

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

Protocol summary

Study aim

To determine The effect of counseling with skill training approach on postpartum maternal functioning

Design

Randomized controlled trial with two parallel arms

Settings and conduct

This study will be conducted on women who are referred to Tabriz health centers, so that the researcher will attend in the health centers and will select women with first and second birth, based on their records and invite them to participate in the study through phone contact. In the face to face meeting, the Barkin Maternity Functioning Questionnaire will be completed, and women who receive a score of under 80 will be included in the study and will receive written consent. Participants will be assigned to two groups of counseling and control. Four counseling sessions will be held for intervention group. Two weeks after the last session, post-test questionnaires including maternal functioning, infant care behavior and maternal self-efficacy will be completed by the participants in both counseling and control groups.

Participants/Inclusion and exclusion criteria

Participants with first and second birth and with maternal functioning score below 80 and postpartum depression score above 12

Intervention groups

For the intervention group, four counseling sessions will be provided from the fourth week after delivery at intervals of one week. The duration of each session will be 60 to 90 minutes. The control group will receive routine care.

Main outcome variables

Maternal functioning at 10 weeks after childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N49**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

Public title

The effect of counseling with skill training approach on postpartum maternal functioning: a randomized controlled clinical trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Woman with First and second birth Maternal functioning score below 80 Mother's ability to take care of the baby Healthy term baby The desire to attend in counseling sessions Not having neonatal anomalies (including diagnosed physical and mental abnormalities) Having at least a secondary or higher education The normal postpartum period until time to enter the study Age between 15 to 49 years

Exclusion criteria:

Uncertainty about being able to attend all consultation sessions Change location to another city Having cardiovascular diseases, high blood pressure, liver disease and other chronic diseases, according to the participant's statement Hospitalization of the child Unsolvable lactation problem Obtaining postpartum depression score higher than 12 Neuropsychiatric diseases and recent disasters according to mother expression

Age

From **14 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted using the website www.random.org and through blocking with block sizes of four and six and an allocation ratio of 1: 1 to the two groups of counseling and control.

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 Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

513894797

Approval date

2019-01-08, 1397/10/18

Ethics committee reference number

IR.TBZMED.REC.1397.789

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

Postpartum maternal functioning

ICD-10 code

Z39.0

ICD-10 code description

Encounter for care and examination of mother immediately after delivery

Primary outcomes**1****Description**

Maternal functioning

Timepoint

Before the intervention and 2 weeks after the end of intervention (four weeks after childbirth)

Method of measurement

Maternal Functioning Barkin Index (MFBI)

Secondary outcomes**1****Description**

Infant care behavior

Timepoint

Before the intervention and 2 weeks after the end of the intervention (four weeks after childbirth)

Method of measurement

Infant Care Behavior Questionnaire

2**Description**

maternal self-efficacy

Timepoint

Before the intervention and 2 weeks after the end of the intervention (four weeks after childbirth)

Method of measurement

Intervention groups

1

Description

Intervention group: For intervention group, four 60-90 minutes counseling sessions with a skill-based approach will be provided.

Category

Behavior

2

Description

Control group: The control group will received routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tabriz city

Full name of responsible person

Fatemeh Karami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Karami

Position

MSc student of conseling in Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Data of participants are privacy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

What processes are involved for a request to access data/document

Maximum one week after the communication by email.

Comments