

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Evaluation of effectiveness of Neuro Linguistic Programming individual treatment on depression, anxiety, stress, quality of life and the course and severity of the disease in patients with relapsing-remitting multiple-sclerosis (RRMS): a Randomized Clinical Trial

#### Protocol summary

##### Study aim

Evaluation OF Effectiveness Of Neuro Linguistic Programming Individual Treatment On Symptom of Depression, Anxiety ,Stress and Quality Of Life, And Also On Proceeding And Severity On The Course Of Multiple Sclerosis in patients with Relapsing Remitting (RRMS) In a Randomized Clinical Trial

##### Design

This is a randomized phase 2 concurrent parallel clinical trial. Sina MS Clinic's sixty RRMS were selected and randomized into control and test groups and after pre test, they have individual NLP therapy sessions, after follow up post test will apply. Tests are DASS and MSQ-54 questionnaire and also Kurtzke Expanded Disability Status Scale and Magnetic Resonance Imaging according to this schedule: pre test, 6,12,18 months after first intervention and 24 months after first intervention as post test

##### Settings and conduct

MS Clinic in Sina Hospital, Tehran, Iran

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of relapsing-remitting MS, using Interferons, 20 to 40 years old, diagnosis of stress, anxiety and depression. Exclusion criteria: pregnancy or planning for it, having a history of Hospitalization due to psychiatric disorders, parallel psychotherapy session, cancer, diabetes, other nervous system disease

##### Intervention groups

Intervention group: 30 patients, 45 sessions: One hour individual intervention, sessions, The therapist's team consists of two masters of Neuro Linguistic Programming, Control group: 30 patients, without any intervention and with routine care,

##### Main outcome variables

Depression, Anxiety, Stress, Quality of Life, the course and severity of the disease in patients with MS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171217037917N1**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **retrospective**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

##### Registration date

2018-10-30, 1397/08/08

##### Registrant information

##### Name

Bahare Pourkiani

##### Name of organization / entity

Khatam university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2219 0588

##### Email address

mkhademi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-06-20, 1397/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of effectiveness of Neuro Linguistic Programming individual treatment on depression, anxiety, stress, quality of life and the course and severity of the disease in patients with relapsing-remitting multiple-sclerosis (RRMS): a Randomized Clinical Trial

**Public title**

The Effect of NLP Individual Psychotherapy On The Reduction Of Symptom Of Depression, Anxiety, Stress and Improving Quality of Life and Control of proceeding Disease on RRMS Patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of MS based on McDonald criteria by neurologist Type of MS (relapsing-remitting) Age range (20 to 40) years old Residing in Tehran Having the consent and commitment to attend the course of treatment Diagnosis of stress, anxiety and depression on DSM criteria by psychiatrist using of first-line drugs for the MS treatment: Interferons

**Exclusion criteria:**

pregnancy or planning for pregnancy having any type of psychotherapy session during this research having history of Hospitalization due to psychiatric disorders diagnosis of other psychiatric disorders according to DSM by a psychiatrist having cancer having diabetes Other diseases of the nervous system other than multiple sclerosis

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization: After announcement and filling the demographic forms, considering the include and exclude criteria and initial scores in Depression, Anxiety, Stress, Quality of Life and Course of the MS Disease, a total of 60 patients were selected according to a randomized table. Based on the random number table, 30 subjects were divided into two groups: 30 for control and 30 for test

**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 in research committee of medicine school of Tehran University of Medical Sciences

**Street address**

16th Azar St., Enghelab Sq., Tehran, Iran

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Tehran

**Province**

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**Postal code**

1417466191

**Approval date**

2017-12-30, 1396/10/09

**Ethics committee reference number**

IR.TUMS.REC

**Health conditions studied****1****Description of health condition studied**

Multiple sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis

**2****Description of health condition studied**

Anxiety

**ICD-10 code****ICD-10 code description****3****Description of health condition studied**

Depression

**ICD-10 code****ICD-10 code description****4****Description of health condition studied**

Stress

**ICD-10 code****ICD-10 code description****Primary outcomes**

## 1

### **Description**

Level of stress

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

DASS Questionnaire (Depression, Anxiety, Stress)

## 2

### **Description**

Level of anxiety

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

DASS Questionnaire (Depression, Anxiety, Stress)

## 3

### **Description**

Level of depression

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

DASS Questionnaire (Depression, Anxiety, Stress)

## 4

### **Description**

Disability Status

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

Kurtzke Expanded Disability Status Scale (EDSS)

## 5

### **Description**

quality of life

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

Multiple Sclerosis Quality of Life-54 (MSQOL-54) questionnaire

## 6

### **Description**

course of MS disease

### **Timepoint**

pre test and 6,12,18 months after start of treatment, and 24 months after first intervention as post test

### **Method of measurement**

MRI (Magnetic Resonance Imaging)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Experimental or intervention group: 30 patients, One hour individual therapy sessions, intervention: Neuro Linguistic Programming Therapy, 45 sessions: first 16 sessions are weekly, 18 sessions are twice a month and 11 sessions are monthly basis. The therapist's team consists of two masters of Neuro Linguistic Programming, evaluator team who examine the initial implications consist of a psychologist and a psychiatrist and a neurologist.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: 30 patients, without any intervention and with routine care, evaluator team who examine the initial implications consist of a psychologist and a psychiatrist and a neurologist (MS fellowship)

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sina Hospital

##### **Full name of responsible person**

Dr.Sahraian

##### **Street address**

Imam Khomeini ave.

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Tehran

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##### **Postal code**

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<http://www.sinahospital.tums.ac.ir>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Dr.Mohammad-Ali Sahraian

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**Grant name**

Research Grant

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

16

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Bahare Pourkiani

**Position**

researcher

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**  
due to ethics codes for psychotherapists and counselors

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available