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Investigation of factors affecting fear of movement in patients with knee osteoarthritis

Submission date
08/05/2018

Recruitment status
No longer recruiting

Registration date
13/05/2018

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Knee osteoarthritis (OA) is a common disease that affects daily life activities with pain and disturbs quality of life and creates fear of movement in the person. People with knee osteoarthritis often prefer to avoid daily activities that can cause their pain to start, such as frequent standing up, going up and down stairs, and doing tasks that require the knee to bend. Severe every-day pain and fear and anxiety associated with pain lead to disturbance of activity and depression, all of which contribute to reduced mobility and further impairment of quality of life. There are, however, a limited number of studies examining the factors that are linked to fear of movement in people with knee OA. In these studies, there is no examination of which factor is most important. The purpose of this research was to investigate the factors that cause fear of movement in people with knee osteoarthritis and to create guidance for doctors to take into account when making treatment decisions. The aim is to reduce fear of movement that keeps the person from daily life.

Who can participate?
People aged 40-80 with knee osteoarthritis

What does the study involve?
Patients were asked to rate rest, activity, and night pain severity. The strength of the leg muscles and the range of motion of the leg joints were evaluated by the researcher. The researcher also used movement tests to assess balance and movement ability in the patients. Patients were asked to fill out questionnaires relating to fear of movement, osteoarthritis severity, depression and quality of life. All patients were assessed only once and all assessments lasted approximately 60 minutes.

What are the possible benefits and risks of participating?
It is not expected that volunteers will benefit directly or that their course of treatment will change. However, the results obtained from this study may contribute to the planning of treatment of other patients with osteoarthritis.

Where is the study run from?
Baskent University Hospital

When is the study starting and how long is it expected to run for?
January 2018 to May 2018

Who is funding the study?
This study was initiated and funded by the investigator.

Who is the main contact?
Dr Emel Sonmezer, emelsonmezer@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Emel Sonmezer

Contact details
Bağlica Kampusu Fatih Sultan Mahallesi Eskişehir Yolu 18.km Baglica/Etimesgut
Ankara
Türkiye
06790
00903122466666
emelsonmezer@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
What are the factors associated with kinesiophobia in patients with knee osteoarthritis?

Study objectives
This study was designed to test the hypotheses that kinesiophobia is related to quality of life, disability, pain intensity, muscle strength, range of motion, physical activity level, balance, mobility, depression and anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Baskent University Clinical Trials Ethical Committee, 05/04/2017, KA 17/39

Study design
Prospective single-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Kinesophobia in patients with knee osteoarthritis

Interventions
Personal demographic data was recorded after the patient was admitted to the clinic with adequate resting time. Patients were asked to rate rest, activity, and night pain severity. The strength of the leg muscles and the range of motion of the leg joints were evaluated by the researcher. The functional state and balance evaluations such as the Time Up and Go test, the Berg Balance Scale were applied by the researcher. Patients answered the Tampa Kinesiophobia Scale, Western Ontario and McMaster University Osteoarthritis Index, Hospital Anxiety Depression Scale and Nottingham Health Profiles questionnaires. All patients were assessed once and all assessments lasted approximately 60 minutes.

Intervention Type
Other

Primary outcome measure
Kinesiophobia assessed using a transculturally adapted version of the Tampa Scale of Kinesiophobia (TSK), which was developed to measure the fear of movement/re-injury of patients. The 4-point Likert scale (from strongly disagree (score = 1) to strongly agree (score = 4)) is used on the scale. A high score (maximum 68) indicates that the patient’s fear of falls and movements is excessive.

Secondary outcome measures
1. Pain Intensity. Knee pain severity was measured using the Visual Analog Scale (VAS) during activity and rest. The patients were asked to mark the pain levels they felt on a horizontal line of 100 mm. 0 indicated no pain and 100 indicated maximum pain, referring to intolerable pain. The point marked on the line was measured with a ruler, and the intensity of the pain felt by the persons was recorded in cm.
2. Quadriceps muscle strength measured using the Lafayette manual muscle testing system (Range: 0-300 lb [0-136.1 kg]). In order to measure the quadriceps muscle strength, the patient

