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Intervention of cognitive reassessment on rumination thinking in breast cancer patients during postoperative chemotherapy

Submission date 31/08/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/09/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/09/2024	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to create a cognitive reappraisal intervention program on ruminative thought in breast cancer patients undergoing postoperative chemotherapy and to evaluate its clinical application effect in order to provide a reference for the emotional symptom management of breast cancer patients.

Who can participate?
Breast cancer patients aged 18 years and over undergoing postoperative chemotherapy

What does the study involve?
From June 2022 to November 2022, breast cancer patients in the postoperative chemotherapy period who met the acceptance criteria were continuously included in the breast surgery department of two Class A tertiary hospitals in Suzhou. The patients were divided into a control group and a cognitive reappraisal group using a random number table. During the hospitalization of the control group, nursing staff provided nursing, health education, and rehabilitation guidance in accordance with the routine nursing care of breast surgery specialists. At the four intervention timepoints, they entered the pre-arranged activity room and received one-on-one routine psychological care from the department. After discharge, the patient underwent routine telephone follow-up; The intervention duration was four chemotherapy cycles. On the basis of the control group, patients in the cognitive reappraisal group entered the activity room at the same intervention time point to receive a one-on-one cognitive reappraisal intervention program on ruminative thought, including four thematic interventions: mutual familiarity, cognitive reappraisal symptom rumination intervention, cognitive reappraisal compulsive meditation intervention, and cognitive reappraisal reflection contemplation intervention. Ruminative thought levels and depressive emotions of the two groups of patients were measured before the first intervention and after the second, third, and fourth interventions.

What are the possible benefits and risks of participating?
Possible benefits include reduced ruminative thoughts and depression. There are no expected risks.

Where is the study run from?
The First Affiliated Hospital of Soochow University and the Second Affiliated Hospital of Soochow University (China)

When is the study starting and how long is it expected to run for?
December 2021 to May 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Yueyue Zhang, 15850130176@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of cognitive reappraisal on ruminative thought in breast cancer patients with postoperative chemotherapy

Acronym
CRRT

Study objectives
In this study, the cognitive reappraisal intervention scheme of ruminative thought in breast cancer patients during postoperative chemotherapy can reduce ruminative thought level and alleviate depression.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/03/2022, Ethics Committee of Soochow University (No.1 Shizi Street, Gusu District, Suzhou City, 215000, China; +86 (0)65884048; guangyinxu@suda.edu.cn), ref: SUDA20220304H04

Study design
Parallel randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Participants were randomly divided into a control group and a cognitive reappraisal group according to a random number table. In order to avoid contamination between the two groups, both the control group and the cognitive reappraisal group were asked to enter a pre-arranged activity room for one-on-one communication with the researchers and were told to keep the communication confidential because the study was still ongoing.

During the hospitalization of the control group, nursing staff provided nursing, health education, and rehabilitation guidance according to the routine nursing care of the breast surgery specialty.

They entered the pre-arranged activity room at four intervention time points and received one-on-one routine psychological care from the department; After discharge, patients will receive routine telephone follow-up; The intervention duration is four chemotherapy cycles. On the basis of the control group, patients in the cognitive reappraisal group entered the activity room at the same intervention time to receive one-on-one rumination thinking cognitive reappraisal intervention, including four thematic interventions: mutual familiarity, cognitive reappraisal symptom rumination intervention, cognitive reappraisal compulsive meditation intervention, and cognitive reappraisal reflection deep thinking intervention.

Intervention Type
Supplement

Primary outcome measure
Ruminative thought is measured using a Ruminative Responses Scale (RRS) at baseline, 4, 7, and 10 weeks

Secondary outcome measures
Depression is measured using a Self-Rating Depression Scale (SDS) at baseline, 4, 7, and 10 weeks

Overall study start date
01/12/2021

Completion date
24/05/2024

Eligibility

Key inclusion criteria
1. Female patients diagnosed with breast cancer by pathological report
2. Age 18 years and above
3. Tumor Node Metastasis (TNM) stages I-III
4. First four cycles of postoperative adjuvant chemotherapy
5. Understanding one's own disease diagnosis without the need for protective medical care
6. Having certain abilities in reading, writing, comprehension, and language expression
7. Informed consent and voluntary participation in this study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
64

Total final enrolment
68

Key exclusion criteria
1. Individuals with severe physical diseases such as other malignant tumors
2. Individuals with organic brain diseases or combined with other mental disorders
3. Patients who have recently participated in other psychological interventions or received psychotherapy

Date of first enrolment
01/06/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
China

Study participating centre
First Affiliated Hospital of Soochow University
China
215000

Study participating centre
Second Affiliated Hospital of Soochow University
China
215000

Sponsor information

Organisation
Soochow University

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Sponsor type
University/education

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ROR
https://ror.org/05t8y2r12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The paper has been submitted to a journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication