

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The impact of motivational counseling on increasing couples interest for premarital genetic tests during marriage in referents to counseling center in Arak in 1396 year

Protocol summary

Study aim

The impact of motivational counseling on increasing couples interest for premarital genetic tests during marriage in referents to counseling center in Arak in 1396 year

Design

The present study is a clinical and double blind clinical trial that is carried out on 280 couples aged 20 to 35 years old referred to marriage counseling center in Arak. Out of 280, 40 couples are selected and randomly divided into two groups.

Settings and conduct

The present study is a clinical and double blind clinical trial that is carried out on 280 couples aged 20 to 35 years old referred to marriage counseling center in Arak. Out of 280, 40 couples are selected and randomly divided into two groups. This study is double blind. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Couples married at the age of 20 to 35 ,no disturbance in couples' alertness ,having written consent from the couples to participate in the research ,not having previous marriage history in each of the couples,lack of cognitive problems and special diseases in the referring people Exclusion criteria:Unwilling couples to participate in motivational interviews,unsatisfactory of couples to complete questionnaire forms incomplete data entry in the questionnaire by couples ,if motivations for interviewing are reduced in each stage of the session ,non-attending intervention sessions (one meeting and more)

Intervention groups

For 20 couples in the intervention group, the motivational interview sessions will be held in 5 sessions for 60 minutes in 5 weeks. There are no interventions for

20 couples for the control group.

Main outcome variables

Attitude

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N95**

Registration date: **2019-01-13, 1397/10/23**

Registration timing: **retrospective**

Last update: **2019-01-13, 1397/10/23**

Update count: **0**

Registration date

2019-01-13, 1397/10/23

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

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty	Not used
Actual recruitment end date	Assignment
empty	Parallel
Trial completion date	Other design features
empty	
Scientific title	Secondary Ids
The impact of motivational counseling on increasing couples interest for premarital genetic tests during marriage in referents to counseling center in Arak in 1396 year	empty
Public title	Ethics committees
The impact of motivational counseling on increasing couples interest for premarital genetic tests during marriage in referents to counseling center in Arak in 1396 year	1
Purpose	Ethics committee
Education/Guidance	Name of ethics committee
Inclusion/Exclusion criteria	Ethics Committee Of Arak University Of Medical Sciences
Inclusion criteria:	Street address
Couples married at the age of 20 to 35 No disturbance in couples' alertness Having written consent from the couples to participate in the research Not having previous marriage history in each of the couples Lack of cognitive problems and special diseases in the referring people	Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
Exclusion criteria:	City
Unwilling couples to participate in motivational interviews Unsatisfactory of couples to complete questionnaire forms incomplete data entry in the questionnaire by couples If motivations for interviewing are reduced in each stage of the session Non-attending intervention sessions (one meeting and more)	Arak
Age	Province
From 20 years old to 35 years old	Markazi
Gender	Postal code
Both	848176941
Phase	Approval date
2-3	2017-11-26, 1396/09/05
Groups that have been masked	Ethics committee reference number
- Participant - Outcome assessor - Data analyser	IR.ARAKMU.REC.1396.175
Sample size	Health conditions studied
Target sample size: 40	1
Randomization (investigator's opinion)	Description of health condition studied
Randomized	Genetic
Randomization description	ICD-10 code
Simple individual randomization with random number in division of groups in two groups A and B.The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups.	D72.0
Blinding (investigator's opinion)	ICD-10 code description
Double blinded	Genetic anomalies of leukocytes
Blinding description	Primary outcomes
This study is double blind.Outcome elevator and analyzer are blind (double blind).Outcome elevator and analyzer don't aware from grouping.	1
Placebo	Description
	Change attitude
	Timepoint
	before and 2 months after intervention
	Method of measurement
	Structural questionnaire based on variables of behavioral intention model included 13 general questions (demographic), 14 questions attitude, 10 awareness questions and 6 questions related to behavioral temperament
	Secondary outcomes
	empty

Intervention groups

1

Description

Intervention group: For 20 couples in the intervention group, the motivational interview sessions will be held in 5 sessions for 60 minutes in 5 weeks.

Category

Behavior

2

Description

Control group: There are no interventions for 20 couples for the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Center Arak city marriage counseling

Full name of responsible person

Dr Katayon Vakilian

Street address

Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

848176941

Phone

+98 86 3417 3505

Email

cattyV2002@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

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Phone

+98 86 3222 2003

Email

arjmandzadegan@arakmu.ac.ir

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

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

Arak University of Medical Sciences

Full name of responsible person

Dr Katayon Vakilian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Midwifery and nursing department, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

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cattyv@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Hamidreza Jamilian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Amirkabir hospital, Parastar square

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Province

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Web page address**Postal code**

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sa_shojaei2006@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

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Jamilian

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

They have to write letters to the professors and the university

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Samaneh Shojaeefar

Position

Midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Payambar Azam Complex, Basij square, Sardasht,
Arak

City

Arak

Province

Markazi