

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### The effect cognitive behavioral therapy on the mental health of women in polygamous families

#### Protocol summary

##### Study aim

The purpose of this study was to determine the effectiveness of cognitive behavioral counseling and mental health on women with multiple spouses.

##### Design

This study is a randomized controlled trial. The samples are randomly divided into two groups of intervention and control.

##### Settings and conduct

This study is a randomized clinical trial study that will be referred to Ahwaz East Health Center after submitting a written letter from Ahwaz University of Medical Sciences and receiving a code of ethics from Ahwaz Jundishapur University of Medical Sciences Ethics Committee.

##### Participants/Inclusion and exclusion criteria

This study is a clinical trial on 90 women in polygamous families with mental health problems. Inclusion criteria included: mental health score higher than 50 based on the SCL -25 mental health questionnaire, women in polygamous families of childbearing age 18 to 45 years, minimum education level is cycle, spouse has mental health. Exclusion criteria include: Women's unwillingness to continue in collaborating in research, having a history of adverse event in the last 6 months, having a history of Drugs use or Alcohol, Infertile women, Cerebral lesions, mental retardation, taking psychotropic drugs, having underlying disease of hypertension diabetes mellitus.

##### Intervention groups

The intervention group will receive 8 sessions of 120 minutes weekly Cognitive behavioral Counseling, After the end of counseling period and one month later both group will be assessed again with the mental health questionnaire. The control group will not receive any intervention during the study but they will be offered two sessions of group counseling to follow the ethics of the research

##### Main outcome variables

Mental health Level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190906044709N1**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **retrospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

##### Registration date

2019-12-22, 1398/10/01

##### Registrant information

##### Name

Soghra Moradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3323 2171

##### Email address

sghrymrady9@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-07, 1398/04/16

##### Expected recruitment end date

2019-09-11, 1398/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect cognitive behavioral therapy on the mental health of women in polygamous families

**Public title**  
effect cognitive behavioral therapy on the mental health

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Earning a Mental health score higher than 50 on the SCL-25 mental health questionnaire Women in polygamous families aged 18 to 45 years minimum cycle education Lack of severe mental disorders of wife  
**Exclusion criteria:**  
 women,s unwillingness to continue collaborating in research Having a history of adverse event in the last 6 months Having a history of drug or alcohol abuse Infertile women Cerebral lesions and mental retardation Taking psychotropic drugs Having underlying disease of hypertention , diabetes mellitus

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, women in polygamous families will be identified through family case studies and completion of screening criteria for entry and exit among women in polygamous families. individuals who qualify for the study will complete a mental health questionnaire. 90 of the women whose mental health is below average with written consent, this will be included in the research. in this study, according to the sample size formula, 90 people were included in the study, then, using random allocation method in each group, using random number table, the creation of 4 blocks will be divided in to two groups of 45 each intervention and control groups.

**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 Ahwaz University of Medical Sciences  
**Street address**  
 Vcie chancellor for Research, Information Technology, Ahvaz Jundishapur University of Medical Sciences, Ground Floor.  
**City**  
 Ahwaz  
**Province**  
 Khouzestan  
**Postal code**  
 15794-61357  
**Approval date**  
 2019-04-28, 1398/02/08  
**Ethics committee reference number**  
 IR.AJUMS.REC.1398.095

**Health conditions studied**

**1**

**Description of health condition studied**  
Mental health

**ICD-10 code**  
F00-F09

**ICD-10 code description**  
Organic, including symptomatic, mental disorders

**Primary outcomes**

**1**

**Description**  
Mental health

**Timepoint**  
Befour Intervention , one month after intervention

**Method of measurement**  
Mental health questionnaire SCL-25

**Secondary outcomes**  
empty

**Intervention groups**

**1**

**Description**  
Intervention group: Intervention group eight meeting CBT gets for each session 120 minutes and has structure

**Category**  
Behavior

**2**

**Description**  
Control group: The control group received no intervention and was on the waiting list.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Health care center No : 9

**Full name of responsible person**

Soghra Moradi

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Amini Street., Behbahani Blvd

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Behzad Sharif Makhmal Zadeh

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Medical Sciences School of Nursing and Midwifery -  
Midwifery group - Khuzestan Iran**City**

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**Web page address**<http://vchresearch.ajums.ac.ir>**Grant name**Sponsor Vice Chancellor for research Ahwaz University of  
Medical Sciences**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**

Soghra Moradi

**Position**

MS.c Student Midwifery Cunselling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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Street Esfand, Golestan

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**Web page address**<http://vchresearch.ajums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mitra Tadayon

**Position**Master of Midwifery, Lecturer in Midwifery  
Department, Ahwaz Jundishapur Univercity of Medical  
Scien**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

**Contact**

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Ahvaz University of Medical Sciences

**Full name of responsible person**

Soghra Moradi

**Position**

Student in Midwifery Counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## 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**

Yes - There is a plan to make this available

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

All peoples data can be shared after it is unrecognizable

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

2 months after the article was published

**To whom data/document is available**

Anyone interested can access the data

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

If used for other research or comparing result with other research

**From where data/document is obtainable**

Soghra Moradi - sghrymrady9@gmail.com-0098  
9161593556

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

Correspondence with researcher email and explanation  
of the purpose of reading and using data

**Comments**