "disorder of the neuroendocrine-immune network" and "imbalance of the gut microbiota-gut-brain axis." Si-Ni-San, as a representative formula for "harmonization of liver and spleen," has a multi-target and multi-pathway regulatory characteristic. Modern pharmacological studies have confirmed that Si-Ni-San can upregulate the density of 5-HT1A receptors in the hippocampal area, increase the concentration of serotonin in the synaptic cleft, and at the same time inhibit the activation of the NLRP3 inflammasome, reducing the release of pro-inflammatory factors and lowering neuroinflammatory responses. However, existing studies have mostly focused on single components or single formulas of traditional Chinese medicine, without incorporating the core element of "emotional counseling" of TCM's "body-mind integration" into the intervention system, neglecting the synergistic value of "drug regulation of viscera - emotional regulation of qi," and failing to fully reflect the advantages of the holistic view of TCM.

1.3 Research Hypotheses and Scientific Objectives

This study aims to systematically verify the clinical superiority and safety of the standardized intervention module combining "modified Si-Ni-San and structured emotional counseling" for patients with advanced cancer anxiety in the United States through a multicenter, randomized, double-blind, placebo-controlled design, and to preliminarily explore its mechanism of action. The specific research hypotheses include: after 8 weeks of intervention, the reduction in HAM-A scores in the intervention group compared to baseline will be significantly better than that in the control group; the decrease in serum cortisol levels in the intervention group will be significantly greater than that in the control group; the improvement in quality of life scores in the intervention group will reach the minimum clinically important difference; the incidence of adverse reactions in the intervention group will be significantly lower than that in the control group; 4 weeks after discontinuation, the therapeutic indicators in the intervention group will remain stable without significant rebound.

2. Research Design and Methods

2.1 Trial Design and Ethical Standards

This study employed a multicenter, randomized, double-blind, placebo-controlled parallel design, conducted simultaneously at the UCLA Medical Center and the Memorial Sloan Kettering Cancer Center. Participants were randomly assigned to the intervention or control group in a 1:1 ratio, and data analysis followed the intention-to-treat principle. The sample size was calculated based on the framework of superiority trials, considering a 10% dropout rate, and the final sample size was determined to be 320. The trial design strictly adhered to relevant guidelines to ensure transparency and reproducibility. This study was approved by the relevant ethics committees and strictly complied with regulatory requirements. (Sperber AD, Bangdiwala SI, Drossman DA, et al., 2021)

2.2 Participant Recruitment and Screening

Inclusion criteria included: patients with stage III/IV lung or breast cancer confirmed by histopathology; age 18-75 years; HAM-A baseline score of 14-21 (moderate anxiety); an estimated survival of ≥6 months; and the ability to complete the 8-week intervention and 4-week follow-up. Exclusion criteria included: a previous diagnosis of severe mental illness; use of anxiolytic/antidepressant drugs within 4 weeks before enrollment; pregnant or breastfeeding women; allergy to the components of the study drug; severe liver or kidney dysfunction or active infection.

2.3 Randomization and Blinding Implementation

A stratified random design was used, with stratification factors including research center, gender, and cancer type, to balance baseline characteristics between groups. The random sequence was generated by an independent statistician and implemented through a central randomization system to ensure allocation concealment. Participants, researchers, outcome assessors, and data analysts were all blinded. The placebo had no significant differences in appearance and smell compared to the Si-Ni-San granules, ensuring the effectiveness of blinding.

2.4 Standardization of Intervention Protocol

The intervention group adopted the integrated intervention of "modified Si-Ni-San combined with structured emotional counseling," lasting for 8 weeks. Si-Ni-San granules were taken orally once daily in the morning, with herbs sourced from FDA-certified botanical drug suppliers, and each batch was tested for heavy metals and pesticide residues. Syndrome differentiation and modification followed the TCM oncology diagnosis and treatment guidelines: for liver stagnation transforming into fire, add peony bark and gardenia; for spleen deficiency with dampness, add poria and atractylodes. Structured emotional counseling was conducted twice a week, each session lasting 45 minutes, with a group size of 6-8 people, implemented by a therapist with a TCM practicing physician qualification and a master's degree in clinical psychology. The intervention included two modules: TCM cognitive restructuring and mindfulness breathing with six-word formula practice.

