

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of Range Of Motion training on Activity Daily Living of patients with hip fractures that admitted to orthopedic ward

Protocol summary

Study aim

Determining the effect of range of motion training on daily life activities of patients with hip fractures

Design

The present study is a quasi-experimental with pre-test-post-test design and with a control group

Settings and conduct

Samples will be selected by continuous sampling method and simple random method. Also, in order to access the research samples, refer to the orthopedic ward of Shahid Beheshti Hospital in Babol and select your samples from among the patients admitted to the orthopedic wards with hip fracture by continuous random sampling method based on simple inclusion criteria. And then will be randomly divided into test and control groups. In order to prevent information contamination, the researcher first selected 40 patients from the hospitalized patients with hip fractures for the experimental group

Participants/Inclusion and exclusion criteria

Age between 18 and 65 years. No heart, lung, kidney, muscle, skeletal disease, history of major surgery, brain and psychiatric disorders. No restrictions on range of motion (ROM). No restrictions on daily activities due to other physical and psychological

Intervention groups

Then the questionnaire of daily life activities will be completed by all patients of both groups (test and control) at the beginning of the work. Training sessions begin after the patient's surgery with the permission of the patient's physician, and are taught by the researcher during the hospital stay and every day for 10-15 minutes until discharge

Main outcome variables

Training(rom) exercises on daily life activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220129053855N1**

Registration date: **2022-10-12, 1401/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-12, 1401/07/20**

Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name

Raheleh Faraje fard

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Range Of Motion training on Activity Daily Living of patients with hip fractures that admitted to orthopedic ward

Public title

The effect of Range Of Motion training on Activity Daily Living of patients with hip fractures that admitted to orthopedic ward

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 65 years No heart, lung, kidney, muscle, skeletal disease history of major surgery ,No restrictions on range of motion (ROM) ,No restrictions on daily activities due to other physical injuries No restrictions on daily activities due to psychological damage. Patients with physical pain or lack of energy to perform activities

Exclusion criteria:

Taking nonsteroidal anti-inflammatory drugs during the stud Exacerbation of symptoms and pain unwillingness of the patient to continue treatment ,Do not attend training classes for more than two consecutive sessions Occurrence of any unpredictable stressful event during the intervention

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: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Shahid Salehi-Gotab road, village below the border

City

Babol

Province

Mazandaran

Postal code

4734181370

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.IUMS.REC.1400.905

Health conditions studied**1****Description of health condition studied**

hip fracture

ICD-10 code

M84.4

ICD-10 code description

Pathological fracture, not elsewhere classified

Primary outcomes**1****Description**

Barthel Index (daily life activities)The original version of the instrument was in English and was designed in 1965 in the United States by Dorothea Barthel and Mahoney Florence. This tool has 10 questions and 0-5-10-15 style scoring and measures the state of self-sufficiency in daily life activities.

Timepoint

Training sessions begin after the patient's surgery with the permission of the patient's physician, and are taught by the researcher during the hospital stay and every day for 10-15 minutes until discharge.

Method of measurement

Lawton Index (instrumental activities of daily living)This index was designed by Lawton and Brody in 1969 to measure the skills related to independence in life. This tool has eight items, which include the items of using the phone, shopping, preparing food, tidying the house (housekeeping), washing clothes, moving with vehicles, the ability to accept responsibility, taking one's own medicine, and financial ability. . Each item includes a score of one (more ability) and a score of zero (less ability), and in women, the total score of the questionnaire is eight, which means independent performance in instrumental activities of daily life, but in men, the item is preparing food, washing Clothes and housekeeping are removed and the total score is calculated out of five (Lawton and Brody, 1969). In its Persian version, due to the lack of difference between men and women in the above questions, the total scores for women and men were considered eight (Soltanmohamadi et al., 2014).

Secondary outcomes**1****Description**

activity daily living are the skills and tasks that a person

deals with during the day and do their daily affairs, they are one of the most basic components of life.

