Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Randomized clinical trial of the effects of prayer on depression, anxiety and stress in mothers of preterm infants

Protocol summary

Summary

Study objective: Postpartum depression is a serious and preventable disorder. Premature birth is a stressful event and 28 to 70 percent of the mothers had a high degree of stress. Among the treatments, religion has been considered as a complementary approach and the prayer is usually used in the harsh conditions. Study design: A randomized , non- blind , controlled , non- placebo, Study population: Mothers with preterm newborn less than 35 weeks gestational age, singleton and hospitalized in neonate intensive care unit(NICU). Sample size: In both groups: 60, in each group: 30 Intervention: Tavasol praying with Mr. Farahmand's voice played by audio devices Intervention time: 20 minutes daily for 7 days Study outcome: The effect of praying on depression, anxiety and stress of mothers with preterm newborn hospitalized in neonatal intensive care unit (NICU) immediately and one month after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100719429N1**
Registration date: **2015-01-07, 1393/10/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-07, 1393/10/17

Registrant information

Name

Maryam Sharifnia

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Mashhad University of Medical Sciences. Building Qureshi, Daneshgah Avenue, Mashad. Zip code: 91375-345 Tell: 00985138411538 00985138412081-5 Fax:00985138430249 Email: vcresearch@mums.ac.ir

Expected recruitment start date

2013-08-08, 1392/05/17

Expected recruitment end date

2014-01-07, 1392/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of the effects of prayer on depression, anxiety and stress in mothers of preterm infants

Public title

Effect of praying on depression, anxiety and stress of mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria of mother: • No more than two standard deviations from the mean difference of prayer questionnaire • Infants with gestational age less than 35 weeks • Obvious lack of psychiatric disorders such as psychosis , major depression , obsessive - compulsive ,

personality disorder characterized by a questionnaire SCL90 • A singleton baby • No obvious physical deformities newborn • Iranian nationality Exclusion criteria: • Infant death • Infants discharged during 7 days • Lack of cooperation and implementation of intervention by mother

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashad University of Medical Sciences

Street address
Building Qureshi, Daneshgah Avenue, Mashhad

City
Mashhad

Postal code
91375-345

Approval date
2013-08-17, 1392/05/26

Ethics committee reference number
920142

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F53.0

ICD-10 code description
Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

2

Description of health condition studied
Anxiety

ICD-10 code
F53.8

ICD-10 code description
Other mental and behavioural disorders associated with the puerperium, not elsewhere classified

3

Description of health condition studied
Stress

ICD-10 code
F53.8

ICD-10 code description
Other mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description
Anxiety

Timepoint
At the beginning of the study, After intervention and 1 month later

Method of measurement
Depression, Anxiety, Stress Scale (DASS21)

2

Description
Depression

Timepoint
At the beginning of the study, After intervention and 1 month later

Method of measurement
Depression, Anxiety, Stress Scale (DASS21)

3

Description
Stress

Timepoint
At the beginning of the study, After intervention and 1 month later

Method of measurement
Depression, Anxiety, Stress Scale (DASS21)

Secondary outcomes

1

Description
Evaluate adherence to pray

Timepoint
At the beginning of the study

Method of measurement
Prayer Questionnaire Mravgylya

2

Description
Evaluation of mental health
Timepoint
At the beginning of the study
Method of measurement
Mental health Questionnaire(SCL90)

Intervention groups

1

Description
Tavasol praying with Mr. Farahmand's voice played by audio devices 20 minutes daily for 7 days
Category
Prevention

2

Description
No intervention for control group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Educational, Research and Treatment Center
Full name of responsible person
Fateme Chitgar Rahimi- Bachelor of Science in Nursing- Head nurse of Neonatal intensive care unite
Street address
Imam Reza Square,Avenue Ibn Sina
City
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2

Recruitment center
Name of recruitment center
Bent al hoda hospital
Full name of responsible person
Maryam Jahani- Bachelor of Science in Nursing - Nurse Consulting Services
Street address
Bahar Street
City
Mashhad

3

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Zahra Parvini-Bachelor of Science in Nursing. Head Nurse of neonatal intensive care unite
Street address
Ahmedabad street, Doctor Shariarti square
City
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4

Recruitment center
Name of recruitment center
Mosa Ben Jafar Hospital
Full name of responsible person
Mehrnaz Molai- Bachelor of Science in Nursing- Head Nurse of Neonatal intensive care unite
Street address
Emamreza Street - Emamreza 21
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Doctor Mohsen Tafaghodi
Street address
Building Qureshi, Daneshgah Avenue, Mashad
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Mashhad
Grant name
Grant code / Reference number
920142
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Soheila Karbandi
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty