

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The Effects of emotion regulation training on The level of Mother-to-Child Attachment in Mothers of Insecure Attachment in the First Pregnancy

#### Protocol summary

##### Summary

This study investigates the effects of emotion regulation training on mother-infant attachment in Mothers of Insecure Attachment in the First Pregnancy. Inclusion criteria: women 18-35 years old; pregnant; 30-34 week gestational age, at least secondary education, insecure attachment, lack of following in the past year: chronic diseases, mental disorders, major, on a psychiatrist or admitted drug consumption ; drug addiction. Exclusion criteria: Cancel mother; absence of more than one session, doing homework, birth before 37 weeks and after 41 weeks, weighing less than 2500 and more than 4000 grams. Random sampling method that divided the mothers into two groups. Two health centers in Mashhad, were selected randomly. The mother's eligible for both health center - treatment through questionnaires attachment Collins and Reid are determined. Mothers entered the study are insecure. Cassidy and Kranly completed questionnaires in both groups. For the intervention group, 8 sessions of emotional regulation based on dialectical behavior therapy, a two-hour sessions a week for two months in the training room runs. At the last meeting questionnaires Cassidy, Collins, Kranly and re-completed. The control group did not and only health center to receive prenatal care. 15-19 days after delivery to the filing mothers to newborns are admitted to both

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014100519407N1**  
Registration date: **2015-10-30, 1394/08/08**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-30, 1394/08/08

##### Registrant information

###### Name

Aliye Shojafar

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3859 1511

###### Email address

shojafara1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research deputy of Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-11-13, 1393/08/22

##### Expected recruitment end date

2015-03-10, 1393/12/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of emotion regulation training on The level of Mother-to-Child Attachment in Mothers of Insecure Attachment in the First Pregnancy

##### Public title

The effects of emotion regulation training on maternal attachment to the baby in the mother's first pregnancy

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria for mothers: informed consent; gestational age between 30 and 34 weeks according to records; insecure attachment style mother by questionnaire Collins-Reed; age 18 to 35 years; first pregnancy; mothers at least guidance; lack of disease chronic mother like diabetes, hypertension, heart disease and epilepsy; the absence of major psychological disorders, psychiatric history, medication or hospitalization due to mental illness in the mother during the last year; no abuse and addiction drugs and stimulants, according to parents and health care records in; the absence of major stress in recent years (mother or wife's serious illness, death of a close, migration). Exclusion criteria during the study: criteria related to the mother include: withdrawing from further participation in the training sessions; the absence of the mother in more than a training session doing homework outside of class for more than one session; taking stimulants, narcotics, alcohol and smoking in our study; the incidence of major stress during the study period; the incidence of severe complications of pregnancy; separation of mother and baby for more than 24 hours after birth and during the study period; the mother died. Criteria for the newborn: birth before 37 weeks or after 41 weeks; birth weight less than 2,500 or more than 4,000 grams; congenital malformations in infants to prevent mother hugging baby; the baby died.

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **20**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

Research deputy, Mashhad University of Medical Sciences

## **Street address**

Research deputy, Qureshi Building, Daneshgah Street, Doctora Crossroads, Mashhad

## **City**

mashhad

## **Postal code**

## **Approval date**

2014-10-28, 1393/08/06

## **Ethics committee reference number**

research/930155/1/180

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Mothers in the First Pregnancy

#### **ICD-10 code**

Z34.0

#### **ICD-10 code description**

Supervision of normal first pregnancy

## **Primary outcomes**

### **1**

#### **Description**

The level of Mother-to-Child Attachment

#### **Timepoint**

15-19 days after delivery, after intervention

#### **Method of measurement**

Muller Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention1: Mother's insecure groups, trained in dialectical behavior therapy based on emotion regulation, at 8 weeks and 11-13 hours on Sundays every week (for two months).

#### **Category**

Behavior

### **2**

#### **Description**

Intervention2: The control group only prenatal Health center according to the protocol, received no intervention does not occur to them

#### **Category**

N/A

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Health Center Shahrak-e-lashkar

**Full name of responsible person**

Reyhani Tayebe

**Street address**

Fatemiyeh 14-blvd Shahid Fallahi

**City**

Mashhad

## 2

### Recruitment center

**Name of recruitment center**

Health Center Najafi

**Full name of responsible person**

Reyhani Tayebe

**Street address**

Piroozi blvd

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research deputy, Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Qureshi Building, Daneshgah Street, Doctora Crossroads, Mashhad

**City**

Mashhad

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

Yes

**Title of funding source**

Research deputy, Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Aaliye Shojafar

**Position**

MSc in Nursing, Neonatal Intensive Care

**Other areas of specialty/work****Street address**

School of Nursing and Midwifery, Doctora Crossroads, Mashhad

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+98 51 3868 6997

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shojafara1@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Position**

MSc Nursing, Faculty member of School of Nursing and Midwifery, Mashhad

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*