Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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Navab Safavi Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Kamal Solati
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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
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
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Person responsible for updating data

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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