

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effectiveness of Reality Therapy & Positive psychotherapy on Emotional Reactions and the Quality of Life and Sleep of Female Patients with Multiple Sclerosis

Protocol summary

Study aim

Comparison of the effectiveness of reality therapy and positive psychotherapy on emotional reactions, quality of life, and sleep quality of patients with multiple sclerosis

Design

The research is quasi-experimental with pre-test and post-test designs for two experimental groups and one control group. The clinical trial consisted of 30 members for intervention groups and 15 members for control group (randomized parallel groups). The first stage will be performed as available and the second stage will be randomly performed and patients will receive three questionnaires of emotional reactions, quality of life and sleep quality. The intervention process was performed on experimental groups in 8 sessions, then both experimental and control groups will fill all three questionnaires again as post-tests, and the data related to these 45 individuals will be analyzed.

Settings and conduct

The research will be carried out in Mehr-Ara Clinic with the permission of the Guilan MS Association and under the supervision of the Guilan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

45 female patients with MS who are the members of Guilan MS Association. The selecting criteria: age between 17 and 55 years, having literacy, not being in the acute stage of the disease, not having a history of hospitalization due to mental illnesses, regular participation in medical meetings, not being addicted to any drugs. no hearing or speech issues.

Intervention groups

There are two groups of reality therapy and positive psychotherapy, and one control group that does not receive any intervention.

Main outcome variables

Emotional reactions; Quality of life; Sleeping quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200616047804N1**

Registration date: **2020-07-16, 1399/04/26**

Registration timing: **retrospective**

Last update: **2020-07-16, 1399/04/26**

Update count: **0**

Registration date

2020-07-16, 1399/04/26

Registrant information

Name

Seyyad Hadi Rafiee

Name of organization / entity

Department of Psychology, Ardabil Branch, Islamic Azad University, Ardabil, Iran

Country

Iran (Islamic Republic of)

Phone

+98 13 3314 2921

Email address

hrafiee1363@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

2020-05-23, 1399/03/03

Actual recruitment end date

2020-05-28, 1399/03/08

Trial completion date

2020-06-30, 1399/04/10

Scientific title

The Effectiveness of Reality Therapy & Positive psychotherapy on Emotional Reactions and the Quality of Life and Sleep of Female Patients with Multiple Sclerosis

Public title

The Effectiveness of Reality Therapy & Positive psychotherapy on Emotional Reactions and the Quality of Life and Sleep of Patients with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 17 and 55 years old Reading and writing literacy Not being in the critical level of the disease Not being hospitalized due to mental illnesses Regular participation in therapeutic meetings

Exclusion criteria:

Not participating in the therapeutic meetings or using other psychotherapy methods during the research No drug addiction Having no hearing or speaking issues Do not attend a maximum of one-third of the training sessions

Age

From **17 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

About 60 female patients who are members of the MS Association of Guilan Province were introduced to the researcher by the director of the association according to the criteria for admission. After placing the names of the individuals individually in the lottery bag, 45 people in three groups of 15 (two experimental groups and one control group) were randomly removed from the lottery bag by the clinic secretary.

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 committee of Guilan University of Medical Sciences

Street address

Head Office of Guilan University of Medical Sciences - Fifth Floor of central office, in front of Azodi Stadium, Namjoo St, Rasht; Contact Number: 33310209-33329706 - 013 Telegram: 33329706; Email: ravabetomomi@gums.ac.ir

City

Rasht

Province

Guilan

Postal code

1311141937

Approval date

2020-05-27, 1399/03/07

Ethics committee reference number

IR.GUMS.REC.1399.067

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**

emotional reactions

Timepoint

Beginning of study, end of study (eighth week)

Method of measurement

depression, anxiety and stress questionnaire (DASS21)

2**Description**

quality of life

Timepoint

Beginning of study, end of study (eighth week)

Method of measurement

MS quality of life scale (MSIS-29)

3**Description**

sleep quality

Timepoint

Beginning of study, end of study (eighth week)

Method of measurement

sleep quality questionnaire (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

In this study, group reality therapy will be used. In this study, 30 female patients who are members of Guilan Province MS Association were randomly selected and were divided to two experimental and control groups. The data collection and then intervention on the experimental group were performed for eight 90-minute sessions during a 2-month period and during this period no intervention will be applied to the control group.

Category

Treatment - Other

2

Description

In this study, the method of positive psychotherapy will be used. The number of samples in this study are 30 female patients who are members of the MS Association of Guilan Province are randomly selected and divided into two groups of 15 people for experimental and control one. Data collection and then intervention on the experimental group will be performed for 8 sessions of 90 minutes for 2 months and during this period no intervention will be applied on the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan MS Association

Full name of responsible person

Seyyed Hadi Rafiee

Street address

Guilan MS Association, Nabat Building, Poursina Crossroads, Poursina Street, Rasht, Iran.

City

Rasht

Province

Guilan

Postal code

4193743138

Phone

+98 13 3333 7656

Fax

+98 13 3332 6065

Email

Hrafiee1363@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Psychology, Islamic Azad University of Ardabil, Ardabil, Iran

Full name of responsible person

Dr. Aref Jalili Irani, Director of Research and Technology, Islamic Azad University (Ardabil)

Street address

Basij Square, Islamic Azad University of Ardabil, Ardabil, Iran

City

Ardebil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3372 8029

Fax

+98 45 3372 7799

Email

info@iauardabil.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Department of Psychology, Islamic Azad University, Ardabil Branch, Ardabil, Iran

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Islamic Azad University of Ardabil, Ardabil, Iran

Full name of responsible person

Dr. Somayyeh Taklavi

Street address

Basij Square, Islamic Azad University of Ardabil, Ardebil, Iran

City

Ardebil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3372 8029

Email

staklavi@gmail.com

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

No

Title of funding source

Department of Psychology - Islamic Azad University of Ardabil, Ardabil, Iran

Proportion provided by this source

100

Public or private sector

Private

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**

Department of Psychology, Islamic Azad University, Ardabil Branch, Ardabil, Iran

Full name of responsible person

Seyyed Hadi Rafiee

Position

PhD Student in General Psychology, Department of Psychology, Islamic Azad University, Ardabil Branch,

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Basij Square, Islamic Azad University Complex, Ardabil Branch, Ardabil, Iran

City

Ardebil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3372 8029

Email

Hrafiee1363@yahoo.com

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

Department of Psychology, Islamic Azad University, Ardabil Branch, Ardabil, Iran

Full name of responsible person

Seyyed Hadi Rafiee

Position

PhD Student in Psychology, Department of Psychology, Ardabil Branch, Islamic Azad University, Ardabil

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Basij Square, Islamic Azad University of Ardabil, Ardabil Twon

City

Ardebil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3372 8029

Email

Hrafiee1363@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Department of Psychology, Ardabil Branch, Islamic Azad University, Ardabil, Iran

Full name of responsible person

Seyyed Hadi Rafiee

Position

PhD Student in Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Department of Psychology, 7th Floor, Imam Sajjad Clinic, in front of Azodi Stadium, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

5615731567

Phone

+98 13 3314 2921

Fax

+98 45 3372 7799

Email

Hrafiee1363@yahoo.com

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

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

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

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

Clinical Study Report

Not applicable

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