

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of counseling based on mindfulness on quality of life and psychological well-being in woman with cervical cancer

#### Protocol summary

##### Study aim

The effect of counseling based on mindfulness on quality of life and psychological well-being in women with cervical cancer

##### Design

Clinical trial with control group, with parallel groups, triple blind, randomized

##### Settings and conduct

This study will be conducted at the Imam Khomeini and Golestan hospitals of Ahwaz. The researcher will be referred to the research environment with the aim of collecting data and will be included in the study if the patients are willing and have eligibility criteria. The samples were selected by available sampling method. After the initial interview and completion of the questionnaires, the eligible group will be included in the study and will be divided into two groups of intervention and control with random allocation. The intervention group will be subjected to eight sessions of Mindfulness training. The quality of life questionnaire and psychological well-being questionnaires were completed before intervention, immediately after intervention and one month after the intervention, Will be completed in the research environment. In this study, the researcher, samples and statistical analyst are blind.

##### Participants/Inclusion and exclusion criteria

eligibility criteria : 1. Women with stage IV cervical cancer 2. The quality of life score is less than 50% 3. Score of psychological well-being less than 50 4. Married 5. Having reading and writing skills 6. Accommodation in Ahvaz city 7. Ability to speak Persian in order to answer the questionnaire questions Exit criteria: 1. Drug Addiction 2. History of the technique of mind-consciousness 3. Getting other acute physical abnormalities 4. Being afflicted with known psychiatric disorders 5. Existence of stressful events during the past six months

##### Intervention groups

A group that learns mindfulness.

#### Main outcome variables

Quality of life; psychological well-being

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181030041505N1**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

##### Registration date

2018-11-12, 1397/08/21

##### Registrant information

##### Name

shima Bahri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5372 7300

##### Email address

shimabahri2016@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-11, 1397/08/20

##### Expected recruitment end date

2018-11-21, 1397/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of counseling based on mindfulness on quality of life and psychological well-being in woman with cervical cancer

**Public title**

The effect of counseling based on mindfulness on quality of life and psychological well-being in woman with cervical cancer

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with stage IV cervical cancer The quality of life score is less than 50% The psychological well-being score is less than 50 Being married Have reading and writing skills Accommodation in Ahvaz city Ability to speak Persian in order to answer the questionnaire questions

**Exclusion criteria:**

Drug Addiction History of Mindfulness Technique Cause of other acute physical abnormalities Affected by known psychiatric disorders Existence of stressful events(Divorce, the death of a family member, the loss of his or her individual job, change in life)Over the past six months

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of assigning type of intervention to patients was randomized and random blocked blocks with block size 6 (by Using the table of random permutations)With a ratio of 1: 1

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

A randomized list is provided by a statistician. According to a randomized list, codes are assigned by an outside person to any illness that is included in the study

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan Blvd University of Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2018-05-12, 1397/02/22

**Ethics committee reference number**

IR.AJUMS.REC.1397.109

**Health conditions studied****1****Description of health condition studied**

Cervical Cancer

**ICD-10 code**

N87

**ICD-10 code description**

Dysplasia of cervix uteri

**Primary outcomes****1****Description**

Quality of Life

**Timepoint**

At the beginning of the study and one month after the end of the study

**Method of measurement**

questionnaire

**Secondary outcomes****1****Description**

Psychological well-being

**Timepoint**

Before the study and one month after the end of the study

**Method of measurement**

questionnaire

## Intervention groups

1

### Description

Intervention group: Mentally educated people

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Ahvaz Imam Khomeini Hospital

#### Full name of responsible person

mogahi sasan

#### Street address

Golestan Blvd. Academic town

#### City

ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8396

#### Email

montazeri-s@ajums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

montazeri simin

#### Street address

Golestan Blvd. Academic town

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8396

#### Email

montazeri-s@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

#### Full name of responsible person

montazeri simin

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Midwifery

#### Street address

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#### Province

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#### Email

montazeri-s@ajums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

shahid Chamran University of Ahwaz

#### Full name of responsible person

Naser Behrozi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Psychology

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Golestan Blvd. Academic town

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Ahvaz

#### Province

Khouzestan

#### Postal code

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#### Phone

+98 61 3333 3477

#### Email

behroozyn@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

shima bahri

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

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**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

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**Email**

shimabahri2016@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

A portion of the original outcome data will be shared.

**When the data will become available and for how long**

6 months after printing the results

**To whom data/document is available**

No restrictions.

**Under which criteria data/document could be used**

Educational and consulting assistance is allowed.

**From where data/document is obtainable**

shimabahri2016@yahoo.com

**What processes are involved for a request to access data/document**

Request documentation and data by email and send them in the shortest possible time

**Comments**