

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of individual counseling on anxiety of women with unwanted pregnancy

Protocol summary

Summary

The purpose of this study are to determine the effect of individual counseling on anxiety of women with unwanted pregnancy. The study was randomized clinical trials on women with unwanted pregnancy in the intervention and control groups. At least sample volume for each group of 20 people and a total are considered of 40 people. participants in research are selected between pregnant women that referred to health centers in dependent on the city of Qom that are in the first trimester of pregnancy. The inclusion criteria are: gestational age less than 14 weeks, unwanted pregnancy, absence of anxiety disorders and depression. The exclusion criteria are: participants' unwillingness to continue cooperation in research, lack of participating in sessions 2 sessions or more, any pregnancy complications. In this study at first the Cattell questionnaire and demographic as the test is completed by both groups and anxiety levels measured in both groups, in the next stage intervention as individual consulting is begins for the intervention group, So that unit of the research groups in terms case are participating in consultation meetings that 3 to 4 sessions of individual counseling with intervals of 4 to 7 days. the time of sessions are 30 to 50 minutes in terms tolerance. Finally, a month after the last counseling session level of anxiety in both groups are measured and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110824943N1**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Leila Safdari

Name of organization / entity

School of Nursing and Midwifery, Kermanshah
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 1083

Email address

lsafdari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of
Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of individual counseling on anxiety of women with
unwanted pregnancy

Public title

Effect of individual counseling on anxiety of women with
unwanted pregnancy

Purpose

Health service research

Inclusion/Exclusion criteria
inclusion criteria: Including consent for the study, gestational age less than 14 weeks, unwanted pregnancy, marital status, absence of anxiety disorders and depression, lack of taking medications that increase anxiety and depression, absence of mental illness in wife and is living in the city of Qom. Exclusion criteria: Exclusion criteria in this study included participants' unwillingness to continue cooperation in research, lack of participating in sessions 2 sessions or more, of any pregnancy complications such as symptoms of threatened abortion, fetal death and more.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study randomized was conducted using a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd, the number 2 Building

City

kermanshah

Postal code

Approval date

2015-10-20, 1394/07/28

Ethics committee reference number

KUMS.REC.1394.156

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F40.8

ICD-10 code description

Other phobic anxiety disorders

Primary outcomes

1

Description

anxiety

Timepoint

Before and one month after intervention

Method of measurement

cattell

Secondary outcomes

empty

Intervention groups

1

Description

control group, at first The Cattell questionnaire was completed by patients and measured level of anxiety in people. In this group the subjects not given counseling and special training and just receiving prenatal care. Finally, a month after the last session of the counseling groups Cattell questionnaire was completed by subjects and level of anxiety is measured and compared.

Category

Other

2

Description

intervention group, at first the Cattell questionnaire in order to assess the anxiety completed with intervention group. Then participate in counseling sessions. For individual counseling are using advice steps of GATHER. unit of the research groups in terms case are participating in consultation meetings that 3 to 4 sessions of individual counseling with intervals of 4 to 7 days. the time of sessions are 30 to 50 minutes in terms tolerance. Finally, a month after the last counseling session anxiety of subjects are assessed and compared.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza (AS) Health Center

Full name of responsible person
Leila Safdari
Street address
Imam zade Ebrahim Street, Qom
City
Qom

2

Recruitment center
Name of recruitment center
Health center khorakian
Full name of responsible person
Leila Safdari
Street address
15 Khordad Street, Qom
City
Qom

3

Recruitment center
Name of recruitment center
Imam khomeini Health center
Full name of responsible person
Leila Safdari
Street address
Boniat Street
City
Qom

4

Recruitment center
Name of recruitment center
Health center baghiat alah
Full name of responsible person
Leila Safdari
Street address
Alley 17, Shahregheem street
City
Qom

5

Recruitment center
Name of recruitment center
Health center panbe chi
Full name of responsible person
Leila Safdari
Street address
Imam Khomeini Street
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Kermanshah University of Medical Sciences

Full name of responsible person
cyrus hamzehi
Street address
shahid beheshti Blvd, Number 2 Building
City
kermanshah

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research Kermanshah 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
Kermanshah University of Medical Sciences, School of Nursing and Midwifery
Full name of responsible person
Marzieh Kaboudi
Position
Ph.D., Scientific Advisory Board
Other areas of specialty/work
Street address
Dolatabad, School of Nursing and Midwifery
City
Kermanshah
Postal code
Phone
+98 83 3827 9394
Fax
Email
fkaboudi@kums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences, School of Nursing and Midwifery
Full name of responsible person
Marzieh Kaboudi
Position
Ph.D., Scientific Advisory Board
Other areas of specialty/work
Street address

Dolatabad, School of Nursing and Midwifery
City
kermanshah
Postal code
Phone
+98 83 3827 9394
Fax
Email
fkaboudi@kums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences, School of
Nursing and Midwifery
Full name of responsible person
Leila Safdari
Position
P.H.D
Other areas of specialty/work
Street address
Dolatabad, School of Nursing and Midwifery
City

kermanshah
Postal code
Phone
00
Fax
Email
lsafdari@kums.ac.ir
Web page address

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