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Effect of recreational therapy in patients with breast cancer

Submission date	Recruitment status	[ ] Prospectively registered
12/07/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/07/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/07/2024	Mental and Behavioural Disorders	[ ] 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

Contact name
Dr Junli Liang

ORCID ID
https://orcid.org/0009-0004-7443-4466

Contact details
No. 12 of Jiankang Road, Chang'an District
Shijiazhuang
China
050011
+86-311 8609 5225
nienannan@126.com

Additional identifiers

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

Primary study design
Interventional

Study design
Single-centre interventional randomized controlled trial

Study type(s)
Quality of life

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(s)
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)

Key secondary outcome(s)
There are no secondary outcome measures.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit

50 Years

Sex
Female

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

Funder(s)

Funder type
Government

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

Results and Publications

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