Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Oral Probiotic Capsules on Postpartum Quality of Life in Primiparous women

Protocol summary

Study aim
Determining the effect of oral probiotic capsule on the quality of life after delivery of primiparous women

Design
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 60 samples. Randomization with r software

Settings and conduct
After obtaining written consent, in the first stage, non-probability sampling will be available, in the second stage, how to assign people to two groups (intervention group of 30 people and the second group of 30 people) randomly and using the method Blocking will be done with 15 blocks of 4 blocks.

Participants/Inclusion and exclusion criteria
The inclusion criteria include Iranians living in Mashhad, first-born, age 18-35 years, living with a spouse, no current illness and no history of depression and mental illnesses during pregnancy, a score of "less than severe" from the DASS21 questionnaire in the depression and anxiety subscale and Stress, no chronic disease, no smoking and alcohol, singleton pregnancy, birth of a healthy and mature baby weighing 2500 to 4000 grams, no use of probiotics from 2 weeks before the start of the intervention, low-risk pregnancy and uncomplicated delivery, vaginal delivery. The exclusion criteria include the mother's reluctance to continue participating in the study, the occurrence of unfortunate events in the last three months, failure to breastfeed the baby, suffering from complications after childbirth, the baby suffering from jaundice and any other problems, death of the baby.

Intervention groups
will take one Bioflora probiotic capsule from Tekgen Bio company containing Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis and Bifidobacterium longum daily from the fifth day after delivery to four weeks after receiving the medicine, and the control group will receive a placebo containing Avicel powder.

Main outcome variables
life quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230419057959N1**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **prospective**

Last update: **2023-07-09, 1402/04/18**
Update count: **0**

Registration date
2023-07-09, 1402/04/18

Registrant information

Name
maryam rastegar

Name of organization / entity

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Iran (Islamic Republic of)

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+98 71 3228 0317

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rastegarm4001@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-22, 1402/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Oral Probiotic Capsules on Postpartum Quality of Life in Primiparous women

Public title

Investigating the effect of probiotics on the postpartum quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian and resident of Mashhad primiparous age 18-35 No current illness and no history of depression and mental illnesses during pregnancy (including anxiety disorders and postpartum grief and mental illnesses acknowledged by the mother herself, Any type of mental disorder that has led to outpatient or inpatient drug treatment) Obtaining a "less than severe" score from the DASS21 questionnaire in the subscale of Depression (score zero to 20), anxiety (score zero to 14) and stress (score zero to 25) Not having a chronic disease (including: chronic heart and lung diseases, kidney, diabetes, blood pressure, cancer, diseases, rheumatism, immune deficiencies (allergy and asthma confirmed by a doctor), anemia and any disease that has lasted more than three months) No smoking and alcohol and Tobacco singleton pregnancy The birth of a healthy and mature baby with a weight of 2500 to 4000 grams Not using probiotics from 2 weeks before the start of the intervention during low-risk pregnancy and delivery without complications (absence of premature delivery, pre-eclampsia, eclampsia, blood pressure during pregnancy, gestational diabetes, infectious diseases such as hepatitis or AIDS, Not having an IUGR fetus, liver disorders (pregnancy fatty liver), polyhydraminosis and oligohydraminosis, placenta provia and placental adhesion. vaginal delivery without 3rd and 4th degree rupture) vaginal birth Living with a spouse Absence of the fetus suffering from any abnormality during pregnancy (any type of abnormality and disorder detected in pregnancy screening tests and ultrasounds)

Exclusion criteria:

The unwillingness of the mother to participate in the study Unfortunate events in the last three months (suffering from mental illness, serious illness of oneself or spouse, death of a close relative, unemployment, accident, and severe family disputes) Failure to breastfeed the baby for any reason Postpartum complications (postpartum bleeding, hysterectomy, infection, and hospitalization of the mother or baby for any reason) A newborn suffering from jaundice and any other problems (heart, respiratory problems) Mother's breastfeeding problems that cause the inability to breastfeed the baby Death of a baby Taking antibiotics at the same time as taking probiotics A baby with an abnormality (any type of abnormality diagnosed by a doctor)

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning people to two groups (the intervention group of 30 people and the second group of 30 people) will be randomly and using the block method with blocks of 4 and 15 blocks of 4 will be done. Randomization according to the previously randomized list will be done by the statistics consultant using the random number table or R software and will be given to the researcher. Considering that the block size is 4, we will have 6 different combinations of 2 intervention groups, which we enter in the block variable. In the next step, we take a random sample of 15 of these combinations. To complete our randomization list. Commands in R are shown: bloks<- c("AABB","ABAB","ABBA","BABA","BABA","BBAA") n=15 list<-sample(bloks,n,replace=TRUE) list "AABB" "BABA" "BABA" "BABA" "ABAB" "BBAA" "AABB" "BABA" "BBAA" "BABA" "ABBA" "ABAB" "BBAA" "BABA" "ABAB" The method of assigning people to two groups will be randomly and using the block method with blocks of 4. For concealment, we use concealment allocation in such a way that the assigned group is not known before assigning the individual. By using non-transparent and closed envelopes with a random sequence of envelopes opaque, sealed, numbered sequentially (in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order). In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. The lids of the envelopes are glued and placed in a box respectively. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

People in the placebo group will receive a capsule with the same smell, color, shape and size as the medicine capsule of the test group. In order to eliminate the bias caused by the awareness of the patient or the researcher, the study was conducted in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Ebnesina St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2023-05-30, 1402/03/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1402.031

Health conditions studied

1

Description of health condition studied
Mood and psychological symptoms after childbirth
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Physical symptoms after childbirth
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Quality of life after childbirth
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Social support after childbirth
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Measuring physical activity
ICD-10 code
ICD-10 code description

6

Description of health condition studied
Pittsburgh Sleep Quality Survey
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life after childbirth
Timepoint
3rd to 5th day after delivery, 10-14 days after delivery, 30 days after taking medicine
Method of measurement
Postnatal Quality Of Life Specialized Questionnaire

Secondary outcomes

1

Description
Improvement of mood and psychological symptoms after childbirth
Timepoint
3rd to 5th day after delivery, 10-14 days after delivery, 30 days after taking medicine
Method of measurement
A specific measuring tool for the quality of life after childbirth, the Edinburgh Depression Questionnaire

2

Description
Improvement of physical symptoms after childbirth
Timepoint
3rd to 5th day after delivery, 10-14 days after delivery, 30 days after taking medicine
Method of measurement
A specific measuring tool for the quality of life after childbirth, the Edinburgh Depression Questionnaire

Intervention groups

1

Description
Intervention group: Daily consumption of one Bioflora probiotic capsule from Tekgen Biot company with a dose of 1.8 containing effective ingredients of Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis and Bifidobacterium longum from the fifth day after delivery to four weeks after taking the medicine.
Category
Treatment - Drugs

2

Description
Control group: Daily consumption of one Avicel capsule

with a similar appearance to the medicine of the intervention group from the fifth day after delivery to four weeks after starting to take the capsules

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Health Center Number 2

Full name of responsible person
Nahid Jahani Shorab

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2

Recruitment center

Name of recruitment center
Mashhad Health Center Number 3

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Jahani Shorab

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Bachelor
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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