Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of oral health status and effectiveness of an online oral health promotion program multiple sclerosis patients

Protocol summary

Study aim
The aim of this study is to evaluate the effectiveness of a social cognitive theory–based digital oral health education program on knowledge, attitudes, and oral health–related behaviors among patients with multiple sclerosis in Zanjan

Design
randomized controlled trial with two parallel groups, enrolling 100 MS patients equally randomized by age and sex using Excel's RAND function; study is not double-blinded.

Settings and conduct
The study will be conducted at the Omid Rehabilitation Center in Zanjan. Participants will be randomly assigned to two groups: intervention (receiving WhatsApp education) and control (no education), stratified by age and sex. Outcome assessments will be performed by blinded evaluators who are unaware of group assignments to prevent bias.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of MS (based on medical records) At least 6 months since diagnosis Active medical file at Omid MS Center in Zanjan No dementia, psychiatric disorders, or severe physical disability Basic literacy (reading and writing skills) Not completely edentulous Exclusion Criteria: Severe physical disability preventing clinic attendance Systemic diseases affecting oral health No access to a smartphone Unwillingness to participate in the study

Intervention groups
Intervention Group: a six-week oral health education program via WhatsApp, covering key oral hygiene topics with short quizzes to reinforce learning. Control Group: receive usual care at the center without additional education during the study. After the study, educational materials will be provided to them.

Main outcome variables
Knowledge, attitudes, and practices (KAP) of patients with multiple sclerosis toward oral health; Plaque Index (PI); Periodontal Disease Index (PDI)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250414065316N1**
Registration date: **2025-09-23, 1404/07/01**
Registration timing: **prospective**

Last update: **2025-09-23, 1404/07/01**
Update count: **0**

Registration date
2025-09-23, 1404/07/01

Registrant information
Name
Seyed kian Haji seyed javadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 912 641 7256
Email address
kian.javadi.dentist@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-26, 1404/10/05
Expected recruitment end date
2026-02-24, 1404/12/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Assessment of oral health status and effectiveness of an online oral health promotion program multiple sclerosis patients

Public title
Oral Health Status and the Impact of an Online Educational Program in People with Multiple Sclerosis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a confirmed diagnosis of multiple sclerosis (diagnosis verified through review of the patient's medical records) Having a minimum of six months since the confirmed diagnosis of multiple sclerosis Patients attending the Omid MS Center in Zanjan who have an active medical file at the center No history of dementia, psychological disorders, or severe physical mobility limitations Ability to read and write (basic literacy) Not completely edentulous (having at least some natural teeth) Possession of a smartphone and the ability to use it

Exclusion criteria:
Voluntary withdrawal from the study after enrollment Development of new health conditions or worsening of multiple sclerosis that prevents continued participation Failure to complete more than two educational sessions or follow-up assessments

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **201**

Randomization (investigator's opinion)
Randomized

Randomization description
To perform randomization, participants were first stratified based on gender (female/male) and age group (18–39 years / 40–60 years) into four distinct strata. Within each stratum, individuals were assigned sequential numerical codes (1, 2, 3, etc.). A random selection of codes was then performed within each stratum using either a table of random numbers or a computer-generated randomization tool. This stratified randomization method helped ensure a balanced distribution of key demographic variables, such as age and gender, across the three intervention groups, thereby enhancing the internal validity of the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the behavioral and educational nature of the interventions, participant blinding is not feasible, as they will be aware of the type of intervention they receive. However, to minimize bias in outcome assessment, blinding of the outcome assessor and blinding of the clinical supervisor will be implemented. The outcome assessor, responsible for collecting quantitative and qualitative data such as the Plaque Index and Gingival Index, will remain unaware of participants' group allocation to ensure objective and unbiased evaluations. Similarly, the clinical supervisor who monitors participants' overall health status and manages follow-up will also be blinded to group assignments, reducing potential bias in adverse event reporting and clinical follow-up. Blinding these two roles helps reduce assessment and reporting bias, thereby enhancing the internal validity of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Dental Sciences Research Center – Shahid Beheshti University of Medical Sciences

Street address
Tehran, Shahrak-e Ghods (West), between South Falak and Zarfshan streets, Sima-ye Iran Street – Central Headquarters of the Ministry of Health and Medical Education, Block A, 13th Floor

City
tehran

Province
Tehran

Postal code
۱۹۳۶۷۷۳۴۹۳

Approval date
2025-07-26, 1404/05/04

Ethics committee reference number
IR.SBMU.DRC.REC.1404.021

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
Knowledge of basic concepts of oral health and dentistry
Timepoint
At baseline and three weeks after intervention
Method of measurement
A previously validated questionnaire to assess patients' knowledge of basic oral health concepts.

