

BMJ Open Study protocol for an observational register-based study on health and risk factors in patients with hip and knee osteoarthritis

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To cite: Gustafsson K, Rolfson O, Eriksson M, *et al.* Study protocol for an observational register-based study on health and risk factors in patients with hip and knee osteoarthritis. *BMJ Open* 2018;**8**:e022812. doi:10.1136/bmjopen-2018-022812

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-022812>).

Received 11 March 2018
Revised 28 June 2018
Accepted 31 July 2018

ABSTRACT

Introduction Hip and knee osteoarthritis is a leading cause of disability worldwide. Currently, the course of deterioration in pain and physical functioning in individuals with osteoarthritis is difficult to predict. Factors such as socioeconomic status and comorbidity contribute to progression of osteoarthritis, but clear associations have not been established. There is a need for early identification of individuals with slow disease development and a good prognosis, and those that should be recommended for future joint replacement surgery.

Methods and analysis This nationwide register-based study will use data for approximately 75 000 patients who sought and received core treatment for osteoarthritis in primary healthcare, and were registered in the Swedish population-based National Quality Register for Better Management of Patients with Osteoarthritis. These data will be merged with data for replacement surgery, socioeconomic factors, healthcare consumption and comorbidity from the Swedish Hip Arthroplasty Register, the Swedish Knee Arthroplasty Register, Statistics Sweden and the National Board of Health and Welfare, Sweden. The linkage will be performed using personal identity numbers that are unique to all citizens in Sweden.

Ethics and dissemination The study was approved by the Regional Ethical Review Board in Gothenburg, Sweden (dnr 1059–16). The results from this study will be submitted to peer-reviewed journals and reported at suitable national and international meetings.

Trial registration number NCT03438630.

INTRODUCTION

Osteoarthritis (OA) is the most common joint disease and has a major public health impact.¹ In Sweden, one in four people aged over 45 years suffers from OA in some joint.² The disease develops slowly over time and leads to joint stiffness, gradually increased pain and difficulty performing activities of daily living.^{2–4} Diagnosis is based on clinical criteria, with radiographs only needed in uncertain diagnostic cases or when surgical interventions are planned.^{5–7} Radiographic findings often correlate poorly with patients' symptoms, and awaiting radiography may also

Strengths and limitations of this study

- This study will use a nationwide population-based cohort to capture data for socioeconomic factors, comorbidity and patient-reported measures that affect individuals with osteoarthritis.
- This study will include a reference cohort from the general Swedish population, matched by year of birth, sex and residence.
- The study design will allow investigation of changes over time in the same individual and the progression of osteoarthritis to be followed.
- A limitation of register-based studies is that the data to be collected are predetermined, and it is difficult to add other individual data for study purposes.

delay treatment early in the disease.^{8,9} Today, OA is considered a whole-organ disease in which joint structures such as the ligaments, tendons, synovium, meniscus and subchondral bone are affected as well as the cartilage.⁴ The causes of OA are not fully established; however, the strongest predictor for an OA diagnosis is age,³ and disease development is associated with an interplay between different risk factors in combination with the common biomechanic denominator.^{10,11} Physical inactivity due to the symptoms of OA is in itself a risk factor for physical and mental illness and premature death.¹² Individuals with OA have a higher risk for comorbidity-related mortality than the general population, especially in cardiovascular diseases.¹³ With the increased prevalence of obesity and population ageing, OA is likely to be a major burden for health systems and a challenge for the future.^{2,3}

Research and guidelines show that individually adapted physical exercises, information about OA, self-management and weight control help prevent disability and impairment in health,^{14–16} and may have potential to delay replacement surgery^{16,17} in individuals with OA. In Sweden, core treatment



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for OA comprising education and supervised exercises in a supported self-management programme has been standardised since 2008. Evaluation and follow-ups are registered in the National Quality Register for Better Management of Patients with Osteoarthritis (BOA).¹⁵

