Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Street address
Eram Blvd, Neshat Comprehensive Rehabilitation Center

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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
Nursery

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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
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