

# 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

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##### 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

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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Professor

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**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*