Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Protocol summary

Study aim
Determining the effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted to Beasat hospital in Sanandaj, 2019

Design
Clinical trials with control group, available sampling and randomized sampling using the Pack envelopes containing letters A and B

Settings and conduct
This study will be carried out in the high risk mothers section of Beasat Hospital in Sanandaj. Intervention in people who entered the intervention group, will be in such a way that for 4 consecutive days each day for 10 minutes at 6-4 pm in a room that has the usual conditions of massage, including dim light, a relaxed place and a suitable chair Will be given massage by the researcher. During the study, patients in the control group will not undergo any other intervention except for the usual treatments.

Participants/Inclusion and exclusion criteria
Mothers with gestational diabetes mellitus with a mild to severe anxiety score (20 and above) based on the Spielberger anxiety inventory

Intervention groups
Intervention group: The diabetic mothers are admitted to the high-risk department of Besat Hospital in Sanandaj, which in addition to receiving usual care during admission, for 4 days, receive 10 minutes a day stroke back massage . Control group: The diabetic mothers admitted to the high-risk department of Besat Hospital in Sanandaj, which received routine care during admission and will not receive any massage.

Main outcome variables
Anxiety; Physiological index including heart rate, blood pressure, respiratory rate, body temperature, blood Sugar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190122042464N1**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-06, 1398/01/17**
Update count: **0**

Registration date
2019-04-06, 1398/01/17

Registrant information

Name
trefa mehri

Name of organization / entity
Medical university of kurdistan

Country
Iran (Islamic Republic of)

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+98 44 4433 0566

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mehri.t@muk.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-04, 1398/01/15

Expected recruitment end date
2019-07-06, 1398/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Public title
The effect of Stroke Back Massage on the anxiety and physiological index of diabetic mothers admitted

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Second and third trimester of pregnancy The second day of hospitalization Women with gestational diabetes

Exclusion criteria:
history of spinal cord injury or surgery Any skin and bone disorders in the neck, back and sacrum High-risk pregnancies such as multiple pregnancies Heart disease, kidney disease, asthma and depression

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization Randomization: Using a packet containing letters A and B. The units were randomly assigned to the packets containing letters A and B in one of the groups of intervention group (A) or control (B) using a simple envelope.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee medical university of kurdistan

Street address
Pasdaran Boulevard, Medical University of Kurdistan

City
sanandaj

Province
Kurdistan

Postal code
6617713446

Approval date
2019-01-18, 1397/10/28

Ethics committee reference number
IR.MUK.REC.1397.312

Health conditions studied

1

Description of health condition studied
Gestational diabet, anxiety, stroke back massage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The level of anxiety in diabetic pregnant Women in the Spielberger Questionnaire

Timepoint
Before the intervention, the fourth day of the intervention, 2 and 4 days after the end of the intervention

Method of measurement
Spielberger Anxiety Inventory

2

Description
Blood pressure

Timepoint
Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement
Using a pressure gauge

3

Description
Heart beat

Timepoint
Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement
Using the clock, the number is counted in a minute by the researcher

4

Description
Number of breaths

Timepoint
Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention

Method of measurement
Using the clock, the number is counted in a minute by the researcher

5

Description
Body temperature
Timepoint
Days 1,2,3,4 interventions before and after intervention then 2 and 4 days after intervention
Method of measurement
Using a thermometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diabetic mothers are admitted to the high risk department of Besat Hospital in Sanandaj, who receive regular care for 4 days at the time of admission and receive 10 minutes a day for back stroke massage every day.
Category
Other

2

Description
Control group: Diabetic mothers are admitted to the high-risk section of Besat Hospital in Sanandaj, who receive routine care during admission and do not receive any massage.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beasat hospital
Full name of responsible person
trefa mehri
Street address
Keshavarz Street, Meroux Crossroads
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6618634683
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Farzin Rezaee
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Kurdistan University of Medical Sciences, Pasdaran Blvd
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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
Kurdistan 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
Kurdistan University of Medical Sciences
Full name of responsible person
Trefa Mehri
Position
Midwifery Master student
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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
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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