Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The Effect Of Oral Capsules Of Jujube Fruit Extract On The Prevention Of Postpartum Depression

Protocol summary

Study aim
Determining The Effect Of Jujube Fruit Capsule On The Prevention Of Postpartum Depression

Design
Clinical Trial With Control Group, With Parallel Groups, Double-Blind, On 128 Samples. Stratified Face Sampling And Then Accident Allocation

Settings and conduct
Research environment of Torbat-e-Jam health center, all comprehensive urban health service centers under the auspices of this center. The research and sampling community is done in a class of 4 comprehensive urban health service centers and then random allocation is done by block method. , The evaluator and the statistical analyst are not aware of the intervention and control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent, 18-40 year old women, wanted pregnancy, no history of recurrent miscarriage or infertility, being on the 10th day after normal delivery, low-risk pregnancy, no stress, depression and severe anxiety, score less than 12 of the Edinburgh Depression Test, no jujube hypersensitivity, no treatment for depression, no history of medical or mental illness. Conditions of non-entry: unwillingness to continue research, not taking medication for two consecutive days, major stress during the study, depression during the study diagnosed by a psychiatrist, the baby has an abnormality or death of the baby, smoking, drinking alcohol or Consumption of any drug

Intervention groups
Intervention group: They will receive 1200 mg of jujube fruit extract daily in the form of two 750 mg capsules after breakfast and dinner and will complete the Edinburgh Depression Inventory two weeks, four weeks and six weeks after the start of the intervention. Control group: It is quite similar to the control group, but instead of the jujube fruit extract capsule, it receives a capsule containing a placebo.

Main outcome variables
Depression Score Before And After The Intervention

General information

Reason for update
Change The Name Of The Scientific Supervisor Of The Project From The Name Of The Student To The Name Of The Project Supervisor

Acronym

IRCT registration information
IRCT registration number: **IRCT20220424054639N1**
Registration date: **2022-06-13, 1401/03/23**
Registration timing: **prospective**

Last update: **2022-06-19, 1401/03/29**
Update count: **1**

Registration date
2022-06-13, 1401/03/23

Registrant information

Name
Mahsa Din mohammadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5252 1811
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

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

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Oral Capsules Of Jujube Fruit Extract On The Prevention Of Postpartum Depression

Public title

The Effect Of Oral Capsules Of Jujube Fruit Extract On The Prevention Of Postpartum Depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious Consent Of The Mother Women 18-40 Years Old Recent Pregnancy Asked No History Of Recurrent Miscarriage Or Infertility Resident Of Torbate Jam Live With His Wife On The 10th Day After Normal Delivery Without Complications (Complication: Any Obstetric Complications Such As High Blood Pressure, Diabetes Or Hospitalization Of The Mother Due To Postpartum Complications) Having A Low-Risk Pregnancy (Low-Risk Pregnancy: A Pregnancy That Has No Potential Side Effects That Threaten The Health Of The Mother And Fetus) Having A Mobile Phone Number No Stress, Depression And Severe Anxiety (Depression And Severe Anxiety: Scores Of 24 And Above On The Stress Subscale And 15 And More On The Anxiety Subscale And 21 And More On The DASS-21 Questionnaire) Score Less Than 12 On The Edinburgh Depression Test Do Not Be Allergic To Jujube No Accidents (Accidents Such As The Death Or Hospitalization Of A Family Member During The Last Three Months) Do Not Currently Be Treated For Depression Have No Medical History (Medical Conditions: Hypertension, Hypothyroidism And Parathyroidism, Heart Disease, Kidney Disease, Hypertension Under Treatment, Migraine, Epilepsy, Respiratory Disease, Hyperlipidemia, Diabetes) Do Not Have Any Mental Illness (Mental Illness: A History Of Depression Or Neurological Disease Or Any Other Mental Disorder According To The Patient)

Exclusion criteria:

Reluctance To Continue Research Do Not Take The Drug For Two Consecutive Days Incidence Of Jujube Allergy Major Stress During Study(Major Stress: Serious Illness Of Yourself Or A Spouse, Death Of A Loved One, Unemployment, Accidents And Severe Family Disputes) Depression While Studying With A Psychiatrist Diagnosis The Baby Has An Abnormality Or The Baby Dies Change Of Residence During The Study Smoking, Drinking Alcohol Or Taking Any Drugs

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

This Study Will Be Performed As A Three-Blind Randomized Controlled Clinical Trial. The Research Environment Is Torbate Jam Health Center And All Comprehensive Urban Health Service Centers (All Four Urban Service Centers) Under The Auspices Of This Center Will Be Selected As The Research Community. Sampling Is Done In A Class Of 4 Comprehensive Urban Health Service Centers And Then Random Allocation (The Method Of Allocating People To Two Groups Will Be Random And Using The Method Of 4 Blocks). The Randomization Tool Will Be A Table Of Random Numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In This Study, Both Participants And Researchers Or Outcome Assessors Are Unaware Of The Allocation Of Study Groups.

