Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Khouzestan

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
Golestan Blvd. Academic town
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8396
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
Street address
Golestan Blvd. Academic town
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
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
Golestan Blvd. Academic town

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3333 3477

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