

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of writing therapy with anxious pregnant women on their infants' quality of sleep

Protocol summary

Study aim

To determine the effect of writing therapy with anxious pregnant women on their infants' sleep quality

Design

This study will be conducted on pregnant women referring to health centers of Tabriz. The researcher will refer to health centers and will select pregnant women with gestational age of 28 to 31 weeks according to their records, then will call them and they will be invited to participate in the study. In face to face session, the anxiety scale will be completed and women who obtain average score of anxiety (score 16 to 26) will be included in study and written consent will be obtained. Participants will be randomly assigned into two groups of counseling and control. Participants will be followed up until 4 months after childbirth and Infant Sleep quality scale will be completed at 2 and 4 months.

Settings and conduct

This study will be conducted in health centers of Tabriz. The researcher will select the eligible women and they will be assigned into two groups. They are no blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with moderate anxiety and gestational age of 31-28 weeks
Exclusion criteria: High risk pregnant women with mild and severe anxiety

Intervention groups

The intervention group will receive three counseling sessions with writing therapy approach in the 28-31, 32-35 and 24-37 weeks and two telephone counseling sessions between face to face sessions and a telephone counseling and follow-up session a month after childbirth. The control group will receive routine cares.

Main outcome variables

Sleep quality in two and four months old

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N45**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-05, 1397/06/14

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of writing therapy with anxious pregnant women on their infants' quality of sleep

Public title

The effect of writing therapy with anxious pregnant women on their infants' quality of sleep

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with gestational age of 31-28 weeks
First or second pregnancy Women with moderate anxiety based on Beck Anxiety Scale Having at least high school certificate

Exclusion criteria:

Pregnant women with mental illness and taking of any psychological drug, according to the person expression
Mothers who have drug addiction and smoke cigarettes, according to their own expression
Mothers with high risk pregnancy who suffer from high stress and anxiety, such as mothers with diabetes, cancer, high blood pressure, kidney disease, epilepsy, multiple pregnancy, personal or family history of congenital birth defects and history of preterm labor
Mothers who will not take care of their infants after giving birth, such as divorce, those who have gestational surrogacy, and ... Mothers with an previous child with known physical or psychological health problem.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with block sizes of 4 and 6

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 of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction

number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2018-08-12, 1397/05/21

Ethics committee reference number

IR.TBZMED.REC.1397.408

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Infant sleep quality

Timepoint

Two and four months after childbirth (1 and 3 months after the end of intervention)

Method of measurement

Infant Sleep Questionnaire (ISQ)

Secondary outcomes

1

Description

Mean score of anxiety

Timepoint

Before the intervention and immediately after the end of counseling

Method of measurement

Beck Anxiety Inventory

2

Description

The frequency of exclusive breastfeeding

Timepoint

Two and four months after childbirth

Method of measurement

check list

3

Description

Infant Anthropometric Indices

Timepoint

At birth, two and four months after childbirth

Method of measurement

Scale and meter

4**Description**

Infant developmental index

Timepoint

Four months after childbirth

Method of measurement

ASQ questionnaire

Intervention groups**1****Description**

The intervention group will receive three counseling sessions with writing therapy approach in the weeks of 28-31, 32-35, 34-37 and two telephone counseling and follow-up sessions between face to face counseling sessions and a telephone counseling and follow-up session a month after childbirth.

Category

Treatment - Other

2**Description**

The control group will also receive routine cares

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health centers of Tabriz city

Full name of responsible person

Mayam Montazeri

Street address

South Shariati

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5138947977

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+98 41 3479 6969

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

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mirghafourvandm@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

Maryam Montazeri

Position

MSc student of conseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Faculty of Nursing & Midwifery, South Shariati street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
PhD of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Position
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Other areas of specialty/work
Midwifery

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data of participants are privacy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article.

From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

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

حداکثر تا یک هفته بعد از مکاتبه از طریق ایمیل

Comments