

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of intervention based on ecological and educational diagnosis phase of PRECEDE_PROCEED model for promoting quality of life in headed household women

Protocol summary

Summary

Aim of the study is determination of the effect of intervention based on PRECEDE- PROCEED model for promoting quality of life in headed household women. Inclusion criteria is being household woman and working in Tehran Welfare Organization and Exclusion criteria is not being household woman more and stop working in Tehran Welfare Organization. Target is household women who work in Tehran Welfare Organization. Sample size is 180 headed household women. Collection tools were a researcher made questionnaire based on ecological and educational diagnosis phase of PRECEDE_PROCEED model (predisposing, enabling and reinforcing factors) and quality of life WHO standard questionnaire. In first stage, questionnaires will be filled in two groups in their work places. Then an intervention will be planned based on analysis of the data. Intervention consists 10 educational sessions. Duration of each session is 45 minutes and teaching methods will be lecture, group discussion, question and answer, counseling. Educational materials are a blog, a CD and a leaflet. Intervention will be done in case group workplace which each group consist 10 people. In second stage, one month and three months after intervention, questionnaires will be filled again. Data will be analyzed and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012115650N4**

Registration date: **2015-03-13, 1393/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-13, 1393/12/22

Registrant information

Name

Mahnaz Solhi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 9928

Email address

solhi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and Technology, Iran University of medical Sciences

Expected recruitment start date

2015-02-21, 1393/12/02

Expected recruitment end date

2016-02-21, 1394/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intervention based on ecological and educational diagnosis phase of PRECEDE_PROCEED model for promoting quality of life in headed household women

Public title

Intervention based on PRECEDE_PROCEED model for

promoting quality of life in headed household women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: The women are headed households and work in Tehran welfare organization exclusion criteria: Sample not be a headed households woman and don't work in Tehran welfare organization more

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Iran University of Medical Sciences

Street address

Ethics Committee, Iran University of Medical Sciences, near Milad Hospital, Hemmat highway

City

Tehran

Postal code

1471613151

Approval date

2014-09-29, 1393/07/07

Ethics committee reference number

93-03-27-25123

Health conditions studied

1

Description of health condition studied

Quality of life

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Quality of life

Timepoint

Before intervention, one month after intervention and three months after intervention

Method of measurement

WHOQOL - BREF questionnaire

2

Description

Quality of life

Timepoint

Before intervention, one month after intervention and three months after intervention

Method of measurement

WHOQOL - BREF questionnaire

Secondary outcomes

1

Description

Physical Health

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

WHOQOL - BREF questionnaire

2

Description

Mental Health

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

3

Description

Social Health

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

4

Description

Environmental Health

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

5**Description**

Knowledge

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

6**Description**

Attitude

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

7**Description**

Enabling factors

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

8**Description**

Reinforcing factors

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

9**Description**

Behavioral causes

Timepoint

Before intervention, one month after intervention, three months after intervention

Method of measurement

Researcher made questionnaire

Intervention groups**1****Description**

Intervention in control group: No intervention will be done in control group.

Category

N/A

2**Description**

Intervention in case group: It consists 10 educational sessions. Duration of each session is 45 minutes and teaching methods will be lecture, group discussion, question and answer, counseling. Educational materials are a blog, a CD and a leaflet. Intervention will be done in case group workplace which each group consists 10 persons.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Enghelab Welfare Center

Full name of responsible person

Marzieh Shabani

Street address**City**

Tehran

2**Recruitment center****Name of recruitment center**

Hor Welfare Center

Full name of responsible person

Marzieh Shabani

Street address**City**

Tehran

3**Recruitment center****Name of recruitment center**

Rahe Woo Welfare Clinic

Full name of responsible person

Marzieh Shabani

Street address**City**

Tehran

4**Recruitment center****Name of recruitment center**

Behravesht Clinic

Full name of responsible person

Marzieh Shabani

Street address**City**

Tehran

5

Recruitment center

Name of recruitment center

Seddighin Charity Center

Full name of responsible person

Marzieh Shabani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research and technology

Full name of responsible person

Dr. Syyed Ali Javad Moosavi

Street address

Near Milad Hospital, Iran University of Medical Sciences, Shahid Hemmat highway, near Milad Hospital

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for research and technology

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

Department of Health services and Health Education ,
School of Health, Iran University of Medical Sc

Full name of responsible person

Mahnaz Solhi

Position

PhD in Health Education and Health
Promotion/Associate Prof.

Other areas of specialty/work

Street address

Shahid Hemmat highway, near Milad Hospital

City

Tehran

Postal code

Phone

+98 21 8670 4817

Fax

Email

solhi.m@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Health Services and Health Education,
School of Health, Iran University of Medical Sci

Full name of responsible person

Mahnaz Solhi

Position

Associate Prof./PhD in Health Education and Health
Promotion

Other areas of specialty/work

Street address

Shahid Hemmat highway, near Milad Hospital

City

Tehran

Postal code

Phone

+98 21 8670 4817

Fax

Email

solhi.m@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Health Services and Health Education,
School of Health, Iran University of Medical Sci

Full name of responsible person

Mahnaz Solhi

Position

Associate Prof./ PhD in Health Education and Health
Promotion

Other areas of specialty/work

Street address

Shahid Hemmat, near Milad Hospital

City

Tehran

Postal code

Phone

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Fax

Email

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