

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of individual counseling on pregnancy loss grief intensity in mothers who referred to Shahid Motahari Educational Center in Urmia in 2018

Protocol summary

Study aim

Determining the effect of individual counseling on pregnancy loss grief intensity in mothers who referred to Shahid Motahari Educational Center in Urmia in 2018

Design

Clinical trial with control group with parallel nodes

Settings and conduct

Shahid Motahari Educational Therapy Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: losing pregnancy in a maximum of a week; the desire to participate in the study; being literate; speaking in Persian or Azeri; living in Orumiyeh city; mother's age of 18 to 39 years old; tending pregnancy; losing pregnancy at 8 weeks of pregnancy up to 28 days after childbirth; gain score less than 23 in GHQ28; phone access. Exclusion criteria: having mental illness and psychiatry; use of psychiatric drugs; experience a traumatic event, such as an accident or death, passed through 6 months; infertility history; the occurrence of a stressful incident during the implementation of the plan (such as the death of loved ones, separation from the spouse); getting pregnant again; abandonment of more than two-seated in counseling.

Intervention groups

A maximum six of individual counseling sessions will be held for the intervention group. The group will receive routine post-partum care or abortion care.

Main outcome variables

In the event of effective interventions to reduce the severity of mourning, frustration and difficult coping, and in general, the reduction in the severity of the loss of early and late pregnancy loss in mothers who have lost their pregnancy or earlier mothers' recovery. Mothers who do not receive interventions will be advised to provide advocacy interventions in the maternity care program with the loss of pregnancy by midwifery

counselors.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024340N13**

Registration date: **2018-08-14, 1397/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-14, 1397/05/23**

Update count: **0**

Registration date

2018-08-14, 1397/05/23

Registrant information

Name

Hamideh Mohaddesi

Name of organization / entity

Urmia University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4963

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of individual counseling on pregnancy loss grief intensity in mothers who referred to Shahid Motahari Educational Center in Urmia in 2018

Public title
The effect of individual counseling on pregnancy loss grief intensity in mothers

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Losing pregnancy in a maximum of a week The desire to participate in the study Being literate Mastery in Persian or Azeri Living in Orumiyeh Mother's age of 18 to 39 years old Wanting pregnancy Losing pregnancy at 8 weeks of pregnancy up to 28 days after childbirth Gain score less than 23 in GHQ-28 Phone Access
Exclusion criteria:
 Having mental illness and psychiatry, according to the mother Use of psychiatric drugs Experience a traumatic event, such as an accident or death, passed through 6 months Infertility history The occurrence of a stressful incident during the implementation of the plan (such as the death of loved ones, separation from the spouse) Getting pregnant again Abandonment of more than two-seated in counseling

Age
From **18 years** old to **39 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment by blocking method and using all possible combinations of AAABBB blocks. For each combination, a code will be allocated and 20 codes will be randomly selected. Then, with regard to the blocks corresponding to each code and the existing combinations, we will add people to the study.

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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Urjhans alley, Resalat Boulevard

City

urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

IR.UMSU.REC.437

Health conditions studied

1

Description of health condition studied

Grief

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

2

Description of health condition studied

Social-Family Scale Support

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

4

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

5

Description of health condition studied

depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

pregnancy loss grief intensity

Timepoint

At the beginning of the study and 4 weeks after the last consultation session

Method of measurement

Perinatal Grief Scale

Secondary outcomes

1

Description

Social support of family

Timepoint

At the beginning of the study and 4 weeks after the last consultation session

Method of measurement

Social support scale of the family

2

Description

Stress

Timepoint

At the beginning of the study and 4 weeks after the last consultation session

Method of measurement

Dass-42 Stress, Anxiety and Depression Questionnaire

3

Description

Anxiety

Timepoint

At the beginning of the study and 4 weeks after the last consultation session

Method of measurement

Dass-42 Stress, Anxiety and Depression Questionnaire

4

Description

Depression

Timepoint

At the beginning of the study and 4 weeks after the last consultation session

Method of measurement

Dass-42 Stress, Anxiety and Depression Questionnaire

Intervention groups

1

Description

Intervention group: for this group, a maximum of 6 individual consultation sessions will be held one hour a week and a weekly meeting will be held at the Motahari Educational Center of Urmia. During the follow-up, the researcher's telephone number will be provided to the intervention team, who will contact the counselor if necessary, and the researcher will send positive messages to the mothers during the intervention period.

Category

Other

2

Description

Control group: this group will receive routine care after childbirth or abortion.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational - Therapy Shahid Motahari Center

Full name of responsible person

Khatereh Oladbaniadam

Street address

Motahari hospital, Kashani Street

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Urmia

Province

West Azarbaijan

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57147

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Iraj Mohabbi

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Mohebi.i@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Khatereh Oladbaniadam

Position
Master's student in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Urmia University of Medical Sciences, college of Midwifery and Nursing

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Hamideh Mohaddesi

Position
Master Educated of Midwifery, Scientific Committee
Member of Nursing & Midwifery Faculty, Urmia

Latest degree

Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
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Position
Master's student in midwifery counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
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West Azarbaijan

Postal code
5756115111

Phone
+98 44 3275 4963

Email
oladbaniadam@gmail.com

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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Publishing research results in the form of article

publishing

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

Public

Under which criteria data/document could be used

Consultation and support program in health centers

From where data/document is obtainable

Hamideh Mohaddesi Contact number 00989143413242 E-mail: Mohaddesi.han@gmail.com

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

Login to Urmia University of Medical Sciences and search for thesis

Comments