

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

effect of counseling with a positive approach on the worries of pregnant women with a history of prenatal loss

Protocol summary

Study aim

Relieving pregnancy worries to help maintain the health of mothers with a history of fetal loss.

Design

From the Block method to volume 4 to create the allocation sequence - has two groups of control and intervention - is a parallel group - is double-blind - the total sample studied for both groups is 104 people.

Settings and conduct

By referring to the mother file by inviting telephone clients, the samples are finished. In order not to contact the intervention group with the control group, when invited to the introductory session, they are asked to refrain from contacting other pregnant mothers of Amir Semnan Hospital. The load is up to 4 sessions of 60 minutes. There are two blinds and the data collector completes the basic questionnaires for the participants before randomly assigning them. After the intervention, the questionnaires are completed by a person who is not aware of the group and the information analyst is not aware of the group of people.

Participants/Inclusion and exclusion criteria

: Age over 18-Normal pregnancy and non-high-risk pregnancy-Single-Ability to complete the questionnaire-Ability to speak Persian-History of abortion and stillbirth and infant death in previous pregnancy Exclusion criteria: mental disorder - addiction - any crisis of death of loved ones with physical illness in the last 6 months.

Intervention groups

Group intervention between 12 to 30 weeks of gestation with a history of fetal loss - Consultation with Seligman positivity approach - Pennsylvania questionnaire for screening for mental illness - Navidpor concern questionnaire for the intervention group Nutrition Consulting Control Group

Main outcome variables

The primary outcome is to measure the anxiety and happiness of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211030052913N1**

Registration date: **2021-11-25, 1400/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

Registration date

2021-11-25, 1400/09/04

Registrant information

Name

somaye ghods

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3332 8777

Email address

somayeghods@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-08, 1400/08/17

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of counseling with a positive approach on the worries of pregnant women with a history of prenatal loss

Public title

effect of positive approach on the worries

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant Women With a Gestational Age of 12 to 30 Weeks Pregnant Mother Over 18 Years Old Normal Pregnancy and High risk non Pregnancy Single History of Late Abortion- Still Birth or Infant Death In a Previous Pregnancy Ability to Complete The Questionnaire Ability to Speak Persian

Exclusion criteria:

The Arrival of Any Social Crisis Such As The Death Of a Loved One Incidence Of Physical Problems and Serious Illness In The Last Six Months

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

For Randomization The Block Method With Volume 4 Was Used To Create The Allocation Sequence; With Envelopes Were Used To Hind The Sequence; Each Sequence Is Placed Inside a White Envelope and The Envelopes Are Placed Side By Side; Each Envelope Is Numbered; An Envelope Is Opened For Each Person In The Order Of Their Entry In To The Study And Is Assigned To The Desired Group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Gather Information to Blind The Individual Before Assigning Individual to Groups Basic Questionnaires Are Completed For Participants; After Interference 'It Is Done By a Person Who Is Not Aware Of The Group; The Data Analyst Is Also Not From The Study Group; Participants Are Trained And Fill Out Informed Consent Forms; They Know Their Group From The Beginning.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Shahrod University of Medical Sciences

Street address

No.1-90, Sixth Street, Abozar Blvd,semnan Town

City

semnan

Province

Semnan

Postal code

3516878457

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.SHMU.REC.1400.156

Health conditions studied**1****Description of health condition studied**

Investigation of Concerns In Pregnant Women With a History Of Fetal Loss

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The Primary Outcome Is To Measure The Anxiety And Happiness Of Pregnancy

Timepoint

In the intervention group, a positive counseling program will be performed during one month. At the end of one month, the mothers' concern will be measured again using a questionnaire.

Method of measurement

First, Dr. Navidpour's anxiety questionnaire and Seligman positivity questionnaire and for screening patients with mental disorders, the Pennsylvania questionnaire will be provided to mothers with inclusion criteria.

Secondary outcomes**1****Description**

There Is No Secondary Variable

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: Pregnant Women With a History of Fetal Loss-The intervention is a group and lasts from 12 to 30 weeks of pregnancy and counseling sessions once a week for four weeks for 60 to 90 minutes. For screening patients with mental disorders before random allocation, along with the Pregnancy Concern Questionnaire, the Pennsylvania Questionnaire is given so that patients with mental disorders can be isolated and only mothers with pregnancy concerns can be included in the study.

Category

N/A

2

Description

Control group: The control group will receive 4 sessions of nutrition training during pregnancy and counseling sessions will be held in groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir al momenin Hospital

Full name of responsible person

somaye ghods

Street address

No.90-1;Sixth Street; Abozar Blvd

City

Semnan

Province

Semnan

Postal code

3516878457

Phone

+98 23 3332 8777

Email

somayeghods@yahoo.com

Web page address

<https://fa.irct.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Emamion Mohamad Hasan

Street address

No.90-1;Sixth Street; Abozar Blvd

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Email

Somayeghods@yahoo.com

Web page address

<https://fa.irct.ir>

Grant name

-

Grant code / Reference number

0

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

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

Shahroud University of Medical Sciences

Full name of responsible person

somaye ghods

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Somaye ghods

Position

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Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Somaye ghods

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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

Data Can Be Shared After People Are Not Identified

When the data will become available and for how long

Access Period Starts 6 Months After The Results Are Published

To whom data/document is available

All Employed and Students In Academic Institutions and Pregnant Women

Under which criteria data/document could be used

To Reduce The Anxiety Of Pregnant Women With Fetal Loss Problems To Help Them Reduce Anxiety And Get Pregnant

From where data/document is obtainable

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

Comments
