

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

City

Esfahan

Province

Isfahan

Postal code

8173958351

Phone

+98 31 3626 9587

Fax

+98 31 3626 3938

Email

mkheirollahi@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abas Pardakhty

Street address

Haftbagh

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

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

Street address

Tavakoli,Roodaki,Vahid

City

Esfahan

Province

Isfahan

Postal code

8176848691

Phone

+98 31 3627 7989

Email

m_ghadere@yahoo.com

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.

Other areas of specialty/work

Midwifery

Street address

Haftbagh

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5219

Email

f_mirzaee@Kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

MaryamGaderi NajafAbadi

Position

student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Tavakoli,Roodaki,Vahid

City

Esfahan

Province

Isfahan

Postal code

8176848691

Phone

+98 31 3627 7989

Email

m_ghadere@yahoo.com

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