Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of online mindfulness base stress reduction intervention on sleep quality, fatigue and psychological well-being among breast cancer patients

Protocol summary

Study aim
Determining the effect of online mindfulness-based stress reduction intervention on sleep quality, fatigue and psychological well-being of breast cancer patients in Birjand in 1400

Design
The sample of this study is based on the number of breast cancer patients undergoing chemotherapy referred to Iran Mehr Hospital in Birjand, by available sampling method; And according to the studies performed in the field of variables studied in this study was calculated.

Settings and conduct
To conduct this research, after the approval of the research ethics committee and receiving the code of ethics, by referring to Iran Mehrshahr Hospital in Birjand, after a complete explanation of the research process, the participants were selected by available sampling method and calculated according to the sample size. Will be done according to the entry and exit criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Having the consent to participate in the study • The diagnosis of breast cancer has been confirmed by an oncologist and the results of diagnostic tests. • The patient has the ability to understand, read, write and speak Persian. • Be between 25 and 60 years old. No metastasis to other organs. • The patient is being treated and has received at least one course of chemotherapy. Has not received any psychological intervention in the past year. • Have not had a particular stressful accident in the last 6 months. • The patient is not undergoing other studies or treatments at the same time. • The patient is not under special psychiatric drug treatment during the intervention or all patients are standardized in terms of drug use To be.

Intervention groups
Patients with breast cancer undergoing chemotherapy referred to Iran Mehr Hospital in Birjand

Main outcome variables
Improve sleep quality, fatigue and psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220130053878N1**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **retrospective**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date
2022-06-05, 1401/03/15

Registrant information

Name
Zahra Ahmadi Yegane

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4721 0364

Email address
zahra.a.yegane@outlook.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date

2022-04-21, 1401/02/01

Actual recruitment end date

2022-05-22, 1401/03/01

Trial completion date

2023-07-22, 1402/04/31

Scientific title

Effectiveness of online mindfulness base stress reduction intervention on sleep quality, fatigue and psychological well-being among breast cancer patients

Public title

Effectiveness of online mindfulness base stress reduction intervention on sleep quality, fatigue and psychological well-being among breast cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

• Having the consent to participate in the study• The diagnosis of breast cancer has been confirmed by an oncologist and the results of diagnostic tests.• The patient has the ability to understand, read, write and speak Persian.• Be between 25 and 60 years old.No metastasis to other organs.• The patient is being treated and has received at least one course of chemotherapy.Has not received any psychological intervention in the past year.• Have not had a particular stressful accident in the last 6 months.• The patient is not undergoing other studies or treatments at the same time.• The patient is not under special psychiatric drug treatment during the intervention or all patients are standardized in terms of drug use To be.• The patient does not have a specific psychological disorder.

Exclusion criteria:

• Absence of more than two sessions in the program.• Does not have the desire or ability to continue participating in the study.• Death of the patient.

Age

From **25 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using the coin toss method. At the beginning of each day, by referring to Iranmehr Hospital in Birjand, by dropping a coin, it is determined that the first person, for example, is in the test group, the next people are placed one by one in the test and control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari St., Central Organization of Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2021-06-23, 1400/04/02

Ethics committee reference number

IR.BUMS.REC.1400.100

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improve sleep quality, fatigue and psychological well-being

Timepoint

Before the study and immediately after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire, CFS-D Fatigue Questionnaire, WHO 5-Question Questionnaire (WHO-5)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women with breast cancer undergoing chemotherapy referred to the chemotherapy center of Iran Mehr Hospital in Birjand

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranmehr Cancer and Oncology Hospital, Birjand

Full name of responsible person

Dr. Ahmadreza Sebzari

Street address

Ghaffari Street, in front of Ghaffari 30

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3162 6810

Email

zahra.a.yegane@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr.Ahmad Nasiri

Street address

Ghaffari St., School of Nursing and Midwifery

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Phone

+98 56 3239 5000

Email

www.nasiri2006@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr.Ahmad Nasiri

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Ghaffari St., Central Organization of Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Phone

+98 56 3239 5000

Email

www.nasiri2006@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Ahmad Nasiri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Ghaffari St., School of Nursing and Midwifery

City

Birjand

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Phone

+98 56 3239 5000

Email

www.nasiri2006@bums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Zahra Ahmadi Yegane

Position
nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 3, Golestan St. 1, Farhangian 2

City
Quchan

Province
Razavi Khorasan

Postal code
9471716545

Phone
+98 51 4721 0364

Email
www.zahra.a.yegane@outlook.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Participants' personal information is not shareable and only information about the main outcome can be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions and medical centers

Under which criteria data/document could be used
It is not clear yet.

From where data/document is obtainable
Corresponding author Dr. Ahmad Nasiri Email address: www.nasiri2006@bums.ac.ir

What processes are involved for a request to access data/document
6 months after printing the results.

Comments