

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of counseling based intervention on anxiety in women undergoing amniocentesis admitted to Motahari hospital in Urmia in 2015-2016

Protocol summary

Summary

In this clinical trial, the effect of counseling interfere on anxiety in two groups of intervention and control in pregnant women candidate for amniocentesis of Urmia Motahari Hospital to come in 2015 - 2016 will be measured. In fact, perinatal midwife, reduces the anxiety of pregnant women by giving advice and answering their questions. This study consists of 120 patients (60 cases and 60 controls) is determined. The study population was pregnant women who were in their 20th week of pregnancy and candidating for amniocentesis. Inclusion criteria included not applying certain psychotropic medications, without having any psychotropic record in past, no history of mental disorder or hospitalization in a psychiatric hospital, and a gestational age of 20 weeks (second trimester). Exclusion criteria included people who are not having necessary cooperation in completing questionnaire. In this experimental study, women undergoing amniocentesis and gestational of 20 weeks of pregnancy, divided in two groups of intervention and control and will fill in the Perceived Stress Scale and State-Trait Anxiety questionnaire and researcher made one, containing the personal and pregnancy information. The intervention group receive the necessary date in one and half hour taking sitting and finally both groups will get the educational brochure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041227347N1**

Registration date: **2016-06-11, 1395/03/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-11, 1395/03/22

Registrant information

Name

Nayaf Karimi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4964

Email address

karimi.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling based intervention on anxiety in women undergoing amniocentesis admitted to Motahari hospital in Urmia in 2015-2016

Public title

The effect on anxiety in women undergoing amniocentesis advice

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria will include: consent for inclusion; not

applying certain psychotropic medications:
psychotherapy having had a past: no history of mental disorder and hospitalized in a psychiatric hospital: the literate and the gestational age to 20 weeks (second trimester) will be. Exclusion criteria included people who fill in the questionnaire: did not have the necessary cooperation.

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Urmia University of Medical Sciences

Street address

Urjhans Street , Resalat Bivd , Urmia , Iran

City

Urmia

Postal code

571478334

Approval date

2015-11-30, 1394/09/09

Ethics committee reference number

ir.umsu.rec.1394.3.1

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

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Anxiety in women undergoing amniocentesis

Timepoint

Before and immediately after intervention

Method of measurement

Cohen Perceived Stress Scale and State – Trait Anxiety Inventory

Secondary outcomes

empty

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

The demographic and fertility of the mother and the Spielberger State Anxiety Inventory and Cohen Perceived Stress Questionnaire to be completed in both the intervention and control groups. Mothers in the intervention group undergoing amniocentesis to measure anxiety levels before and after the counseling advice (before amniocentesis) Cohen Perceived Stress Scale and Spielberger State Anxiety Inventory will be completed. Videos how to perform amniocentesis for 15 minutes and for 30 minutes Bardarbh advice about women's concerns. paid for 15 minutes.

Category

Behavior

2**Description**

In the control group without consultation questionnaire is completed and evaluated. And finally to the control group offering educational brochure

Category

Behavior

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

Prinatology Center, Kowsar

Full name of responsible person

Nayaft Karimi

Street address

Street Kashani : Motahari Hospital : Urmia : Iran

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Nayaft Karimi (Reasercher)

Street address

Urmia University of Medical Sciences : Nursing and
Midwifery Faculty Urmia

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Nayaft Karimi

Position

Master Student of Midwifery Counseling

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Soheila Rabii Poor

Position

Phd in Reproductive Health , Science Committe

Member of Nursing & Midwifery Faculty , Urmia

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty