Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of supportive educative program on quality of life and caregiver burden of patients with hip fracture

Protocol summary

Study aim

The effect of supportive training program on caregiving pressure and quality of life of caregivers of patients with hip fracture referred to the orthopedic department and clinic of Sina Hospital in Tehran.

Design

Clinical trial with control group, single blind, randomized, phase on 70 patients. and the data was used through spss software.

Settings and conduct

Blinding was done in Sina Hospital, Tehran, in such a way that the participant and the analyst did not know the differences between the control and experimental groups

Participants/Inclusion and exclusion criteria

Inclusion criteria for caregivers included: kinship with the patient, active participation in home care of a patient with a hip fracture, willingness to participate, age over 18 years, literacy, and no mental or neurological disorders. Also, the absence of severe family conflicts and not being employed in caregiving professions were mandatory. For patients, hospitalization in the surgical or orthopedic departments of Sina Hospital due to a hip fracture and the presence of the primary caregiver at home were inclusion criteria. Exclusion criteria included lack of cooperation of caregivers, participation in similar educational programs, occurrence of a family crisis, voluntary withdrawal, absence from educational sessions, and death of patients.

Intervention groups

Intervention group: Caregivers in this group underwent a structured support training program that included four training sessions on the principles of home care after hip fracture and problem-based coping skills. Control group: Caregivers in this group did not receive any direct training from the researcher.

Main outcome variables

Care pressure, quality of life, care education

General information

Reason for update

This trial record is being updated following consultation with methodological experts and senior academic advisors regarding the study's clinical trial documentation. Based on their review and recommendations, several fields have been revised to more accurately and comprehensively reflect the study's design and conduct, thereby improving the methodological transparency and reporting quality of the trial. All amendments described below were finalized prior to the start of actual participant recruitment and were applied consistently and prospectively to all enrolled participants; none affected the study's ethical approval, primary research question, target sample size, or overall study design. The specific reason for each field update is as follows: Randomization description: Following consultation with methodological experts, the randomization description was revised to more precisely reflect the method implemented: block randomization (block size of four), generated by an independent statistician, with concurrent 1:1 enrollment of both groups. This refinement was recommended to improve baseline comparability between groups and to strengthen the rigor of the allocation process. The field has also been corrected to resolve an internal inconsistency in the original entry (which described 40 participants per group in the free-text description, inconsistent with the formally registered target sample size of 70). Intervention group description: Based on expert recommendations aimed at enhancing the comprehensiveness of the educational content delivered, the intervention was structured as six sessions rather than four, allowing more thorough and gradual coverage of both practical home-care skills and problem-focused emotional-coping strategies. This field has been updated to reflect the six-session structure, frequency (three sessions per week), and content areas as implemented.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250329065176N2**
Registration date: **2025-04-30, 1404/02/10**
Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**
Update count: **1**

Registration date
2025-04-30, 1404/02/10

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-05-22, 1404/03/01
Expected recruitment end date
2025-08-23, 1404/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of supportive educative program on quality of life and caregiver burden of patients with hip fracture

Public title
The effect of supportive educative program on quality of life and caregiver burden of patients with hip fracture
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being a relative or family member of the patient Actively participating in the home care of a hip fracture patient Demonstrating a willingness to engage in the study Being at least 18 years of age Possessing literacy skills Having no psychological or neurological disorders
Exclusion criteria:
Lack of caregiver cooperation Participation in similar educational programs The occurrence of family crises during the study Voluntary withdrawal from the study,
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
- Care provider
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization (block size of four) was used to allocate participants to the intervention and control groups. The unit of randomization was individual. The random sequence was computer-generated by an independent statistician. The allocation ratio was 1:1 (control group: 35 participants; intervention group: 35 participants; total target sample size: 70). Recruitment for both groups occurred concurrently. Allocation concealment was ensured using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Envelopes were opened exclusively by an independent research assistant who had no role in recruitment, intervention delivery, data collection, or statistical analysis only after the principal investigator had confirmed participant eligibility and obtained informed consent.
Blinding (investigator's opinion)
Single blinded
Blinding description
Clinical caregivers: Doctors, nurses and physiotherapists responsible for the treatment of patients were not involved in the research educational intervention and were (blinded to the grouping of companies). Data analyst (data analyst) The person responsible for the statistical analysis of the data had access only to the numerical coding of the groups (without knowledge of whether they were control or intervention). Therefore, complete blinding was observed in this role.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sina Hospital, Tehran University of Medical Sciences (Research Ethics Committee)
Street address
Room 604, 6th Floor, Central Building, Tehran University of Medical Sciences, Qods Street and Keshavarz Boulevard Intersection, Tehran University, Secretariat of the Ethics Committee in Biomedical Research
City
Tehran
Province
Tehran

Postal code
1581749811
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.045

Health conditions studied

1

Description of health condition studied
Caregivers of hip fracture patients
ICD-10 code
S72.0
ICD-10 code description
Fracture of head and neck of femur

Primary outcomes

1

Description
Caregivers' caregiving pressure questionnaire (CBI)
Timepoint
Before the start of the intervention (baseline) and six weeks after baseline (approximately four weeks after completion of the final intervention session)
Method of measurement
The Caregiver Burden Inventory (CBI) consists of 24 items, which were developed by Novak & Guest in 1989 to measure objective and subjective caregiving burden, and it measures subjective caregiving burden with greater emphasis. This questionnaire consists of five subscales: time-related caregiving burden (questions 1 to 5), developmental caregiving burden (questions 6 to 10), physical caregiving burden (questions 11 to 14), social caregiving burden (questions 15 to 19), and emotional caregiving burden (questions 20 to 24). The caregivers' responses will be measured on a 5-point Likert scale (completely false to completely true), so that the samples will choose one of the following options for each question: completely false (score 1), false (score 2), somewhat true (score 3), true (score 4), and completely true (score 5). Accordingly, the scores obtained from this questionnaire will range from 24 to 120, and according to the mean and standard deviation of the total caregiving stress scores, scores of 24 to 39 will be considered mild caregiving stress, 40 to 71 moderate caregiving stress, and 72 to 120 severe caregiving stress (Abbasi et al., 2012).

2

Description
SF-36 Quality of Life Questionnaire
Timepoint
Before the start of the intervention (baseline) and six weeks after baseline (approximately four weeks after completion of the final intervention session)
Method of measurement
The SF-36 Quality of Life Questionnaire has 36 items divided into three levels: 1- Questions 2- Eight scales, each of which is obtained by combining 2 to 10 questions, which are: physical function, physical limitation, physical pain, general health, vitality, social function, mental problems, and mental health 3- A summary bi-scale that is formed by combining the scales in the form of physical health (physical function, physical limitation, physical pain, general health) and mental health (social function, mental problems, mental health, and vitality). Each dimension of the questionnaire measures different options in accordance with the questions, which, depending on its needs, include questions with two options (yes, no) and six options (all the time, most of the time, most of the time, sometimes, sometimes, never). The scores of each subscale vary from 0 to 100, with 0 reporting the worst and 100 reporting the best situation in the subscale in question. The score of each dimension will be determined by the scores of the headings in that dimension. The score for each subscale is calculated separately and averaged. The score is given as a percentage of health in that dimension. To calculate the total questionnaire, the sum of the scores for each subscale is divided by 8, and the resulting number should be between 0 and 100. The lowest score in this questionnaire is zero and the highest is 100, with zero representing the worst and 100 representing the best on the overall scale, and the closer the average score is to zero, the lower the quality of life will be, and the closer the average score is to 100, the higher the quality of life will be (55).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Caregivers in this group underwent a structured supportive-educational program comprising six one-hour sessions, delivered three times per week over two consecutive weeks. Content included: (1) introduction to hip fracture and recovery stages, (2) home-care management and prevention of secondary complications, (3) the caregiving role and adaptation to it, (4) problem-focused coping and effective communication skills, (5) anger management strategies, and (6) practical application of coping and stress-reduction techniques. Sessions were delivered by the principal investigator, a supervising professor, and a specialized psychiatric nurse, following a standardized protocol and a predefined fidelity checklist. Teaching methods included short lectures, group discussion, role-playing, and Q&A. A validated educational booklet, reviewed by ten nursing faculty members, was provided in the first session.
Category
Lifestyle

2

Description
Control group: They did not receive any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital, Tehran
Full name of responsible person
Seyyed Hossein Shafi'i
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Sina Hospital, Hassan Abad Square, Imam Khomeini Street, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
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Vice President for Research and Technology, 6th Floor, Central University Organization, Corner of Qods Street and Keshavarz Boulevard, Tehran, Iran
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Golnar Ghane
Position
Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Our study, which was designed to investigate the effect of a supportive education program on the caregiving stress and quality of life of caregivers of patients with hip fractures referred to the orthopedic department and clinic of Sina Hospital in Tehran, includes a set of valuable documents and files that can be shared in accordance with ethical principles. First, the questionnaires that the samples completed in two stages before the intervention and 14 days after the last training are the main treasure trove of our data. These questionnaires include demographic information, caregiver caregiving stress questionnaires, and the SF-36 quality of life questionnaire, which were measured with standard tools. If we hide the identities of the individuals with anonymous coding, these data can be fully available to other researchers to conduct further analyses or compare the results with similar studies. In addition, the data analysis file prepared in SPSS software, which shows our statistical results; from means and standard deviations to tests such as t-tests. This file can also be shared, but perhaps only parts of it will be made public. We will probably only share the raw, more detailed data with others upon formal request and approval from the ethics committee, because participant confidentiality is a red line for us. As for the educational content; the educational booklet that we used and because it is also going to be given to the control group after the study, it is completely ready to be shared. Imagine this content as a small library that can reach universities and other researchers and help train nurses. In general, we would like our data and findings to be shared with the world, but with caution and care, so that both science advances and the privacy of the samples is preserved.

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
Researchers working in academic institutions and industry

Under which criteria data/document could be used
Our anonymized data is a treasure trove that we can share with caution. Researchers can use this data for statistical analyses, such as comparing means or examining correlations, or use educational documentation to design similar courses. All of this will be under the supervision of an ethics committee and with a commitment to confidentiality. To request access, they must provide a formal letter stating the purpose of the research, ethical approval from a reputable institution, and a commitment not to publish the raw data so that we can safely share this information with them.

From where data/document is obtainable
To Dr. Golnar Ghane, the project's faculty executive, golnarghane@gmail.com

What processes are involved for a request to access data/document
In order for the documents or data files to reach the applicant, there are a few simple but important steps that need to be taken. Your request is like a letter that first reaches Dr. Golnar Ghane, the study administrator; simply apply via email or by calling the Tehran University of Medical Sciences School of Nursing and Midwifery. She will review your request—including the purpose of use and ethical documents—and if everything is complete, she will give initial approval. This usually takes a week. Next, the data must be anonymized; for example, student names and codes are removed to maintain privacy. This step, which is carried out by the research team, takes about 5 to 7 days. Then, the Ethics Committee of Tehran University of Medical Sciences takes a final look to make sure everything is in accordance with the principles—this also takes another week. Finally, the files (such as questionnaires or educational content) will be sent to you via email or secure drive. Overall, if your application is complete and flawless, it will take about 2 to 3 weeks for this treasure to reach you.

Comments