# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jul 2026

## Comparison of therapeutic effectiveness based on the analysis of lived experiences of social stigma with positive psychotherapy method in mental toighness, cognitive flexibility, distress tolerance and feeling of entrapment in patients with multiple sclerosis.

## Protocol summary


**Study aim**
Reducing the symptoms of multiple sclerosis and complementary therapies

**Design**
This clinical trial with a quasi-experimental design with control group on 45 patients used coin tossing method by an independent person to randomize the groups.

**Settings and conduct**
The method and place of study of this clinical trial was conducted in the Darya Psychology Clinic, under the supervision of the research department of the Isfahan faculty of Psychology. By calling through WhatsApp and also the clients of the supervisor professor, 45 eligible patients with MS who wished to participate were registered. Participants in two experimental groups of 15, underwent a 90 minutes session for 8 weeks as a group undergoing positive psychotherapy and treatment based on lived experiences of social stigma in patients with MS, while the control group which included 15 people, did not receive any therapy. In order to evaluate the effects of therapy, subjects were assessed before and after the therapy and one month after the intervention, respectively.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Diagnosis of MS by a specialist. Willingness and signing of written consent. Form of consent to participate in the research project. Not suffering from a severe physical illness, severe neurological disorders, or having symptoms of psychosis. Exclusion criteria: relapse of illness and inability to continue sessions absence of more than two sessions

**Intervention groups**
The intervention group includes patients with multiple sclerosis who have received a positive psychotherapy intervention. The intervention group includes patients with multiple sclerosis who have received treatment intervention based on lived experience.

**Main outcome variables**
mental toughness, cognitive flexibility, distress tolerance, feeling of entrapment


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210808052113N1**
Registration date: **2021-09-17, 1400/06/26**
Registration timing: **retrospective**

Last update: **2021-09-17, 1400/06/26**
Update count: **0**

**Registration date**
2021-09-17, 1400/06/26

**Registrant information**


**Name**
Yaghoob Harooni Jamalooei

**Name of organization / entity**
University of Isfahan

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-01-19, 1399/10/30

**Expected recruitment end date**
2021-01-29, 1399/11/10
**Actual recruitment start date**
2021-01-19, 1399/10/30
**Actual recruitment end date**
2021-01-29, 1399/11/10
**Trial completion date**
2021-06-10, 1400/03/20

**Scientific title**
Comparison of therapeutic effectiveness based on the analysis of lived experiences of social stigma with positive psychotherapy method in mental toighness, cognitive flexibility, distress tolerance and feeling of entrapment in patients with multiple sclerosis.

**Public title**
Comparison of therapeutic effectiveness based on the analysis of lived experiences of social stigma with positive psychotherapy method in mental toighness, cognitive flexibility, distress tolerance and feeling of entrapment in patients with multiple sclerosis.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of MS by a specialist. Age range between 18 and 55 years. Willingness and signing of written consent. Form of consent to participate in the research project. Not suffering from a severe physical illness, severe neurological disorders, or having symptoms of psychosis.
**Exclusion criteria:**
relapse of illness and inability to continue sessions absence of more than two sessions
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **45**
Actual sample size reached: **45**
**Randomization (investigator's opinion)**
Not 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**
University of Isfahan
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Isfahan university, Daneshgah st
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**Postal code**
8174673441
**Approval date**
2021-01-12, 1399/10/23
**Ethics committee reference number**
IR.UI.REC.1399.082

## Health conditions studied

**1**

**Description of health condition studied**
Multiple Sclerosis
**ICD-10 code**
G35
**ICD-10 code description**
Multiple sclerosis

## Primary outcomes

**1**

**Description**
mental toughness
**Timepoint**
Before and after the therapy
**Method of measurement**
Mental toughness survey

## Secondary outcomes

**1**

**Description**
Cognitive flexibility
**Timepoint**
Before and after the therapy
**Method of measurement**
Cognitive flexibility survey(CFI)

**2**

**Description**
Mental toughness
**Timepoint**
Before and after the therapy
**Method of measurement**
Mental toughness survey(MTQ)

**3**

**Description**
Distress tolerance
**Timepoint**
Before and after the therapy
**Method of measurement**
Distress tolerance survey(DTF)

**4**

**Description**
feeling entrapment
**Timepoint**
Before and after the therapy
**Method of measurement**
feeling entrapment survey(Gilbert and Allen)

## Intervention groups

**1**

**Description**
The method of intervention is phenomenology of lived experiences in the field of qualitative research. The contents of the treatment session based on the stigmatized life experiences of MS patients to explain and effectiveness of treatment, after the information was done through in-depth interviews with patients and interpretation of data by Colaizzi method, analysis and coding and categorization during data collection and Data collection and analysis continued until theoretical saturation within the scope of the research. Then, the extracted factors were presented and developed to develop a treatment model based on the analysis of lived experiences of stigma. It was held in eight one-and-a-half hour sessions during a week.
**Category**
Behavior

**2**

**Description**
Content of Positive Psychotherapy Sessions has been done in eight consecutive sessions. The sessions included recording a positive self-introduction on a page and directing clients in a positive psychotherapy framework, recording each person's ability by themselves, mentioning blessings and repeating tasks which is adapted from Seligman(2006). In the review session, whether writing these three good things or three blessings and emphasizing positive memories and recollections over the past week has had a positive effect or not, using the worksheet related to gratitude, reviewing the relation of treatment of clients with their progress in writing booklets and letters of forgiveness and gratitude and using their capabilities in practice based on their activity plans which began in the second session were examined.Focusing on the topics of hope, faith and optimism, using the art of improving relationships and creating positive social relationships and happiness in life, teaching response style and training to improve relationships and completing questionnaires by participants in eight sessions of one and a half hours per week were done.
**Category**
Behavior

**3**

**Description**
Control group: includes 15 people who are in the waiting list group and do not receive therapy at the time of intervention.But at the end of the therapy, for the sake of ethics, the control group can also use positive psychotherapy and lived-experience therapy if needed.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
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University of Isfahan
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## Sponsors / Funding sources

**1**

**Sponsor**
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Deputy of Research, University of Isfahan
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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**
Deputy of Research, University of Isfahan
**Proportion provided by this source**
100
**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**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
The group data is related to the main messages of the interview without mentioning the demographic characteristics of the buyers
**When the data will become available and for how long**
Five months after printing
**To whom data/document is available**
Academic researchers after authentication
**Under which criteria data/document could be used**

Request to use the data is permitted only for use in cross-cultural studies, multiple sclerosis treatment centers, or meta-combination and meta-analytic studies.

**From where data/document is obtainable**

send a request to email address yaghoob.harooni2014@gmail.com

**What processes are involved for a request to access data/document**

Data information will be provided to individuals via email or WhatsApp after evaluating the request.

**Comments**