Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Betty Newman System Model on death anxiety, fear of progression, and psychosocial adjustment to the disease in patients with Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of Betty Newman's systemic model on death anxiety, fear of disease progression, and psychosocial adjustment to the disease in patients with multiple sclerosis.

Design
Randomized clinical trial with two control and experimental groups, with parallel groups, on 72 patients with Multiple Sclerosis, randomized using a four-size randomized block design.

Settings and conduct
MS Academic Committee affiliated with Shahrekord University of Medical Sciences and MS Association The control group will receive only routine training. In addition to routine care, the intervention group will receive a care program based on the Betty Newman nursing model. The intervention group will receive a program based on the Betty Newman model in 4 sessions, each session lasting 40 minutes, in groups (3 groups of 12 people) using educational videos, whiteboards and podcasts and lectures in the community and clinic environment to reduce the likelihood of encountering stressors or reducing reactions to stressors and strengthening flexible and natural defense lines with a focus on the nursing process.

Participants/Inclusion and exclusion criteria
1. Willingness to participate in the study and complete the informed consent form 2. Age 20 years and older 3. Definite diagnosis of multiple sclerosis in patients based on medical records 4. Being literate enough to read and write and understand the research questionnaire 5. Absence of other incurable diseases 6. EDSS criterion less than 4

Intervention groups
The intervention group will receive an educational intervention based on Betty Newman's systems model in four sessions, while the control group will only receive routine hospital education.

Main outcome variables
Death anxiety, Fear of disease progression, and Psychosocial adjustment to illness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240806062674N3**
Registration date: **2025-12-14, 1404/09/23**
Registration timing: **prospective**

Last update: **2025-12-14, 1404/09/23**
Update count: **0**

Registration date
2025-12-14, 1404/09/23

Registrant information

Name
Farshad Heidari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-31, 1404/10/10

Expected recruitment end date
2026-07-01, 1405/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Betty Newman System Model on death anxiety, fear of progression, and psychosocial adjustment to the disease in patients with Multiple Sclerosis

Public title

The effect of Betty Newman Model on death anxiety, fear of progression, and psychosocial adjustment to the disease in patients with Multiple Sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1- Willingness to participate in the study and completing the informed consent form 2- At least 20 years old 3- Definite diagnosis of multiple sclerosis in patients based on medical records 4- Being literate enough to read and write and understand the questionnaire 5- EDSS criterion less than 4

Exclusion criteria:

The presence of another incurable disease in addition to multiple sclerosis

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The random assignment method of the samples to the groups was in the form of random blocks of four without permutation. For this purpose, first the letter A was considered for the control group and the letter B for the experimental group, and the different four-letter forms of the two groups (ABBA, ABAB, AABB, BAAB, BABA, BBAA) were written on six cards and placed in a sealed and opaque envelope. These envelopes were placed in a box, and the researcher did not know which group the units under study would be placed in until the card was selected. Then, the researcher determined which group the patients entering the study would be placed in by removing one of the envelopes from the box. This process continued until all the cards were removed from the bo,x and the cards were returned to the box again, and this random selection was repeated three times to provide the desired sample size.

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

Research Ethics Committees of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2025-02-04, 1403/11/16

Ethics committee reference number

IR.SKUMS.REC.1403.133

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 obtained from the Templer Death Anxiety Questionnaire

Timepoint

Before, immediately after and two months after the intervention

Method of measurement

Death anxiety will be measured by the Templer Death Anxiety Questionnaire. This questionnaire consists of 15 items that measure the subjects' attitudes in three components: death anxiety alone, general factor, fear of pain, and surgery. Subjects indicate their answers to each question with yes or no options, with scores of zero and one assigned to each item. Thus, the scores on this scale vary between 4 and 15. A high score (a score

higher than "score 8") indicates high anxiety about death.

Secondary outcomes

1

Description
Score obtained from the Fear of Disease Progression Questionnaire by Hershbach et al.
Timepoint
Before, immediately after, and two months after the intervention
Method of measurement
Fear of disease progression will be measured by the Fear of Disease Progression Questionnaire by Hershbach et al. This questionnaire consisted of 13 items and had 5 subscales (emotional reaction, family, work, loss of independence, coping with anxiety). Responses to it include a Likert scale from 0 to 5 points from never to most of the time. The total score is calculated by summing the scores of the subscales except the coping subscale.

2

Description
Score obtained from the Drogatis Psychosocial Adjustment Questionnaire
Timepoint
Before, immediately after, and two months after the intervention
Method of measurement
Psychosocial adjustment to the disease will be measured by the Drugatis Psychosocial Adjustment to Disease Questionnaire. This questionnaire has 45 questions and seven subscales: attitude towards the disease (eight questions), work environment (six questions), family environment (eight questions), sexual relations (six questions), development of family relationships (five questions), social environment (six questions), and psychological disorders (seven questions). The scoring of this questionnaire is based on a four-choice Likert scale (not at all, sometimes, most of the time, and completely) from 0 to 3 for each question, and the total score of the test ranges from 0 to 135. The average adjustment score for each component is obtained from the sum of the scores for each component and divided by the number of questions in that component, and the average total adjustment score is obtained from the sum of the scores for all questions and divided by the number of questions. Higher scores indicate an inappropriate adjustment status. The total adjustment score is classified into three categories: high adjustment, moderate adjustment, and low adjustment.

Intervention groups

1

Description
Intervention group: First, the study questionnaires will be completed by all samples. After reviewing the scores of the questionnaires and determining the areas that received lower scores and needed more intervention, potential and actual stressors and intrapersonal, interpersonal, and created (transpersonal) factors will be determined by evaluating the 5 variables that make up the Betty Newman model (physiological-evolutionary-psychological-social, cultural-spiritual). Then, the intervention group will receive a program based on the Betty Newman model in 4 sessions, each session lasting 40 minutes, in groups (3 groups of 12 people) using educational videos, whiteboards, podcasts, and lectures in the community and clinic environment to reduce the likelihood of encountering stressors or reducing reactions to stressors and strengthening flexible and natural defense lines with a focus on the nursing process.
Category
Behavior

2

Description
Control group: The control group will receive only routine care and education.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord MS Association
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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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

No - There is not 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