

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Reality therapy on the Level of Anxiety, Stress, Depression and Cortisol in Pregnant Mothers in anticipation of Amniocentesis in Isfahan ,2019

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

The main objective Determining the Effect of Health Reality on the Level of Anxiety, Stress, Depression and Cortisol in Pregnant Mothers in anticipation of Amniocentesis in Isfahan City in 1398

Last update: **2019-08-09, 1398/05/18**

Update count: **0**

#### Registration date

2019-08-09, 1398/05/18

#### Design

Clinical trial with intervention and control group, one blinded, with a sample size of 39 available for separation on a couple of days.

#### Registrant information

##### Name

maryam ghaderi najaf abadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3627 7989

##### Email address

m\_ghadere@yahoo.com

#### Settings and conduct

The observer community is the mothers who are referring to the genetic laboratories of the city of Isfahan for delivery of amniocentesis samples. The sampling method will be available. A DASS questionnaire 21 and demographic information and blood cortisol blood tests will be used to collect information.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Criteria for entering the study: age between 15-9 years, lack of underlying diseases, Nervous.Psychological and substance abuse, readiness or eligibility to participate in the study. Exit criteria: Absenteeism of each counseling session, non-attendance of instructions and training during the sessions, participants' reluctance to attend training sessions, incidental or unexpected events in each stage of the program, acute psychiatric illness

#### Expected recruitment start date

2019-06-22, 1398/04/01

#### Expected recruitment end date

2019-08-23, 1398/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

A group for which real-therapeutic counseling is provided

#### Scientific title

The Effect of Reality therapy on the Level of Anxiety, Stress, Depression and Cortisol in Pregnant Mothers in anticipation of Amniocentesis in Isfahan ,2019

#### Main outcome variables

Stress, Anxiety, Depression, Cortisol

#### Public title

The Effect of Reality therapy on the Level of Anxiety,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190423043351N1**

Registration date: **2019-08-09, 1398/05/18**

Stress, Depression and Cortisol in Pregnant Mothers in anticipation of Amniocentesis

### **Purpose**

Education/Guidance

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Age between 15-49 years Pregnancy Carry out an amniocentesis test Readiness and satisfaction to participate in the study

#### **Exclusion criteria:**

Underlying diseases Neurological and neurological diseases Drug abuse

### **Age**

From **15 years** old to **49 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)**

Single blinded

### **Blinding description**

People in both intervention and control groups are not aware of their group

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kerman University of Medical Sciences

##### **Street address**

Haftbagh

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

7616913555

#### **Approval date**

2019-04-10, 1398/01/21

#### **Ethics committee reference number**

IR.KMU.REC.1398.020

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Stress

#### **ICD-10 code**

F43.0

#### **ICD-10 code description**

Acute stress reaction

### 2

#### **Description of health condition studied**

#### **ICD-10 code**

#### **ICD-10 code description**

### 3

#### **Description of health condition studied**

#### **ICD-10 code**

#### **ICD-10 code description**

### 4

#### **Description of health condition studied**

Anxiety

#### **ICD-10 code**

F06.4

#### **ICD-10 code description**

Anxiety disorder due to known physiological condition

### 5

#### **Description of health condition studied**

Depression

#### **ICD-10 code**

P91.4

#### **ICD-10 code description**

Neonatal cerebral depression

## **Primary outcomes**

### 1

#### **Description**

Score stress Stress score in DOS 21questionnaire

#### **Timepoint**

First and last meeting

#### **Method of measurement**

DOS 21 questionnaire

### 2

#### **Description**

Anxiety score in the DOS21 questionnaire

#### **Timepoint**

First and last meeting

#### **Method of measurement**

DOS21 questionnaire

### 3

**Description**

DOS21 questionnaire

**Timepoint**

First and last meeting

**Method of measurement**

DOS21 questionnaire

### 4

**Description**

Blood cortisol levels

**Timepoint**

First and last meeting

**Method of measurement**

blood test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Individuals in groups of 2 to 10 will participate in reality therapy counseling sessions, which consist of 4 sessions, which will last 90 to 120 minutes. In the first session, each individual will complete a DOS 21 questionnaire and 5 cc of blood. The cortisol test is performed and this process is repeated in the last session.

**Category**

Other

### 2

**Description**

Control group: People complete the questionnaire in the first session and do a blood test to measure blood cortisol levels. This process is repeated after one week and then a counseling session is performed.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Genazma Genetic Lab

**Full name of responsible person**

Majid Kheirolahi

**Street address**

No.208.West Shariati Street

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**Province**

Isfahan

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**Email**

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Abas Pardakhty

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**Province**

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**Phone**

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

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Maryam Ghaderi NajafAbadi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Firooze Mirzaee

**Position**

Assistant Professor in Reproductive Health.  
Department of Midwifery

**Latest degree**

Ph.D.

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## Person responsible for updating data

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**Position**

student

**Latest degree**

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**Other areas of specialty/work**

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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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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