Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of empowering based on problem solving on awareness, understanding and skills of brain damaged patients' families and health status of these patients .

Protocol summary

Summary

The effect of empowering based on problem solving on awareness, understanding and skills of brain damaged patients' families and health status of these patients. The goal of this clinical trial study will be empowering based on problem solving on understanding and skills of families with a brain damaged patient and health status of these patients. The intervening period will be two months. Sixty caregivers and patients will be randomly selected. Thirty people will be in intervention group and thirty people in control group. The study will be started by administering a pre-test and studying the health condition of patients. The control group will not receive any intervention. Intervention includes training based on problem solving at the bedside of the patient for 4 to 6 sessions for one hour. This training will include: 1. Determining the problem 2. Defining the problem 3. Finding a possible solution 4. Acting based on possible solutions 5. Evaluating After patient's releasing from hospital the telephoning follow-ups will be started for 8 weeks. After 2 months the health condition of patients will be checked at home and the post test will be administered. Inclusion criteria caregiver: Willingness to participate in the study; being as the main caregiver of the patient; age over 18 to 60 years old; not having hearing or speaking problems; not having cognition or mental disorders; not having teach in health and treat filed; have a mobile or phone in house. Exclusion criteria: Unable to continue in the study for any reason. Outcome measures include empowerment of the brain damaged patients caregivers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051813367N1**

Registration date: **2014-11-04, 1393/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-04, 1393/08/13

Registrant information

Name

Mahbube Aliabadi

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

aliabadi.m@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Gonabad University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowering based on problem solving on

awareness, understanding and skills of brain damaged patients' families and health status of these patients .

Public title
Training caregivers of patients with brain damage
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria Patients: First reference of patients as brain damaged; definitive diagnosis of brain damage; consciousness coefficient over 7 or equal to 7; not suffering from diabetes or fractures. Inclusion criteria caregiver: Willingness to participate in the study; being as the main caregiver of the patient; age over 18 to 60 years old; not having hearing or speaking problems; not having cognition or mental disorders; He or she should not teaching in health and treat field; have a mobile or phone in house. Exclusion criteria: Unable to continue in the study for any reason.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethic Committe of Gonabad University of Medical Sciences
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi es , Gonabad
City
Gonabad
Postal code
Approval date
2013-10-23, 1392/08/01
Ethics committee reference number
GMU.REC.1392.55

Health conditions studied

1

Description of health condition studied
Brain stroke
ICD-10 code
G46
ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

2

Description of health condition studied
traumatic brain injury
ICD-10 code
S00-S09
ICD-10 code description
Injuries to the head

3

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35-G37
ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
The level of the brain damage caregivers' awareness
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Questionnaire

2

Description
The level of the brain damage caregivers' understand
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Questionnaire

3

Description
The level of the brain damage caregivers' skill
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Questionnaire

4

Description
health status of patients with brain damage
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the empowering programs in caregivering of patients based on problem solving in 4 to 6 sessions based on the patient's need before releasing and at the bedside of him or her theoretically or practically about individual health, caring about skin and preventing bedsore, care taking of catheter, care taking of tracheostomy, suction Physiotherapy of breathing and organs, feeding and care taking of nose- stomach tube, taking the patient to toilet. Using wheelchair, moving from chair to bed and vice versa, preventing from embolism, taking drugs based on solving method. The duration of every session will be 1 hour as follow: 1. Determining the problem 2. Defining the problem 3. Finding a possible solution 4. Acting based on possible solutions 5. Evaluating After patient's releasing from hospital the telephoning follow-ups will be started for 8 weeks. After 2 months the health status of patients will be checked at home and the post test will be administered.
Category
Rehabilitation

2

Description
Control group: The control group does not receive any intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman hospital
Full name of responsible person
Mohammad Jahangiry
Street address
No. 27, Imam Khomeini Avenue, Neyshabur, khorasane razavi
City
Neyshabur

2

Recruitment center
Name of recruitment center
22 Bahman hospital
Full name of responsible person
Mohammad Khajavi
Street address
Imam Khomeini Avenue, Gonabad, khorasan-e-razavi
City
Gonabad

3

Recruitment center
Name of recruitment center
Hakim hospital
Full name of responsible person
Zahra Moghadam
Street address
Baghrud Square, Neyshabur, Khorasane razavi
City
neyshabur

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Gonabad University of Medical Sciences
Full name of responsible person
Mohammadpour Ali
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi
City
Gonabad
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Gonabad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Aliabadi Mahbube

Position
Nursing Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Khosravan Shahla

Position
Nursing Professor

Other areas of specialty/work

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aliabadi.m.9013104007@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty