Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effect of mental relaxation technique on self –efficacy, breastfeeding sufficiency and performance of primiparous women

Protocol summary

Study aim

Determining the effect of mental relaxation technique on self-efficacy, adequacy and breastfeeding performance of primiparous women.

Design

A clinical trial with a control group, a blind strain, randomized, on 60 patients, rand function of Excel software was used for randomization.

Settings and conduct

The present study on sedation in lactating primiparous women in Talash city is a single-blind randomized clinical trial with blinding of the participants by block randomization method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being Iranian and living in Talesh city, having a pregnancy file in one of the comprehensive health centers in Talesh city health and treatment center, possessing elementary literacy, pregnancy age 30-32 weeks, being primiparous , no abuse of drugs, tobacco and alcohol, no disease or any disorder that prohibits breastfeeding, low-risk pregnancy and no chronic physical or mental debilitating diseases. Maternal and infant discharge criteria: The strong unwillingness of the mother to breastfeed, occurrence of mental or physical disorders that disrupt or prohibit the continuation of the breastfeeding, unwillingness to continue participating in the study or his simultaneous participation in another research, performing body relaxation exercises and mental imagery for less than 60 days, simultaneous and daily use of milk-increasing drugs, giving birth before 37 weeks of pregnancy, -hospitalization of the baby in the NICU, any abnormality of the jaw and A baby's face that interferes with the baby's natural breastfeeding, preterm birth.

Intervention groups

The intervention group: received trainings on relaxation and guided mental imagery, and the control group received only the usual breastfeeding trainings.

Main outcome variables

Breastfeeding self-efficacy; Breastfeeding performance; Adequacy of breastfeeding; Exclusive feeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231028059885N1**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

Registration date

2024-01-27, 1402/11/07

Registrant information

Name

Noosha Farzaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4423 8815

Email address

nooshafarzaie2023@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of mental relaxation technique on self –efficacy, breastfeeding sufficiency and performance of primiparous women

Public title
The effect of mental relaxation technique on self –efficacy, breastfeeding sufficiency and performance of primiparous women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian and resident of Talesh city Having a pregnancy record in one of the comprehensive health centers or urban health centers covered by the health and treatment center of Talash city Elementary school Gestational age 30-32 weeks Nulliparous singleton pregnancy No abuse of drugs, tobacco and alcohol Not having diseases or any disorders that prohibit breastfeeding such as HIV/AIDS,Active Genital Herpes, Active untreated tuberculosis in the mother, or Breast abscess, Extensive breast burn or any abnormality that makes it difficult to breastfeed. Low-risk pregnancy and the mother's absence of chronic physical or mental debilitating diseases requiring medical treatment according to the doctor's opinion.

Exclusion criteria:
Mother's strong unwillingness to breastfeed after delivery Occurrence of mental or physical disorders diagnosed by the doctor during the implementation of the study, which requires referral and necessary medical/surgical interventions that disrupt or prohibit the continuation of the breastfeeding process. Unwillingness to continue participating in the study or her simultaneous participation in another research with similar educational interventions Performing relaxation exercises and mental imagery for less than 60 days Simultaneous and daily use of milk-enhancing drugs Delivery before the 37th week of pregnancy (in this case, it is reported as perinatal outcomes) Admission of the baby to the NICU Any abnormality of the baby's jaw and face that interferes with the baby's natural breastfeeding Preterm birthday Absence or development of gagging and sucking reflexes up to 3-5 days

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants do not know which group they belong to and this study is a blind strain

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commite of Shahid Beheshti University of Medical Sciences

Street address
Nursing and Midwifery Faculties of Shahid Beheshti University of Medical Sciences, In front of Shahid Rajaei Heart Hospital, Hashemi Rafsanjani Blv., Valiasr Ave.

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Tehran

Province
Tehran

Postal code
1996835119

Approval date
2023-06-05, 1402/03/15

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.073

Health conditions studied

1

Description of health condition studied
Self-efficacy, adequacy and performance of breastfeeding

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Breastfeeding self-efficacy

Timepoint
The beginning of the study, the third, 15th and 60th day after delivery.

Method of measurement
Abbreviated Breastfeeding Self-Efficacy Questionnaire

2

Description
Lactation performance
Timepoint
The beginning of the study, the third, 15th and 60th day after delivery.
Method of measurement
Breastfeeding performance checklist

3

Description
Adequacy of breastfeeding
Timepoint
The beginning of the study, the third, 15th and 60th day after delivery.
Method of measurement
Breastfeeding adequacy questionnaire

Secondary outcomes

1

Description
Infant weight
Timepoint
3rd day, 10th day and 30th day after birth
Method of measurement
scales

2

Description
Around the infant's head
Timepoint
3rd day, 10th day and 30th day after birth
Method of measurement
tape measure

3

Description
Around the infant's chest
Timepoint
3rd day, 10th day and 30th day after birth
Method of measurement
meter reading

Intervention groups

1

Description
Intervention group:In the first session, the researcher holds a training session and teaches them about the definition, importance and types of Aramaic body through lectures and film screenings. The researcher teaches mental relaxation technique technique practically for women. Then the second session is held on another day and the women are asked to implement the training techniques for the researcher. The maximum duration of each training session is 60 minutes. Until the day of delivery, women perform mental relaxation techniques at home twice a day (in the morning and evening) and each time for 20 minutes. The mental relaxation technique continues until 60 days after delivery, and during this period, mothers follow up They can feed their baby exclusively with their own milk for 60 days after giving birth. After completing the intervention, women refer to the research environment on days 3, 10 and 30 after giving birth. In these sessions, the infant's weight, head circumference and chest circumference are measured.
Category
Treatment - Other

2

Description
Control group: The participants in the control group will only receive the usual breastfeeding training from the instructors of childbirth preparation classes that are taught to both groups during the seventh and eighth sessions, and no additional training will be provided by the researcher.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Noorani Talash Hospital
Full name of responsible person
Dr. Mohsen Sharqi
Street address
No.11, Next to the workers Stadium,Talesh-Rasht Road,Talesh Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi

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Shahid Beheshti University of Medical Sciences Building, Parvaneh Ave., Yemen Ave., Shahid Chamran highway
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Web page address
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Sepideh Hajian
Position
Consultant
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available