

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of fordyse happiness model on depression, anxiety and fatigue of multiple sclerosis patients

Protocol summary

Summary

This study was performed to investigate the effect of fordyce happiness model on depression, anxiety, stress, and fatigue of multiple sclerosis patients'. Design of this study was randomized clinical trial. The fordyce happiness program applied in trial group and then stress; anxiety; depression; and fatigue questionnaires completed before and after intervention. Participants of this study included patients and their families that had the main inclusion criteria such as enabling read and write; having age range between 18 - 60; and complete the informed consent and main exclusion criteria include having history of other diseases such as mental disorders include major depression (according to records of the patient and the treating physician) or bipolar disorder; addiction; other neurological disorders; and history of steroid use or relapse during the past 6 weeks. Educational intervention after obtained the consent form applied eight sessions (each sessions: ninety-minute) once a week in trial group and fourteen principle of fordyce happiness model were taught. Specified goals and tasks for each session and feedback was requested. The questionnaires includes demographic and DASS-21 questionnaire for depression, anxiety and stress and Piper for fatigue before and after the program education.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112420064N1**

Registration date: **2015-04-02, 1394/01/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-02, 1394/01/13

Registrant information

Name

Fereydoon Khayeri

Name of organization / entity

Iran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1000

Email address

khayeri.f@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of rehabilitation center of Tehran University of Medical Sciences

Expected recruitment start date

2013-05-15, 1392/02/25

Expected recruitment end date

2013-09-16, 1392/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fordyse happiness model on depression, anxiety and fatigue of multiple sclerosis patients

Public title

The effect of fordyse happiness model on depression, stress, anxiety and fatigue of multiple sclerosis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Main inclusion criteria include enabling read and write; having age range between 18 - 60 and complete the informed consent and main exclusion criteria include having history of other diseases such as mental disorders include major depression (according to records of the patient; and the treating physician) or bipolar disorder; addiction; other neurological disorders; and history of steroid use or relapse during the past 6 weeks.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

N/A

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

Ethic commite of Tehran University of Medical Sciences

Street address

Ethic commite of Vice chancellor of international spinsl cord research center of Tehran University of Medical Sciences, keshavarz Avenue, Imam Khomeini hospital, Reihane bulding, Tehran.

City

Tehran

Postal code

8196131489

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

125899

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Stress

Timepoint

Baseline; Imediately After; 2 months After

Method of measurement

DASS21 Standard Questionnaire

2

Description

Anxiety

Timepoint

Baseline; Imediately After; 2 months After

Method of measurement

DASS21 Standard Questionnaire

3

Description

fatigue

Timepoint

Baseline; Imediately After; 2 months After

Method of measurement

Piper Standard Questionnaires

4

Description

Depression

Timepoint

Baseline; Imediately After; 2 months After

Method of measurement

DASS21 Standard Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

6months After intervention

Method of measurement

SF-36 Standard Questionnaire

Intervention groups

1

Description

after obtaining the consent from from trial group, fordyce happiness program carried out in 8 sessions of 90

minutes once a week and happy principle taught with 14 element. Specified goals and tasks for each session and requested feedback from the people designed and followed during the program educating. During the meetings of audiovisual equipment and techniques were also used questions and answers.

Category

Behavior

2

Description

In the control group during the routine activities are follow-up and after the collection of questionnaires in in both groups, fordyce happiness program was taught in two sessions in the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Multiple Sclerosis Society

Full name of responsible person

Dr.Reza Masoudi

Street address

Number2, first flour, Behesht building, Alkarim Mosque, Bozorgmehr Avenue, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of rehabilitation center of Tehran University of Medical Sciences

Full name of responsible person

Abbas Norouzi Javidan

Street address

7flour, Vice chancellor for research, Tehran University of Medical Sciences, Tehran, Iran

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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 of rehabilitation center of 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

Freidoon Khayeri

Position

Lecturer, Exective member of Neuroscience Department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Dr.Reza Masoudi

Position

Assisstant Professor of Shahrekord University of Medical Sciences

Other areas of specialty/work

Street address

Ph.D in Nursing Education

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Full name of responsible person

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

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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