

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Dialectical Behavioral Therapy to Postpartum Depression Rate and Breastfeeding Success in Traumatic Childbirth

Protocol summary

Study aim

Effectiveness of dialectical behavioral therapy to postpartum depression rate and breastfeeding success in traumatic childbirth

Design

Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment. The control group just take routine cares and intervention group will receive consultation, weekly in five session. Post test will be done for both groups.

Settings and conduct

Location of study: Bahar hospital, Shahrood city In the beginning of study the traumatic childbirth scale will complete by primiparous women who come to hospital for delivery. If they have suffered by traumatic childbirth in the second step they will complete postpartum depression scale and if they get the point under 10, they can participate in the study. The participants of each group do not aware about Existence of another group. Researcher dose not aware about randomized allocation because of closed packets. After intervention questionnaires will complete by another person except researcher. The analyzer dose not aware about the people in the group's neither

Participants/Inclusion and exclusion criteria

Inclusion criteria: Giving healthy birth Having literacy Ability to speak and realize persia Desire to participate in study Not addicted to drugs Not occur stressful accidents before, in pregnancy No background of mental illnesses or using psychological drugs before, in or After pregnancy Lack of getting chronic and hard diseases before, in and after pregnancy Not use drugs can lead to depression symptoms Attaining point 10 or more in edinburg postpartum depression scale

Intervention groups

All of primiparous women

Main outcome variables

effectiveness of dialectical behavioral therapy on postpartum depression rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038265N1**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

Niloofer Rabiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3237 1061

Email address

n.rabiee2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Dialectical Behavioral Therapy to Postpartum Depression Rate and Breastfeeding Success in Traumatic Childbirth		Secondary Ids
		empty
Public title	Effectiveness of Dialectical Behavioral Therapy to Postpartum Depression	Ethics committees
Purpose	Education/Guidance	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
Inclusion criteria:	Giving healthy birth Having literacy Ability to speak and realize persian Tend to participate in study Not addicted to drugs Not occur stressful accidents before, in pregnancy No background of mental illnesses or using psychological drugs before, in or after pregnancy Lack of getting chronic and hard diseases before, in and after pregnancy Not use drugs can lead to depression symptoms	Name of ethics committee
Exclusion criteria:		Ethics committee of Shahrood University of Medical Sciences
Age	No age limit	Street address
Gender	Female	7th tir square, shahrood University of Medical Sciences
Phase	N/A	City
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	shahrood
Sample size	Target sample size: 180	Province
Randomization (investigator's opinion)	Randomized	Semnan
Randomization description	The randomized sequences under the web and by person who out of the research team will be done. Randomized foursome block as a limited method will be used and the people in the order of arrival will stay on blocks. The researcher put each allocation in closed white packet and numbered it. Qualified people in the order of arrival will be register by researcher and receive a code and the basic questionnaire complete for theme. Then according to the codes one packet will be opened and the person will be allocated to one of the groups.	Postal code
Blinding (investigator's opinion)	Triple blinded	3614773947
Blinding description	The Participants of each group do not aware about existence of another group. Researcher dose not aware about randomized allocation because of closed packets. After intervention questionnaires will complete by another person except researcher. The analyzer dose not aware about the people in the groups nether	Approval date
Placebo	Not used	2017-12-16, 1396/09/25
Assignment	Parallel	Ethics committee reference number
Other design features		960227
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Postpartum depression, traumatic childbirth
		ICD-10 code
		F53
		ICD-10 code description
		Puerperal psychosis
		Primary outcomes
		<u>1</u>
		Description
		Postpartum depression that will be measure by Edinburg scale
		Timepoint
		Before initiate of intervention, Immediately after the end of intervention, In the follow up, One month later (the end of 12th week after delivery)
		Method of measurement
		Postpartum depression scale of Edinburg
		Secondary outcomes
		empty
		Intervention groups
		<u>1</u>
		Description
		Control group: dose not recieve any intervention
		Category

Behavior

2

Description

Intervention group: this group will receive the consultation (dialectical behavioral therapy)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar hospital

Full name of responsible person

Narges Sarkardei

Street address

22 bahman St, Bahar hospital

City

shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

info@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

student's research committee

Street address

7th tir square, Shahrood University of Medical Sciences

City

shahrood

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3239 5054

Email

info@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrood 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

Shahrood University of Medical Sciences

Full name of responsible person

Niloofar Rabiee

Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

25th Alley, tehran Ave

City

shahrood

Province

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Postal code

3614646118

Phone

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Email

n.rabiee2016@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Niloofar Rabiee

Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Phone

+98 23 3237 1061

Email

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Niloofer Rabiee

Position

midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

publishable data include thesis interpreted results and papers and protocol if needed

When the data will become available and for how long

Access from 2018-2019

To whom data/document is available

Data are access for all researchers in scientific institutes

Under which criteria data/document could be used

In case of Author's permission

From where data/document is obtainable

To corresponding author or executive author

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

By contact with the department or send an email to authors

Comments