

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of mobile-based self-care program on motor disorders and activity daily living of people with Multiple Sclerosis

#### Protocol summary

##### Study aim

Design and create a mobile-based self-care program as a new care plan for people with MS.

##### Design

Clinical trials with control group, with parallel groups, blinded, randomised

##### Settings and conduct

This study will be conducted in 1398 at the Center for MS Society of Chaharmahal and Bakhtiari province.

##### Participants/Inclusion and exclusion criteria

Having a smart phone and writing literacy, having no underlying problem

##### Intervention groups

After assigning individuals to intervention and control groups, the status of daily activities of life, balance and walking and tremor are measured in both groups. The intervention group will receive a mobile-based self-care program, and only routine care will be provided for the control group. After the end of 2 months of interventions (training and application of mobile applications), the status of everyday life, balance, walking and tremor in both groups is reassessed. To evaluate the efficacy of the interventions, the mean score of each variable before and after intervention in both groups as well as the mean of variables before and after the intervention will be compared between the two groups

##### Main outcome variables

Reducing and controlling symptoms, getting acquainted with the disease, improving lifestyle

#### General information

##### Reason for update

##### Acronym

MSP

##### IRCT registration information

IRCT registration number: **IRCT20190318043087N1**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **prospective**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

##### Registration date

2019-04-29, 1398/02/09

##### Registrant information

###### Name

Shirmohammad Davodvand

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3225 1988

###### Email address

sh.davodvand@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-30, 1398/02/10

##### Expected recruitment end date

2019-05-05, 1398/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of mobile-based self-care program on motor disorders and activity daily living of people with Multiple Sclerosis

##### Public title

The effect of mobile-based self-care program on motor disorders and activity daily living of people with MS

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Diagnosis by neurologist Age range from 20 to 50 years  
 Not having a history of underlying diseases such as orthopedic and cardiovascular diseases according to medical records of the patient Not having severe mental disorders such as major depression Have a smartphone EDSS scores between zero and 4 if they get score from 0 to 4 The desire to participate in the study Ability to read and write in Persian language Ability to use smart phone

**Exclusion criteria:**

Unwillingness to continue participating in the study  
 Creating complications that cause the patient to not be able to continue studying Failure to fill out self-reporting checklist at least 80% of the days of the study

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sample entry will be done by easy sampling method and then the distribution of samples in the test and control group is randomly assigned to the block

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, both the primary and secondary evaluators as well as those who analyze the data are unaware of the test and control groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study, a self-care program with MS-related content, symptom management, daily life with MS, nutrition, motor vehicle accessories, exercise movements, corrective movements and appropriate tensile movements on the wheelchair installation patients smart phones.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrekord University of Medical

Sciences

**Street address**

Kashani Blvd, Shahrekord University of Medical Sciences

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8815713471

**Approval date**

2019-02-27, 1397/12/08

**Ethics committee reference number**

IR.SKUMS.REC.1397.290

**Health conditions studied****1****Description of health condition studied**

Multiple Sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Demyelinating diseases of the central nervous system

**Primary outcomes****1****Description**

Motordisorders

**Timepoint**

At the beginning of the study and two months later

**Method of measurement**

Tinetti Performance Oriented Mobility Assessment , Fahn Tolosa Marin Tremor Rating Scale

**2****Description**

Activity daily living

**Timepoint**

At the beginning of the study and two months later

**Method of measurement**

Barthel Index of Activities of Daily Living

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Self-care program is installed on the patient's mobile phone and patients should follow this program for 2 months. Before and after the study, the completed questionnaires will be completed for patients.

**Category**

Prevention

## 2

### Description

Control group: This group will not receive any interventions during the study period and they will complete the questionnaires only before and 2 months after the start of the study.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

MS association

##### Full name of responsible person

Abbas Safian

##### Street address

Navab Safavi Street

##### City

Broujen

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8876135698

##### Phone

+98 38 3423 9960

##### Email

abbas.safian@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Dr Kamal Solati

##### Street address

Kashani Blvd

##### City

ShahreKord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8815713471

##### Phone

+98 38 3333 0061

##### Email

kamal\_solati@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

#### Full name of responsible person

Abbas Safian

#### Position

Masters student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Shahid Barati street

#### City

Boldaji

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

8876133337

#### Phone

+98 38 3464 0091

#### Email

abbas.safian@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahre-kord University of Medical Sciences

#### Full name of responsible person

Abbas Safian

#### Position

Masters student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

Shahid Barati street

#### City

Boldaji

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

8876133337

#### Phone

+98 38 3464 0091

#### Email

abbas.safian@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Abbas Safian

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Barati street

**City**

Boldaji

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8876133337

**Phone**

+98 38 3464 0091

**Email**

abbas.safian@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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable