Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Dialectical Behavioral Therapy (DBT) Training and Aromatherapy Training (Lavender) on Psychological Symptoms of Pregnancy, indicators and Pain Intensity of the First and Second Stages of Childbirth and Competence for the role of Mother after Childbirth of Primiparous Women with Insecure Attachment to the Husband

Protocol summary

Study aim

Does the training of Dialectical Behavior Therapy(DBT) and aromatherapy techniques (Lavender) affect the psychological symptoms of pregnancy, delivery indices, pain intensity in the first and second stages of labor, and the suitability of maternal role after delivery of nulliparous women with insecure attachment to their husbands?

Design

Clinical trial on 75 patients in three groups of 25 entitled 1. Control group 2. Aromatherapy 3. Dialytic behavior therapy and aromatherapy

Settings and conduct

75 pregnant mothers in Birjand will be selected by purposive sampling and then randomly sampled into three experimental groups. First, the pre-test will be completed before the intervention in all three groups and then the post-test will be completed in the last session of the questionnaires. Beck Depression Inventory, Wendenberg Pregnancy Anxiety Questionnaire, Maternal Fetal Attachment, Spouse Attachment, Fear of Childbirth, and Patience will be completed and will receive aromatherapy during delivery, followed by Edinburgh Postpartum Depression Inventory and Parental Competence two weeks after delivery. And overt anxiety and patience will also be measured. A double-blind study in which participants and analyzers became blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant mothers close to their spouse, no high-risk pregnancy Exclusion criteria: Any pregnancy disorders such as preeclampsia, threat of preterm delivery

Intervention groups

Intervention 1 (dialysis behavior therapy 10 sessions twice a week + aromatherapy with lavender, 25 people) Intervention 2 (aromatherapy with lavender, 25 people) Control (25 people aromatherapy with water or placebo)

Main outcome variables

Evaluation of psychological consequences during pregnancy and postpartum; Consequences of motherhood and infancy during childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200604047655N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **retrospective**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Elham Zameni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3244 1097

Email address

elham_z2010@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20
Expected recruitment end date
2020-07-31, 1399/05/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Dialectical Behavioral Therapy (DBT) Training and Aromatherapy Training (Lavender) on Psychological Symptoms of Pregnancy, indicators and Pain Intensity of the First and Second Stages of Childbirth and Competence for the role of Mother after Childbirth of Primiparous Women with Insecure Attachment to the Husband

Public title
Evaluation of the effectiveness of Dialectical Behavioral Therapy and Aromatherapy of Lavender on pregnancy and Childbirth Outcomes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous Pregnant Women with Insecure Attachment to their Husbands
Exclusion criteria:
Literacy Single Pregnancy Voluntary Natural Childbirth and no Medical reason for Cesarean section Lack of high-risk pregnancies such as Heart Disease, Preeclampsia, Diabetes, threat of Preterm Delivery ... Failure to participate in psychological Interventions in the last 6 Months Lack of Experience of Traumatic and Stressful Events in the last 6 Months Do not take Psychological Drugs No Allergies to Lavender and no Olfactory Problems
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be performed in a simple, individual random way, using a lottery and assigning each number to a patient. First, determine a total sample size of 75 people, then randomly assign a set of them to group A and set. Assign E to group B and the rest to group C. For example, 25 balls for group A and 25 balls for group B and 25 balls for group C are placed in the lottery container, then the balls are randomly removed from the container without replacement and the created sequence is recorded.
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 of Birjand University of Medical Sciences
Street address
No. 93, Golchin 3., Ghaffari 18
City
Birjand
Province
South Khorasan
Postal code
9717963741
Approval date
2020-06-14, 1399/03/25
Ethics committee reference number
IR.BUMS.REC.1399.115

Health conditions studied

1

Description of health condition studied
The effect of Lavender and Dialysis Behavior Therapy on delivery outcomes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pregnancy depression
Timepoint
At the beginning of the Study and 35 Days after the start of the intervention
Method of measurement
Beck Depression Inventory

2

Description
Pregnancy anxiety

Timepoint
At the beginning of the Study and 35 Days after the start of the intervention
Method of measurement
Wendenberg Pregnancy Anxiety Questionnaire

3

Description
Maternal attachment to the fetus
Timepoint
At the beginning of the Study and 35 Days after the start of the intervention
Method of measurement
Maternal attachment questionnaire to Cranley fetus

4

Description
Attachment to spouse
Timepoint
At the beginning of the Study and 35 Days after the start of the intervention
Method of measurement
Attachment Questionnaire to Fraley's wife, Waller and Brennan

5

Description
Obvious anxiety score in the Spielberger questionnaire
Timepoint
At the beginning of the study and 35 days after the intervention and during labor and two weeks after delivery
Method of measurement
Spielberger Obvious Anxiety Questionnaire

6

Description
Patience score in Khormai, Farmani and Soltani questionnaires
Timepoint
At the beginning of the study and 35 days after the intervention and two weeks after delivery
Method of measurement
Questionnaire of Patience of Date, Command and Soltani

