

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Implementing a Mental Health Intervention Program for Oocyte Donor Women

Protocol summary

Study aim

Implementing a mental health intervention program for oocyte donors

Design

Quasi-experimental study, 2 Groups, as concurrent on 72 Oocyte donors

Settings and conduct

The program is designed as a semi-experimental study on Oocyte donors eligible to enter the study, which will be conducted in the Isfahan and in the fertility infertility center. Before the donation process begins, the mental health of the oocyte donors is measured using the DASS-21 questionnaire. After implementing the program, the mental health of oocyte donors is measured again with the mentioned questionnaire.

Participants/Inclusion and exclusion criteria

Iranian Healthy oocyte donors

Intervention groups

First, in the control group and before the implementation of the mental health intervention program, the mental health of Oocyte donors are measured using the DASS-21 questionnaire. Then, The intervention program that designed based on interviews with Oocyte donors and service providers to them, is implemented in order to improving the structure of service delivery. After then, the mental health of Oocyte donors is measured again using the DASS-21 questionnaire.

Main outcome variables

Depression, Anxiety and stress

General information

Reason for update

edit the kind of study

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047811N1**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **prospective**

Last update: **2022-10-13, 1401/07/21**

Update count: **1**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Elham Adibmoghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 4869

Email address

e.adib@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-21, 1399/06/31

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

2020-09-21, 1399/06/31

Actual recruitment end date

2021-02-08, 1399/11/20

Trial completion date

2021-02-18, 1399/11/30

Scientific title

Implementing a Mental Health Intervention Program for Oocyte Donor Women

Public title

Mental Health Program in Oocyte Donor Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian oocyte donors that a maximum of six months

have passed from their entrance to the process of donation No history of hospitalization or the use of medicine because of mental disorders Absence of stress, anxiety and severe depression No history of ovarian hyper-stimulation syndrome in previous donation No legal problem related to donation

Exclusion criteria:

More than 6 months have passed from their last donation Occurrence of medical problems following previous donations Existence of psychological illness based on the diagnosis of a psychiatrist

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

Thai Clinical Trials Registry

Secondary trial Id

TCTR20191209001

Registration date

2019-12-05, 1398/09/14

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St., Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-11-19, 1398/08/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.492

Health conditions studied

1

Description of health condition studied

Mental Health

ICD-10 code

F34

ICD-10 code description

Persistent mood [affective] disorders

Primary outcomes

1

Description

Depression

Timepoint

Before the start of the oocyte donation and after oocyte pick-up

Method of measurement

Depression, anxiety and stress DASS 21 Scale

2

Description

Anxiety

Timepoint

Before the start of the oocyte donation and after oocyte pick-up

Method of measurement

Depression, anxiety and stress DASS 21 Scale

3

Description

Stress

Timepoint

Before the start of the oocyte donation and after oocyte pick-up

Method of measurement

Depression, anxiety and stress DASS 21 Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention is a program that will be done with the aim of improving the structures. It should be noted that the exact content of the program will be

determined after interviewing key participants. The program will implement until the end of the day of ovulation as each person enters the oocyte donation process.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Fertility Infertility Center

Full name of responsible person

Seyyed Mehdi Ahmadi

Street address

No. 23, Corner of Behesht St., Salman Farsi St., (Moshtagh II St.), Bozorgmehr Square, Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8158858151

Phone

+98 31 3267 0030

Email

info@isf-ific.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Behrooz Ataie

Street address

Vice-Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St., Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

international@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Adib Moghaddam

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Pardis II Complex, 5th Ta'avon St., Shahed Blvd., Sepahanshahr, Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8179997363

Phone

+98 31 3650 4869

Email

adibme921@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Elham Adib Moghaddam

Position

PhD Candidate

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

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Email

adibme921@gmail.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

Data on the main consequences of depression, anxiety and stress are generally shared.

When the data will become available and for how long

Start access 6 months after printing results

To whom data/document is available

Everyone has access.

Under which criteria data/document could be used

Available for systematic review and meta-analysis.

From where data/document is obtainable

For information, applicants can refer to the library of the Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences. Also, the resulting articles can be sent by e-mail to adibme921@gmail.com, if needed.

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

After publishing the articles and publishing the obtained dissertation, the applicant can access the desired information by referring to the library of Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences or by requesting email to adibme921@gmail.com.

Comments