

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of life skills training on pregnancy anxiety in pregnant women over 30 years old

Protocol summary

Study aim

Effect of life skills training on pregnancy anxiety in pregnant women over 30 years old

Design

The intervention group was 39 and in the non-intervention group was 39. With a 10% drop, there would be 43 in each group. (86 people in total).

Settings and conduct

Abadan health centers were randomly selected from 6 clinics. 3 clinics as intervention group and 3 clinics as control group. 180 questionnaires were given to pregnant women referred to these clinics. Of the total women, only 86 who received a pregnancy anxiety score of 280 - 160 from the Wendenberg Pregnancy Anxiety Scale were selected for the intervention group (43) - control (43)

Participants/Inclusion and exclusion criteria

Women over 30 years old; pregnant women after the first trimester; pregnancy anxiety diagnosis based on Wendenberg questionnaire with pregnancy anxiety score between 160 - 280; minimum literacy reading; willingness to participate in the project and having written consent; not receiving psychiatric treatment or other medication (at least one month before the study) for anxiety-related problems Exclusion criteria: diagnosed cases of mental disorders; diagnosis of death of a loved one in the last 6 months; history of drug use affecting mental health

Intervention groups

Based on the inclusion criteria, the intervention group was divided into 5 groups, each consisting of 3 to 4 persons. Life skills training sessions lasted 2 sessions per week and each session lasted 2 minutes. During these sessions, life skills were taught to pregnant women. The control group again completed the Vandenberg Pregnancy Anxiety Questionnaire after 6 weeks without any training.

Main outcome variables

Life skills training; pregnancy anxiety

General information

Reason for update

Acronym

LSTAP

IRCT registration information

IRCT registration number: **IRCT20191001044945N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Fateme Hassanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5335 2505

Email address

fatemehasanpoor50@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-13, 1398/01/24

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-08-22, 1398/05/31

Trial completion date

2019-08-22, 1398/05/31

Scientific title

Effect of life skills training on pregnancy anxiety in pregnant women over 30 years old

Public title

The effect of life skills training on pregnancy anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women over 30 years old Pregnant women after the first trimester Diagnosis of pregnancy anxiety based on Wendenberg questionnaire with pregnancy anxiety score between 160-280 Minimum literacy Willingness to participate in the study and obtain written consent Not receiving psychotherapy or other medication concurrently (at least one month before the study) for anxiety-related problems

Exclusion criteria:

Diagnosed cases of mental disorders Detection of a loved one's death in the last 6 months A history of taking drugs that affect mental health

Age

From **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **43**

Actual sample size reached: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

After receiving the code of ethics and obtaining a license from Ahvaz Jundishapur University of Medical Sciences, Abadan University of Medical Sciences, six clinics were randomly selected by submitting it to Abadan clinic centers and bases. Pregnant women referred to 3 clinics as intervention group and 3 clinics as control group were included in the study. These centers were selected from health centers of the three socio-economic zones of Abadan city, 2 centers from each district. Thus, two centers were selected from the prosperous area, 2 medium and 2 low, and each center was assigned one intervention group and one control group. The specimens were examined by referring to existing system files and then by telephone or in-person referral to clinics and the inclusion criteria were assessed. Then, 180 questionnaires were given to pregnant women referring to these clinics, who were eligible for inclusion in the study, Wendenberg Pregnancy Anxiety Questionnaire. The researcher received written informed consent in an individual interview with each pregnant mother after introducing herself and providing a fuller description of the aims and method of study of the participant with inclusion criteria and assurance of confidentiality. After explaining how to complete the questionnaires, at the same place the questionnaire was completed by pregnant women and only 86 women out of all women

who had received the Wendenberg Anxiety Inventory completed pregnancy anxiety scores between 280 and 160 for the intervention group (43). - Control (43) subjects were selected

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 Ahvaz jundishapur University of Medical Sciences

Street address

University City, Ahvaz Jundishapur University of Medical Sciences and Health Services Vice Chancellor for Research and Technology, ground floor- zip code: 15794-61357

City

Abadan

Province

Khouzestan

Postal code

15794-61357

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJUMS.REC.1398.026

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

Pregnancy Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Pregnancy anxiety score based on Vendenberg Pregnancy Anxiety Questionnaire PRAQ

Timepoint

Before intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The present quasi-experimental study consists of three parts: pre-test, intervention and post-test. When the initial questionnaires were completed by pregnant women. Based on the inclusion criteria, the intervention group was divided into 5 groups, each consisting of 3 to 4 persons, and for each group, life skills training was conducted separately by the researcher in a face-to-face workshop. In the life skills training sessions, the researcher first obtained information through question and answer, group discussion, brainstorming from mothers' knowledge and attitudes about those topics, and then through lecture methods and PowerPoint presentations to better understand her topics. The session was offered to pregnant mothers, and each training session was organized as a workshop with the participation of pregnant women. It should be noted that in order to make the training more effective and effective, and taking into account the specific circumstances of the pregnant women during the week, virtual training was provided in the WhatsApp groups. These tutorials included relaxation exercise videos, reviewing the content of each session in the form of videos, photos and audio recorded by the researcher, PowerPoint Educational, which provided fun and enjoyable moments for mothers. Life skills training sessions lasted 2 sessions per week and each session lasted 2 minutes. Pregnant women were taught life skills (self awareness, problem solving skills, stress control, emotion control, communication skills, and interpersonal relationships). Then, in the sixth session, the Vandenbergh Pregnancy Anxiety Questionnaire was completed by the intervention group.

Category

Behavior

2

Description

Control group: The control group completed Vendenberg Pregnancy Anxiety Questionnaires after 6 weeks without receiving any training and then ethically trained and given virtual training videos, relaxation exercise videos and songs for moral control. Calming and PowerPoint tutorials were provided in the form of a DVD.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

6 Abadan Health Center

Full name of responsible person

Fateme Hasanpoor

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No 16, Dr. Mohammadi, Doctors' Home, 17 Shahrivar Hospital, Shoteite

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Karandish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojgan Javad Noori

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of the confidentiality of the information

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

Not applicable

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