Currently, the course of pain and physical functioning in individuals with hip or knee OA is difficult to predict and can vary over time.^{4 18 19} Factors that may predict deterioration include high comorbidity, low level of education, presence of OA in several joints and a low physical activity level.^{18 19} At this stage, early identification of those who will have a good prognosis of slow disease progression and those who will need more interventions or replacement surgery is not possible. Replacement surgery is an effective treatment method to decrease pain and improve function and health-related quality of life (HRQoL) in patients with OA. However, it is only suitable for a minority of patients,²⁰ those with severe symptoms in combination with radiographic-verified OA and where other non-surgical treatments have failed.^{15 21} Treatment guidelines and systematic reviews describe three main indicators for replacement surgery: a) pain that does not respond to non-surgical treatment and b) impairment in HRQoL and function, in combination with c) radiographic changes. To optimise outcomes after surgery and reduce the risk of revision surgery, it is important that patients are carefully selected according to indicators and timing of surgery.^{21 22} As the evidence base is weak and indicators for replacement surgery are mostly subjective, the need for surgery is often determined by the individual surgeon in consultation with the patient.²² More knowledge is needed to facilitate early identification of factors that can predict deterioration of OA. This knowledge can be used to design treatment according to prognosis, improve criteria for surgery^{18 19} and identify factors predicting better or worse postoperative outcomes.²²

Merging data from the BOA Register with data from other health and socioeconomic data sources in Sweden will allow us to follow patients with OA through the progress of their disease. The overriding aim of this study is to increase knowledge about those who have received education and supervised exercises as a core treatment for hip and knee OA and are registered in the BOA Register, and identify factors that can predict long-term outcomes for this population.

METHODS AND ANALYSIS

Study design and research questions

This nationwide observational cohort study will use prospectively obtained individual-level data from five main sources: the BOA Register, the Swedish Hip Arthroplasty Register (SHAR), the Swedish Knee Arthroplasty Register (SKAR), Statistics Sweden and the National Board of Health and Welfare. Data will be merged using the personal identity number (PIN) that is unique to all citizens in Sweden. This will create a research database that will be used to answer three research questions:

1. What are the differences between the population included in the BOA Register and the general Swedish population regarding health and socioeconomic factors?
2. What factors that predict replacement surgery can be identified among patients with hip or knee OA at their first registration in the BOA Register?
3. What factors that predict outcomes after replacement surgery can be identified among patients with hip or knee OA at their first registration in the BOA Register?

Study population

The study cohort will comprise all patients with a first registration (baseline) in the BOA Register between 2008 and 2016 (approximately n=75 000). These patients sought treatment for knee and/or hip pain in primary healthcare in Sweden, and were referred for standardised core treatment (education and supervised exercises) after a confirmed clinical/radiographic OA diagnosis. Recommendations for OA diagnosis from the Swedish National Board of Health and Welfare are used to determine inclusion in the standardised core treatment and registration in the BOA Register; namely, an overall assessment of medical history, symptoms and clinical findings.⁵ These guidelines are in line with internationally accepted diagnostic criteria,^{6 7} and according to the guidelines, radiographic examination should only be used in uncertain cases, if the patient is not responding to treatment or when a surgical intervention is planned.

A reference cohort (approximately n=225 000) drawn from the general Swedish population who had never been included in the BOA Register will be identified from the Statistics Sweden Swedish Population Register, and matched (1:3) to each patient in the study cohort (as at baseline) by year of birth, sex and residence (geographical county areas in Sweden).

Data sources

The BOA Register

The BOA Register was initiated in 2008. Since 2010, it has been a national Swedish quality register that includes patients with hip/knee OA and evaluates the standardised core treatment (education and supervised exercises). Exclusion criteria for participation and registration in the BOA Register are: suspicion of or confirmed tumour, rheumatoid arthritis, sequel hip fracture, chronic pain or fibromyalgia, total joint replacement within the past 12 months, other surgery of the knee or hip joint within the past 3 months and patients not able to read or understand Swedish.¹⁵ Data from patients and physiotherapists are reported to the BOA Register at baseline, and outcomes of the standardised core treatment are evaluated and reported through patient-reported outcome measures at 3 and 12 months and physiotherapist-reported outcome measures at 3 months¹⁵ (see [table 1](#) for description of single variables). This supported self-management programme is today an implemented activity that is available in all geographical county areas in Sweden,

Table 1 Description of the single variables collected from the Better Management of Patients with Osteoarthritis Register

