

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### the effect of laughter by Katarya method on depression of elderly residing at nursing homes for the elderly and disabled in Rasht city

#### Protocol summary

##### Summary

This study is a clinical trial aimed to determine the effect of laughter by Katarya method on depression of elderly residing at nursing homes for the elderly and disabled in Rasht city. Sample consisted of 94 elderly patients with mild and moderate depression selected by random sampling method from elderly residing at nursing home. The samples were divided into two groups of experiment (47 patients undergoing laughter therapy program) and control (47 patients with routine care). Inclusion criteria: age 60 years and older, living full-time at nursing home, no history of admittance to psychiatric wards, lack of grief experience during the past six months, residing at nursing home for at least six months, no serious health condition, no surgery in past three month, no history of heart disease, chest pain or open heart surgery, no simultaneous participation in clinical trial, earning depression scale score between 5 and 11, physical ability to participate in the study, interested in participating in the study and signing a consent form. Exclusion criteria: lack of personal interest to participate in any stage of study. Data will be gathered using a 2-part tool consisting of demographic information and geriatric depression questionnaire by interview method. Data will be gathered in two stages of pre intervention and one month after the laughter therapy program. Laughter therapy program by Katarya method will be conducted for 30 minutes twice a week for 5 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091424003N2**

Registration date: **2015-10-30, 1394/08/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-30, 1394/08/08

##### Registrant information

###### Name

Shahla Asiri

###### Name of organization / entity

Gilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 133555056

###### Email address

shahlaasiri@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Gilan University of Medical Sciences

##### Expected recruitment start date

2015-10-23, 1394/08/01

##### Expected recruitment end date

2016-01-05, 1394/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

the effect of laughter by Katarya method on depression of elderly residing at nursing homes for the elderly and disabled in Rasht city

##### Public title

The effect of laughter on the depressed elderly

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: age 60 years and older, living full-time at nursing home, no history of admittance to psychiatric wards, lack of grief experience during the past six months, residing at nursing home for at least six months, no serious health condition, no surgery in past three months, no history of heart disease, chest pain or open heart surgery, no simultaneous participation in clinical trial, earning depression scale score between 5 and 11, physical ability to participate in the study, interested in participating in the study and signing a consent form. Exclusion criteria: lack of personal interest to participate in any stage of study.

#### Age

From **60 years** old to **139 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **94**

#### 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

Gilan University of Medical Sciences

##### Street address

Daneshjoo st., Shahid Beheshti ring way, Rasht

##### City

Rasht

##### Postal code

4146939814

#### Approval date

2015-08-24, 1394/06/02

#### Ethics committee reference number

IR.GUMS.REC.1394.206

## Health conditions studied

### 1

#### Description of health condition studied

DEPRESSION

#### ICD-10 code

F32.0

#### ICD-10 code description

Mild depressive episode

## Primary outcomes

### 1

#### Description

DEPRESSION

#### Timepoint

Before the intervention and one month after the end of intervention

#### Method of measurement

Questionnaire Geriatric Depression Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

without any intervention on the control group

#### Category

Other

### 2

#### Description

Laughter therapy program by Katarya method will be conducted for 30 minutes twice a week for 5 weeks. Training program includes performing breathing and physical exercises as well as laughter techniques.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Homes for the Elderly and Disabled in Rasht

##### Full name of responsible person

Shahla Asiri

##### Street address

Esteghamat 2 St., Malolin St., Shivan Fomani Blvd

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Social Determinants Of Health Research Center,

Guilan University Of Medical Science,Rasht,Iran.

**Full name of responsible person**

Abtin Heidar zadeh

**Street address**

Social Determinants Of Health Research Center,  
Shahid Beheshti Nursing & Midwifery College,  
Daneshjoo Street, Shahid Beheshti Bolv.

**City**

Rasht

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Social Determinants Of Health Research Center, Guilan  
University Of Medical Science,Rasht,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**

Social Determinants Of Health Research Center, Gilan  
University Of Medical Science, Rasht, Iran.

**Full name of responsible person**

Shahla Asiri

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Social Determinants of Health Research Center,  
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**Position**

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**Street address**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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University Of Medical Science, Rasht, Iran

**Full name of responsible person**

Shahla Asiri

**Position**

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**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*