

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

counseling based on reality therapy and the attitude and intention to have children

Protocol summary

Study aim

Determining the effect of counseling based on reality therapy on the attitude and intention to have children of women

Design

Women seeking premarital counseling at two randomly selected counseling centers were invited to participate. Data Collection: Before the intervention, participants completed questionnaires on demographics, attitudes towards childbearing, and intentions to have children. Group Assignment: Participants were randomly assigned to either an intervention group or a control group.

Settings and conduct

Sampling will be done continuously. It should be noted that among the 31 comprehensive health centers that are supervised by Iran University of Medical Sciences and they are located in the north and northwest of Tehran, 4 centers are chosen (Can. Tehransar. Fazel. Taghiniya). In order to prevent research samples from receiving information from each other, random allocation of research samples will not be done. so. two centers consider as intervention and two centers consider control

Participants/Inclusion and exclusion criteria

Women aged 18 to 45 who are about to get married, who have visited pre-marriage centers and are able to use the virtual world. Conditions of non-entry into the drug consumption study. A history of previous marriage or having a child

Intervention groups

The intervention group receives 8 sessions (60 minutes) once a week of reality therapy intervention based on their acceptance online by Bale application and the control receive the usual training of premarital counseling centers.

Main outcome variables

Improving the attitude towards fertility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240915063054N1**

Registration date: **2024-11-10, 1403/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-11-10, 1403/08/20**

Update count: **0**

Registration date

2024-11-10, 1403/08/20

Registrant information

Name

Elahe Sadeghi Sahebzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 478 5098

Email address

sadeghi.e@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-03, 1403/08/13

Expected recruitment end date

2025-03-03, 1403/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

counseling based on reality therapy and the attitude and intention to have children

Public title

the effect of counseling based on reality therapy on the attitude and intention to have children in women who referring to premarital counseling centers

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 18 to 45 about to get married Capable of using virtual space networks Access to mobile phones and authorized virtual networks (yes) Having at least middle school education

Exclusion criteria:

Mental illness under medication Physical illness

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: **78**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Iran university of medical sciences

Street address

Iran University of medical Sciences

City

Tehran

Province

Tehran

Postal code

1383957631

Approval date

2024-10-02, 1403/07/11

Ethics committee reference number

IR.IUMS.REC.1403.593

Health conditions studied**1****Description of health condition studied**

Attitude and intention to have children

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Attitude

Timepoint

The beginning of the study, 8 weeks after the start of the study

Method of measurement

Demographic questionnaire, : Attitudes toward fertility and childbearing scale. : Childbearing Motivations Scale

2**Description**

attention to have children

Timepoint

The beginning of the study, 8 weeks after the start of the study

Method of measurement

Demographic questionnaire, : Attitudes toward fertility and childbearing scale. : Childbearing Motivations Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Women 18 to 45 years old about to get married. The intervention group, divided into groups of 8-10 people, will receive 8 sessions (60 minutes) once a week based on their acceptance of reality therapy online and in the form of counseling.

Category

Treatment - Other

2**Description**

Control group: Women 18 to 45 years old about to get married

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran west health center

Full name of responsible person

Elaheh Sadeghi Sahebzad

Street address

ostad moeen avenue

City

Tehran

Province

Tehran

Postal code

1383957631

Phone

+98 912 478 5098

Email

sadeghi.se22@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reze Aflak

Street address

Iran University of medical Sciences

City

Tehran

Province

Tehran

Postal code

1383957631

Phone

+98 912 478 5098

Email

sadeghi.se22@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Elahe Sadeghi Sahebzad

Position

assistant proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Iran University of medical Sciences

City

Tehran

Province

Tehran

Postal code

1383957631

Phone

+98 912 478 5098

Email

sadeghi.se22@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Elahe Sadeghi Sahebzad

Position

assistant proffsor

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Person responsible for updating data

Contact**Name of organization / entity**

Iran University of Medical Sciences

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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

The data of the samples will be coded and the results of the study will be published in the form of a thesis

When the data will become available and for how long

Access starts from 1404

To whom data/document is available

Iran university of medical sciences

Under which criteria data/document could be used

around thesis limitation

From where data/document is obtainable

thesis publication

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

The application is accepted only from the officials of Iran University of Medical Sciences

Comments