

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of educational program on Health-promoting behaviours pregnant women , application of “self-efficacy theory “

Protocol summary

Summary

The present study is an intervention research from quasi-experimental type. In order to investigate the effect of an educational program on health promoting behaviors among pregnant women by self-efficacy theory in Mahshahr city . In this study, the effect of the independent variable (training program) on dependent variables (stress, physical activity and self-efficacy) will be examined. Considered group is included 78 pregnant women at 12 - 16 weeks gestational age (divided into two groups: 39 people in control group and 39 people in intervention group). Direct educational intervention is done in 5 sessions of 1 hour in 2 days of week. A pre-test and post-test is held one month after the educational intervention. To collect data, a valid questionnaire is used which are included demographic variables, the Persian edition of health-promoting lifestyle profile, symptoms of depression, anxiety and stress, physical activity in pregnancy period and a prepared questionnaire based on the theory of self-efficacy which is completed by pregnant women in both groups before and 1 month after the end of educational intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015073015015N12**

Registration date: **2015-09-07, 1394/06/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-07, 1394/06/16

Registrant information

Name

Leila Ghahremani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

ghahramanl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences (SUMS)

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational program on Health-promoting behaviours pregnant women , application of “self-efficacy theory “

Public title

The effect of educational program on Health-promoting behaviours pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women at 12 - 16 weeks gestational age; interest of volunteers for participating in this study; have a pregnancy without risk and no evidence of disease; at least secondary school education without speech or accent problems Exclusion criteria:

having more than one session absences in classes;
inaccessibility of pregnant women when completing the questionnaire.

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Street,-headquarters Shiraz University of
Medical Sciences, Shiraz

City

Shiraz

Postal code

71345-2307594

Approval date

2015-07-05, 1394/04/14

Ethics committee reference number

IR.SUMS.REC.1394.61

Health conditions studied

1

Description of health condition studied

health-promoting lifestyle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health-promoting lifestyle

Timepoint

Pretest- posttests one month after the intervention

Method of measurement

HPLP Questionnaire

Secondary outcomes

1

Description

Stress

Timepoint

pretest-posttest one month after the intervention

Method of measurement

DASS Questionnaire

2

Description

Pregnancy Physical Activity

Timepoint

pretest-posttest one month after the intervention

Method of measurement

Pregnancy Physical Activity Questionnaire

Intervention groups

1

Description

The control group do not recived any training

Category

Other

2

Description

Direct intervention in 5 sessions of 1 hour for two sessions per week for pregnant women in the intervention group at the end of each session was carried out. The training program, group discussion and Q & A was assigned.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Care Center No.1

Full name of responsible person

Street address

City

Mahshahr

2

Recruitment center

Name of recruitment center

Health Care Center No.2

Full name of responsible person

Street address

City

Mahshahr

3

Recruitment center

Name of recruitment center

Health Care Centers Rah-e Zeinab

Full name of responsible person

Street address

City

Mahshahr

4

Recruitment center

Name of recruitment center

Health Care Center No.3

Full name of responsible person

Street address

City

Mahshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences (SUMS), Shiraz, Iran

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

zand street -Shiraz University of Medical Sciences (SUMS), Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences (SUMS), Shiraz, Iran

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

Contact

Name of organization / entity

School of Health, Shiraz University of Medical Sciences (SUMS), Shiraz, Iran

Full name of responsible person

Dr Leila Ghahramani

Position

Assistant Professor, School of Public Health, Shiraz University of Medical Sciences

Other areas of specialty/work

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Web page address**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