

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 caregiving 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 bedsores, 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**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

City

Gonabad

Postal code**Phone**

+98 51 5722 3028

Fax**Email**

aliabadi.m@gmu.ac.ir;

aliabadi.m.9013104007@gmail.com

Web page address**Email**

mma-khosravan@yahoo.com

Web page address

Person responsible for updating data

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**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi es, Gonabad

City

Gonabad

Postal code**Phone**

+98 51 5722 3028

Fax**Email**

aliabadi.m@gmu.ac.ir;

aliabadi.m.9013104007@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Khosravan Shahla

Position

Nursing Professor

Other areas of specialty/work**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad, Khorasan Razavi

City

Gonabad

Postal code**Phone**

+98 51 5722 3028

Fax

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