Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of using the Newman's systems model on the level of stress and the needs of depressed patients

Protocol summary

Study aim
Determining the Effect of Applying the Neuman Systems Model on Stress Levels and Needs of Patients with Depression

Design
A randomized controlled clinical trial with two parallel groups (intervention and control), involving 80 participants, with blinding at the statistical analyst level. Convenience sampling will be used, and participants will be allocated to the two groups using block randomization and sealed, opaque, numbered envelopes.

Settings and conduct
This randomized controlled clinical trial involving 80 patients will be conducted at counseling centers in Zanjan, Iran, using block randomization for allocation to two parallel groups and blinding of the statistical analyst through anonymous coding.

Participants/Inclusion and exclusion criteria
In this study, the inclusion criteria are as follows: 1) A clinical diagnosis of depression based on DSM-5 or ICD-10 (regardless of the specific subtype). 2) Patients must be between 18 and 65 years of age. 3) Clinical stability (defined as no psychiatric hospitalizations and the maintenance of social functioning) and no use of psychiatric medications for the 3 months prior to the start of the study. 4) Provision of informed consent and explicit agreement by the patient to participate in the study. 5) Absence of other psychiatric disorders. The exclusion criteria are as follows: 1) The patient is unwilling to continue participation for any reason. 2) The patient experiences serious psychological or physical adverse effects. 3) The patient fails to adhere to the study's recommendations and protocols. 4) The occurrence of an emergency or death that renders the continuation of the study impossible.

Intervention groups
Intervention group: Receives nursing care based on the Neuman Systems Model in addition to routine care. Control group: Receives routine care provided at the healthcare center.

Main outcome variables
Stress levels; basic needs of patients with depression; depression severity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261013071422N1**
Registration date: **2026-11-02, 1405/08/11**
Registration timing: **prospective**

Last update: **2026-11-02, 1405/08/11**
Update count: **0**

Registration date
2026-11-02, 1405/08/11

Registrant information

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Name of organization / entity

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2026-12-01, 1405/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of using the Newman's systems model on the level of stress and the needs of depressed patients

Public title
Investigating the effect of using the Newman's systems model on the level of stress and the needs of depressed patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical diagnosis of depression according to the DSM-5 or ICD-10 criteria, without distinguishing between different types of depression Age between 18 and 65 years Clinical stability, defined as no psychiatric hospitalization and maintenance of social functioning, and no use of psychiatric medications during the three months preceding the start of the study Provision of informed consent and explicit agreement to participate in the study Absence of other psychiatric disorders in the participants.
Exclusion criteria:
The patient is unwilling to continue participating in the study for any reason The patient experiences serious psychological or physical adverse effects. The patient does not adhere to the study recommendations and protocol. The occurrence of emergencies or death that make continued participation in the study impossible.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Considering the study conditions and the need for rapid and practical access to the target population, convenience sampling was employed. In this method, individuals who met the inclusion criteria and were accessible to the researcher were selected. Accordingly, after identifying eligible participants, they were randomly allocated to the intervention and control groups using a block randomization technique, taking into account individual characteristics (gender, age, marital status, and educational level) to reduce bias and ensure balance between the groups. To implement random allocation, standard procedures were used, including sealed, coded envelopes and a pre-generated randomization list. Each allocation was placed in an opaque, numbered envelope. The researcher, without knowledge of the envelope's contents, opened the envelopes sequentially according to their numbers and assigned each participant to the designated group. Furthermore, the following formula was used to estimate the sample size as an alternative to Cochran's formula, which is commonly applied to small and finite populations: In this formula, N represents the sample size for an effectively infinite population, which is generally assumed to be 384; t is the coefficient corresponding to the selected confidence level; S represents the estimated existing or preliminary variance; and d denotes the acceptable margin of error. In statistical and research methodology references, this formula is commonly referred to as a modified sample size formula or a formula suitable for small samples. It is also known by other terms, such as the “sample size formula based on population variance for a finite sample” or the “sample size formula for a finite population.” Based on this formula, with a 95% confidence level, a 5% margin of error, a statistical power of 80%, and a variance of 1.96, the calculated sample size for a population of 384 was 80 participants.
Blinding (investigator's opinion)
Single blinded
Blinding description
Given the nature of the intervention and the way the research program was implemented, complete blinding of participants and researchers was not feasible. However, to reduce bias in the analysis of the results, blinding was implemented at the level of the statistical analyst. Specifically, data related to participants were provided to the analyst using anonymous codes, without identifying group allocation (intervention or control). Therefore, the statistical analyst was unaware of participants’ group assignments, and data analysis was performed without knowledge of the type of intervention received. This approach helps reduce observer bias during the data analysis phase.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Sciences Ethics Committee
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Professor Sobouti Boulevard
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Zanjan

