Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 MSQL-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)

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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

City
Tehran

Province
Tehran

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 testT
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.Sahraiyan
Street address
Imam Khomeini ave.
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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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MS Clinic,Sina Hospital, Imam Khomeini Ave.
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Web page address
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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
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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