Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of Imolementation a Therapeutic Communication Program Based on Hilgard Peplau Theory on Depression And Fatigue In Patients With Stroke

Protocol summary

Study aim

Determining the effect of implementation of communication therapy program based on Hilgard Peplau model on the level of depression and fatigue of stroke patients

Design

This study is a two-group pre-test and post-test clinical trial of the type of clinical trial with simultaneous independent or parallel witnesses in phase 3.

Settings and conduct

The research population is stroke patients. The participants will include 40 patients from the neurology department of Ghaem Hospital.The intervention group will receive the communication therapy program designed based on the Peplav model and the control group will receive conventional care. The program designed based on the Peplau model includes 3 face-to-face communication sessions during the patient's stay in the hospital for 30 to 40 minutes and one online session after the patient is discharged from the hospital. For both groups, one and three months after the end of the intervention, the depression and fatigue questionnaire of the patients will be completed.

Participants/Inclusion and exclusion criteria

Entry requirements 1. Having written consent and willingness to participate in the study 2. Age between 18 and 65 years 3. Persian language 4. He has passed the acute stage of stroke 5. Relative ability to communicate 6. Having mild to moderate depression and fatigue scores based on the study tool Non-entry conditions - History of suffering from mental illnesses or taking psychiatric drugs 2. Having a history of major stressful events in life 3. Perceptual aphasia

Intervention groups

For the intervention group, the communication therapy program Peplau model includes 3 face-to-face communication sessions during the patient's hospitalization and one online session after the patient's discharge from the hospital within 30 to 40 minutes. The control group will also receive usual ward care.

Main outcome variables

Tiredness Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220817055731N1**
Registration date: **2022-11-15, 1401/08/24**
Registration timing: **prospective**

Last update: **2022-11-15, 1401/08/24**
Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Fatemeh Mirshabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Imolementation a Therapeutic Communication Program Based on Hilgard Peplau Theory on Depression And Fatigue In Patients With Stroke

Public title
Investigating the effect of communication therapy on stroke patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having written consent and willingness to participate in the study Age 18 to 65 years Farsi language He has passed the acute stage of a stroke (the first 48 hours after the stroke and his hemodynamic conditions have been stabilized) Relative ability to communicate (complete verbal aphasia) Having mild to moderate depression and fatigue scores based on the study tool
Exclusion criteria:
History of mental illness or taking psychiatric drugs Having a history of major stressful events in life (death of first-degree relatives, serious illness of family members, financial bankruptcy, accident, divorce) during the last six months Perceptual aphasia
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization The participants will include 40 patients from the neurology department of Ghaem Hospital, who will be included in the study if they have the desire and criteria to enter the study. The samples will be randomly divided into intervention and control groups. The intervention group will receive the communication therapy program designed based on the Peplav model and the control group will receive conventional care. SNOSE method will be used for Allocation Concealment. In this way, the sequence created based on the number "one to eighty-four" will be kept in 84 individual envelopes closed in the dark -invisible-. On each envelope, a number is written and inside the envelope, the group assigned to that number is written. The allocation of people entered into the study in the groups will be determined as soon as they enter the study. All envelopes will be given to a team member before the start of the study. As soon as each person enters the study, according to the order of his entry, the corresponding envelope number will be opened and thus it will be determined in which group he will be placed. Also, the person who prepared the sequence is not the same as the person who assigns the samples to two groups (executor of the sequence).
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 Mashhad University of Medical Sciences
Street address
Mashhad, Ibn Sina Street, Doctora Crossroads
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2022-06-18, 1401/03/28
Ethics committee reference number
IR.MUMS.REC.1401.072

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
Depression
Timepoint
Depression, which is measured using the Beck questionnaire, before and immediately after the intervention.

Method of measurement
Beck depression questionnaire

2

Description
Tiredness
Timepoint
Fatigue, which is measured using the FSS questionnaire, before and immediately after the intervention.
Method of measurement
FSS Fatigue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group will receive communication therapy designed based on the Peplav model. The program designed based on the Peplau model includes 3 face-to-face communication sessions during the patient's stay in the hospital and one online session after the patient is discharged from the hospital. Depending on the needs of the client, the nurse-client communication sessions will last 30 to 40 minutes.
Category
Lifestyle

2

Description
Control group: This group receives conventional care in the department.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Gholamali Mamouri
Street address
Mashhad, Ibn Sina Street, Doctor's Crossroad Corner
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Province
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99199-91766
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayor Mobarhan
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Sadat Manzari
Position
science Committee
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Position

undergraduate student

Latest degree

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable