

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Design and evaluation of an interventional education model on happiness, inner strength and mental health of women; Appropriate framework

Protocol summary

Summary

The purpose of this study was to design and evaluation of an educational intervention in the field of happiness, inner strength and mental health of women then proposed a proper model. Inclusion criteria: middle-aged women referred to health houses of the municipalities who do not suffer from mental illness and mood disorders. Exclusion criteria: mood disorders, anxiety and depression and other disorders that lead to a lack of appropriate participation and more than two sessions absence during educational sessions. The study population was women aged 60-40 years referred to health houses of Tehran and the sample size was 200 people. This study is a randomized clinical trial and case-control; include the educational programs based on model, and carried out to determine the effect of interventional education based on fitted model to enhance the mental health of women referred to health houses in Tehran during two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052522404N1**

Registration date: **2016-11-08, 1395/08/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-08, 1395/08/18

Registrant information

Name

Samaneh Zanjani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 6351

Email address

s_zanjani@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, International Campus

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of an interventional education model on happiness, inner strength and mental health of women; Appropriate framework

Public title

interventional education model on happiness, inner strength and mental health of women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: The middle-aged women referred to municipality health house; Age 40-60 years; The alertness and reluctant to express their inner feelings about the concept studied; The lack of diagnosed

psychiatric and mood disorders and cognitive disorders; The lack of exposure to a particular case or the accident which led to has been the psychological trauma in the past 6 months; Desire and satisfaction to participate in the study; Having certain and available address and phone number for follow-up. Exclusion criteria: Items such as mood disorders, anxiety, depression and other disorders that lead to a lack of appropriate participation; Having a psychiatric history; Using drugs for psychiatric disorders; The loss of a close person during the study; Unwillingness to participate voluntarily in the study by filling out the questionnaire incomplete; More than two sessions Absence during the training sessions.

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

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

Tehran University of Medical Sciences and Health Services

Street address

School of Public Health and Institute of Health Research, Health Education and promotion department, Poorsina Ave, 16 Azar Ave

City

Tehran

Postal code

Approval date

2015-05-10, 1394/02/20

Ethics committee reference number

IR.tum.rec.1394.133811

Health conditions studied

1

Description of health condition studied

Mental Health

ICD-10 code

Z00.4

ICD-10 code description

General psychiatric examination, not elsewhere classified

Primary outcomes

1

Description

Happiness

Timepoint

Before the intervention, immediately after the end of intervention and six months after intervention

Method of measurement

questionnaire

2

Description

inner strength

Timepoint

Before the intervention, immediately after the end of intervention and six months after intervention

Method of measurement

questionnaire

3

Description

Mental Well-being

Timepoint

Before the intervention, immediately after the end of intervention and six months after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Case Group: Educational programs in the field of mental health promotion by lecture, group discussion and problem solving methods, Receive training package included pamphlets and CD

Category

Other

2

Description

Control Group: Receive training package included pamphlets and CD after the post-test

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghezel Ghale Health House

Full name of responsible person

Amineh Parandlo

Street address

Ghezel Ghale Health House, 15th Street (Shahid Azizi), Jahanara Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-President for Research Affairs, International Campus, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Hadian

Street address

Office of Vice-President for Research Affairs, Number 124 , Baradaran-e-Mozaffar St., Dameshgh St., Vali-e Asr Ave., Tehran 3439123900, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-President for Research Affairs, International Campus, Tehran 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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roya Sadeghi

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health and Institute of Health Research, Health Education and promotion department, Poorsina Ave, 16 Azar Ave

City

Tehran

Postal code**Phone**

+98 21 8895 5888

Fax**Email**

sadeghir@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Davood Shojaizadeh

Position

Professor

Other areas of specialty/work**Street address**

School of Public Health and Institute of Health Research, Health Education and promotion department, Poorsina Ave, 16 Azar Ave

City

Tehran

Postal code**Phone**

+98 21 4293 3211

Fax**Email**

Shojaei@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Samaneh Zanjani

Position

Health education MS

Other areas of specialty/work**Street address**

School of Public Health and Institute of Health Research, Health Education and promotion department, Poorsina Ave, 16 Azar Ave

City

Tehran

Postal code**Phone**

00

Fax**Email**

zanjani.samaneh@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty