STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Official title:
Physical Therapist as Primary Assessor for Patients With Knee Pain in Primary Care

NCT number: NCT03715764

The Regional Ethical Review Board in Gothenburg approved the study 2013-03-15, reference numbers: 979–12, T674–13, T497–14, T791–15.

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Study Description

Brief Summary:

In order to manage the future increase in osteoarthritis consultation, patients with osteoarthritis could be assessed by a physical therapist first, so that other patients with more severe conditions could get faster access to a primary care physician. In Swedish primary care, physicians and physical therapists are primary assessors for patients with suspected knee osteoarthritis. However, it is unclear if there are any differences between these managements in improving health-related quality of life (HrQoL), pain, physical function and self-efficacy.

There is a limited amount of studies about the impact on HrQoL, pain intensity, self-efficacy and physical performance in patients with knee pain being assessed and evaluated by a physical therapist as a primary assessor.

The overall purpose of this study is to evaluate the effects on self-rated HrQoL, pain intensity, self-efficacy and physical performance with either a physical therapist or a physician as primary assessor for patients with knee pain within primary health care.

Problem statements

Which effect does a clinical pathway with a physical therapist as primary assessor for patients with knee pain…

… have on self-rated HrQoL compared with a physician as primary assessor?

… have on self-rated pain intensity compared with a physician as primary assessor?

… have on physical performance compared with a physician as primary assessor?

… have on self-efficacy compared with a physician as primary assessor?

It is expected that this study will show the effects of two different primary assessors for patients with knee pain consulting primary health care. The results could clarify which profession that is most appropriate to be the primary assessor for patients with knee pain in primary health care.

Detailed Description:

Patient Recruitment Recruiters: Primary care centers.

Screening procedure

Nurses at the primary care centers will get information about the study and the screening protocol from the data collector and project leader. There will be contact persons at each recruiting unit that will be responsible for the protocols and to contact the data collector when a patient fulfills all the criteria for participation. The project leader will have regular contact with the contact persons at the recruiting units. All screening protocols will be sent to the data collector. All participants will get orally and written information about the study from the data collector, and patients will provide written informed consent.

Randomization

Using a computer-generated list of random numbers, participants will be randomly assigned to being assessed, diagnosed and treated either by a physiotherapist or a physician first. A project coordinator is included among the health care providers in the study, but will not be involved in the screening procedure nor the data collection. The project coordinator will manage the sequence generation, allocation concealment, enrolment and assignments of participants and keep the concealed randomization scheme and sequentially numbered, sealed envelopes in a locked cupboard (in the same building where the enrolment will be), only available for the project coordinator. The project coordinator reveals the allocation to the participant shortly after the baseline measurement and to the health care providers.

Participants and health care providers in both groups will be aware of the allocated group, whereas data collector, data analyst and statistician will be kept blinded of allocation until completion of all outcome assessments.

The blinded data collector and analyst (is a physical therapist) whom is not involved in assessing diagnosing and treating patients with knee osteoarthritis while the study is conducted.

Data Collection

Measurements will be collected at baseline (before randomization), at 3- , 6- , and at 12 months follow up. All data will be coded and managed according to the Data Protection Act (1998:204), which means that all data will be confidential, and no unauthorized will have access to the patient registry. The results will be presented at group level; therefore, no individual information can be identified. Data will be saved for at least 10 years to enable audit.

Sample size

To detect a minimal clinical improvement in health-related quality of life of 0.121(SD 0.2) on the EQ5D-index, with a two-sided 5% significance level and a power of 80%, a sample size of 50 patients per group will be necessary, given an anticipated dropout rate of 14%.

Statistical analysis

Data will be analyzed descriptively and presented as numbers and percent, mean and standard deviation or median and 25th to 75th percentiles. The primary outcome will be mean change in HrQoL (EQ5D-index and EQ5D-scale) and secondary outcomes will include mean change in pain intensity (VAS), physical performance (30CST) and self-efficacy (ASES-S). The changes in scores for the outcomes will be constructed by calculating raw differences between baseline and the follow ups.

