

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of nursing telephone counselling on depression and anxiety among family caregivers of patients with head trauma and cerebrovascular accident (CVA) in Shohadaye Haftome Tir hospital

Protocol summary

Study aim

Assessing the effect of nursing telephone counselling on depression and anxiety among family caregivers of patients with head trauma and cerebrovascular accident (CVA)

Design

Randomized controlled trial, parallel group, not blinded

Settings and conduct

The intervention will be done at home and through telephone counseling with 79 patients with trauma and CVA discharged from the 7-Tir Hospital during the first half of 1396. For intervention group, 24-hour nursing counseling will be provided by three nurses for 12 weeks. Both groups will complete Beck anxiety and depression questionnaires before and after the intervention and the results will be compared.

Participants/Inclusion and exclusion criteria

Inclusion: Main person in taking care of a patient with head trauma and CVA who needs daily care, Aged ≥ 15 , Residing in Tehran, Receiving at least one nursing counselling service per week. Exclusion: Participating in relevant patient care educational programs, history of hospitalization in psychiatric wards, receiving psychological therapies or having cognitive disorders, Experiencing loss and mourn in past six months

Intervention groups

Intervention group: Receiving 24 hours telephone counselling provided by 3 nurses for 12 weeks. Control group: Not receiving any nursing counselling from the team members or others.

Main outcome variables

Anxiety level, depression level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181020041391N1**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Hassan Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-20, 1398/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing telephone counselling on depression and anxiety among family caregivers of

patients with head trauma and cerebrovascular accident (CVA) in Shohadaye Haftome Tir hospital Public title Effects of nursing telephone counselling on depression and anxiety among patients' family caregivers Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: Being a main person taking care of the patient (such as father, mother, son, daughter, son or daughter in law, brother or sister who lives with the patient) Aged ≥ 15 years Residing in Tehran Taking care of a patient with head trauma and CVA who needs daily primary care Being literate and able to speak and listen Receiving at least one nursing telephone counselling service per week from the study team Exclusion criteria: Simultaneous participation in other psychotherapy sessions Having a history of hospitalization in psychiatric wards or having cognitive disorders (Dementia and Delirium) Participating in educational programs relating to patient care concurrently or in the past Experiencing loss and mourn in past six months Age From 15 years old Gender Both Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 79 Randomization (investigator's opinion) Randomized Randomization description Following simple random sampling approach, a random number table will be used to generate 80 two digit random numbers. Each number will be printed in a separate card. The cards will be shuffled and a single card will be randomly picked up while eligible individuals enrolled and signed the consent form. The samples will be assigned into control and intervention groups based on the odd (intervention) and even number (control). The sample's number and group name will be recorded and the card will be returned and merged with other cards. If the same card was picked up it will be regarded as blank. The process will be continued until all samples will be allocated to the groups. 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 Iran University of Medical Sciences Street address Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran City Tehran Province Tehran Postal code 1449614535 Approval date 2017-10-13, 1396/07/21 Ethics committee reference number IR.IUMS.REC 1396.31164 Health conditions studied 1 Description of health condition studied Depression ICD-10 code F32 ICD-10 code description depressive disorder 2 Description of health condition studied Anxiety ICD-10 code F41.9 ICD-10 code description Anxiety disorder, unspecified Primary outcomes 1 Description Depression Timepoint Depression score before and after receiving nursing consultations Method of measurement Beck Depression Inventory 2 Description Anxiety
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Timepoint

Anxiety score before and after receiving nursing consultations

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving 24 hours telephone counselling provided by 3 nurses for 12 weeks. Telephone counseling will often be done with a request from a caregiver. Consults will be about primary nursing care at home such as suction, gavage, position change, proper feeding, physiotherapy, etc.

Category

Behavior

2**Description**

Control group: Receiving routine patient education before discharge from the hospital along with educational pamphlet and CD, without receiving any 24 hours nursing telephone counselling

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Haftome Tir hospital

Full name of responsible person

Shirin Nasrollah Nezhad Tasouj

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number**

96-02-203-31164

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Hassan Amiri

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Private data of participants, statistical output, study protocol

When the data will become available and for how long

Six months after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Maintaining confidentiality of participants data and referring the source of data in their publications

From where data/document is obtainable

Contacting the person in charge of the project or the corresponding author of the published article

What processes are involved for a request to access data/document

Sending email or written letter to implementer or author of study

Comments