Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing two model of counseling (direct and indirect) on family stress and Anxiety in delivery of nulliparous pregnant women

Protocol summary

Summary

This study is a clinical trial. The aim of this study is to compare the effect of direct and indirect counselling on family stress and Anxiety in delivery of nulliparous pregnant women. Families' nulliparous pregnant women (spouse of pregnant women and /or the person who is responsible for the care of pregnant women during labor and after it. this person could be mother or mother-in-law or sister or sister-in-law of pregnant women) make the studies population. Samples were refered to 17 Shahrivar Maternity and Shahid Chamran hospital center and obstetrics clinics for prenatal care .they are elected with Using random permutation blocks and are placed in intervention and control groups. This study is not blinded. At the beginning of the third trimester of pregnancy Cohen perceived Stress Scale (PSS-14) and Cattell Anxiety Scale are filled out by families. Then six sessions of group cognitive counselling held weekly intended to create knowledge and to increase awareness on delivery issues, for one group. Tele-counseling with some training material in written form is offered for the second group, and there is no intervention for control group. Questionnaires are completed by all three groups once again by the time when pregnant mothers go for delivery and these questionnaires are compared with the previous ones. Each group consists of 36 families, so sample size totally equals 108 families. Inclusion criteria: first pregnancy and singleton; participants of the counselling sessions must be the main caregiver and the only responsible person of pregnant women during pregnancy, delivery and postpartum period; all of the participants in this study must not suffer from any kinds of physical diseases, mental disorders or depression and also they must not experience drug abuse (via asking in demographic form); pregnant women and participants of the counselling sessions must not attend such training classes on delivery preparation. exclusion criteria: Preterm delivery of pregnant mothers before the end of counselling sessions; pregnancy complications in pregnant women including preeclampsia, placental abruption, gestational diabetes and any other events that is considered as an indication for high risk pregnancy; Two or more missed absent sessions for participants; being elected for caesarean; Absence of participants at the time of delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071428924N1**
Registration date: **2016-10-01, 1395/07/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-01, 1395/07/10

Registrant information

Name

Mozhgan Khalili

Name of organization / entity

School of Nursing and Midwifery Kermanshah, Science committee

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 8588

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Kermanshah University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date
2016-12-20, 1395/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing two model of counseling (direct and indirect) on family stress and Anxiety in delivery of nulliparous pregnant women

Public title
Effect of counseling on family stress and anxiety.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Nulliparous pregnant women, have singleton pregnancies; Cases without high risk pregnancy criteria; Participants must be the main caregiver and only responsible individual for the pregnant woman during her pregnancy and postpartum period; The pregnant women must deliberately decide to deliver their babies in health centers of Saveh city; They must not be mournful during the last three months; The pregnant women and the participants must not have any physical diseases, surgery, mental disorders and depression (via asking in demographic form); The pregnant women and the participants must not have any drug abuse and addiction (via asking in demographic form); They must be fluent in Persian; The pregnant women and their participants must not have any previous training experiences about delivery; There is no history of maternal death in the family; The health staffs must not be presented in these families. Exclusion criteria: Preterm delivery of pregnant mothers before the end of counselling sessions; pregnancy complications in pregnant women including preeclampsia, placental abruption, gestational diabetes and any other events that is considered as an indication for high risk pregnancies; Two or more absent sessions for participants; Being elected for caesarean; Absence of other participants at the time of delivery.

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Kermanshah University of Medical Sciences

Street address
Central Building Kermanshah University of Medical Science, shahid Beheshti Blvd, Kermanshah

City
Kermanshah

Postal code
6715847141

Approval date
2016-06-08, 1395/03/19

Ethics committee reference number
KUMS.REC.1395.174

Health conditions studied

1

Description of health condition studied
Stress

ICD-10 code
R46.6

ICD-10 code description
undue concern and preoccupation with stressful events

2

Description of health condition studied
Anxiety

ICD-10 code
F41.1

ICD-10 code description
Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances

Primary outcomes

1

Description
Stress

Timepoint
Before intervention and Three months after the intervention

Method of measurement

Cohen perceived Stress Scale (PSS-14)

2

Description
Anxiety
Timepoint
Before intervention and Three months after the intervention
Method of measurement
Cattell Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 2: Some training material with telephone counselling.
Category
Lifestyle

2

Description
Intervention 1: six sessions of group cognitive counselling were held weekly intended to create knowledge and to increase awareness on delivery issues, for one group
Category
Lifestyle

3

Description
Control group: Do not cause any interference.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Fariba Alaem
Street address
Saveh Social Security Hospital
City
Saveh

2

Recruitment center
Name of recruitment center
17 Shahrivar Maternity
Full name of responsible person
Fariba Alaem
Street address
17 Shahrivar hospital,Saveh
City
Saveh

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor Of Research Kermanshah University of Medical Sciences
Full name of responsible person
Kurosh Hamzehi
Street address
Building Kermanshah University of Medical Science, Kermanshah, shahid Beheshti Blvd
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 Of 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
Full name of responsible person
Fariba Alaem
Position
Post Graduate Student in Midwifery Advice
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Mozhgan Khalili

Position
Post Graduate

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Person responsible for updating data

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School of Nursing and Midwifery

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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