Timepoint

In order to check ADL daily life activities, the standard questionnaire of ADL daily life activities will be used. In this way, before starting the exercises in both groups, the questionnaire is completed first, and after the training of the range of motion exercises in the test group and the routine training of the department, it is also completed at the time of discharge one week later and one month later in the clinic.

Method of measurement

In this questionnaire, 7 items are examined, each item has three points (0, 1, and 2), and the score 1 to 6 is classified as dependent, 7 to 10 as necessary, and 11 to 14 as independent. The general index of ADL ranges from zero to 14.

Intervention groups

1

Description

Intervention group: The present study is a semi-experimental study with a pre-test-post-test design and a control group. First, after the proposal is approved by the research council and the code of ethics is obtained from the vice president of research, the researcher sends a letter of introduction to the research environment from the university, and then goes to the research environment and while introducing himself to them, obtains permission to carry out the activity. Also, in order to conduct the research, in order to access the research samples, visit the orthopedic department of Shahid Beheshti Hospital in Babol and select your samples from among the patients hospitalized in the orthopedic departments with hip fracture using a continuous sampling method and in a simple random manner and based on the inclusion criteria. and then they will be divided into two test and control groups in a simple random manner.. Before any intervention and measurement, the written consent form of the company in the study will be completed by the subjects in order to prevent contamination of the researcher's information first from the patients. The hospital that suffers from hip fracture selects 40 patients for the test group and after the completion of the above number, the next 40 patients for the control group. Before doing any intervention and measurement, the written consent form of the company in the study will be completed by the subjects and it will be collected along with the patient's demographic profile form. Then, the daily life activities questionnaire will be completed by all patients of both groups (test and control) at the beginning of the work. For the test group, training sessions are started after the patient's surgery with the permission of the patient's treating physician, and during the hospitalization period and every day for 10-15 minutes until the discharge, training sessions are conducted by the researcher and for the convenience of the test group members, the sessions are held in a separate room. It will also be possible to continue the exercises at home using a

training booklet that contains sports pictures and in the form of training how to move in detail and how to perform daily activities. The question of being able to contact the researcher at the time of discharge More about this source text Source text required for additional translation information Send feedback Side panels

Category

Rehabilitation

2

Description

Control group: After 24 hours after the surgery, the control group will receive only the routine exercises and trainings of the department by the personnel after 24 hours after the surgery. In order to prevent contamination, the researcher first selects the test group based on the entry criteria and until the desired number is reached. He will perform this activity until the discharge and then select the control group and examine it for a week until the discharge. Considering that a month later, both the control and test groups will go to the clinic, the educational pamphlet will be given to the control group at the end, but the test group will receive the pamphlet from the beginning.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Rahele Faraji Fard

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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
 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
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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
 Not applicable
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

The present study is a quasi-experimental with pre-test-post-test design and with a control group. First, after the proposal is approved by the Research Council and the code of ethics is obtained from the Vice Chancellor, the researcher sends a request for a letter of introduction to the research environment from the university and then refers to the research environment and introduces himself to them and obtains permission to carry out activities.

When the data will become available and for how long

Training sessions begin after the patient's surgery with the permission of the patient's physician, and during the hospital stay and every day for 10-15 minutes until discharge by the researcher and for the convenience of the test group, sessions will be held in a separate room. The house will be done using an educational booklet that contains sports pictures and in the form of training on

how to move in detail and how to perform daily activities, and the samples will be given a phone number so that they can contact the researcher in case of any problems or questions. In addition, the control group will not experience any training protocol during the test and will receive daily activities and routines, but at the end of the work, the control group will be given a training booklet. Then one month after dischargeThe patient of the experimental group will refer to the clinic to check the daily life activities questionnaire again.

To whom data/document is available

Researchers working in academic and scientific institutes

Under which criteria data/document could be used

No copy

From where data/document is obtainable

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

It can be accessed using the contact number and email

Comments