

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effectiveness of Problem Solving Counseling Approach on Adaptation with The Motherhood Role in Women with Preterm Infant

Protocol summary

Study aim

To Determine The Effectiveness of The Problem Solving Counseling Approach on Adaptation With The Motherhood Role in The Mother with Pre-Term Infant

Design

In This Clinical Trial With The Control Group, 80 Eligible Pregnant Women will be selected Using Convenience Sampling Method and They will be Randomly allocated to Two Groups Intervention and Control using Quaternary Block. The Outcomes of Study is The Adaptation With Motherhood Role. The Adaptation With The Motherhood will be checked by Iranian Version of Adaptation With The Motherhood Questionnaire In two steps before Intervention and Four weeks after delivery.

Settings and conduct

For the Intervention Group, Individually problem-solving Counseling will be done After Childbirth for Four Sessions One Time per week at Ayatollah Mousavi Hospital of Zanjan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The Mothers with The Preterm Child 34-36 Weeks, Lack of Medical and Obstetric Complication, Living in The City of Zanjan, Having Writing and Reading Literacy, Healthy Baby, Lack of Breastfeeding Contraindication, Getting Score Less Than 13 Basis of Edinburgh Test, The Absence of Anomalies in Infant, Living With Spouse. No Known Mental Illness, Exclusion Criteria: No Desire To Continue The Study Participating. In Any Educational Program, Having More Than Two Sessions Absent in Counseling Meetings, Lack of Access to The Phone Call

Intervention groups

The Intervention Group will be done Individually Problem Solving Counseling. Totally Four Sessions will be done One Time per Week and The Control Group will be got Routine Care.

Main outcome variables

Adaptation With The Motherhood Role

General information

Reason for update

Acronym

PSC

IRCT registration information

IRCT registration number: **IRCT20150731023423N11**

Registration date: **2018-06-24, 1397/04/03**

Registration timing: **retrospective**

Last update: **2018-06-24, 1397/04/03**

Update count: **0**

Registration date

2018-06-24, 1397/04/03

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3345 4264

Email address

malekia@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-31, 1396/03/10

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Problem Solving Counseling Approach on Adaptation with The Motherhood Role in Women with Preterm Infant

Public title

The Effectiveness of Problem Solving Counseling Approach on Adaptation with The Motherhood Role in Women with Preterm Infant

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm Labor 34-36 Weeks Living in The City of Zanjan Having Writing and Reading Literacy Lack of Medical and Obstetric Complication Lack of Breastfeeding Contraindication Getting Less Than 13 Score Basis of Edinburgh Test The Absence of Anomalies in Infant Living With Spouse No Known Mental Illness

Exclusion criteria:

No Desire To Continue The Study Participateing In Any Educational Program Having More Than Two Sessions Absent in Counseling Meetings Lack of Access to The Phone Call

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible Women will be Selected Using The Convenience Sampling Method and will be Randomly Allocated to The Intervention and The Control Groups Using Quaternary Block.

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 of Zanjan University of Medical

Sciences

Street address

Azadi Blvd, Zanjan University of Medical Sciences, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

45154

Approval date

2017-05-16, 1396/02/26

Ethics committee reference number

ZUMS.REC.1396.22

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

The Adaptation With The Motherhood Role

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Adaptation With The Motherhood Role

Timepoint

Before Intervention, Four Weeks After Intervention

Method of measurement

Questionnaire of Adaptation With Motherhood Role

Secondary outcomes

empty

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

Individually Counseling will be based On The Problem-Solving Approach Concerning Adaptation with The Motherhood Role. It Includes Care of The Baby, Breastfeeding, Strengthening The Relationship with The Spouse and Child. Counseling will be done in 45-60 Minutes at 4 Sessions.

Category

N/A

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

Ayatollah Mousavi Hospital of Zanjan

Full name of responsible person

Atefeh Rajabi, MSc in Midwifery Counseling
Street address
Gavazang Road, Ayatollah Mousavi Hospital of
Zanjan, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
45154
Phone
+98 24 3345 4264
Email
malekia41@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Shoghli Alireza
Street address
Azadi Blvd, Zanjan University of Medical Sciences,
Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
45154
Phone
+98 24 3342 0677
Email
Resaerch@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University Of Medical Sciences
Full name of responsible person

Dr. Alireza Shaghli
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Service Management
Street address
Azadi Blvd, Zanjan University Of Medical Sciences,
Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
45154
Phone
+98 24 3315 6394
Fax
Email
research@zums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Znjan University Of Medical Sciences
Full name of responsible person
Dr. Maleki Azam
Position
PHD Mother & Child Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Gavazang Road, Zanjan University Of Medical
Sciences, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4515789589
Phone
+98 24 3314 8364
Fax
+98 24 3314 8319
Email
Malekia@Zums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Atefeh Rajabi
Position

MSc in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Gavazang Road, Zanjan University of Medical Sciences, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

02433148319

Phone

+98 33420651024

Fax

Email

Atefeh.Rajabi80@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It will be done by The Rules of the Ethics Committee.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available