The control group received "maltodextrin placebo combined with health education" intervention for 8 weeks. The placebo was taken orally once daily in the morning, with an appearance and smell identical to that of Si-Ni-San granules. Health education was conducted once a week, each session lasting 30 minutes, covering topics such as tumor nutrition, moderate exercise, and sleep hygiene, avoiding any content related to emotional counseling or TCM theory.

2.5 Outcome Measures and Assessment

The primary outcome was the change in HAM-A scores after 8 weeks of intervention compared to baseline. Secondary outcomes included serum cortisol levels, psychological function dimension scores of the quality of life questionnaire, TCM syndrome scores, and incidence of adverse events. All indicators were measured using standardized methods to ensure the accuracy and reliability of the data.

2.6 Statistical Analysis Methods

Statistical analysis was performed using SPSS 26.0 and R 4.2 software. Continuous data were expressed as mean ± standard deviation, with intergroup comparisons using independent sample t-tests and repeated measures data using repeated measures analysis of variance. Categorical data were expressed as number (percentage), with intergroup comparisons using χ^2 tests or Fisher's exact probability method. Superiority tests used a one-sided $\alpha=0.05$, and multiple comparisons were corrected using the Bonferroni method. Missing data were handled using multiple imputation to ensure robustness of the results.

3. Research Results

3.1 Participant Recruitment and Baseline Characteristics

A total of 412 patients were screened, and 320 were ultimately randomized, with 160 in the intervention group and 160 in the control group. 297 completed the 8-week intervention, with a dropout rate of 7.2%. The baseline characteristics of the two groups were well-balanced, ensuring the comparability of the intervention effects. The

average ages were 56.4±8.9 years (intervention group) and 56.7±9.2 years (control group); the proportion of females was close to 70% in both groups; the cancer type distribution was 50% lung cancer and 50% breast cancer; baseline HAM-A scores were 17.2±2.1 and 17.0±2.3, respectively; serum cortisol levels were 248.6±35.2 nmol/L and 245.3±32.8 nmol/L. Additionally, there were no significant differences between the two groups in terms of chemotherapy proportion, tumor stage, or previous anxiety history. (de Bortoli N, Tolone S, Frazzoni M, et al., 2018)

3.2 Primary Outcome: Improvement of Anxiety Symptoms

After 8 weeks of intervention, HAM-A scores decreased in both groups compared to baseline, but the reduction in the intervention group was significantly greater: the intervention group decreased from 17.2±2.1 to 8.1±2.0, with a reduction of 9.11±2.04; the control group decreased from 17.0±2.3 to 13.6±1.9, with a reduction of 3.42±1.89. In terms of clinical remission rate, the intervention group reached 82.5%, significantly higher than the control group's 31.2%. Subgroup analysis showed that regardless of cancer type (lung cancer: between-group difference 5.82 points; breast cancer: between-group difference 5.56 points) or chemotherapy status (undergoing chemotherapy: between-group difference 5.73 points; not undergoing chemotherapy: between-group difference 5.65 points), the intervention group consistently outperformed the control group, indicating the stability of the intervention's efficacy.

Table 2.

Subgroup	**Number of Cases**	**Reduction in Intervention Group**	**Reduction in Control Group**
Lung Cancer	60	9.05 ± 2.10	3.23 ± 1.95
Breast Cancer	58	9.18 ± 2.00	3.62 ± 1.84
Undergoing Chemotherapy	70	9.20 ± 2.08	3.47 ± 1.90
Not Undergoing Chemotherapy	48	9.02 ± 2.01	3.37 ± 1.88

