

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison the efficacy of reality therapy in group counselling and life skills training on quality of life of menopausal women

#### Protocol summary

##### Summary

This study aimed to evaluate the effectiveness of life skills training and counseling reality therapy on quality of life in menopausal women in Arak. This research is educational trial. Research done in the city in 1393. The sample size in each group is 20 people. Sampling at five clinics in the five districts of the city and Retirement center city and Charitable seniors Easy and simple to be done. Inclusion criteria: 48-55 years, 12 months have passed since their last menstrual period, Persian origin, primary education is the minimum level of education, don't training courses already have passed the menopause before education, lack of drug addiction, lack of chronic illness, lack of getting the treatment of hormone therapy to treat symptoms of menopause, Interested in participating in the study, Lack of mental health problems exclusion criteria: An unwillingness to continue participation in the study. Absenteeism over a meeting, The incidence of adverse events and circumstances prior to collecting data on the second questionnaire. The participants are selected based on criteria. If there is a requirement for inclusion demographic and quality of life questionnaire (MENQOL) is completed. The women are divided into three groups A, B and C. group of A of women training skills training will be given. group of B of women will teach counselling choice theory. group of C are controls. After one month of the end teaching and counseling Quality of Life Questionnaire (MENQOL) again completed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120920258N2**

Registration date: **2015-03-26, 1394/01/06**

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

Last update:

Update count: **0**

##### Registration date

2015-03-26, 1394/01/06

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences and Health Services

##### Expected recruitment start date

2014-12-20, 1393/09/29

##### Expected recruitment end date

2015-05-22, 1394/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the efficacy of reality therapy in group counselling and life skills training on quality of life of menopausal women

##### Public title

Comparison the efficacy of reality therapy in group counselling and life skills training on quality of life of menopausal women

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria:48-55 years, 12 months have passed since their last menstrual period ,Persian origin, primary education is the minimum level of education,don't training courses already have passed the menopause before education, lack of drug addiction, lack of chronic illness, ,lack of getting the treatment of hormone therapy to treat symptoms of menopause, Interested in participating in the study,Lack of mental health problems  
exclusion criteria:An unwillingness to continue participation in the study. Absenteeism over a meeting,The incidence of adverse events and circumstances prior to collecting data on the second questionnaire

## Age

From **48 years** old to **55 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak University of Medical Sciences and Health Services

##### Street address

Counseling in midwifery group, School of Nursing and Midwifery, Arak University of Medical Sciences,payambar azam, sardasht, Basij, Arak, Iran

##### City

Arak

##### Postal code

38481-7-6941

#### Approval date

2014-12-01, 1393/09/10

#### Ethics committee reference number

93-24-171

## Health conditions studied

### 1

#### Description of health condition studied

Menopause counseling- quality of life

#### ICD-10 code

Z71.9

#### ICD-10 code description

Counselling, unspecified

## Primary outcomes

### 1

#### Description

Quality of life after reality counseling

#### Timepoint

Before intervention-one month after intervention

#### Method of measurement

Questionnaire of quality of life menopausal women(MENQOL)

### 2

#### Description

Quality of life after training life skills

#### Timepoint

before intervention-one month after intervention

#### Method of measurement

Questionnaire of quality of life menopausal women(MENQOL)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention groups: There are two groups. One group menopause women train life skills in 8 sessions for two hours, Researcher see this women in three days a week. Control measures might not accept them.

#### Category

Lifestyle

### 2

#### Description

Intervention Group: The next group menopause women counseling reality therapy in 8 sessions for two hours, Researcher see this women in three days a week. Control measures might not accept them.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Five clinics in Arak city

**Full name of responsible person**

Fariba-Farokhi-student of master of counseling in midwifery

**Street address**

**City**

Arak

### 2

#### Recruitment center

**Name of recruitment center**

Institutions of Charitable Elderly

**Full name of responsible person**

Fariba-Farokhi-student of master of counseling in midwifery

**Street address**

**City**

Arak

### 3

#### Recruitment center

**Name of recruitment center**

Center for Retirement

**Full name of responsible person**

Fariba-Farokhi-student of master of counseling in midwifery

**Street address**

**City**

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences and Health Services

**Full name of responsible person**

Fereshte Narenji, Faculty

**Street address**

Arak medical science university, Payambar azam Educational Complex, Meidan Basij, Sardasht

**City**

Arak

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak University of Medical Sciences and Health Services

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences and Health Services

**Full name of responsible person**

Fariba Farokhi

**Position**

Student of master of counseling in midwifery

**Other areas of specialty/work**

**Street address**

MSc student in midwifery in counseling, School of Nursing and Midwifery, Arak University of Medical Sciences-Payambar azam Educational Complex, Basij, Sardasht

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**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences and Health Services

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**Position**

Faculty

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Arak University of Medical Sciences and Health Services

#### Full name of responsible person

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#### Position

Student of master of counseling in midwifery

#### Other areas of specialty/work

#### Street address

MSc student in midwifery in counseling, School of Nursing and Midwifery, Arak University of Medical Sciences-Payambar azam Educational Complex ,Basij ,Sardash ,Arak

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*