

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

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<b>Registration date</b> 03/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/09/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## **Study type(s)**

Efficacy

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **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

### ROR

<https://ror.org/05t8y2r12>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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