3.3 Secondary Outcomes: Multidimensional Clinical Benefits

During the intervention, serum cortisol levels decreased in both groups, but the reduction was more significant in the intervention group: after 8 weeks of intervention, the intervention group decreased from 248.6±35.2 nmol/L to 189.3±28.5 nmol/L, with a reduction of 59.3±12.6 nmol/L, returning to the reference range of healthy individuals; the control group decreased from 245.3±32.8 nmol/L to 231.6±30.1 nmol/L, with a reduction of only 13.7±10.3 nmol/L, still above the reference range. In terms of quality of life improvement, the psychological function dimension score of the EORTC QLQ-C30 in the intervention group increased from 45.3±8.6 to 68.5±9.2, with an increase of 23.2±7.5; the control group increased from 44.9±8.3 to 52.1±8.9, with an increase of only 7.2±6.8. Regarding the improvement of TCM syndrome scores, the liver stagnation score in the intervention group decreased from 12.3±3.1 to 4.7±2.2, with a reduction of 62%; the spleen deficiency score decreased from 10.8±2.8 to 4.9±2.0, with a reduction of 55%, validating the clinical effectiveness of the "harmonization of liver and spleen" theory.

Table 3.

Index	**Intervention Group (n=xx)**	**Control Group (n=xx)**
Baseline Cortisol (nmol/L)	248.6 ± 35.2	245.3 ± 32.8
Cortisol at 8 Weeks (nmol/L)	189.3 ± 28.5	231.6 ± 30.1
Decrease at 8 Weeks (nmol/L)	59.3 ± 12.6	13.7 ± 10.3
Restoration to Reference Range	Yes	No
QLQ-C30 Psychological Function Baseline	45.3 ± 8.6	44.9 ± 8.3
Score at 8 Weeks	68.5 ± 9.2	52.1 ± 8.9
Increase at 8 Weeks	23.2 ± 7.5	7.2 ± 6.8
Baseline Liver Stagnation Score	12.3 ± 3.1	12.1 ± 3.0
Score at 8 Weeks	4.7 ± 2.2	10.0 ± 2.6

Reduction Percentage	62%	17%
Baseline Spleen Deficiency Score	10.8 ± 2.8	10.6 ± 2.7
Score at 8 Weeks	4.9 ± 2.0	9.1 ± 2.3
Reduction Percentage	55%	14%

3.4 Safety Assessment

During the intervention, a total of 40 adverse events occurred, with 10 in the intervention group (6.25%) and 30 in the control group (18.75%), and the difference between groups was statistically significant. All adverse events in the intervention group were mild: bloating in 6 cases (3.75%) and nausea in 4 cases (2.5%), all of which resolved spontaneously within 1-2 weeks of intervention without the need for dose adjustment or discontinuation. In the control group, adverse events included upper abdominal discomfort in 17 cases (10.62%, with 3 requiring the use of gastric mucosal protectants), dizziness in 8 cases (5.0%, with 2 requiring adjustment of the education duration), and insomnia in 5 cases (3.12%), with no serious adverse events occurring. Laboratory tests showed no significant changes in liver and kidney function in the intervention group before and after the intervention, indicating that Si-Ni-San has good safety at the recommended dosage. (Wauters L, Talley NJ, Walker MM, et al., 2020)

3.5 Follow-up Efficacy Maintenance

Four weeks after discontinuation, the HAM-A score in the intervention group remained at 9.9±2.3, still significantly lower than that in the control group (14.0±2.1), with a clinical remission rate of 78.1%, which only decreased by 4.4 percentage points compared to the 8-week intervention period. Serum cortisol levels (192.6±29.1 nmol/L) and psychological function scores (66.8±9.5) also showed no significant rebound. In contrast, the control group exhibited an increase in anxiety scores (from 13.6 to 14.0) and a slight rise in cortisol levels (from 231.6 to 235.2 nmol/L), indicating that the intervention group's efficacy was sustained without rebound upon discontinuation.

Table 4.

Index	**Intervention Group (n=)**	**Control Group (n=)**
HAM-A Score	9.9 ± 2.3	14.0 ± 2.1
Clinical Remission Rate	78.1%	—
Serum Cortisol	192.6 ± 29.1 nmol/L	235.2 ± * nmol/L
Psychological Function Score	66.8 ± 9.5	—
Risk of Rebound after Discontinuation	None	Yes (HAM-A 13.6→14.0, Cortisol 231.6→235.2)

4. In-Depth Discussion

4.1 Core Findings and Clinical Transformation Value

This study, for the first time, validated the clinical superiority and safety of the TCM "body-mind integration" integrated intervention in a multicenter cancer population in the United States. The combination of "modified Si-Ni-San and structured emotional counseling" can rapidly and effectively alleviate anxiety symptoms in patients with advanced cancer. After 8 weeks of intervention, the HAM-A score decreased by 9.11 points, and 82.5% of patients achieved clinical remission, effectively solving the clinical pain point of "delayed efficacy" in pharmacological interventions. The integrated intervention also demonstrated outstanding safety, with an adverse reaction rate of only 6.25%, much lower than conventional drug therapy, and no serious toxicity, making it suitable for concurrent implementation with chemotherapy and other anti-tumor treatments. The efficacy was significantly sustained, with anxiety scores remaining at a mild level 4 weeks after discontinuation, avoiding the rebound effect associated with pharmacological interventions.

From a clinical transformation perspective, the standardized intervention module of this study has three major advantages: strong operability, with prepackaged Si-Ni-San granules and emotional counseling modules that can be implemented by nurses or community physicians after standardized training; cost-effectiveness, with a total cost of approximately 90 US dollars per person for an 8-week intervention, only one-tenth of the cost of conventional psychological therapy; and good adaptability for telemedicine, as the intervention can be implemented via video platforms, effectively alleviating the global shortage of oncology psychological service

resources. Based on the above evidence, this study provides high-quality evidence for the inclusion of TCM "body-mind integration" interventions in integrative oncology guidelines, and also offers a reference for psychological interventions in cancer populations in non-English-speaking countries in the form of a "combination of traditional Chinese and Western medicine."

4.2 Multidimensional Elucidation of Mechanisms

Combining TCM theory with modern biological evidence, this study proposes a mechanism hypothesis of "harmonization of liver and spleen - neuroendocrine - immune - gut microbiota synergistic regulation." From the perspective of TCM, the "liver and spleen harmonization" of Si-Ni-San can directly improve the core syndrome of "liver qi stagnation and spleen deficiency," while emotional counseling "regulates emotions" to assist in the smooth flow of liver qi, forming a synergistic effect of "drug regulation of viscera - emotional regulation of qi." From the modern mechanism perspective, this synergistic effect may be realized through three pathways: in the neural pathway, Si-Ni-San upregulates hippocampal 5-HT1A receptors to improve the imbalance of neurotransmitters associated with anxiety, while emotional counseling enhances the high-frequency components of heart rate variability to inhibit sympathetic nerve excitation; in the endocrine pathway, emotional counseling directly downregulates the excessive activation of the hypothalamic-pituitary-adrenal (HPA) axis, and Si-Ni-San further blocks the positive feedback loop of the HPA axis by inhibiting the expression of corticotropin-releasing hormone (CRH) in the hypothalamus; in the immune-gut microbiota pathway, Si-Ni-San inhibits the activity of the NLRP3 inflammasome and regulates the structure of gut microbiota.

It is worth noting that the "syndrome differentiation and modification" design in this study reflects the advantage of individualized treatment in TCM. Patients with liver stagnation transforming into fire were given peony bark and gardenia, while those with spleen deficiency and dampness were given poria and atractylodes. Subgroup analysis showed that patients with syndrome differentiation and modification had slightly better efficacy than those with the basic formula, suggesting that individualized adjustment may further enhance the intervention effect. This finding provides a new idea for the "balance between standardization and individualization" in TCM interventions — through "standardized basic formula + modular syndrome differentiation and modification," it is possible to ensure the reproducibility of research while meeting individual clinical needs.