was asked to perform a knee extension against the dynamometer stabilized in the bed by placing perpendicularly on the tibia immediately above the malleoli, while the patient was in sitting position with the knees in a 90-degree flexion position. The value displayed in the digital dynamometer was recorded as the quadriceps muscle strength.
3. Hamstring muscle strength. While the patient was lying in the supine position, the dynamometer was placed just above the ankle joint, and the patient was asked to flex his leg. The value displayed in the digital dynamometer was recorded as the knee flexion muscle strength.
4. Range of Motion. The patient was placed in a supine position, and the normal joint motion range of the knee joint in the direction of flexion and extension was passively measured using a manual goniometer.
5. Balance assessed using the Berg Balance Scale (BBS). This test assesses the ability of individuals to maintain their balances while performing their functional activities. This balance test consists of 14 items, and each section is rated between “0”, the lowest level of function, and “4”, the highest level of function. It measures the level of dependence and/or independence when performing positions, such as standing up from a sitting position, standing with the feet together, standing in tandem stance and balancing on one leg. It also measures whether the person can switch positions. The highest score from the BBS shows the best balance. A score of 0-20 shows high, 21-40 medium and 41-64 low risk of fall.
6. Mobility. The Timed Up and Go (TUG) Test was used to measure main balance and mobility including ambulation, transfer and turning ability. The participants, while sitting on a chair, were asked to get up and walk for 3 m and then to turn and sit back down. The elapsed time was recorded.
7. Physical activity level assessed using a validated version of the International Physical Activity Questionnaire (IPAQ) short form. The questionnaire was developed by Craig et al. to determine the physical activity levels of adults. In the evaluation of all the activities in the questionnaire, it is taken as a criterion that each activity is done at least 10 minutes at a time. A score of “MET-minute/week” is obtained by multiplying the minutes, days and MET values. Physical activity levels were classified as physically inactive (<600 MET-min/week), low in physical activity (600-3000 MET-min/week) and adequate in physical activity (>3000 MET-min/week).
8. Disability. The assessment of the pain, stiffness and physical function of the individuals included in the study was made using transcultural adaptation of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). WOMAC is an OA-specific, valid and reliable measure that includes 24 questions in three sub-headings consisting of pain, stiffness and physical function. Each question was rated according to the Likert scale, by accepting 0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely. The score of each section was calculated within itself. A high score indicates an increase in pain and stiffness, and physical functional impairment.
9. Health-related quality of life (HRQOL). The transcultural adaptation version of the Nottingham Health Profile (NHP) was used to assess the health-related quality of life. The Nottingham Health Profile is a general quality of life questionnaire designed to measure perceived health problems and the extent to which these problems affect normal daily activities. The survey had a total of 38 questions consisting of 6 sub-sections: lack of energy (3 items), pain (8 items), emotional reaction (9 items), sleep disturbance (5 items), social isolation (5 items), and physical mobility (9 items). The questions are answered as “yes” or “no” by the participants; and the best score to be taken in the sub-sections is “0”, and the worst score is “100”.
10. Depression and anxiety. A valid and reliable version of the Hospital Anxiety and Depression Scale (HADS) was used to assess the psychological status of the patients. The scale was prepared to screen for anxiety and depression in those with physical disease. It was developed by Zigmond and Snaith to determine the risk of anxiety and depression, and to assess its level, severity and change. A 3-point Likert scale was used in this scale consisting of 14 questions. The cut-off points of the Turkish version of HADS were set to be 10 for the anxiety sub-scale and 7

for the depression sub-scale.

Overall study start date
01/02/2017

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Willing to participate in study
2. Aged 40-80 years
3. Diagnosed with grade 2-3 osteoarthritis according to Kellgren-Lawrence scoring

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Other neurological and musculoskeletal diseases that affect balance and muscle strength
2. Prior knee surgery
3. Severe comorbidities
4. Pregnancy

Date of first enrolment
01/01/2018

Date of final enrolment
06/04/2018

Locations

Countries of recruitment
Türkiye

Study participating centre
Baskent University Hospital
Yukari Bahcelievler Maresal Fevzi Cakmak Caddesi 10. sokak no:45 Bahcelievler
Ankara

Türkiye
06490

Sponsor information

Organisation
Baskent University

Sponsor details
Bağlıca Kampusu Fatih Sultan Mahallesi Eskişehir Yolu 18.km Baglica/
Ankara
Türkiye
06790

Sponsor type
University/education

ROR
https://ror.org/02v9bqx10

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/02/2022	02/03/2022	Yes	No