Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Design and Evaluation of the Efficacy of Customized Oral Health Intervention in Individuals with Multiple Sclerosis (MS) : A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of a customized oral health intervention on oral health status (including Plaque Index, Bleeding on Probing , saliva production, and oral health knowledge) in patients with Multiple Sclerosis.

Design

This study will be conducted as a randomized controlled clinical trial on multiple sclerosis patients at the Omid Center in Zanjan. Participants will be randomly selected after informed consent and assigned to intervention or control groups using sealed envelopes. In the intervention group, hand molds will be taken to create customized toothbrushes, which will be provided along with detailed oral hygiene instructions, while the control group will receive education only. Oral health indices will be measured at baseline and reassessed after three months, and pre- and post-intervention results will be compared.

Settings and conduct

This study will be conducted on patients with multiple sclerosis registered at the Omid Charity Center in Zanjan, Iran. Participants will be randomly selected from this center, and if they are unable to attend due to physical limitations, assessments and interventions will be carried out at their homes.

Participants/Inclusion and exclusion criteria

Multiple Sclerosis patients from the Omid Charity Association in Zanjan without mental disorders. All provided written informed consent.

Intervention groups

In the intervention group, customized toothbrushes will be made using hand molds, and a strap will be added to improve control. Individualized oral hygiene education will be provided based on motor ability (Modified Bass for better function and Horizontal for greater limitation). In the control group, only similar tailored education will be provided, and no customized toothbrush will be given.

Main outcome variables

Plaque Index (PI) and Bleeding on Probing (BOP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240303061155N5**
Registration date: **2026-04-25, 1405/02/05**
Registration timing: **prospective**

Last update: **2026-04-25, 1405/02/05**
Update count: **0**

Registration date

2026-04-25, 1405/02/05

Registrant information

Name
Maryam Fazli
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 912 043 6943
Email address
drfazli@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-10, 1405/02/20

Expected recruitment end date

2026-06-10, 1405/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and Evaluation of the Efficacy of Customized Oral Health Intervention in Individuals with Multiple Sclerosis (MS) : A Randomized Controlled Trial

Public title

Assessing the Effect of a Customized Method on Improving Oral Health in Patients with Multiple Sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria are patients who are members of the Omid Charity Association of Zanjan, which is a non-governmental organization (NGO) in the city of Zanjan, who have been diagnosed with Multiple Sclerosis, do not have any mental disorders, and have provided written informed consent to participate in the study.

Exclusion criteria:

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants will be randomly selected from a list of patients with multiple sclerosis using a lottery method. They will then be randomly allocated into intervention and control groups using sealed envelopes. Equal numbers of envelopes will be prepared for each group, labeled with specific colors (green for intervention and red for control). For each participant, one envelope will be randomly opened, and group assignment will be determined based on the color inside the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind trial. Participants will be unaware of the type of intervention they receive. Outcome assessors will also be blinded to group allocation. To maintain blinding, group assignment will be performed by an independent individual, and group codes will remain concealed until data analysis is completed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical School

Street address

Zanjan, Azadi Square, Beginning of Jomhouri Eslami Boulevard, Central Headquarters of Zanjan University of Medical Sciences

City

zanjan

Province

Zanjan

Postal code

۴۵۱۳۹۵۴۱۱۱

Approval date

2025-04-08, 1404/01/19

Ethics committee reference number

IR.ZUMS.REC.1404.010

Health conditions studied

1

Description of health condition studied

Design and Evaluation of the Efficacy of Customized Oral Health Intervention in Individuals with Multiple Sclerosis : A Randomized Controlled Trial

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Oral Health Knowledge

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Through a Valid and Reliable Questionnaire

Secondary outcomes

1

Description

Plaque Index (PI)

Timepoint

Measurements will be performed at baseline (on the day of intervention) and three months after the intervention for all participants.

Method of measurement

It will be measured using the Silness-Löe index with a

periodontal probe on different tooth surfaces.

2

Description
Bleeding on Probing (BOP)
Timepoint
This assessment will be carried out at baseline (on the day of intervention) and three months after the intervention for all participants.
Method of measurement
It will be assessed using a periodontal probe by recording the presence or absence of bleeding after probing.

3

Description
Saliva Production
Timepoint
Measurements will be conducted at baseline (on the day of intervention) and three months after the intervention for all participants.
Method of measurement
It will be measured using a sterile gauze method by calculating the weight difference before and after one minute of placement in the mouth using a precision scale.

Intervention groups

1

Description
Intervention group: patients with multiple sclerosis will receive a customized toothbrush with a handle specifically designed according to their hand anatomy using a molding technique. A strap will be added to improve grip and prevent dropping. In addition, individualized oral health education will be provided based on each patient's motor ability; the Modified Bass technique will be taught to those with adequate motor function, while the Horizontal technique will be used for patients with significant motor limitations.
Category
Behavior

2

Description
Control group: Participants in the control group will receive only individualized oral health education similar to the intervention group, adjusted to their motor abilities. However, they will not receive the customized toothbrush or any additional physical intervention.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
The Omid Charity Association of Zanjan is a non-governmental organization (NGO) in the city of Zanja
Full name of responsible person
Maryam Fazli
Street address
Mahdavi Blv.Faculty of Dentistry, Department of Oral Health and Social Dentistry
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Azin nourian
Street address
Mahdavi St., Dentistry Department, Zanjan Univeristy of Medical Science
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Postal code
4513956111
Phone
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Email
azin.nourian@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr.Maryam Fazli
Street address
Mahdavi blv. Zanjan University of Medical School-Dentistry Faculty
City
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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
Zanjan University of Medical Sciences
Proportion provided by this source
20
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Maryam Fazli
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Community oral health
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All participant data can be shared after de-identification.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

To receive the data and documents, send an email to Dr.Maryam Fazli Or contact the research office of Zanjan School of Dentistry. Dr.Maryam Fazli's email: drfazli@zums.ac.ir Zanjan Faculty of Dentistry research office phone number: +98-24-33148215

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

Data requests are usually answered after two working weeks.

Comments