Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Feb 2026

The effect of tele-rehabilitation nursing on the pain, joint stiffness, physical functions of knees and Health locus of control (HLC) among persons with knee osteoarthritis

Protocol summary

Study aim
Determining the effect of tele-rehabilitation nursing on the pain, joint stiffness, physical functions of knees and Health locus of control (HLC) among persons with knee osteoarthritis

Design
A clinical trial with a control group, with parallel groups, single blind, randomized on 36 patients

Settings and conduct
After receiving ethics code and IRCT code, In the Imam Reza Clinic and Shahid Rajaei Hospital located in Shiraz, after reviewing the existing files based on the entry and exit criteria, called people to enter the study via SMS or phone call. Will then be assigned to the intervention and control groups by a 4-block randomization method. People will not know which group they belong to (blind one-way blinding)

Participants/Inclusion and exclusion criteria
Major admission requirements: Primary osteoarthritis of the knee, ages 18-60, chronic knee pain over the past three months, no disease-related surgery, or no intra-articular injection in the knee for the past three months, having a smartphone and internet access. Major conditions of non-entry: Concomitant treatment with physiotherapy, chiropractic or acupuncture, secondary osteoarthritis of the knee, history of trauma, severe cognitive or psychological disorder.

Intervention groups
In the intervention group, in addition to routine visits and care, they receive multidisciplinary tele-rehabilitation care in the form of 8 Absentee meeting using the Internet and via a smartphone with WhatsApp platform. this program includes training and performance improvement in 3 dimensions: 1- The nature, symptoms and problems of the disease and methods of controlling them 2- Care related to diet and medication 3- Exercise. Then, for 6 weeks, people will exercise 3 times a week and perform rehabilitation care and will be followed up by phone.

Main outcome variables
pain, joint stiffness, physical functions of knees, Health locus of control (HLC)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220216054038N1**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**

Registration date
2022-07-11, 1401/04/20

Registrant information

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Fateme Keshavarzian

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
2022-08-08, 1401/05/17

Expected recruitment end date
2022-10-09, 1401/07/17

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of tele-rehabilitation nursing on the pain, joint stiffness, physical functions of knees and Health locus of control (HLC) among persons with knee osteoarthritis

Public title
The effect of tele-rehabilitation nursing on knee osteoarthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Complete and sign the consent form Being 18-60 years old Having chronic knee pain for the past three months Having primary type of knee osteoarthritis Based on the 0-4 Kellgren and Lawrence scale, people with a severity of 1-3 osteoarthritis of the knee according to this criterion No history of disease-related surgery (such as replacement and joint repair) Absence of any other disease around the affected limb Do not give any intra-articular injections during the last three months Having a smartphone and internet access Ability to use a smartphone Failure to participate in similar research
Exclusion criteria:
People who are being treated with physiotherapy, chiropractic or acupuncture Secondary knee osteoarthritis such as secondary to gout, metabolic arthritis, inflammatory rheumatism Grade 0 and 4 Kellgren-Lawrence scale recorded in the client's medical record and approved by the treating physician Morning joint stiffness more than 30 minutes History of trauma, fracture and dislocation of the affected knee Having radiculopathy or nerve damage and neuropathies Severe cognitive or mental disorder (dementia, Alzheimer's ...) that is recorded in the client's medical record and approved by the treating physician. History of allergies to herbal supplements and dietary recommendations used in the study Pregnant women or women who decide to become pregnant Use of anticoagulants Diseases or other malignancies (such as unstable cardiovascular disorders or lung disease, cancer, dementia) that limit the ability to adhere to recommended OA treatment, or uncontrolled diabetes Chronic use of Narcotics Inability to communicate and complete questionnaires Patients' unwillingness to continue participating in the training course
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Volunteers are assigned to one of the two groups of control and intervention using block randomization (A form of restricted randomization). Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all blocks is equal and in this two-group experiment we will have 4 blocks (including 2 participants in the intervention group and 2 participants in the control group). Randomization tools are also available from the website https://www.sealedenvelope.com) A useful site for generating a random sequence will be used for Block randomization. For concealment, random allocation concealment will be used, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, one of the envelopes of the letter will be opened, respectively, based on the order in which the eligible participants enter the study. After the random assignment concealment method, in order to protect their personal information, the subjects' names are entered in a booklet along with a numeric code that is not related to their national code or ID number or personnel number, and all information is based on computers, forms and analyzes. It is a numerical code and the booklet will only be kept safe by the researcher and out of the reach of others, and the information reported in the research will not be such that the identities of the subjects can be ascertained.
Blinding (investigator's opinion)
Single blinded
Blinding description
To reduce bias or bias related to the intervention and evaluate the consequences, the method of blind or covering a single blind blind is followed, with this method, the outcome can be measured objectively. In this method, the trial is planned in such a way that the participant does not know which of the two control or test groups belongs to. Because both groups go to the doctor according to routine visits and are routinely treated and ask the nurse and the doctor any questions they have about the disease and care. In addition, both groups are given a pamphlet on the set of nursing care related to the disease.
Placebo
Not used
Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, University of Rehabilitation Sciences and Social Health