7

Description
Fear of childbirth score in Harman questionnaire
Timepoint
At the beginning of the study and 35 days after the start of the intervention
Method of measurement
Harman Maternity Fear Questionnaire

Secondary outcomes

1

Description
Postpartum Depression Score from the Edinburgh Questionnaire
Timepoint
Two weeks after delivery
Method of measurement
Edinburgh Postpartum Depression Inventory

2

Description
Parental Competency Score from the Wallston-Gibbord Questionnaire
Timepoint
Two weeks after delivery
Method of measurement
Walston-Gibbord Parental Competency Score Questionnaire

3

Description
Check the duration of labor
Timepoint
The active phase of the first stage of dilatation The duration of labor will be measured twice during 5-7 and 8-10 cm dilatations of the cervix. The second phase of labor is from dilatation of 10 cm of the cervix until the fetus leaves
Method of measurement
Through vaginal examinations

4

Description
Evaluation of labor pain intensity
Timepoint
Evaluation of labor pain intensity before active phase and in the first and second stage of labor
Method of measurement
McGill Pain Pain Ruler

Intervention groups

1

Description
Intervention group: First, during pregnancy, dialysis behavior therapy sessions are presented in 10 sessions of 90 minutes by a doctor of psychology. During childbirth, dilation of 3-4 cm 5 drops in 1 liter of lavender essential oil water is used by inhalation, taking into account the private room for delivery, the administration of essential oil is repeated every 30 minutes. From the beginning of aromatherapy, the mother's pulse and blood pressure are monitored and also at the time of delivery, the duration of the first and second stages of labor, the severity of the mother's pain at the beginning of arrival, before 3-4 cm and 20 minutes after the onset of odor in dilation 5 7.8 at 10-10 cm, second stage of labor, neonatal Apgar score, fetal tachycardia and

bradycardia, maternal demand for analgesia, maternal satisfaction with labor during labor, and overt anxiety also assessed by a trained researcher in the intervention group.

Category

N/A

2

Description

Intervention group: This group also started the active phase of labor from lavender essential oil made by Barij Essential Oil Company with a concentration of 1% in the form of 5 drops in 1 liter of water by inhaler with inhaler by considering a private room for labor. And delivery, from dilatation of 3-4 cm to the time of delivery is used and the administration of essential oil will be repeated every 30 minutes. One hour after starting aromatherapy, the mother's pulse and blood pressure are checked and also during delivery, the duration of the first and second stages. Delivery, the severity of maternal pain at arrival, before 3-4 cm and at 20 minutes after the onset of odor in dilatations 5-7 and at 8-10 cm, the second stage of labor, neonatal Apgar score, tachycardia and fetal bradycardia, Maternal demand for analgesia, maternal satisfaction with labor during labor, and overt anxiety will also be measured with the help of a trained researcher in the intervention group.

Category

N/A

3

Description

The intervention group of this group during childbirth with the beginning of the active phase of labor from lavender essential oil made by Barij Essential Oil Pharmaceutical Company with a concentration of 1% in the form of 5 drops in 1 liter of water by inhaler with inhaler taking into account the private room for labor and Delivery is used from dilatation of 3-4 cm until delivery and the administration of essential oil will be repeated every 30 minutes. One hour after starting aromatherapy, the mother's pulse and blood pressure are checked and also during labor, the duration of the first and second stages of labor. Intensity of maternal pain at arrival, before 3-4 cm and at 20 minutes after the onset of odor in dilatations 5-7 and at 8-10 cm, second stage of labor, neonatal Apgar score, tachycardia and fetal bradycardia, rate Maternal demand for analgesia, maternal satisfaction with labor during labor, and overt anxiety will also be measured with the help of a trained researcher in the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

All health centers in Birjand

Full name of responsible person

Elham Zameni

Street address

Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717963741

Phone

+98 56 3162 2000

Email

Valiasr@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Elham Zameni

Street address

Ghaffari Street

City

Birjad

Province

South Khorasan

Postal code

9717963741

Phone

+98 56 3239 5000

Email

Public_r@bums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Birjand 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

Islamic Azad University

Full name of responsible person

Elham_zameni

Position
Employee of Birjand University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No. 93, Golchin 3., Ghaffari 18

City
Birjand

Province
Razavi Khorasan

Postal code
9717963741

Phone
+98 56 3244 1097

Email
elham_z2010@YAHOO.COM

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Eham Zameni

Position
Employee of Birjand University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No. 93, Golchin 3., Ghaffari 18

City
Birjand

Province
South Khorasan

Postal code
9717963741

Phone
+98 56 3244 1097

Email
elham_z2010@YAHOO.COM

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Eham Zameni

Position
Employee of Birjand University of Medical Sciences

Latest degree
Master

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No. 93, Golchin 3., Ghaffari 18

City
Birjand

Province
South Khorasan

Postal code
9717963741

Phone
+98 56 3244 1097

Email
elham_z2010@YAHOO.COM

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
There is no more information

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available