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4513956184

Approval date

2026-08-31, 1405/06/09

Ethics committee reference number

IR.ZUMS.REC.1405.119

Health conditions studied

1

Description of health condition studied

Depressive Disorder

ICD-10 code

F33.0

ICD-10 code description

Major depressive disorder, recurrent, mild

Primary outcomes

1

Description

Perceived Stress ScoreChange in the total perceived stress score among patients with depression, measured using the 10-item Perceived Stress Scale (PSS-10), from baseline to post-intervention following four weeks of nursing care based on Neuman Systems Model.

Timepoint

At baseline, before the intervention (pre-test), and at the end of Week 4, after completion of the intervention (post-test).

Method of measurement

The ten-item Perceived Stress Scale, consisting of ten questions rated on a five-point Likert scale, with a total score ranging from zero to forty, used to assess patients' perceived stress over the previous month.

2

Description

Basic Needs ScoreChange in the basic needs score among patients with depression, measured using the Asgharipour Basic Needs Questionnaire based on Maslow's hierarchy of needs, from baseline to post-intervention following four weeks of nursing care based on Neuman Systems Model.

Timepoint

At baseline, before the intervention (pre-test), and at the end of Week 4, after completion of the intervention (post-test).

Method of measurement

The Maslow Basic Needs Questionnaire developed by Asgharipour, consisting of sixty-four dichotomous yes-or-no questions, used to assess five dimensions of basic needs: physiological needs, safety needs, belongingness needs, esteem needs, and self-actualization needs.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Participants in this group received nursing care based on the Neuman Systems Model over a four-week period, consisting of four 45-minute sessions. The intervention was delivered by a trained researcher and was designed according to the three levels of prevention: primary, secondary, and tertiary prevention.Sessions 1 and 2 aimed to reduce stressors, strengthen patients' lines of defense, and increase awareness of depression and stress management. The content included education about depression and stressors, progressive muscle relaxation, diaphragmatic breathing, basic mindfulness, healthy nutrition principles, and daily activity planning.Session 3 aimed to manage symptoms and reduce stress responses. It included training in adaptive coping skills, guided mindfulness exercises, introductory cognitive restructuring, identification of stress triggers, and development of an individualized stress-reduction plan.Session 4 aimed to prevent relapse and maintain behavioral changes. It included developing an individualized relapse-prevention plan in collaboration with the patient, reviewing the skills learned, teaching patients to recognize early warning signs, and planning timely actions when symptoms emerge.Participants' perceived stress and basic needs were assessed using the corresponding questionnaires at baseline, before the intervention, and at the end of Week 4, after completion of the intervention.

Category

Rehabilitation

2

Description

Control Group: Participants in this group received usual care, including general education and visits with a psychiatrist. During the four-week study period, no structured nursing intervention based on the Neuman Systems Model was provided to this group. The Perceived Stress Scale and the Basic Needs Questionnaire were completed at baseline and at the end of Week 4.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Piaget General Counseling Center

Full name of responsible person

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3

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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
Zanjan 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
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