For group comparison the X2-test will be used for nominal data and Fischer's exact test for small numbers, parametric student t-test for continuous variables and Mann-Whitney's test for ordinal data and at skewed distributions. Statistical analysis will be made in SPSS Windows and the analysis will be applied with intention-to-treat (ITT). The level of significance will be $p< 0.05$.

Study Design

Study Type: Interventional (Clinical Trial)

Actual Enrollment: 69 participants. Anticipated enrollment, 100 participants.

Allocation: Randomized

Intervention Model: Crossover Assignment

Masking: Double (Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Arms and Interventions

Intervention: Physical therapy assessment

Patients allocated to the intervention group will be assigned to an assessment and evaluation by a physical therapist. If they are diagnosed with knee osteoarthritis they will get an offer to participate in a patient education program and physical training with an individualized exercise program made by a physical therapist. Patients will be offered individual treatment if they decline to participate in the education program, or if they have another diagnosis than osteoarthritis. Anytime after the first assessment by the physical therapist, the patient will be able to contact a physician if they want to.

Control: Physician assessment

Allocation to the control group will involve an assessment and evaluation made by a physician. Further measures will then be determined by attending physician and the procedures that might get included are drug prescriptions, referral to x-ray examination, referral to a physical therapist or another health care provider. Anytime after the first assessment by the physician, the patient will be able to contact a physical therapist if they want to, even though if they have not been referred by the physician.

Outcome Measures

Primary Outcome Measures

Change from health related quality of life (HrQoL) at 12 months

[Time Frame: Baseline (before randomization) to 12 months]

A Swedish version of Euroqol-5 dimensions-3 levels (EQ5D-3L) will be used to assess perceived self-rated health-related quality of life. EQ5D-index respectively EQ5D-VAS will be presented. The questionnaire contain five dimensions and results in an index ranging from -0,549 to 1 using the UK tariffs. An index of 1 indicate full health. The EQ5D-VAS is a visual analogue scale ranging from 0 to 100, where 0 is worst imaginable health state and 100 is best imaginable health state.

Secondary Outcome Measures

Change from pain intensity at 12 months

[Time Frame: Baseline (before randomization) to 12 months]

The mean pain intensity (over the past month) will be measured by a visual analogue scale (VAS) ranged from 0 which will correspond no pain and 100 the worst imagined pain.

Change from physical function at 12 months

[Time Frame: Baseline (before randomization) to 12 months]

Physical performance will be measured with 30 seconds chair stand test (30CST). Number of stands will be counted.

Change from self-efficacy at 12 months

[Time Frame: Baseline (before randomization) to 12 months]

Self-efficacy will be assessed with Arthritis Self-Efficacy Scale-Swedish version (ASES-S). Each question range from 10-100, where 10 is very insecure and 100 is very confident. The questionnaire consists three subscales in how patients are experiencing their 1) pain, 2) physical function, 3) other symptoms. Each subscale results in a mean score ranging from 10 to 100 where 10 means very insecure and 100 means very confident.

Other Outcome Measures:

Demographic data

[Time Frame: Baseline (before randomization)]

Demographic data such as age, sex, origin, marital status (married/living with partner or single household), education, self-reported work status and pain duration, will be included in a standardized questionnaire. Patients' body weight and height will be measured to calculate a Body Mass Index (BMI).

Eligibility Criteria

Ages Eligible for Study: 38 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Inclusion Criteria:

Age >38 years old, knee pain most of the days the last month, crepitus on active motion, morning stiffness, duration less than 30 minutes. The patient has to understand the Swedish language to follow test instructions and to complete the self-administered questionnaires.

Exclusion Criteria:

Already been assessed/diagnosed by a healthcare provider for current knee pain, knee pain due to a traumatic cause, other rheumatic or systemic diseases, severe somatic or mental disease, pregnancy.