# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of premarital counseling through motivational Interview on the knowledge, attitude and intention to refer to couples in need of genetic counseling

## Protocol summary

**Study aim**
Determining the effect of premarital counseling through motivational Interview on the knowledge, attitude and intention to refer to couples in need of genetic counseling

**Design**
A clinical trial with a control group with parallel groups, without blinding, randomized, on 70 patients

**Settings and conduct**
This study is a clinical trial. Couples will be selected from Mashhad health centers. After completing the questionnaires, they are divided into two intervention and control groups by random allocation. In addition to routine care, the intervention group will receive three sessions of 60-90 minutes, once a week, pre-marital counseling based on motivational interview.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria : Iranian couple,Having at least primary education , Do not have addiction to tobacco and alcohol , Having an Android phone , Based on the doctor's approval and the genetic screening questionnaire, they should have a genetic counseling indication at the time of marriage , Couples who do not intend to do genetic counseling.Exclusion criteria: Diagnosis of a known psychiatric disorder in the couple (having a mood and anxiety disorder and being treated), Uncertainty about continuing the research

**Intervention groups**
Intervention group: couples will receive three counseling sessions based on motivational interviewing for 60-90 minutes once a week in one face-to-face session and two online sessions in groups of 4-5 couples.The control group will receive routine care according to the instructions of the social genetics program, which includes training and identification and follow-up of couples in need of genetic counseling.

**Main outcome variables**
knowledge, attitude and intention to refer

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221022056264N1**
Registration date: **2023-02-04, 1401/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-04, 1401/11/15**
Update count: **0**

**Registration date**
2023-02-04, 1401/11/15

**Registrant information**

**Name**
Maryam Imani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3605 4850

**Email address**
imanimr3@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-12-31, 1401/10/10

**Expected recruitment end date**
2023-04-30, 1402/02/10

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of premarital counseling through motivational Interview on the knowledge, attitude and intention to refer to couples in need of genetic counseling

**Public title**
The effect of motivational interviewing on couples in need of genetic counseling

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Iranian couple Have at least primary education. Do not have addiction to tobacco and alcohol Have an Android phone. Based on the doctor's approval and the genetic screening questionnaire, they should have a genetic counseling indication at the time of marriage. Couples who do not intend to do genetic counseling.

**Exclusion criteria:**
Diagnosis of a known psychiatric disorder in the couple (having a mood and anxiety disorder and being treated) Uncertainty about continuing the research

**Age**
No age limit

**Gender**
Both

**Phase**
N/A

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

**Sample size**
Target sample size: **70**

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

**Randomization description**
Random allocation: using the website www.random.org and through blocking with block sizes of four and six and an allocation ratio of 1:1 to the two groups of counseling and control.

**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 the School of Nursing and Midwifery Mashhad University of Medical Sciences

**Street address**
Qurashi Building, Daneshgah Street

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9138813944

**Approval date**
2022-10-04, 1401/07/12

**Ethics committee reference number**
IR.MUMS.NURSE.REC.1401.070

## Health conditions studied

### 1

**Description of health condition studied**
Family history of mental retardation

**ICD-10 code**
Z81.0

**ICD-10 code description**
Family history of mental retardation (Conditions classifiable to F70-F79)

## Primary outcomes

### 1

**Description**
Knowledge score in the knowledge questionnaire

**Timepoint**
The measurement periods will be before the intervention, immediately after the end of the intervention and one month after the intervention.

**Method of measurement**
Knowledge questionnaire ( Researcher made )

### 2

**Description**
Attitude score in the attitude questionnaire

**Timepoint**
The measurement periods will be before the intervention, immediately after the end of the intervention and one month after the intervention.

**Method of measurement**
Attitude questionnaire based on Zaien study

### 3

**Description**
Referral intention score in the questionnaire

**Timepoint**
The measurement periods will be before the intervention, immediately after the end of the intervention and one month after the intervention.

**Method of measurement**
Referral intention questionnaire ( Researcher made )

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The intervention will be implemented in three sessions once a week for 60-90 minutes, one face-to-face session and two online sessions in groups of 4-5 couples. In the first meeting, greeetings, stating the rules and goals of the meeting, encouraging couples to express their information, feelings and beliefs about genetic counseling and genetic diseases, introducing a motivational approach; Expressing the effects of having a baby with a genetic disorder in different aspects of life; Introducing the stages of change and doing exercises (thinking and reflection stage) and in the second session, answering the doubts and questions formed in the minds of couples and examining the existing problems and obstacles and the causes of resistance to genetic counseling, determining the advantages and disadvantages of changing behavior. The short-term evaluation of the advantages and disadvantages of genetic counseling (readiness to change behavior and action) and the third session of empowerment (transmission of correct information) and support, review of values, perspective and conclusions are expressed (maintenance stage).

**Category**
Behavior

### 2

**Description**
Control group: They will receive routine care provided in Mashhad health centers number 1 and 2, which includes education about 6 genetic diseases (Duchen and Becker, Down syndrome, sickle cell anemia, G6PD, neural tube defects, hemophilia) and identification and follow-up of couples in need of genetic counseling.

**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Health Center No. 1

**Full name of responsible person**
Maryam Imani

**Street address**
Between 66 and 68 Vakil Abad, Vakil Abad Boulevard

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### 2

**Recruitment center**

**Name of recruitment center**
Health Center No. 2

**Full name of responsible person**
Maryam Imani

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No. 2, Mashhad Health Center , Panjarah

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Dr. Majid Ghayor Mobarhan

**Street address**
Research and Technology Vice-Chancellor, Qurashi Building next to Hoizeh Cinema, University Street

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GhayourM@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Nahid Jahani Shurab

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Imani

**Position**

Master's student in counseling in midwifery

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available