

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of family visit everyday on anxiety and depression in pregnant women with preterm rupture of membranes (PROM) hospitalized in the third trimester of pregnancy.

Protocol summary

Study aim

Effect of family visit everyday on anxiety and depression in pregnant women with preterm rupture of membranes (PROM) hospitalized in the third trimester of pregnancy.

Design

Clinical trial with intervention and control group, 70 patients, with parallel groups, single blinded, randomized.

Settings and conduct

Background: Anxiety and depression in pregnant women. Patients will be divided randomly into two groups, intervention (35 patients) and control group (35 patients). Patients will be admitted to separate rooms to be unaware of the type of intervention they receive each other. Both groups will be receive all routine care and medication but in intervention group, along with the standard care, will walk each day for half an hour and at least 5 days a week with a spouse or a close member of the family in the hospital's yard. The questionnaire for depression and anxiety is then re-evaluated within a week up to 3 consecutive weeks. The assignment sequence will be performed by a person who has no role in the entry of participants in the research, data collection and analysis of the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20-35 years; have a steady family status Exclusion criteria: Having a history of depression or anxiety; gestational age greater than 38 weeks

Intervention groups

The intervention group: Along with the standard care, will walk each day for half an hour and at least 5 days a week with a spouse or a close member of the family in the hospital's yard. Control group: Will receive the care and medications prescribed by the respective physician.

Main outcome variables

Depression and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038879N3**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Fatemeh Abbasalizadehf

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9161

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abbasalizadehf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family visit everyday on anxiety and depression in pregnant women with preterm rupture of membranes (PROM) hospitalized in the third trimester of pregnancy.

Public title

The effect of daily family visits on anxiety and depression in pregnant women admitted to hospital

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with aged between 20-35 years The desire to participate in the study The possibility of a daily presence of at least 5 days a week for for the patients husband or a close family member in hospital preterm rupture of membranes

Exclusion criteria:

Having a history of depression and anxiety Gestational age greater than 38 weeks

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

To hide allocations (Allocation Concealment), Will be written type of intervention on paper and placed inside matte envelopes in numerical order, respectively. The assignment sequence will be performed by a person who has no role in the entry of participants in the research, data collection and analysis of the data. Random Allocation of four and six will be done using the site (<http://www.random.org>).

Blinding (investigator's opinion)

Single blinded

Blinding description

To hide allocations (Allocation Concealment), Will be written type of intervention on paper and placed inside matte envelopes in numerical order, respectively. The assignment sequence will be performed by a person who has no role in the entry of participants in the research, data collection and analysis of the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor., Central Building of Number2., Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.TBZMED.REC.1397.463

Health conditions studied

1

Description of health condition studied

Premature rupture of membranes

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes

Primary outcomes

1

Description

Depression

Timepoint

At the beginning of the study and the end of the first, second and third weeks of the study

Method of measurement

Depression and Anxiety questionnaire

2

Description

Anxiety

Timepoint

At the beginning of the study and the end of the first, second and third weeks of the study

Method of measurement

Depression and Anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" In addition to standard care, they will walk each day for half an hour and at least 5 days a week with a spouse or a close family member in the hospital's yard, up to 3 consecutive weeks and at the end of the study if the patients in the intervention group continue to be admitted, It is possible for them to continue the study conditions until delivery and if the delivery is earlier than a week, patients are excluded from the study.

Category

Behavior

2

Description

"Control group" will receive all routine care and medication.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Fatemeh Abbasalizadeh

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Alzahra Hospital., South Artesh St.

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lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University Of Medical Sciences

Full name of responsible person

Abolghasem Juiban

Street address

Third Floor., Central Building of Number2., Golgasht Street

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Tabriz

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ajouyban@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for Research, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Abbasalizadeh

Position

Professor Obstetricians and Gynecologists

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Abbasalizadeh

Position

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