Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of educational-religious intervention on pregnantwomen referred to Baqiyatallah medical science hospitals in 2014-2015

Protocol summary

Summary

Purpose: The Effect of Educational-religious Intervention on pregnant women referred to Baqiyatallah Medical Sciences' hospitals in 2014. 2. Comparing the mean scores of stress, anxiety and depression before the intervention in two experimental and control groups. Method: In this study, a randomized clinical trial with allocation to experimental and control groups with convenience sampling method, 84 pregnant women participated in two clinics. Four training sessions for mothers were done within two weeks. All participants demographic questionnaire, DASS42 and religious index at Duke University in the pre-test session (first trimester) were completed and then test 1 and Track 2 at weeks 20 and 32 was conducted after the training sessions. Intervention: first session; initial assessment, knowledge and research objectives, pre-test, the definition of pregnancy and Anatomic and physiologic changes and stressors during pregnancy and define religiously important pregnancy. Session II: Introduction to pregnancy stress and its effects on the mother and fetus. Third session: religious education recommended in this period and the ways to achieve relaxation religious. Fourth session: the review conference.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080923565N1**
Registration date: **2015-09-15, 1394/06/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-15, 1394/06/24

Registrant information

Name
Zarindokht Sheikholia
Name of organization / entity
Baqiyatallah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2220 9979
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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Vice Chancellor for research .

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational-religious intervention on pregnantwomen referred to Baqiyatallah medical science hospitals in 2014-2015

Public title

The effect of religious educational intervention on stress, anxiety and depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the pregnant woman with singleton pregnancies in the first trimester pregnancy; low-risk

pregnancy; lack of mental health problems in the past; not applying specific drug or medications; no history of mental disorder; adequate literacy; signing informed consent in research; participate in all training sessions. Exclusion criteria: the incidence of pregnancy complications, including bleeding, diabetes, hypertension, internal medicine; having sever trauma and stress; unwillingness to participate in research.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Baqiyatallah University of Medical Sciences

Street address
Baqiyatallah University of Medical Sciences, Sheikh Bahai St., Hemmat highway

City
Tehran

Postal code

Approval date
2014-11-15, 1393/08/24

Ethics committee reference number
5904

Health conditions studied

1

Description of health condition studied
Stress in pregnancy

ICD-10 code
O20-29

ICD-10 code description
Other maternal disorders predominantly related to pregnancy

Primary outcomes

1

Description
Anexiety

Timepoint
Before the intervention, one and three months after intervention

Method of measurement
Stress, anxiety and depression questionnaire DASS42

2

Description
Stress,

Timepoint
Before the intervention, one and three months after intervention

Method of measurement
A standard questionnaire on stress, anxiety and depression DASS42

3

Description
Depression

Timepoint
Before the intervention, one and three months after intervention

Method of measurement
Stress, anxiety and depression questionnaire DASS4

Secondary outcomes

1

Description
Infant anthropometric factors, including weight, height, head circumference and chest circumference newborn baby

Timepoint
At birth time

Method of measurement
Physical examination

2

Description
Delivery time

Timepoint
Delivery times below 38 weeks and after 38 weeks

Method of measurement
Medical records

Intervention groups

1

Description
In intervention group: Educating mothers on the basis of religious orders and methods of religious plan in 4 sessions of the first quarter every two weeks for 60 minutes per session through group discussions, questions and answers, with educational manual and pamphlets.
Category
Prevention

2

Description
No intervention in control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital's gynecology clinic
Full name of responsible person
Zarindokht Sheikholia, Master's degree in health education and health promotion.
Street address
Sheykh Bahaee St., Hemmat highway
City
Tehran

2

Recruitment center
Name of recruitment center
Najmieh hospital gynecology clinic
Full name of responsible person
Zarindokht Sheikholia, Master's degree in health education and health promotion.
Street address
Jomhoori street - Hafez crossroad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr Morteza Izadi
Street address
Baqiyatallah University of Medical Sciences, Sheikh Bahai St., Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Baqiyatallah 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
School of Public Health, Baqiyatallah University of Medical Sciences
Full name of responsible person
Zarindokht Sheikholia
Position
Msc health education
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Hormoz Sanaee Nasab
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Associate professor of health education and health promotion
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Person responsible for updating data

Contact
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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