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-minute 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
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 shouldn't 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 intervener 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.

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

Health conditions studied

1

Description of health condition studied
Mother's attachment to the fetus in unwanted pregnancy

ICD-10 code

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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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
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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

Other areas of specialty/work
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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