

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of nursing process based on the goal attainment theory on activities of daily living & quality of life in individuals with multiple sclerosis

Protocol summary

Study aim

the effect of nursing process based on the goal attainment theory on activities of daily living & quality of life in individuals with multiple sclerosis

Design

Experimental clinical trial on 70 patient, quad permutation randomization method.

Settings and conduct

the research environment is Hamedan MS Association .
The nursing process is based on the theory of goal achievement in the experimental group.

Participants/Inclusion and exclusion criteria

Have at least primary education, age limit of 20 to 50, at least 6 months have passed since the diagnosis, diagnosis with relapsing and remitting multiple sclerosis, not being in acute phase of disease, not having other physical and mental illnesses (based on the person's medical history), able to speak Persian, has a balanced mental state and is aware of time and place. Exclusion criteria include: any problem that leads to termination of participation at any time during the study (such as death, transfer to another city) and the patient should be in the condition of the crisis during the study .

Intervention groups

experimental group, will have at least one face-to-face session to review the patient and prioritize goals and care planning for each patient, then the follow-up will be done for 4 consecutive weeks, by phone or through social networks. The control group, no interventions are performed and they are subject to the routine program of the MS Association.

Main outcome variables

Quality of life and activities of daily living

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201210049668N1**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **prospective**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Firuzeh Payamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4323 9589

Email address

fi_payamani@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing process based on the goal

attainment theory on activities of daily living & quality of life in individuals with multiple sclerosis

Public title

The effect of nursing process based on the goal attainment theory in individuals with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Have at least educational level of primary school Age limit of 20 to 50 At least 6 months have passed since the diagnosis Confirmation of the disease by a neurologist Diagnosis with relapsing and remitting multiple sclerosis Not being in acute phase of disease No other physical and mental illnesses (based on medical history) Able to speak Persian Has a balanced mental state and is aware of time and place

Exclusion criteria:

Any problem that leads to termination of participation at any time of the study (Such as death, transfer to another city) The patient should be in the condition of the crisis during the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The research units will be selected using convenience sampling method and the subjects were quad permutation randomization divided into two groups experimental (35) and control (35).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Science

Street address

Fahmideh St, Hamadan University of Medical Science

City

Hamadan

Province

Hamadan

Postal code

6517838698

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.UMSHA.REC.1399.773

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

Score of quality of life

Timepoint

Before and two months after the intervention

Method of measurement

Quality of Life SF-12 questionnaire

2

Description

Score of Activities of Daily Living

Timepoint

Before and two months after the intervention

Method of measurement

Activities of Daily Living questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the number and duration of nursing process sessions will be determined based on the number of patient goals, desire and fatigue. We will have at least one face-to-face session to review the patient and prioritize goals and care planning for each patient, then the follow-up will be done for 4 consecutive weeks, by phone or through social networks. Then, one month after the intervention, the participants will complete the quality of life questionnaire and the questionnaire of daily life activities

Category

Other

2**Description**

Control group: The questionnaire of demographic characteristics, quality of life, and questionnaire of activities of daily living questionnaire will be completed by the participants, and the patient examination will be completed by the researcher based on King's goal achievement theory and the GAS scale and the patient will be completed based on King's goal attainment theory and GAS scale by the researcher. For the control group, no interventions are performed and they are subject to the routine program of the MS Association.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamedan MS association

Full name of responsible person

Firuzeh Payamani

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

Street address

Shahid Fahmideh Blvd., Hamadan University of Medical Sciences

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mahnaz.khatiban@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Firuzeh Payamani

Position

PhD student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mahnaz Katiban

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

PhD student in nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available