BOA Register		First registration (baseline)	Evaluation 3 months	Evaluation 12 months
Variable category	Variable			
Date	Date of visits	x	x	x
Patient-reported measures	Age, sex, weight, height	x		
	Smoking	x		
	Most affected joint (hip, knee or hand)	x	x	x
	Other affected joints	x	x	x
	Fear avoidance	x	x	x
	Request for surgery	x	x	x
Physical activity level	Duration of physical training *	x	x	x
	Duration of physical activity †	x	x	x
Satisfaction	Satisfaction with treatment		x	x
Musculoskeletal comorbidity	Charnley class‡	x	x	x
Pain	Pain severity§ NRS	x	x	x
	Pain frequency	x	x	x
Health-related quality of life	EuroQoL-5 dimensions	x	x	x
	EuroQoL VAS	x	x	x
Self-efficacy	Arthritis self-efficacy scale	x	x	x
Physiotherapist-reported measures	Earlier radiography/MRI/surgery in the most affected or the contralateral joint	x		
	Earlier treatments (including physiotherapy/adapted training/information on weight reduction/pharmaceuticals)	x		
	Waiting list for surgery	x	x	
Follow-up	Radiography/MRI/surgery in the most affected or the contralateral joint since last evaluation		x	
	Compliance with intervention		x	

*Answering to the question: "During a regular week, how much time do you spend exercising on a level that makes you short winded, for example, running, fitness class or ball games?" graded on categorical scale from '0' to '>120 min'.

†Answering to the question: "During a regular week, how much time are you physically active in ways that are not exercise, for example, walks, bicycling or gardening?" graded on categorical scale from '0' to '>300 min'.³⁴ These questions have been developed by the National Board of Health and Welfare in Sweden for population-based studies on physical activity and have been validated against an accelerometer.³⁴

‡Charnley class: classifications of musculoskeletal impairment. Class A corresponds with unilateral hip or knee OA; class B bilateral hip or knee OA and class C indicates multiple joint OA or some other condition that inhibits the patient's ability to walk.³⁵

§Answering to: "Select the box that corresponds to your average pain from your most affected joint the last week".

NRS, numeric rating scale; OA, osteoarthritis; VAS, visual analogue scale; MRI, magnetic resonance imaging.

with approximate 450 units conducting the therapy and reports to the BOA Register. At the end of 2016, the BOA Register comprised approximately 75 000 patients, with a mean age of 66±9.6 years.²³ The level of coverage (how many of the units that are running the intervention of standardised core treatment, that also register in the BOA Register) calculated by the end of 2014 was 80% and the level of completeness 69% (how many of the patients that have participated in the intervention of standardised core treatment that have been reported to the register). The

response rate for each reported question at baseline and 3 months was 97% and at 1 year 84%.²⁴

The SHAR and SKAR

The SHAR and SKAR collect patient-related and procedure-related data on all hip and knee replacement surgeries in Sweden (tables 2 and 3). In SHAR, patient-reported outcomes such as joint pain, HRQoL and satisfaction with treatment are registered preoperatively and 1, 6 and 10 years postoperatively. Since 2008, SKAR has

Table 2 Description of single variables collected from the Swedish Hip Arthroplasty Register

Swedish Hip Arthroplasty Register		Before surgery	Follow-up 1 year
Variable category	Variable		
Diagnosis (at hip)	ICD-10	x	
	Laterality	x	
Date	Date of surgery	x	
Type of surgery	Primary, revision, reoperation	x	
	Total, partial, resurfacing hip replacement	x	
Patient-reported measures	Smoking	x	
Musculoskeletal comorbidity	Charnley class*	x	x
	Pain	Hip pain VAS	x
Health-related quality of life	EuroQol-5 dimensions	x	x
	EuroQol VAS	x	x
Treatment before hip replacement surgery	Physiotherapy	x	
	Standardised core treatment of education and supervised exercises	x	
Satisfaction	Satisfaction with treatment		x

*Charnley class: classifications of musculoskeletal impairment. Class A corresponds to unilateral hip disease; class B bilateral hip disease and class C indicates multiple joint disease or some other condition that inhibits the patient's ability to walk. ICD-10, International Classification of Diseases, tenth revision; VAS, visual analogue scale.

successively registered preoperative and 1-year postoperative patient-reported outcomes (the same variables as in SHAR along with the knee-specific instrument Knee Injury and Osteoarthritis Outcome Score). In 2016, the SKAR included patient-reported outcomes for approximately 33% of all primary knee replacement surgeries. These registers are two of the oldest quality registers in Sweden; SHAR started in 1979 and SKAR in 1975. Both registers have a high completeness (97%–98%) (number of reported hip/knee replacements divided by the number of hip/knee replacements performed).^{25 26} The response rate to the patient-reported outcomes is in the SHAR 85%, and in the SKAR 84% (calculated on the hospitals who register patient-reported measures). Each year, approximately 14 000 OA-related primary hip replacement surgeries and 12 000 primary knee

