

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)

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+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

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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

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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

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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