

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison study on the effectiveness of midwifery counseling with the cognitive-behavioral approach and logo therapy approach on mother-fetus attachment in pregnant women with an unwanted pregnancy.

Protocol summary

Study aim

Comparison of efficiency of midwifery counseling with cognitive-behavioral approach and logo therapy approach on maternal-fetus attachment in pregnant women with unwanted pregnancy

Design

The clinical trial has two intervention groups and one control group. Groups are parallel and double-blind. Each intervention group receives a separate psychological treatment. Accidental randomization is a randomized block with a sample size of 150 people.

Settings and conduct

This study is carried out on unwanted pregnancy women in the city of Kazeroon , based on available sampling and 150 people are selected. Then, based on random block size of 6, people are divided into three groups, two intervention groups, and one control group. The random assignment sequence is determined by the website. The study is Double blind . Blinding is done on the statistical analyzer and the leading researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria : unwanted pregnancy, low- risk pregnancy, pregnancy age 20-32 weeks, having at least a cycle qualification ,single pregnancy. Exit criteria: having a known mental illness , proven embryonic anomaly, having disabilities and mental retardation.

Intervention groups

In this study, there are three groups, including two intervention groups and one control group. First intervention group receives a logo therapy psychological treatment for four 90-minute sessions in addition to routine pregnancy care. The second group receives a cognitive-behavioral cognitive approach in four 90-minutes sessions of cognitive-behavioral therapy in addition to routine pregnancy care. The third group as a control group does not receive intervention but only receives routine pregnancy care.

Main outcome variables

Mother's attachment to the fetus in unwanted pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180415039311N1**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

Registration date

2019-06-12, 1398/03/22

Registrant information

Name

Somayeh Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4223 1943

Email address

hoseini.s@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-07, 1398/03/17

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison study on the effectiveness of midwifery counseling with the cognitive-behavioral approach and logo therapy approach on mother-fetus attachment in pregnant women with an unwanted pregnancy.

Public title
Comparison of the effectiveness of midwifery counseling with cognitive-behavioral approach and logo therapy approach to maternal-fetal attachment in pregnant women with unwanted pregnancy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Unwanted pregnancy Pregnancy age 20-32 weeks Low-risk pregnancy (mothers shouldnt suffer heart failure, kidney diseases and the diseases that prohibit pregnancy.) Having at least a cycle qualification Single pregnancy
Exclusion criteria:
 Having a known mental illness Proven embryonic anomaly Having disabilities and mental retardation

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

Gender
Female

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The statistical population is the pregnant women with unwanted pregnancy referring to the health centers of the city of Kazeroon. At first, 150 people are selected as the sample by available sampling. The selected individuals were randomly divided into three groups using a block size of 6 subjects. The random assignment sequence is determined by the website. N =50 individuals in the logo therapy group, and n = 50 in the cognitive behavioral group and n = 50 in the control group are replaced. Someone, other than the main intervener, assigns codes to individuals and allocates them to intervention and control groups based on the assignment sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
Pre-test questionnaires are filled out before being assigned to three groups , by a person who has no

knowledge of the groups and the treatment process . The post-test questionnaires should be filled out after intervention by someone other than the leading interventionist who is not aware of the group of people and treatment performed. We also do not inform the information analyst of the group of people and the type of intervention. The employees involved in the research are not aware of the group of people and the type of intervention in each group. There is no possibility of blinding for the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shahroud University of Medical Sciences
Street address
 Haft Tir
City
 Shahroud
Province
 Semnan
Postal code
 36147-73947
Approval date
 2019-03-16, 1397/12/25
Ethics committee reference number
 IR.SHMU.REC.1397.225

Health conditions studied

1

Description of health condition studied
 Mother's attachment to the fetus in unwanted pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Mother's attachment to the fetus
Timepoint
 Before and after intervention
Method of measurement
 Maternal Attachment Questionnaire to Embryonic Cranley

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: This group receives midwifery counseling with a logo therapy approach for four 90-minute sessions in addition to the routine midwifery care during pregnancy.

Category

Treatment - Other

2

Description

Intervention group: Second intervention group: This group receives a cognitive-behavioral midwifery counseling for four consecutive ninety-minute in addition to routine pregnancy care.

Category

Treatment - Other

3

Description

Control group: The third group only receives routine pregnancy care but does not receive any specific advice.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Kazeroon

Full name of responsible person

dr ali bahador

Street address

Taleghani

City

Kazeroon

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

dr Hasan Emamian

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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

Shahroud University of Medical Sciences

Proportion provided by this source

80

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

Shahroud University of Medical Sciences

Full name of responsible person

Zahra Motaghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Somayeh hoseini

Position

student

Latest degree

Master

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Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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