Table 3 Description of single variables collected from Swedish Knee Arthroplasty Register

Swedish Knee Arthroplasty Register		Before surgery	Follow-up 1 year
Variable category	Variable		
Diagnosis (at knee)	ICD-10	x	
	Laterality	x	
Date	Date of surgery	x	
Type of surgery	Primary, revision, reoperation	x	
	Total, partial, resurfacing knee replacement	x	
Patient-reported measures			
Musculoskeletal comorbidity	Charnley class*	x	x
Pain	Knee pain VAS	x	x
Health-related quality of life	EuroQol-5 dimensions	x	x
	EuroQol VAS	x	x
Satisfaction	Satisfaction with treatment		x
Patient-reported knee function	Knee injury and Osteoarthritis Outcome Score	x	x

*Charnley class: classifications of musculoskeletal impairment. Class A corresponds to unilateral knee disease; class B to bilateral knee disease and class C to multiple joint disease or some other condition that inhibits the patient's ability to walk. ICD-10, International Classification of Diseases, tenth revision; VAS, visual analogue scale.

replacement surgeries are performed in Sweden. The mean age of patients in both registers is approximately 69 years.^{25 26}

Statistics Sweden

Statistics Sweden is an administrative governmental agency. The agency's main task is to supply users and consumers with statistics for decision-making and microdata for research purposes (after ethical approval). Statistics Sweden administers several different databases. In this study, socioeconomic microdata will be drawn from the Swedish Population Register and the Longitudinal Integration Database for Health Insurance and Labour Market Studies (LISA). The Swedish Population Register provides data for vital events such as births, deaths, residence and marital status, and LISA provides socioeconomic data (table 4).

The National Board of Health and Welfare

The National Board of Health and Welfare is a Swedish government agency that sits under the Ministry of Health and Social Affairs. Their main task is to contribute to

Table 4 Description of single variables collected from Statistics Sweden

Statistics Sweden		From 3 years before baseline	Baseline	End of 2016
Variable category	Variable			
The Swedish Population Register				
Demography	Year of birth, place of birth		x	
	Sex, residence		x	
	Relocation within Sweden, emigration		x	
	Marital status		x	
	Date of death			x
The Longitudinal Integration Database for Health Insurance and Labour Market Studies				
Income	Individual disposable income	x		
	Family disposable income	x		
Family circumstances	Family type		x	
	Children at home		x	
	Number of people in the household		x	
Education	Educational attainment		x	
	Year of graduation from highest education		x	
Sickness benefits	Days with sickness compensation	x		
	Total income due to sickness	x		
	Days with occupational injury compensation	x		
	Total income due to occupational injury	x		
	Days with rehabilitation compensation	x		
	Total income due to rehabilitation	x		
Unemployment benefits	Unemployment classification	x		
	Total income from unemployment compensation	x		
	Days unemployed	x		
	Days partly unemployed	x		
Welfare benefits	Family welfare benefits	x		
	Housing benefits	x		
Occupation	Occupational classification		x	

equal access to good health and social care by managing healthcare regulations and providing guidelines. All healthcare providers are mandated to continuously report to the authority's health data registers. These data are used to produce and develop statistics for follow-ups and evaluation of the healthcare system. In addition, after ethical approval, researchers can access information from the Board's different health data registers. The Swedish

National Patient Register started in 1964, is nationwide since 1987 and covers all inpatient care and since 2001 all specialised outpatient visits (including day surgery) with diagnosis codes (International Classification of Diseases, tenth revision) and admission/discharge dates from both private and public caregivers. However, primary health-care is not yet covered, and the register only contains information about healthcare provided by physicians.

Table 5 Description of single variables collected from the National Board of Health and Welfare

National Board of Health and Welfare		From 3 years before baseline	End of 2016
Variable category	Variable		
National Patient Register			
Diagnosis	ICD-10	x	
	Diagnosis-related grouping	x	
	Main diagnosis	x	
Intervention	Classification of intervention, including replacement surgery in hip/knee (x)	x	(x)
Date	Admission	x	
	Discharge	x	
	Elective or acute care	x	
	Hospital name	x	
Type of care	Outpatient/inpatient	x	
Swedish Prescribed Drug Register			
Date	Prescription date	x	
	Withdrawal date	x	
Drug	Name	x	
	Dosage	x	
	Anatomic Therapeutic Chemical Classification system	x	
Cost	Patient cost	x	
	Subsidised cost	x	

ICD-10, International Classification of Diseases, tenth revision.

The Swedish Prescribed Drug Register started in 2005 and contains information on expenditure for prescribed drugs. Over-the-counter drugs are not included.²⁷ In this study, we will use data for comorbidity and healthcare consumption from the National Patient Register and data for expenditure on prescribed drugs from the Swedish Prescribed Drug Register, to the end of 2016 (table 5).

PERSONAL IDENTITY NUMBER

In Sweden, all citizens are registered with a unique PIN that provides information on date of birth and sex. Swedish law requires all documentation regarding healthcare contacts to be registered using the patient's PIN.²⁸ The same system is used for registration of data for all types of statistics, such as national population-based registers and healthcare quality registers.^{29 30} The PIN also allows linkage of data at an individual level between the different registers in Sweden with the possibility of creating merged research databases for epidemiological research on large populations, after the relevant ethical approval has been obtained.^{27 28}

Collection of data

The merged database will be created using specific steps (figure 1):

1. Using the unique PIN, a search will be made to determine if any patients in the BOA Register were registered in the SHAR/SKAR before the end of 2016. If so, these data will be merged with BOA data.
2. The data set will then be submitted to Statistics Sweden, where requested variables will be added using the PIN as the unique identifier.
3. Statistics Sweden will replace each PIN with a serial number to anonymise data before the merged database will be returned to the researchers.
4. At the same time, Statistics Sweden will forward the list of PINs and serial numbers to the National Board of Health and Welfare to obtain requested variables.
5. The National Board of Health and Welfare will send data for these variables to the researchers using only the serial numbers, and the serial numbers will be used to merge all data to create the research database.
6. According to the matching criteria, Statistics Sweden will generate the reference cohort, and perform the procedure as described above to add requested variables, anonymise individuals by replacing the PIN with a serial number, send the data to the researchers and forward the list of PINs/serial numbers to the National Board of Health and Welfare.

The key for linking the serial number to the PIN will be saved at Statistics Sweden (without access for the

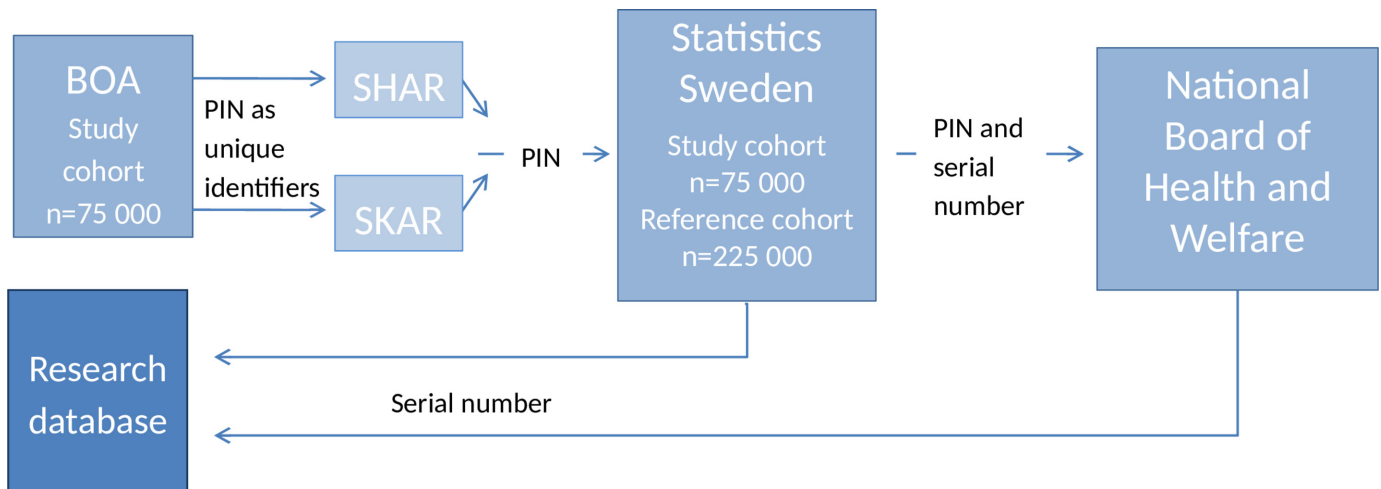


Figure 1 Description of data collection from the Better Management of Patients with Osteoarthritis Register (BOA), the Swedish Hip Arthroplasty Register (SHAR), the Swedish Knee Arthroplasty Register (SKAR), Statistics Sweden and the National Board of Health and Welfare to create a merged research database on patients with osteoarthritis. PIN, personal identity number.

researchers) for 3 years to allow the possibility of adding more year cohorts (eg, 2017, 2018) or new variables to the research database if new research questions arise (with new ethical approval).