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City

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Province

Tehran

Postal code

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Approval date

2022-05-20, 1401/02/30

Ethics committee reference number

IR.USWR.REC.1401.015

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

1- Pain: It refers to knee pain and as a score obtained from the questions (5 items) of the independent pain subscale, from the Osteoarthritis Index of Western Ontario Universities and McMaster in Knee Osteoarthritis (WOMAC) And the pain subscale scores range from 0-20, and higher scores indicate more severe pain. 2. Joint stiffness: refers to knee joint stiffness and is reported as a score obtained from questions related to the joint dryness subscale (2 items) of the Ontario Osteoarthritis Index of the Universities of Western Ontario and McMaster in Knee Osteoarthritis (WOMAC) The range of scores of the joint stiffness subscale is 0-8, and higher scores indicate a worse situation. 3. Physical joint function: refers to the function of the knee joint and is reported as a score obtained from questions related to the Physical Performance subscale (17 items) Osteoarthritis Index of the Universities of Western Ontario and McMaster in Knee Osteoarthritis (WOMAC) The range of scores of the physical function subscale is 0-68, and higher scores indicate a worse condition of the physical function of the knee joint. 4- Health locus of Control : In this study, the meaning of Health locus of Control is the amount of points that participants get from Form C of the Multidimensional Scale of Health locus of Control. This scale includes 4 subscales: 1- Internal belief (with a score range of 6-36), 2- Chance (with a score range of 6-36), 3- Physician (with a score range of 3-18) and 4- Influential people (with Score range 3-18). A higher score in the internal belief subscale than other subscales indicates the internal health locus of control and a higher score in the other three subscales (luck, physician and influential people) indicates the external health locus of control.

Timepoint

All the above variables will be measured at the beginning of the study (before the start of the study) and 49 days (7 weeks) and 70 days (10 weeks) after the start of the study and doing tele-rehabilitation program.

Method of measurement

The Ontario University of Western Ontario and McMaster Index in Knee Osteoarthritis (WOMAC) are used to measure pain, joint stiffness, and physical function, and the Multifaceted Form C Health Control is used to control control settings.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to visits and routine care, they receive multi-faceted tele-rehabilitation care in the form of 8 non-face-to-face (virtual) sessions for 7 weeks (2 sessions in the first week and 1 session per week for the next 6 weeks). The considered intervention aims to improve knowledge and awareness and increase skills in the implementation of multidimensional rehabilitation care. The dimensions of the tele-rehabilitation nursing program include three dimensions: 1- The nature, symptoms and problems of the disease, especially pain and their control methods (including resting the knee, using hot water and ice compresses, reducing heavy activities and modifying the way of life in the form of sleep and rest training and elimination 2- care Related to nutritional and medicinal diet 3- sports exercises. The presentation of this tele-rehabilitation program will be done using the Internet and through a smartphone with the WhatsApp platform, and the content will be sent in the form of voice, images, PDF, video, etc. Then, the participants are asked to perform the mentioned sports exercises 3 times a week for 6 weeks and perform rehabilitation care in the mentioned dimensions. The research participants will be followed up for 6 weeks. It should be noted that the duration of virtual meetings is about 20-40 minutes. Also, during the 6 weeks of the

intervention, the intervention group will be followed up every week in such a way that there will be a question and answer session and a group discussion, and in addition to that 3 times a week for the implementation of sports exercises and care provided individually and they will be followed up by phone call or message.

Category

Rehabilitation

2

Description

Control group: They will routinely go to the clinic and be under the supervision of a physical medicine and rehabilitation specialist and receive common recommendations and care, and so that people do not know which group they belong to, the rehabilitation nurse is in contact with them during the study period to guide them if they have any problems in the field of care and disease complications.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza (A.S.) special specialized and super specialized clinic

Full name of responsible person

Narges Arsalani

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2

Recruitment center

Name of recruitment center

Emtiaz(Shahid Rajaee)trauma Center

Full name of responsible person

Narges Arsalani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

دانشگاه علوم توانبخشی و سلامت اجتماعی تهران

Full name of responsible person

Hamidreza Khanke

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Web page address

https://uswr.ac.ir/index.jsp?fkeyid=&siteid=1&pageid=2285

Grant name

Grant code / Reference number

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

Yes

Title of funding source

دانشگاه علوم توانبخشی و سلامت اجتماعی تهران

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

University of social welfare and rehabilitation sciences

Full name of responsible person

فاطمه کشاورزیان
Position
Researcher - Master's student
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Other areas of specialty/work
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Person responsible for scientific inquiries

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University of social welfare and rehabilitation sciences
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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
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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
study protocol, information about the type of intervention, location, participants, statistical analysis (formula used and calculations and related tables), informed consent form, study report on whether the intervention was effective or not, and information about the main outcome
When the data will become available and for how long
The access period starts 7 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions as well as personnel working in hospitals and other rehabilitation centers
Under which criteria data/document could be used
To educate patients To increase self-care For guidance for similar research works To improve health Access conditions: People who have a valid certificate of qualified people (researchers or medical personnel) mentioned in the box above.
From where data/document is obtainable
Fatemeh Keshavrazian, contact number 00989107000794 Email address: mahsakeshavarzian27@gmail.com
What processes are involved for a request to access data/document
Review of the application by the principal investigator Examination of the application by the scientific officer Review by tutors and advisors
Comments
Greetings and Regards. The above study is related to my

master's thesis, if possible, check my request as soon as possible. Thank you very much