

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of implementing Orem's self care model on the depression in elderly referred to Shiraz Education and Training Retirees Association

Protocol summary

Summary

This study is an interventional study with a pre- post, and follow up test control group design. Goal of the study: Effect of implementing Orem's self care model on the depression in elderly referred to Shiraz Education and Training Retirees Association. Sampling methods: Sample size is determined as 66 and participants are randomly assigned into case and control groups (two groups of 33 each). After obtaining informed consent, the qualified geriatrics are requested to fill in the questionnaires of assessment based on Orem's model as well as depression questionnaire. After data-gathering and indicating every one's need, (independent, partly independent, dependant) according to assessment questionnaires, patients of severe depression are referred to psychoanalyst. Those patients having mild and moderate depression will be randomly placed in two groups of case and control. In the first group, self-care educational programs will be performed based on Orem model while in control group, no intervention will take place. Data are completed and analyzed by case and control group in 3 stages, prior to intervention (week zero), right after the last session of educational programs (fourth week) and two months later (twelfth week).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052715426N3**

Registration date: **2014-07-08, 1393/04/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-08, 1393/04/17

Registrant information

Name

Maryam Hazrati

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Expected recruitment start date

2014-06-10, 1393/03/20

Expected recruitment end date

2014-10-11, 1393/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of implementing Orem's self care model on the depression in elderly referred to Shiraz Education and Training Retirees Association

Public title

Effect of implementing Orem's self care model on the depression in elderly referred to Shiraz Education and Training Retirees Association

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age more than 60years old; having no

recognition disorder (Dementia, Alzheimer disease); having physical capabilities for participation in the research; signing informed consent form; having mild or moderate depression grade based on GDC scale. Exclusion criteria: having severe depression and grade 12-15 based on Geriatric Depression Scale; consuming antidepressants drugs and anti-anxiety while intervention; absence more than 2 sessions; participation simultaneously in consultation sessions and complement treatment (Yoga, Meditation and so on).

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Blvd.

City

Shiraz

Postal code

Approval date

2014-06-09, 1393/03/19

Ethics committee reference number

CT-9378-7038

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Depressive episode, unspecified

Primary outcomes

1

Description

Reducing depression

Timepoint

Prior to intervention, right after the last session of educational programs and two months later

Method of measurement

Questionnaire of assessment based on Orem's model, depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Elderlies of intervention group will participate in a 7 session educational programs of 60-90 minutes during one month (4 weeks) at least twice a week. Group sessions include take self care in time of facing hurtful physical factors, exercise, social and inter-personal relationships and prevention of anxiety and depression. And individual sessions include observing drug and food diet. For educational courses, lecturing and group discussion using power-points and practical exercises will be used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Education and Training Retirees Association

Full name of responsible person

Javad ostovar

Street address

Beside Moade, Poschi st.I

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice Chancellor

for Research Affairs

Full name of responsible person

Dr. Baser Hashemi

Street address

Shiraz University of Medical Sciences, Vice Chancellor
for Research Affairs, Zand Ave.

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, Vice Chancellor for
Research Affairs

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

Fatemeh Collage of Nursing and Midwifery (P.B.U.H)
Shiraz

Full name of responsible person

Sara Ghaedi

Position

MS candidate of Geriatric Nursing

Other areas of specialty/work

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Full name of responsible person

Maryam Hazrati

Position

Candidate of PhD Institute of Gerontology UPM
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Other areas of specialty/work

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Person responsible for updating data

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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