Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of effect of group and individual Education on informed choice of pregnant women about screening tests of fetal chromosomal disorders

Protocol summary

Summary

Objectives: this study will be performed to determine the effect of individual and group education on informed choice of pregnant women about screening of fetal chromosomal abnormalities. Design: the study is a randomized controlled. Setting and conduct: 240 pregnant women will participate in it. The research will be done in three health centers in Mashhad that are similar from social and economic context, in two intervention groups and control group. Major Inclusion and Exclusion criteria: Muslim and Iranian, consent to participate in research, gestational age less than 10 weeks, have at least five elementary education, having full consciousness and the ability to receive auditory and speech training and answer questions, lack of indication for diagnostic tests, not being a member of the health team. Exclusion criteria: absence in one of the training sessions, leave the class before the end of training, lack of The desire to continue participating in the study, fetal death during the study, occurring unpleasant events during training sessions. Intervention: initially all participants will complete questionnaires (demographic, informed choice, anxiety, decision conflict and well-being) .Individual and group training presented to both groups during two consecutive weeks in two sessions. control group will receive usual care in two consecutive weeks. Further questionnaires will be completed in 20-22 weeks of pregnancy.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014081318785N1**
Registration date: **2015-08-03, 1394/05/12**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-08-03, 1394/05/12

Registrant information

Name
Sahar Riyazi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of group and individual Education on informed choice of pregnant women about screening tests of fetal chromosomal disorders

Public title

Comparison of effect of group and individual Education on informed choice of pregnant women about screening tests of fetal chromosomal disorders

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Muslim and Iranian; Consent to participate in research; Gestational age less than 10 weeks; Have at least five elementary education; Having full consciousness and the ability to receive auditory and speech training and answer questions; Lack of indication for diagnostic tests; Not being a member of the health team. Exclusion criteria: Absence in one of the training sessions; Leave the class before the end of training; Lack of The desire to continue participating in the study; Fetal death during the study; Occurring unpleasant events during training sessions.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization method will be blocked.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Street, Central Organization of Mashhad University of Medical Sciences

City

Mashhad

Postal code

9177899191

Approval date

2014-07-15, 1393/04/24

Ethics committee reference number

research/922882/1/12

Health conditions studied

1

Description of health condition studied

Antenatal Screening

ICD-10 code

Z36

ICD-10 code description

Routine Prenatal Care

Primary outcomes

1

Description

Informed Choice

Timepoint

Before Intervention and Three Months after Intervention

Method of measurement

Informed Choic Scale

Secondary outcomes

1

Description

Worry

Timepoint

Before Intervention and Three Months after Intervention

Method of measurement

Cambridge Worry Questionnaire

2

Description

Anxiety

Timepoint

Before Intervention and Three Months after Intervention

Method of measurement

Spielberger Questionnaire

3

Description

Decisional Conflict

Timepoint

Before Intervention and Three Months after Intervention

Method of measurement

Decisional Conflict Questionnaire

4

Description

Well Being

Timepoint

Before Intervention and Three Months after Intervention

Method of measurement

WHO-5-Well Being Questionnaire

Intervention groups

1

Description
control group: the usual care was conducted in two consecutive weeks.
Category
Behavior

2

Description
Intervention group 1: In the individual education, screening and diagnostic information Will be presented to face to face method in during two sessions of 45 to 60 minutes and in two consecutive weeks.
Category
Behavior

3

Description
Intervention group 2: In the group education, screening and diagnostic information Will be presented to lecture method in during two sessions of 45 to 60 minutes and in two consecutive weeks.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
health center No.3 Mashhad
Full name of responsible person
Baratali Arabnejad
Street address
Akhond Khorasani Street, Mashhad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Daneshgah Street, Central Organization of Mashhad University of Medical Sciences
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Mashhad
Grant name
-
Grant code / Reference number
922882
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sahar Riyazi
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Person responsible for updating data

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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