STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Official title:

A Cost-efficiency Analysis of Primary Assessors for Patients With Knee Pain in Primary Care

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The Regional Ethical Review Board in Gothenburg approved the study 2013-03-15, reference numbers: 979–12, T674–13, T497–14, T791–15 and 2020-00432.

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Study Description

Brief Summary

Background: Almost half of the Swedish population are overweight or obese. This will probably affect the incidence of osteoarthritis since overweight is a strong risk factor. Osteoarthritis consultations is expected to increase with 30-50% within the next 20 years. Today, in Swedish primary care, both physicians and physiotherapists are primary assessors for patients with suspected knee osteoarthritis. A task shifting with physiotherapists as the only primary assessor could increase the access rate to physicians in primary care for patients with more severe disorders. Yet, it is unclear what effects these different healthcare processes have and the costs of it.

Purpose: The overall purpose of this study is to perform an economic evaluation of two healthcare processes, where a healthcare process initiated by a physiotherapist is compared with when it is initiated with a physician for patients with suspected knee osteoarthritis.

Methods: 100 patients will be randomized either to a physiotherapist or to a physician for first assessment, diagnosis and treatment. Measurements of health-related quality of life and costs for visits to physiotherapist, physician or other healthcare provider, drug prescriptions and sick-leave will be collected. A cost-effectiveness analysis will be conducted, presenting incremental cost-effectiveness ratio (ICER) and a non-parametric bootstrapping will be conducted to demonstrate the uncertainties surrounding the ICER.

Expected results: It is expected that this randomized controlled study will show the effects on quality adjusted life years, cost-efficiency, and cost-utility of two different primary assessors for patients with suspected knee osteoarthritis consulting primary care. The results could clarify which profession that is most appropriate to be the primary assessor for patients with suspected knee osteoarthritis in primary care.

Detailed Description

Problem statements

What is the difference in cost efficiency between a healthcare process with a physiotherapist as primary assessor and a physician as primary assessor for patients with suspected KOA?

Which effect does a clinical pathway with a physiotherapist as primary assessor for patients with suspected knee osteoarthritis have on quality adjusted life years compared with a physician as primary assessor?

What are the differences in costs between the two healthcare processes initiated by either a physiotherapist or a physician set against the differences in effects?

Patient recruitment

Some data has already been collected for another clinical trial (ID: NCT03715764), which will be used in this study too. The patient recruitment is finished, while data collection regarding cost variables has not started yet.

Patients were recruited from primary care centers and rehabilitation centers in southwestern Sweden.

Screening procedure

Nurses and administration personnel at the recruitment units got information about the study and the screening protocol from the data collector and project leader. Each recruiting unit had a contact person that were responsible for the protocols and to contact the data collector when an eligible patient was found. It was regular contact between the project leader and the contact persons at the recruiting units. All screening protocols were sent to the data collector. All participants got orally and written information about the study from the data collector, and patients provided written informed consent.

Randomization

A computer-generated list of random numbers was used, where participants were randomly assigned to being assessed, diagnosed and treated either by a physiotherapist or a physician first. The project coordinator managed the sequence generation, allocation concealment, enrolment and assignments of participants and kept the concealed randomization scheme and sequentially numbered, sealed envelopes in a locked cupboard (in the same building where the enrolment was), only available for the project coordinator. The project coordinator revealed the allocation to the participant shortly after the baseline measurement and to the health care providers. Data collector, data analyst and statistician were blinded of allocation until completion of data collection for the primary outcome measures at the 12 months follow up for the last recruited patient. Group allocation was revealed when analyzing data for the other clinical trial (ID: NCT03715764).

The project coordinator was not involved in the screening procedure nor the data collection and was not included among the healthcare providers in the study. The blinded data collector and analyst, whom is a physiotherapist, were not involved in assessing, diagnosing and treating patients with knee osteoarthritis while the first study (ID: NCT03715764) was conducted.

Data collection

Demographic data and measurements of health-related quality of life (HrQoL) has already been collected for another clinical trial (ID: NCT03715764). These data will also be used for the cost-efficiency analysis. Demographic data were collected at baseline. Measurements of HrQoL were measured with EuroQol 5 dimensions 3 levels (EQ5D-3L) and collected at baseline (before randomization), 3- , 6- and 12 months follow ups.

New data collection will be made for cost variables. Data regarding costs for the healthcare processes will be extracted from patient journals. The costs for visits to physiotherapist, physician or other healthcare provider will be collected from the healthcare organization. The drug prices will be collected from the Swedish Association of Local Authorities and Regions for the time period the drugs were prescribed. Production loss due to sick-leave and health care visits will be valued according to mean gross salary (including taxes and social fees).

Calculating total costs (number of contacts per patient * costs) for:

- Physiotherapy contacts in primary care
- Physician contacts in primary care
- Referrals to x-ray
- Referrals to other healthcare givers
- Drug prescriptions
- Sick-leave days

Data management

All data will be coded and managed according to the General Data Protection Regulation. All data will be confidential and only authorized will have access to the patient registry. No individual information can be identified since the results will be presented at group level. Data will be saved for at least 10 years to enable audit.

Sample size

A sample size of 50 patients per group will be necessary to detect a minimal clinical improvement of 0.121(SD 0.2) on the EQ5D-3L-index, given an anticipated dropout rate of 14%. The sample size calculation was calculated with a two-sided 5% significance level and a power of 80%.

Statistical analysis plan

Data will be analyzed descriptively and presented as numbers and percent, mean and standard deviation or median and 25th to 75th percentiles. Statistical analysis will be made in SPSS Windows and the analysis will be applied with intention-to-treat (ITT).

The economic evaluation will be developed together with a health economist. The method will be a cost-effectiveness analysis alongside the clinical trial comparing costs and effects for the two alternatives based on collected data from the trial. The EQ5D-3L measurements will be used for analyzing quality adjusted life years. The result will be presented as an incremental cost-effectiveness ratio (ICER) and a non-parametric bootstrapping will be conducted to demonstrate the uncertainties surrounding the ICER.

Study Design

Study Type:	Interventional (Clinical Trial)
Actual Enrollment:	69 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
	Participants with suspected knee osteoarthritis were either randomized to a physiotherapist or a physician as primary assessor for assessment and treatment. After the first assessment that the patients were assigned to, the patients could choose to seek the other health care provider if they wanted to. This study focuses on analyzing cost efficiency of the health care processes for patients with suspected knee osteoarthritis in primary care.
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Treatment

Arms and Interventions

Physiotherapist as primary assessor - Intervention

The healthcare process will be started with a physiotherapist assessment and treatment. Treatments could involve individual or group treatment including patient education and physical exercise. Patients can seek a physician anytime after the first assessment with the physiotherapist.

Physician as primary assessor – control

The healthcare process will be started with a physician assessment and treatment. Treatments could involve drug prescription, referral to x-ray, referral to other healthcare providers and sick-leave.

Patients can seek a physiotherapist anytime after the first assessment with the physician.

Outcome Measures

Primary Outcome Measures

Health related quality of life

[Time Frame: Baseline to one year after baseline.]

A Swedish version of Euroqol-5 dimensions-3 levels (EQ5D-3L) was used to assess perceived self-rated HrQoL. EQ5D-index respectively EQ5D-VAS will be presented. The questionnaire contained five dimensions and resulted 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

A) *Costs for physiotherapy contacts*
   [Time Frame: Baseline to one year after baseline.]

   Number of visits registered in patients journal * cost

B) *Costs for physician contacts*
   [Time Frame: Baseline to one year after baseline.]

   Number of visits registered in patients journal * cost

C) *Costs for sick-leave*

[Time Frame: Baseline to one year after baseline.]

Number of sick-leave periods, including number of days with sick leave * costs

D) *Costs for drug prescription*

[Time Frame: Baseline to one year after baseline.]

Number of drug prescriptions* costs

E) *Costs for referral to x-ray*

[Time Frame: Baseline to one year after baseline.]

Number of referrals to an x-ray examination of the knee * costs

F) *Costs for referral to other healthcare professionals*

[Time Frame: Baseline to one year after baseline.]

Number of referrals to other professionals for an examination of the knee * costs

Eligibility Criteria

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

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Inclusion Criteria

- Knee pain most of the days the last month
- Over 38 years old
- Crepitus on active motion
- Morning stiffness less than 30 minutes

Exclusion Criteria

- Not been diagnosed for current knee pain
- Non-traumatic cause due to current knee pain
- No other rheumatic, severe somatic or psychological diseases that can affect the outcome measures.
- Not pregnant
- Does not know enough Swedish to answer questionnaires.