Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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

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Mojgan Mirghafourvand
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

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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
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
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Person responsible for updating data

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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