

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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	Not used
Actual recruitment end date	Assignment
2022-05-22, 1401/03/01	Other
Trial completion date	Other design features
2023-07-22, 1402/04/31	
Scientific title	Secondary Ids
Effectiveness of online mindfulness base stress reduction intervention on sleep quality, fatigue and psychological well-being among breast cancer patients	empty
Public title	Ethics committees
Effectiveness of online mindfulness base stress reduction intervention on sleep quality, fatigue and psychological well-being among breast cancer patients	1
Purpose	Ethics committee
Supportive	Name of ethics committee
Inclusion/Exclusion criteria	Ethics Committee of Birjand University of Medical Sciences
Inclusion criteria:	Street address
• 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.	Ghaffari St., Central Organization of Birjand University of Medical Sciences
Exclusion criteria:	City
• 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.	Birjand
Age	Province
From 25 years old to 60 years old	South Khorasan
Gender	Postal code
Female	9717853577
Phase	Approval date
N/A	2021-06-23, 1400/04/02
Groups that have been masked	Ethics committee reference number
No information	IR.BUMS.REC.1400.100
Sample size	Health conditions studied
Target sample size: 70	1
Actual sample size reached: 62	Description of health condition studied
Randomization (investigator's opinion)	breast cancer
Randomized	ICD-10 code
Randomization description	ICD-10 code 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)	Primary outcomes
Not blinded	1
Blinding description	Description
Placebo	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

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

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

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

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Postal code

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+98 56 3239 5000

Email

www.nasiri2006@bums.ac.ir

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

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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

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

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Province

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Postal code

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Ahmadi Yegane

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nurse

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Bachelor

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Nursery

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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