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

No. 63, Motahhari St., Motahhari St., Islamic Republic Square

City

Torbate Jam

Province

Razavi Khorasan

Postal code

9571969933

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.016

Health conditions studied

1

Description of health condition studied

Postpartum depression

ICD-10 code

F53

ICD-10 code description

Puerperal psychosis

Primary outcomes

1

Description

Depression Score Before And After The Intervention

Timepoint

At The Beginning Of The Study And At The End Of The Second, Fourth And Sixth Weeks After Entering The Study, The Depression Score Will Be Measured.

Method of measurement

Edinburgh Postpartum Depression Screening Questionnaire

Secondary outcomes

1

Description

Satisfaction With The Sex Of The Baby

Timepoint

At The Beginning Of The Study

Method of measurement

Demographic And Midwifery Profile Questionnaire

Intervention groups

1

Description

Intervention group: Includes An Intervention Group That In Addition To Receiving Routine Care Performed By Midwives Working In Comprehensive Health Service Centers On Days 1-3, 10-15, 30-42 After Delivery, Recipient Of Oral Capsules Of Jujube Fruit Extract From The Tenth Day Are After Childbirth. Mothers In This Group Will Receive 1200 Mg Of Jujube Fruit Capsules Daily Along With 300 Mg Of Excipients Including Avisel In The Form Of Two 750 Capsules Twice A Day For Half An Hour After Breakfast And Dinner For Six Weeks And A Depression Questionnaire. After Giving Birth To Edinburgh, This Group Will Be Completed At The End Of The Second, Fourth And Sixth Weeks After Entering The Study. Inform The Researcher Of Any Allergies, Problems Or Any Side Effects Through The Contact Number Provided To Them.

Category

Treatment - Drugs

2

Description

Control group: Includes A Control Group (Receiving Placebo Capsules): In Addition To Receiving Routine Postpartum Care, The Control Group Will Receive A Placebo Capsule Containing 750 Mg Of Oisel Powder Twice Daily After Breakfast And Dinner For 6 Weeks. Routine Postpartum Care Includes Routine Midwifery Care On Days 1-3, 10-15, 30-42 After Delivery By The Midwife. Mental Health Screening In The First, Second And Third Postpartum Care Is Based On The Edinburgh Questionnaire, And If The Evaluation Results Are Positive Based On The Cut-Off Point Of The Questionnaire (Score 12 And Above), The Mother Suffers From Postpartum Depression And Should Be Additional Evaluation Should Be Referred To A Doctor Immediately (At The Earliest Opportunity).Mothers Whose Test Scores Are 12 And Older Suffer From Postpartum Depression. Scores 14 And 15 Are Severe Depression. Women With Some Symptoms Of Depression (No Suicidal Ideation) Or A Score Between 5 And 9 Should Be Re-Evaluated A Month Later. The Edinburgh Postpartum Depression Inventory For This Group Is Completed At The End Of The Second, Fourth And Sixth Weeks After Entering The Study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Torbate Jam Health Center

Full name of responsible person

Mahsa Din Mohammadi

Street address

Torbat Jam Health Center, Torbate Jam School Of Medical Sciences ,Central Square, Taybad Stree,t

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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
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 Shoorab
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Mahsa Din Mohammadi
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Master Student Of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Statistical Data And Results Of Statistical Analysis Will Be Shared In The Form Of Tables And Graphs. Some Of The Forms And Questionnaires Used Will Be Shared

When the data will become available and for how long

Access Period Starts From Six Months After The Results Are Published Until 1 Year Later

To whom data/document is available

The Data Will Be Available Only To Researchers Working In Academic And Scientific Institutions

Under which criteria data/document could be used

In Order To Use The Data, Only The Responsible Researcher Should Be Contacted And It Will Be Possible To Publish Through Her

From where data/document is obtainable

Applicants Should Contact The Research Officer Via Email JahaniSHN@mums.ac.ir

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

A Data Request And Document Must Be Sent To The Responsible Author In The Form Of A Valid Academic Email

Comments