

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of group social skills education on social anxiety in multiple sclerosis.

Protocol summary

Study aim

Determining the Effect of Social Skills Group Training on Social Anxiety in Patients with Multiple Sclerosis.

Design

The aim of this study was to evaluate the effect of social skills training on social anxiety in multiple sclerosis patients who went to Ahwaz MS community. The statistical population of the study is MS patients. The samples were selected using an available sampling method that had a high score in the social anxiety test, and divided into two groups of case and control. Data were collected using Watson & Fernd social anxiety questionnaire and Matson social skills questionnaire.

Settings and conduct

This study will be carried out at the Ahwaz community. The MS community was chosen because collecting samples is easier at this location due to the referral of patients. After receiving the ethics code from Ahvaz Jundishapur University, samples were sent to the MS society and samples are 66 according to the samples size. They were selected from available samples of, and then randomly divided into Case group and control group.

Participants/Inclusion and exclusion criteria

Inclusion: definite diagnosis of MS by a specialist, had MS attack at least twice, no previous psychiatric problems, ability to move, taking a minimum score of 12 in the social anxiety test. Exclusion criteria: have previous psychiatric problems. in less than three months have passed since their illness.

Intervention groups

The intervention groups consisted of two groups of case and control, which each of them are 33 people according to the sample size. Both groups received a high score from social anxiety test and randomly divided into two groups. The case group received social skills training in eight sessions, but control group did not receive such training.

Main outcome variables

Main variable: Social anxiety

General information

Reason for update

Acronym

Social anxiety

IRCT registration information

IRCT registration number: **IRCT20171025037004N3**

Registration date: **2018-11-23, 1397/09/02**

Registration timing: **retrospective**

Last update: **2018-11-23, 1397/09/02**

Update count: **0**

Registration date

2018-11-23, 1397/09/02

Registrant information

Name

Sedigheh Nikzad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 3477

Email address

nikzad.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study is from research credit points Ahvaz Jundishapur University of Medical Sciences is provided.

Expected recruitment start date

2016-07-29, 1395/05/08

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

2016-08-05, 1395/05/15
Actual recruitment end date
 2016-10-31, 1395/08/10
Trial completion date
 empty

Scientific title
 The effect of group social skills education on social anxiety in multiple sclerosis.

Public title
 The Effect of Social Skills Training on Anxiety

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Definitive diagnosis of MS should be determined by a specialist physician and disease Had MS attack at least twice. Have no psychiatric problems Have the Ability to move Taking a minimum score of 12 in the social anxiety test.
Exclusion criteria:
 Have previous psychiatric problems. Not able to move. Less than three months have passed since their illness.

Age
 From **18 years** old to **45 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **66**
 More than 1 sample in each individual
 Number of samples in each individual: **1**
 In this study, each person is just a sample.
 Actual sample size reached: **66**
 More than 1 sample in each individual
 Actual sample size in each individual: **1**
 In this study, each person is just a sample.

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization was done using simple randomization method using dice.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 This research plan has not been performed in MS patients so far, and due to the many problems of these patients, including social problems, performing such a plan is effective in reducing the social problems of these patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Ahvaz Jundishapur University of Medical Sciences- Deputy of Development and Technol

Street address

Academic town, Golestan,Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

۱۵۷۹۴-۶۱۳۵۷

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

ajums.REC.1394.452

Health conditions studied

1

Description of health condition studied

Social anxiety

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes

1

Description

Social Anxiety

Timepoint

Before the intervention and one month after the end of the intervention

Method of measurement

Watson & FreundS Social Anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

At first Matson s social skills training, which includes dexterity skills, community, self- management skills and communication with peers, was In the intervention group was taught.The training was held in one session per a

week and the last session was held one month later to see the effects of training.

Category

Behavior

2

Description

Control group: In the case of the control group, Watson s social phobia was answered by them and then, they did not receive special training. At the end, the social anxiety questionnaire was answered by the control group again.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Forum- Faculty of Rehabilitation

Full name of responsible person

Ms Bahareh Nedamat

Street address

Shahre Danshgahee- Golestan- Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

۱۵۷۹۴-۶۱۳۵۷

Phone

+98 61 3333 3477

Fax

+98 61 3336 1544

Email

bahareh.nedamat65@gmail.com

Web page address

<https://www.facebook.com/Google>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

University Development and Research Deputy

Street address

shahre daneshgahhy-Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

061-33361544

Phone

+98 61 3333 3477

Fax

+98 61 3336 1544

Email

Hossein148@ymail.com

Web page address

<https://mail.yahoo.com/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Sedigheh Nikzad

Position

Master of Science (MSc) in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty oNursing & Midwifery-shahre daneshgahhy-

Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3333 3477

Fax

+98 61 3336 1544

Email

nikzad.s@ajums.ac.ir

Web page address

<http://mail.ajums.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mr Hossein Komailly sany

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

shahrehe daneshgahhy-Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 33333477

Fax

+98 61 3336 1544

Email

HosseinKomaili@gmail.com

Web page address

<https://www.facebook.com/Google>

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sedigheh Nikzad

Position

Master degree Student of nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing- Jundishapur University- Academic
City- Golestan- Ahwaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 33333477

Fax

+98 61 3336 1544

Email

nikzad.s@ajums.ac.ir

Web page address

<http://mail.ajums.ac.ir/>

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

Because the information of the participants is
confidential and I do not have permission to publish.

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable