

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Problem-solving skill training and marital satisfaction: A study among primiparous breastfeeding mothers

Protocol summary

Study aim

Examine the effect of problem-solving skill training on marital satisfaction among primiparous breastfeeding mothers.

Design

Randomized controlled trial

Settings and conduct

This two-group pretest-posttest randomized controlled trial was held in 2015 on 68 primiparous breastfeeding mothers who referred to healthcare centers located in Babol, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Had a childbirth at 37th–42nd weeks of their pregnancy at least two months before the study. - Had a low-to moderate marital satisfaction based on the results of the ENRICH questionnaire. - Did not divorce. - Possessed basic literacy skills. - Only wife of her husband. - Had a married life of 1–10 years. - Did not have a baby with major congenital anomalies. - Had a planned pregnancy. - Neither experienced any serious stressful life event during the past three months prior to the study nor suffered from post-natal depression and psychosis. - Lack of serious mental and physical illness (cancer) and advanced chronic diseases. - Had no addiction to opioids, psychoactive agents, and alcohol among the mothers or their husbands. exclusion criteria - Failure to respond to more than 5% of the items of the study questionnaire. - Voluntary withdrawal from the study. - Two or more absences from training sessions. - Development of serious health conditions or undergoing any type of surgery during the study. - Participation in any personal or group psychotherapy programs during the study. - A second pregnancy during the study.

Intervention groups

intervention group: problem solving skill training in six 80-minute sessions comparison group: Not receiving problem solving skill training

Main outcome variables

problem solving skill training on marital satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171209037794N2**

Registration date: **2018-10-04, 1397/07/12**

Registration timing: **retrospective**

Last update: **2018-10-04, 1397/07/12**

Update count: **0**

Registration date

2018-10-04, 1397/07/12

Registrant information

Name

Parvaneh Mirabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 7958

Email address

parvaneh_mirabi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-08-03, 1394/05/12

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

2015-08-05, 1394/05/14

Actual recruitment end date

2016-04-10, 1395/01/22

Trial completion date

2017-04-10, 1396/01/21

Scientific title

Problem-solving skill training and marital satisfaction: A study among primiparous breastfeeding mothers

Public title

Problem-solving skill training and marital satisfaction

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Had a childbirth at 37th–42nd weeks of their pregnancy at least two months before the study. Had a low-to moderate marital satisfaction based on the results of the ENRICH questionnaire. Did not divorce. Possessed basic literacy skills. Only wife of her husband Had a married life of 1–10 years. Did not have a baby with major congenital anomalies. Had a planned pregnancy. Neither experienced any serious stressful life event during the past three months prior to the study nor suffered from post-natal depression and psychosis. Lack of serious mental and physical illness (cancer) and advanced chronic diseases. Had no addiction to opioids, psychoactive agents, and alcohol among the mothers or their husbands.

Exclusion criteria:

Failure to respond to more than 5% of the items of the study questionnaire. Voluntary withdrawal from the study. Two or more absences from training sessions. Development of serious health conditions or undergoing any type of surgery during the study. Participation in any personal or group psychotherapy programs during the study. A second pregnancy during the study.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 68 breastfeeding mothers were randomly divided into two groups receiving problem solving skill training (intervention group) or comparison group, based on the blocked randomization with a block size of 4 for the two groups

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 Golestan University of Medical Sciences

Street address

Gorgan Road to Sari, Golestan University of Medical Sciences

City

Gorgan

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Golestan

Postal code

4934174515

Approval date

2015-08-03, 1394/05/12

Ethics committee reference number

lr.goums.rec.1394.75

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

Low to moderate marital satisfaction

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

Comparison marital satisfaction and its dimensions before and after problem solving skill training in experimental and comparison groups

Timepoint

before the intervention, immediately after the intervention and one month afterwards.

Method of measurement

ENRICH questionnaire

Secondary outcomes

empty

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

Intervention group: Problem solving skill training in the intervention group was provided in six 80-minute sessions, in 10–11-person groups. Training sessions focused mainly on breastfeeding-related problems. All sessions were held in one of the recruited healthcare centers which had better training facilities. All mothers in both groups completed the ENRICH inventory before the intervention, immediately after the sixth training session

for the mothers in the experimental group, and one month afterwards. Different content at each session include: The first session: Familiarization of group members with each other; definition of life skills and PSS and the necessity for their training; emotion- and problems-focused coping; emotions and the importance of their management; the phases of PSS; The first step of problem solving (orientation to a problem). The second session: ways to improve orientation to the problem. The third session: the second step of problem solving (clear definition of the problem). The fourth session: The third step of problem solving (generating different solutions to the problem) and the fourth step of problem solving (eliminating unfeasible and irrational solutions and selecting the best one). The fifth session: The use of the 'advantages-disadvantages' technique for selecting the best solution. The fifth step of problem solving (implementation and reassessment of the solution). The sixth session: using the steps of problem solving for a selected problem; giving the posttest; determining the time for the next posttest at one month after the intervention.

Category

Behavior

2

Description

Control group: Mothers in the comparison group received no training.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

healthcare centers of Babol University of Medical Sciences

Full name of responsible person

Fatemeh Abedi

Street address

Babol University of Medical Sciences, Ganj Afrooz Avenue, Babol, Mazandaran

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+98 11 3219 9594

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Fatemeabedi215@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad reza Honarvar

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Fatemeh Abedi

Position

student

Latest degree

Master

Other areas of specialty/work

Midwifery

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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

All rights related to the data is for golestan University of Medical Sciences.

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data will be shared after making characteristics of the persons, unrecognizable.

When the data will become available and for how long

Initiation of the data availability 6 months after publication of the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Using in the systematic review and meta-analysis

From where data/document is obtainable

Golestan University of Medical Sciences

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

Providing a request and receiving the university approval letter

Comments