Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
Street address
Isfahan university, Daneshgah st
City
Isfahan
Province
Isfehan
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
Name of recruitment center
University of Isfahan
Full name of responsible person
Yaghoob Harooni jamalooei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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
Name of organization / entity
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Position
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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