Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of in-home and phone supportive counseling on postpartum depression and anxiety: a randomized controlled clinical trial

Protocol summary

Study aim

Determining and comparing the effect of supportive counseling at home and supportive counseling over the phone on postpartum depression and anxiety

Design

A randomized clinical trial with three parallel arms will be conducted on 93 primiparous women with natural delivery method. The participants will be divided into two intervention groups and a The control group will be allocated.

Settings and conduct

Sampling will be done on women hospitalized in Al-Zahra and Taleghani Medical Education Center in Tabriz, who gave birth the day before; Anxiety and depression scales (10-15 days and 42-60 days after delivery) and maternal quality of life tools (10-15 days after delivery) will be completed by all three groups in Taleghani and Al-Zahra midwifery clinics. The weight at birth and one month old of the baby based on the baby card, the breastfeeding status and the number of visits of the baby will be recorded by the doctor based on the mother's statements in the relevant checklist. The only evaluator of the results will be blind.

Participants/Inclusion and exclusion criteria

Primiparous women who gave birth by natural delivery method, a singleton and full-term baby weighing 2500-4000 grams, no breastfeeding obstacles and contraindications, resident of Tabriz

Intervention groups

In the intervention group, during three supportive counseling sessions at home and telephone supportive counseling, it will be done on days 5-9, 7-3 and 20-25 after delivery, which includes teaching self-care to the mother, breast care, resuming sexual relations. , how to care for the baby, assess stress and teach adaptation skills. The control group will only receive the usual care after delivery.

Main outcome variables

Comparison of the effect of supportive counseling at home and supportive counseling by phone on postpartum depression and anxiety 10-15 days and 42-60 days after delivery will be measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170506033834N11**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Roghaiyeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

nourizadehr@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of in-home and phone supportive counseling on postpartum depression and anxiety: a randomized controlled clinical trial

Public title
Comparison of the effect of in-home and phone supportive counseling on postpartum depression and anxiety: a randomized controlled clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women by vaginal method Having a desire to breastfeed Age 18-45 Living in Tabriz Single birth Mothers with term babies weighing 2500 to 4000 grams
Exclusion criteria:
Mothers with hospitalized babies. Existence of systemic and chronic diseases or aggravating disorders during pregnancy and childbirth, including gestational or overt diabetes, blood pressure disorders, heart disease, and the inability of the mother to care for the baby. Breast anomaly or history of breast surgery The existence of unfortunate events in the last three months, including the death of loved ones, divorce, etc. Obtaining a depression score of 13 or more based on the Edinburgh postpartum depression scale Depressive disorders before pregnancy and delivery according to mother's statement Cases of malformation and infant death Excessive bleeding during childbirth Having breast-feeding contraindications (women undergoing chemotherapy, women with HIV infection, women with untreated active tuberculosis, and the use of radioactive, antimetabolite and illegal drugs during breastfeeding such as methotrexate, mercaptopurine, hydroxyurea, tamoxifen, bromocriptine, Lithium, phenin-dione, phen-cyclidine, cyclophosphamide and doxorubicin, drugs and...
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants were divided into two intervention groups (recipients of supportive counseling at home and supportive counseling over the phone) and a control group (recipients of routine care after delivery) will be allocated. For concealment, the type of allocation will be written on paper and placed in numbered opaque envelopes (Allocation Concealment). The envelopes will be opened in order and by a person not involved in sampling.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, according to the nature of the study, it will not be possible to blind the participants and the researcher, and only the evaluator of the results will be a blind person.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commite of Tabriz University of Medical Sciences
Street address
Golgasht St., Tabriz University of Medical Sciences, Faculty of Dentistry
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2023-08-12, 1402/05/21
Ethics committee reference number
IR.TBZMED.REC.1402.354

Health conditions studied

1

Description of health condition studied
Postpartum
ICD-10 code
Encounter
ICD-10 code description
Z39

Primary outcomes

1

Description
Postpartum Depression
Timepoint
10-15 days and 42-60 days after delivery by controlling the effect of baseline score.

Method of measurement
Edinburgs Postpartum Depression Scale

2

Description
Specific postpartum anxiety
Timepoint
10-15 days and 42-60 days after delivery by controlling the effect of baseline score.
Method of measurement
PSAS-RSF(Postpartum Specific Anxiety Scale Research short-form)

Secondary outcomes

1

Description
Quality of life of mothers
Timepoint
10-15 days after delivery
Method of measurement
MAPP-QOL(Maternal Postpartum Quality)

2

Description
Frequency of exclusive breastfeeding
Timepoint
42-60 days after birth
Method of measurement
A checklist designed to record breastfeeding status

3

Description
Comparison of infant weight
Timepoint
One month after giving birth
Method of measurement
Baby weight card

4

Description
Comparison of the frequency of newborn visits by doctors
Timepoint
42-60 days after birth
Method of measurement
Checklist designed to record the number of baby visits by the doctor

Intervention groups

1

Description
Intervention group: In one of the intervention groups, supportive counseling will be done at home during three sessions on days 5-3 7-9 and 20-25 after delivery for 30-45 minutes .The content of the counseling sessions according to the support counseling protocol will be as follows: The first session (3-5 days after delivery): includes encouraging to talk about the questions and problems that the person has in the process of self-care and caring for the baby and about breastfeeding. Also, criteria of sufficient amount of breast milk, the reasons of infants' crying and refusing to take the breast, nutrition of mothers during breastfeeding, methods to increase breast milk, breast problems, constipation, back pain, care of episiotomy sutures and pain management, and care of the baby's umbilical cord will be explained. The second session (7-9 days after delivery): in this session, in relation to how to store milk and continue breastfeeding, fatigue and the matching of sleeping and waking time with the baby, how the mother interacts with the child, perceived supports, self-care and coping with the responsibilities will be explained. The purpose of this meeting is to recount the person's emotional-emotional reactions to the new situation, and the counselor is looking for performance disturbances, signs such as stress and wrong adaption to explain how to deal with it (teaching relaxation techniques, seeking and attracting social support, improving communication skills with others and especially with husbands). The third session (20-25 days after delivery): in this session, we will talk about the time to resume sexual relations, and contraception methods in breastfeeding mothers and the continuation of breastfeeding. Relaxation techniques will be reviewed and summarized the session details.
Category
Behavior

2

Description
Intervention group: In the other intervention group, phone support counseling will be done in three sessions on days 9-9, 7-3 and 20-25 after delivery for 30-45 minutes. The content of this type of counseling will be the same as home support counseling. If the client needs, one more meeting will be held in each of the groups with prior coordination of the clients. The counseling time will be determined according to the previous agreement with the participants.
Category
Behavior

3

Description
Control group: In this study, the control group will receive only the usual care after delivery.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center

Al-Zahra Hospital

Full name of responsible person
Bita Eskandari

Street address
Al-Zahra Educational-Therapeutic Center, South Army St., Tabriz

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2

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Bita Eskandari

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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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parvizshahabi@gmail.com

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
bita eskandari

Position
Master student of counseling in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Roghaiyeh Nourizadeh

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Ph.D in Reproductive Health

Latest degree
Ph.D.

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Person responsible for updating data

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Full name of responsible person
Dr. Roghaiyeh Nourizadeh
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Latest degree
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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
No more data
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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