

Effect of recreational therapy in patients with breast cancer

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| Submission date 12/07/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 12/07/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 12/07/2024 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Breast cancer is one of the most common malignant tumors in women. This study aimed to observe the effect of recreational therapy on anxiety and depression and quality of life in patients with breast cancer undergoing radiotherapy.

Who can participate?

Female patients aged 20 - 65 years with breast cancer undergoing radiotherapy.

What does the study involve?

160 patients were randomly divided into intervention group (n = 82) and control group (n = 78). The patients in the two groups were investigated by questionnaire. The intervention group was treated with recreational therapy during radiotherapy for about 30 days. Patients in the control group were routinely got nursing education about radiotherapy knowledge and self-care methods after admission. Follow-up was conducted 1 month after surgery.

What are the possible benefits and risks of participating?

Recreational therapy can effectively reduce the negative emotions of anxiety and depression in patients with breast cancer during radiotherapy after radical mastectomy, and Recreational therapy has a significant effect on the quality of life in the field of overall health status.

Where is the study run from?

The Fourth Hospital of Hebei Medical University (China)

When is the study starting and how long is it expected to run for?

May 2012 to December 2013

Who is funding the study?

Key Science and Technology Research Program of Health Commission of Hebei Province (No. 20150809) (China)

Who is the main contact?

Junli Liang, nienannan@126.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 recreational therapy on psychological status and quality of life in patients with breast cancer undergoing radiotherapy

Study objectives

Recreational therapy can effectively reduce the negative emotions of anxiety and depression in patients with breast cancer during radiotherapy after radical mastectomy, and Recreational therapy has a significant effect on the quality of life in the field of overall health status.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 17/11/2021, Ethics Committee of The Fourth Hospital of Hebei Medical University (No. 12 of Jiankang Road, Chang'an District, Shijiazhuang, 050011, China; +86-31186095784; hb4thgcp@126.com), ref: 2021145

Study design

Single-centre interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Prevention of anxiety and depression and improvement of quality of life in patients with breast cancer undergoing radiotherapy

Interventions

160 patients were randomly (using a computer-generated table of random numbers) divided into intervention group (n = 82) and control group (n = 78). The patients in the two groups were investigated by questionnaire. The intervention group was treated with recreational therapy during radiotherapy for about 30 days. Patients in the control group routinely got nursing education about radiotherapy knowledge and self-care methods after admission.

Intervention Type

Behavioural

Primary outcome measure

At baseline and follow-up (1 month after surgery):

1. General demographic characteristics collected by questionnaire
2. Anxiety measured by Self-rating anxiety scale (SAS)
3. Depression measured by Self-Rating Depression Scale (SDS)
4. Quality of life measure by EORTC Cancer Quality of Life Core Scale (QLQ-C30) and Breast Cancer Specific Scale (QLQ-BR23)

Secondary outcome measures

There are no secondary outcome measures.

Overall study start date

01/05/2012

Completion date

31/12/2013

Eligibility

Key inclusion criteria

1. Female patients after modified radical mastectomy
2. Married, aged ≤ 50 years
3. KPS score ≥ 70 points
4. Patients with normal cognition, reading and writing ability, informed consent, voluntary participation in the survey of the first radiotherapy

Participant type(s)

Patient

Age group

Adult

Lower age limit

20 Years

Upper age limit

50 Years

Sex

Female

Target number of participants

200

Total final enrolment

160

Key exclusion criteria

1. Combined with other malignant tumors
2. Severe liver and kidney dysfunction
3. Previous history of mental illness or personality disorders, nearly a month have taken antipsychotic drugs
4. Unmarried, divorced, widowed
5. Spouses during the illness of patients with major diseases

Date of first enrolment

30/06/2012

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

China

Study participating centre

The Fourth Hospital of Hebei Medical University

No. 12 of Jiankang Road, Chang'an District

Shijiazhuang

China

050011

Sponsor information

Organisation

The Fourth Hospital of Hebei Medical University

Sponsor details

No. 12 of Jiankang Road, Chang'an District

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

Key Science and Technology Research Program of Health Commission of Hebei Province

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

30/07/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Junli Liang (nienannan@126.com).

IPD sharing plan summary

Available on request