# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**

m.ghazanfarpour@kmu.ac.ir


**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

**City**

Kerman

**Province**

Kerman

**Postal code**

7613733631

**Phone**

+98 34 3226 5003

**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

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5856

**Email**

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

**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
**City**
Kerman
**Province**
Kerman
**Postal code**
76169-13555
**Phone**
+98 34 3132 5700
**Email**
h.barkhordari@kmu.ac.ir

## 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**
Ph.D.
**Other areas of specialty/work**
Midwifery
**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Phone**
+98 34 3132 5856
**Email**
M.ghazanfarpour@kmu.ac.ir

## 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
**Street address**
Beginning of the axis of seven Alavi Gardens, Campus of the University of Medical Sciences, Faculty of Nursing and Midwifery
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Phone**
+98 34 3132 5700
**Email**
h.barkhordari@kmu.ac.ir

## 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