

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

Khuzestan

##### 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

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Shahre Danshgahee- Golestan- Ahvaz

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

University Development and Research Deputy

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Hossein148@ymail.com

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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**

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

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**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.

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Nursery

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## Person responsible for updating data

**Contact**

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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**

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**Street address**

Faculty of Nursing- Jundishapur University- Academic  
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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**

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