Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of two intervention programs, social support and integration with the health locus of control on decreasing of depression during pregnancy

Protocol summary

Summary

Prenatal depression is a significant predictor of postpartum depression and is detrimental to fetal development. According to the World Health Organization, depression is a leading cause of disability among women worldwide. The aim of this study is determine the comparing the effectiveness of two intervention programs, social support and integration with the health locus of control on decreasing of depression during pregnancy. Method: This study is a quasi-experimental study on 108 pregnant women in the third trimester, have been referred to health centers. Samples through a stage stratified random sample selected were divided into two groups. Educational intervention based on social support and integration with the health locus of control was 6 sessions for each group. After the first test (immediately after the intervention) and after the second test (one month after the end of treatment) was conducted to review the results.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428773N1**
Registration date: **2016-08-07, 1395/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-07, 1395/05/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Gonabad University of Medical Sciences

Expected recruitment start date

2014-03-22, 1393/01/02

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of two intervention programs, social support and integration with the health locus of control on decreasing of depression during pregnancy

Public title

Two intervention programs, social support and integration with the health locus of control on decreasing

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 26-32 weeks; ability to read and write; healthy fetus on ultrasound; aged 18 to 35 years old; lack of depression known in life; absence of pregnancy complications (bleeding, placenta previa,

etc.); consent to participate in the study sample. Exclusion criteria: preterm delivery during the intervention; serious physical and psychological problems such as death of a family during the intervention; lack of participation in training courses for more than two sessions; unwillingness to continue participation in the study subjects.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Imam Khomeini Street

City

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Postal code

96917937180

Approval date

2014-08-03, 1393/05/12

Ethics committee reference number

GMUIRC.1392.61

Health conditions studied

1

Description of health condition studied

Depression during pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Depression during pregnancy

Timepoint

Immediately and one month later after intervention

Method of measurement

Edinburgh Postnatal Depression Scale (EPDS), Multidimensional Health Locus of Control Scales (MHLCS), Vaux

Secondary outcomes

1

Description

Support and health control beliefs

Timepoint

Immediately after the intervention

Method of measurement

Questionnaire Edinburgh Postnatal Depression Scale (EPDS) ,Multidimensional Health Locus of Control Scales (MHLCS), Vaux

Intervention groups

1

Description

In this study, women who were pregnant in the months 26 to 37 urban health centers for routine examination, enrolled by stratified random. Subjects with inclusion criteria were randomly divided into two groups 1 and 2 were tested. After obtaining permission from the relevant authorities and the satisfaction of the samples, questionnaires on demographic, social support and depression Edinburgh HLC theory was completed by the patients. Subjects were also declared that in case of dissatisfaction and lack of willingness to cooperate can quit the application and announce their withdrawal. The data obtained from the pre-test, the information required to prepare an intervention plan was reviewed and analyzed. The intervention began, according to the results. Test 1 and Test 2 groups of 12 to 15 were divided into categories. Average number of sessions 6 sessions per week a meeting was held for each subgroup. Researcher with intimate relationships among pregnant women, their husbands' partnership (holding the first training session for their wives at the start of treatment), and social support did. Topics include theory HLC for your understanding, problem solving skills, decision making, self-confidence and self-esteem, assertiveness, self-efficacy and ..... education was discussed. It is important to note that the research program was set up and run that the intervention sessions in order to enhance social protection and health locus of control theory was pregnant.

Category

Lifestyle

2

Description
After the intervention and post-test, the control group was planning education programs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Public health centers affliated toGonabad University of Medical Sciences and Health Services
Full name of responsible person
Dr. Moshki
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Sponsors / Funding sources

1

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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
Gonabad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty