

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effectiveness of Acceptance and Commitment Therapy for Reducing Interference and improving Verbal and Visual Working Memory in Patients with Multiple Sclerosis

Protocol summary

Study aim

The present research attempted to answer the question whether acceptance and commitment therapy would affect interference, verbal and visual working memory of MS patients?

Design

Regarding its objective, the present study is an applied research, and concerning the data collection method, it is a quasi-experimental one carried out in the form of a pre-test/post-test with a control group.

Settings and conduct

The statistical population included all the MS patients referring to Ahvaz MS Society in 2018. Of those, 30 patients whose disease was classified as mild by the doctors using the Expanded Disability Status Scale (EDSS) were selected through purposive sampling and were randomly divided into the experimental and control groups, each containing 15 individuals.

Participants/Inclusion and exclusion criteria

The statistical population included all the MS patients referring to Ahvaz MS Society in 2018. Of those, 30 patients whose disease was classified as mild by the doctors using the Expanded Disability Status Scale (EDSS) were selected. The participants were selected with regard to the inclusion criteria (having a history of the disease for over 3 years and being diagnosed with mild MS) as well as the exclusion criteria (not having addiction, cancer, epilepsy, renal failure, heart disease, and major psychological problems such as psychosis) which were reviewed through a clinical interview.

Intervention groups

A group included 15 patients with MS as the experimental group, who were received acceptance and commitment therapy. A group included 15 patients with MS as the control group, didn't received acceptance and commitment therapy until the end of the course

Main outcome variables

Reducing Interference, Verbal Working Memory, Visual Working Memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200113046118N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **retrospective**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Maryam Davoodi

Name of organization / entity

Salman Farsi University of Kazerun

Country

Iran (Islamic Republic of)

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+98 71 4225 2956

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

2018-06-05, 1397/03/15

Actual recruitment end date

2018-06-29, 1397/04/08

Trial completion date

2018-09-03, 1397/06/12

Scientific title

The Effectiveness of Acceptance and Commitment Therapy for Reducing Interference and improving Verbal and Visual Working Memory in Patients with Multiple Sclerosis

Public title

The Effectiveness of Acceptance and Commitment Therapy for Reducing Interference and improving Verbal and Visual Working Memory in Patients with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

The participants were selected with regard to the inclusion having a history of the disease for over 3 years and being diagnosed with mild Ms

Exclusion criteria:

not having addiction not having cancer not having epilepsy not having renal failure not having heart disease not having major psychological problems such as psychosis

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **40**Actual sample size reached: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple individual randomization with random number table that create one- digit column in the random number table, by the size of population, and then units are randomly selected. Finally, any number smaller than or equal to the size of the population was considered as the sample of choice. Also, by using sequentially numbered opaque sealed envelopes (SNOSE). according to the order of entry of eligible participants, one of the envelopes was opened sequentially and their assigned group was identified.

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**

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Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.IAU.KAU.REC.1398.165

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**

interference is the relative processing speed, which is most simply argued as the fact that faster processes can affect slower ones, but the opposite is not true.

Timepoint

The evaluation of this variable was when patient only receive drug therapy and didn't receive psychological

Method of measurement

Computerized Stroop Test evaluates the capacity to attend to specific characteristics of a stimulus, ignoring characteristics irrelevant to the task. In this test, 48 matching and 48 mismatching colored words (red, blue, yellow and green) were shown to the subjects. The term matching words refers to the words whose color and name are the same, and mismatching words refer to those whose color and name are different. A total of 96 words were randomly and sequentially presented. The subjects were asked to say each word's color, regardless of its meaning. Each stimulus was shown on the screen for two seconds, and the stimuli were presented at the intervals of 800 milliseconds. According to the researchers, the mismatching color-word task (second phase of the experiment) measured interference. The

degree of interference was obtained by subtracting the number of correct mismatching words from that of correct matching ones.

Secondary outcomes

1

Description

Working memory resources include verbal and visual working memory. Visual memory plays a key role in the formation and manipulation of mental images. On the other hand, verbal memory covers the phonological loop. The verbal information provided verbally enters the phonological loop directly, immediately and automatically, and is stored phonologically for a short time

Timepoint

The evaluation of this variable was when patient only receive drug therapy and didn't receive psychological

Method of measurement

Wechsler Memory Scale - Third Edition (WMS-III) has 18 subscales (11 primaries and 7 optional subscales), and 8 scores are obtained from the 11 primary subscales. In this research, only two subscales were used to measure verbal and visual working memory. Visual Memory Subscale is a visual rehabilitation test, in which the subject is asked to use his/her memory to draw the simple shapes provided to him/her for 10 seconds. The total scores of forward and reverse digit span subtest were also used to measure verbal working memory.

Intervention groups

1

Description

The intervention was acceptance and commitment therapy for Multiple sclerosis. The experimental group according to the model adapted from ACT's six-session protocol for chronic illness in the form of 120-minute sessions once a week and the control group received no therapeutic intervention. Following the completion of the sessions, both groups were given a post-test. At the end of the sessions, post-test was performed on both groups. The main content of the intervention was psychoeducation about MS's thoughts, emotions and behavior, avoidance, relaxation via mindfulness and cognitive restructuring (e.g. Introducing values by purpose, Cognitive Fusion, Problem-solving strategies, Establishing effective relationships to valuable life, Identify obstacles in the path of values and The practice of conscious acceptance). The practice of each session was reviewed via whatsapp for the group between the sessions.

Category

Other

2

Description

Control group: The control group did not receive any

treatment during the treatment period, but after running the post-test the control and groups received therapy in one session.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz MS Society

Full name of responsible person

Nastaran MajdiNasab

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Golestan Street, Jundishapur University of Medical Sciences, Faculty of Rehabilitation

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Salman Farsi University of Kazerun

Full name of responsible person

Leila Shameli

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Maryam Davoodi

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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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

The data is not important for release, but the result obtained from the data is important and release

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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 study protocol, statistical analysis map and clinical report are important because release of the study want to understand the treatment process, data analysis and ultimately the results obtained and application of the results. In other words, it might be a guidance for other researchers, as well as active therapists in this field.

When the data will become available and for how long

By publishing this research in the journal, it can be available to readers for 6 months to a year.

To whom data/document is available

All relevant people, including patients with MS, psychologists, psychiatrists and others can benefit from the research

Under which criteria data/document could be used

MS Associations that communicate, specialists in the

field, including neuroscientists, health psychologists, and patients can access this information. Research has some limitations that are as simple as removing the limitations to obtain more desirable and generalizable results

From where data/document is obtainable

All the information required by the applicants is fully stated in the research, applications can obtain the information by searching. If they need further

information, they can contact the authors of the article by email.

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

The applicant can receive the file by sending an email mentioned in the article. It will be available for a maximum of one week.

Comments