Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative Investigation Between The Effectiveness Of Auriculotherapy And Counselling On Coping And Mental Adjustment To Cancer(MAC) In Women With Breast Cancer Undergoing Chemotherapy

Protocol summary

Study aim

Determining and comparing the effect of auriculotherapy and counseling on coping and mental adjustment to cancer in women with breast cancer undergoing chemotherapy

Design

A randomized, controlled, clinical trial With parallel groups, On 105 patients. Use Random Sequence Generation Online Software.

Settings and conduct

After receiving permission to conduct the research and presenting it to Kerman University of Medical Sciences, the researcher refers to the Office of Adult Blood and Oncology and affiliated centers of Kerman University of Medical Sciences and this clinical trial study will be by random sampling. The list of women with breast cancer under the supervision of selected hematologists and oncologists in Kerman will be obtained through their information registration system.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; having written consent to participate in the study; no substance abuse; literacy; women with breast cancer undergoing chemotherapy at least one month after the start of treatment; stage 1-3 breast cancer; No severe mental disorders based on interview; no lesion or skin problem in the ear area and auriculotherapy site Exclusion criteria: Metastatic patients; substance abuse; use of auriculotherapy technique or any other complementary and alternative medicine during two Last month; participating in a mindfulness-based cancer recovery program or mindfulness-based stress reduction for the past five years; corona

Intervention groups

In the counseling group, eight 90-minute weekly group sessions of counseling are performed by mindfulness-based cancer recovery method. In the auriculotherapy group, two sessions per week and a total of 10 sessions of auriculotherapy will be held. The control group receives their routine medical care.

Main outcome variables

Coping , Mental Adjustment To Cancer .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201027049164N1**
Registration date: **2021-08-16, 1400/05/25**
Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**
Update count: **0**

Registration date

2021-08-16, 1400/05/25

Registrant information

Name

Masumeh Ghazanfarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5856

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Investigation Between The Effectiveness Of Auriculotherapy And Counselling On Coping And Mental Adjustment To Cancer(MAC) In Women With Breast Cancer Undergoing Chemotherapy

Public title
Comparative Investigation Between The Effectiveness Of Auriculotherapy And Counselling On Coping And Mental Adjustment To Cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Having written consent to participate in the study No substance abuse Literacy Women with breast cancer undergoing chemotherapy at least one month after the start of treatment Stage 1-3 Breast cancer No severe mental disorders based on the interview No lesion or skin problem in the ear area and auriculotherapy site
Exclusion criteria:
Metastatic patients Lack of cooperation of authorities and lack of answers to questionnaire questions Drug abuse Participate in psychological classes simultaneously Use of auriculotherapy technique or any other complementary and alternative medicine during the last two months Participate in a mindfulness-based cancer recovery program or mindfulness-based stress reduction for the past five years Application of another complementary medicine method along with auriculotherapy method Corona
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, the selection will be assigned to participants from 1 to 105, respectively. Then, using the online software for generating random sequences (www.randomizer.org) and the method of block random allocation with six blocks, people will be divided into three groups of 35 and in each of the three groups counseling, auriculotherapy and control will be placed
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Deputy of Research and Technology;ebne-e-Sina St.,Jahad Blvd., Kerman,Iran
City
Kerman
Province
Kerman
Postal code
7619813159
Approval date
2021-07-28, 1400/05/06
Ethics committee reference number
IR.KMU.REC.1400.246

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
coping With Cancer
Timepoint
At the beginning (Before starting the intervention) , Immediately upon completion of the intervention , Two months after the end of the intervention
Method of measurement
Carver Short Coping Questionnaire (Brief cope)

2

Description
Mental Adjustment To cancer
Timepoint
At the beginning (Before starting the intervention) ,

Immediately upon completion of the intervention , Two months after the end of the intervention

Method of measurement

Mental Adjustment To Cancer Questionnaire (MINI MAC)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In the counseling group, eight 90-minute weekly group sessions of counseling are performed by mindfulness-based cancer recovery(MBCR) method

Category

Other

2

Description

Second intervention group: In the auriculotherapy group, two sessions per week and a total of ten sessions in the shen men, kidney, relaxation and lung points in the left ear and thalamic points, Mr. sholder, liver, anxiety, cerebral in the right ear using a hand probe for 15 seconds will be done and then Vacaria seed It is pasted in places. The patient is advised to press the seed three times a day for one minute, except at bedtime. On the third day, the seeds will return slowly and after stimulation, the seeds will be reattached.

Category

Other

3

Description

Control group: The control group receives routine care (care provided by the treating physician and nurses, such as prescribing and injecting chemotherapy drugs at the clinic or hospital, and recommendations and care after injection)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of a doctor specializing in blood and cancer

Full name of responsible person

Hediyeh Barkhordari

Street address

No. 3 , Saadi Ave , Mehrad Building

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7613733631

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Email

hdi.br00@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

Tahmasbabad cross road, Vice Chancellor for Research and Technology building

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7616913555

Phone

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h.barkhordari@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Hediyeh Barkhordari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Masumeh Ghazanfarpour
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hediyeh Barkhordari
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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
Undecided - It is not yet known if there will be 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