

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 Zanzan, Zanzan, Iran

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+98 24 3345 4264

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malekia41@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Shoghli Alireza

Street address

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

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanzan 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

Zanzan 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanzan 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

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanzan 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

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

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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