2

Description
Attitude toward oral health
Timepoint
At baseline and three weeks after intervention
Method of measurement
A previously validated questionnaire to assess patients' attitude of basic oral health concepts.

3

Description
Oral health related practice and behavior
Timepoint
At baseline and three weeks after intervention
Method of measurement
A previously validated questionnaire to assess patients' practice of basic oral health concepts.

Secondary outcomes

1

Description
Plaque index
Timepoint
At baseline and three weeks after intervention
Method of measurement
Clinically assessed using the Silness & Löe Plaque Index (1964), scoring plaque accumulation on four surfaces of each tooth (mesial, distal, buccal, and lingual).

2

Description
Gingival index
Timepoint
At baseline and three weeks after intervention
Method of measurement
Clinically assessed using the Löe & Silness Gingival Index (1963), scoring gingival inflammation and condition on four surfaces of each tooth (mesial, distal, buccal, and lingual)

Intervention groups

1

Description
Intervention group: Oral health education using WhatsApp Delivery method: Online education via the WhatsApp messenger, using text messages, educational images, and short videos. Equipment: Smartphone or tablet with internet access and the WhatsApp application. Number of sessions: 6 educational sessions. Duration of each session: Approximately 15–20 minutes for reading or viewing the content. Total duration: 3 weeks (2 sessions per week).Educational content: Basic oral health concepts (daily oral hygiene, role of nutrition, prevention of dental caries and periodontal diseases).Promoting positive attitudes toward oral hygiene and the importance of regular dental visits. Oral health–related behaviors (proper tooth brushing, flossing, care of prostheses and fillings).Interaction: Weekly Q&A with the researcher, reminders, and motivational messages.
Category
Behavior

2

Description
Control group: Participants in this group will not receive any additional educational intervention via messaging platforms or other online methods and will only continue their usual routine care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid MS rehabilitation center
Full name of responsible person
Kazem salahi moghadam
Street address
Zanjan, Gavazang Highway, Saraye Omid Street
City
Zanjan
Province
Zanjan
Postal code
اطلاعاتی در دسترس نی
Phone
+98 24 3343 9095
Email
info@mscharity.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi ghasemi
Street address

Evin, daneshjoo blv, SBMU

City
tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2242 1813

Email
ha.ghasemi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed kian haji seyed javadi

Position
PhD candidate

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Evin, daneshjooblv, SBMU, dental faculty

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2242 1813

Email
kian.javadi.dentist@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed kian haji seyed javadi

Position
PhD student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Evin, daneshjoo blv, SBMU

City
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Province
Tehran

Postal code
1983963113

Phone
+98 21 2242 1813

Email
kian.javadi.dentist@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Seyed kian haji seyed javadi

Position
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Title of the Documents or Data Files: Individual Participant Data from the Clinical Trial on Oral Health Education in Patients with Multiple Sclerosis Details: The collected data include demographic information, Knowledge-Attitude-Practice (KAP) scores regarding oral health, and clinical indicators such as plaque index and periodontal disease index. After de-identification and proper data encryption, partial sharing of the dataset (e.g., primary outcome results) will be possible for research purposes in compliance with ethical standards.

When the data will become available and for how long

Timeframe for Data/Document Availability: Data will be available starting 6 months after publication of the final results and will remain accessible to qualified researchers for a period of 3 years.

To whom data/document is available

Authorized Individuals for Access: The data will only be available to academic researchers and individuals affiliated with recognized research institutions. Requests from non-commercial health-related organizations may also be considered.

Under which criteria data/document could be used

De-identified data can only be used for research purposes and statistical analyses related to oral health and the study topic. Commercial or promotional use is not permitted. Applicants must submit a formal request outlining the research aim, type of intended analyses, and approval from an ethics committee or relevant institution. Requests will be reviewed by the research team, and upon approval, limited access will be granted under a data confidentiality agreement.

From where data/document is obtainable

Applicants wishing to access the data or documents can submit their requests via email to the principal investigator, Dr. Seyed Kian Haji Seyed Javadi, at kian.javadi.dentist@gmail.com. They may also contact by phone at +98 912 641 7256 for further information. For postal correspondence, the research center's address is as follows: Dental Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Shahrak Ghods (West), between Flamark Jonubi and Zarafshan, Simaye Iran Street, Block A, 13th Floo

What processes are involved for a request to access data/document

Applicants requesting data or documents must first submit a formal request via email to the principal investigator, including the purpose of use, the type of data or documents needed, and a commitment to comply with the terms of use. Upon receipt, the research team will review the request and, if complete and in accordance with privacy and ethical policies, approve it. Then, a confidentiality agreement outlining usage restrictions will be signed by the applicant. After signing this agreement, the requested data or documents will be provided in an appropriate format, typically within 2 to 4 weeks. If additional information or documents are required, the process may take longer, and the applicant will be informed accordingly.

Comments