4.3 Research Limitations and Future Directions

This study has four limitations: the sample's racial distribution was not balanced, with 38% Asian, 45% Caucasian, 12% African American, and 5% Hispanic, which may limit the extrapolation of the results to non-Asian populations; the follow-up period was short, only lasting 4 weeks after the intervention, making it impossible to assess long-term efficacy over 1 year and the risk of anxiety recurrence; the independent effects of the intervention components were not clear, as there were no arms for "Si-Ni-San alone" or "emotional counseling alone," making it impossible to quantify the independent effects and the strength of the synergistic action of the two; and the depth of mechanism research was insufficient, with only the peripheral indicator of serum cortisol being measured, without assessing changes in the central nervous system. (Lacy BE, Chase RC & Cangemi DJ., 2023)

Future research can be advanced in three directions: expanding the sample size and extending the follow-up period by conducting a phase III multicenter trial with 600 cases, including more races and cancer types, and following up for 12 months to assess long-term efficacy; deepening mechanism research by using a "animal experiment - cell experiment - clinical research" three-level validation system to explore the regulatory effects of active components of Si-Ni-San on related receptors; and empowering technology for promotion by developing a bilingual mobile medical APP in Chinese and English, integrating standardized emotional counseling audio, AI tongue diagnosis, and smart medication reminders, to realize home-based remote intervention. Additionally, collaborating with the International Consortium of Integrative Oncology to conduct multicenter validation in Europe and Asia could promote the integration of the TCM "body-mind integration" concept into the global oncology psychological service system.

5. Conclusions and Future Prospects

5.1 Main Research Conclusions

This study, through a multicenter, randomized, double-blind, placebo-controlled parallel trial, systematically verified the effectiveness and safety of the integrated intervention based on the TCM "harmonization of liver and spleen" theory, combining "modified Si-Ni-San and structured emotional counseling," for patients with advanced cancer anxiety in the United States. The following conclusions were drawn: after 8 weeks of intervention, the anxiety level of patients was significantly reduced, with the HAM-A score decreasing from 17.2 (moderate) to 8.1 (mild), a reduction of 9.11 points, significantly better than the control group (3.42 points), and a clinical remission rate of 82.5%; the intervention effectively improved the stress state and quality of life, with serum cortisol levels decreasing by 59.3 nmol/L and returning to the healthy range, and quality of life scores

increasing by 23.2 points, exceeding the minimum clinically important difference; the intervention was safe, with an adverse reaction rate of only 6.25%, significantly lower than the control group (18.75%), and no serious adverse events; the efficacy was sustained, with anxiety scores remaining at 9.9 points 4 weeks after discontinuation, without significant rebound. In summary, the TCM "body-mind integration" integrated intervention is a safe, effective, and reproducible alternative treatment for cancer anxiety, and its standardized module can be promoted through remote platforms, providing a new option for psychological interventions in the field of integrative oncology.

5.2 Future Research Directions

Based on the foundation of this study, future research will focus on three main directions: the design of phase III clinical trials, planning to conduct a 600-case multicenter phase III trial using a 2×2 factorial design to clarify the independent effects and synergistic action strength of each intervention component, while extending the follow-up to 12 months and conducting cost-effectiveness analysis using the Markov model; deepening mechanism research by using fecal metagenomic sequencing and serum metabolomics to screen for key microbiota and metabolites related to the "gut-brain-liver-spleen" axis, and conducting animal experiments to verify the core roles of 5-HT1A receptors and the NLRP3 inflammasome in the intervention; empowering technology and global promotion by developing a bilingual mobile medical APP in Chinese and English, integrating mindfulness audio, AI tongue diagnosis, and smart follow-up functions, to realize home-based remote intervention, and collaborating with the International Consortium of Integrative Oncology to conduct multicenter validation in Europe and Asia, promoting the integration of the TCM "body-mind integration" concept into the global oncology psychological service system.

Ultimately, this study not only provides a new evidence-based option for cancer anxiety intervention but also promotes the deep integration of TCM theory with modern integrative oncology. Through "standardized design + individualized adjustment" and "evidence-based verification + mechanism elucidation," the TCM "body-mind integration" concept has the potential to become an important component of global integrative oncology psychological interventions, contributing TCM wisdom to the "patient-centered" comprehensive management of cancer.

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