

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of attachment training on maternal and fetal attachment and happiness of Unintended pregnant women referring to selected hospitals of Shiraz University of Medical Sciences 1396

Protocol summary

Study aim

The aim of this study was to increase the maternal-fetal attachment, which plays an important role in the health of pregnant and fetal mother..

Design

In the intervention group, educational classes with topics related to maternal and fetal attachment and mother's happiness in six sessions and 90 minutes each session are done weekly. In this research, the samples were randomly assigned to two groups, which included the experimental group and the control group. 84 subjects were included in the control group, 42 in the control group and 42 in the experimental group.

Settings and conduct

Pregnant women with unplanned pregnancy referring to perinatal clinics of Hazrat Zaynab and Shooshtari hospitals and the community of the research community constitute the research.

Participants/Inclusion and exclusion criteria

1- Women Without Pregnancy 2. Failure to have mental disorders (psychosis, schizophrenia) 3. Ability to attend classes and complete the written consent form. 4. Earn a mental health score of less than 22 5. Lack of participation in any kind of educational class including physiological delivery Exit criteria: 1-Unwillingness to continue cooperation 2. The occurrence of any pregnancy problem during the study (preterm labor, decolletage, etc.) 3-Uncomfortable company in training classes (2 sessions and more)

Intervention groups

The experimental group, which includes pregnant mothers with a gestational age of at least 28 weeks pregnant, is divided into three groups of 15 and will be formed for each classroom group. The researcher, while introducing himself and expressing the objectives of the plan, will participate in the participation of the subjects There will be no intervention for the control group and

mothers will routinely visit hospitals for routine pregnancy care.

Main outcome variables

maternal and fetal attachment; mother's happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130710013940N5**

Registration date: **2019-02-02, 1397/11/13**

Registration timing: **prospective**

Last update: **2019-02-02, 1397/11/13**

Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

Marzieh Akbarzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4254

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akbarzadm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-14, 1397/11/25

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of attachment training on maternal and fetal attachment and happiness of Unintended pregnant women referring to selected hospitals of Shiraz University of Medical Sciences 1396

Public title

The effect of attachment training on the attachment of mother and son, and Shadkami

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Women Without Pregnancy 2. Failure to have mental disorders (psychosis, schizophrenia) 3. Ability to attend classes and complete the written consent form. 4. Earn a mental health score of less than 22 5. Lack of participation in any kind of educational class including physiological delivery

Exclusion criteria:

participation in any kind of educational class including physiological delivery

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description

By simple sampling, the subjects referred to the two medical centers that are eligible, are randomly divided into intervention and control groups. In this study, the allocation of people to the two groups was done using the permutation block method. Became In this method A represents the person receiving the intervention and B represents the individual in the group. The control is. Considering the quadruple block; the AABB code 0 reversal, to ABAB's permutation Code 1, to ABBA Code 2, to BAAB Code 3, to BBAA Code 4 and to BABA Code 5 to 9. Then use the random number table to select the starting point randomly, followed by 21. Consider the number as a row or column. Given the order of the table numbers, to any number We hit the corresponding permutation for it, for example, if the first three numbers of the random number table 1, 0 and 5, respectively. The order of receiving treatment by the first 12 people in two groups, respectively, was from left to Right ABABAABBBABA will be. So finally choose 21 of the table of the way Allocation of a total of 84 people will be

identified in two groups

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 Shiraz university of medical sciences

Street address

36 Zand street

City

Shiraz

Province

Fars

Postal code

7444135554

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.SUMS.REC.1397.100

Health conditions studied**1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

1.The percentage of attachment – fetal attachment in wanted pregnancy

Timepoint

Before the intervention , 2 weeks after the end of the training session

Method of measurement

Maternal Attachment Questionnaire

2**Description**

2.The percentage of attachment – fetal attachment in unwanted pregnancy

Timepoint

Before the intervention , 2 weeks after the end of the training session

Method of measurement

Maternal Attachment Questionnaire

3

Description

The percent of women's happiness in wanted pregnancy

Timepoint

Before the intervention , 2 weeks after the end of the training session

Method of measurement

Oxford Happiness Inventory,

4

Description

The percent of women's happiness in unwanted pregnancy

Timepoint

Before the intervention , 2 weeks after the end of the training session

Method of measurement

Oxford Happiness Inventory,

Secondary outcomes

empty

Intervention groups

1

Description

1. Intervention group Include pregnant mothers with a gestational age of at least 28 weeks in gestational age of at least 28 weeks divided into three groups of 15 and will be formed for each classroom group. The training sessions included in the intervention group include the importance of maternal and fetal attachment, maternal attachment outcomes And embryos during infancy, teaching how to develop mother and fetus attachment skills, teaching the effect of happiness on pregnancy, methods of creating happiness and its benefits for mother and baby, educating breastfeeding exclusively. Training sessions are 4 weeks and one week in a session. Before and after the intervention, maternal attachment questionnaire and happiness and general health were The researcher will be completed.

Category

N/A

2

Description

2.Control group Includes mothers who are not interrogated by the researcher and are used by the routine care of the hospital.At the same time as the intervention group, the beginning of the study phase and after 4 weeks of training, the intervention group at the end of week 38 will be considered for the attachment of mother to fetus and happiness and general health of the

control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Masomeh Kaviani

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2

Recruitment center

Name of recruitment center

Shooshtari Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Za'inab Hospital

Full name of responsible person

Masomeh Kaviani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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,Sakhtmtn Central University -, Next to the Red
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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

Shiraz 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
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Position
Midwife
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Person responsible for updating data

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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

The whole data information after being unidentifiable is shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and academic institutions

Under which criteria data/document could be used

To carry out more clinical trials and further advancement in this field

From where data/document is obtainable

To the email address below fahime.fati91@gmail.com or to the Vice-Chancellor for Research in Shiraz University of Medical Sciences.

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

Applying for yourself and your research work, the purpose of using the data is to indicate your contact number and address.

Comments