Analysis plan

Since the population in the BOA Register has not been described before or used to study progress of OA over time or treatment effects in OA, the aim with this first part of the study is to contribute to the clarification of the registered patients, by validating the individuals in the BOA Register against the general Swedish population. This will evaluate if the two groups are equal or not based on socioeconomic status and health. We will however not be able to compare the cohorts based on lifestyle habits or other OA risk factors since these data not are available for the reference cohort. Depending on the results from the validation of the BOA population, we further on will be able to discuss the results from the coming research questions in relation to other individuals. It is likely that the study also will generate hypothesis that later can be tested in new studies with other designs.

First research question

The first research question has a descriptive design with both a cross-sectional and longitudinal approach, depending on the different variables that will be studied. Socioeconomic factors (marital status, education level, occupation, country of birth) will be described and compared at baseline. Income, comorbidity (from calculated comorbidity index), healthcare consumption (defined as the total number of healthcare contacts per capita), sick leave and expenditure on prescribed drugs (the amount of analgesic and joint-related) will be described and compared for 3 years before baseline. Finally, the two groups will be described and compared based on eventual replacement surgery or death, up to the end of 2016.

Second research question

The main outcome to answer the second research question is replacement surgery or not. Only the patients from the study cohort will be used in this evaluation. The study cohort will be divided into two groups depending on if they had hip/knee replacement surgery before the end of 2016 (replacement group and non-replacement group). Socioeconomic factors, comorbidity and patient-reported measures at baseline will be compared between the groups and evaluated as eventual risk or health factors for the outcome replacement surgery.

Third research question

To answer the third research question, only the patients from the study cohort who had a hip or knee replacement up to the end of 2015 will be evaluated. The outcome that will be studied is patient-reported outcome measures (joint pain, HRQoL and satisfaction with treatment) from SHAR and SKAR, respectively. The patients will be grouped depending on better or worse patient-reported outcomes 1 year after surgery. The groups (better or worse postoperative outcome) will then be compared to identify differences in socioeconomic factors, comorbidity or patient-reported measures at baseline in the BOA Register, as risk or health factors for outcome after replacement surgery.

The patient-reported outcome measures at 3 and 12 months and the physiotherapist-reported outcome measures at 3 months registered in the BOA Register will also be analysed as eventual predictors for future replacement surgery and for outcome after replacement surgery.

Calculations from the BOA Register, the SHAR Register and the SKAR Register has shown that, in the study population, approximately 10 400 individuals have had a hip replacement surgery and 4900 individuals have had a knee replacement surgery by the end of 2016.

Statistical analysis

Statistical analysis of the data will be performed descriptively and comparatively using parametric or non-parametric statistics depending on the nature of the data, with adjustment for potential confounders by multivariable regression analysis. Separate analyses will be performed for each research question. We will be able to account and adjust for OA in multiple joints and/or multiple joint replacements. Multivariable regression models will be used to analyse the factors (eg, socioeconomic factors, comorbidity and patient-reported measures) that can predict replacement surgery (second research question) and better or worse patient-reported outcomes 1 year after replacement surgery (third research question).

Patients can take different paths after entry into the BOA Register. Ideally, patients stay in their entry stage; however, a patient can proceed to the next stage of having their knee(s) or hip(s) replaced, and further to die during the follow-up period (up to the end of 2016). To identify risk factors that may be associated with transition from one stage to another, we will use competing risks and cumulative incidences to estimate the proportion of patients that moved to each stage. It is likely that we will need to extend this analysis and apply a modified 'illness-death' model. Hip and knee replacements are non-terminal events, and patients can stay in these stages throughout the entire follow-up period or move to the next stage. Death is a terminal stage. Analysis of this model will proceed with semi-competing risks or alternatively a multistate regression analysis.^{31 32} The aim of this analysis is to identify risk factors that may be associated with transition from one stage to another.

Survival of the hip/knee joint for patients in the study cohort will be summarised using Kaplan-Meier curves to estimate the probability of replacement surgery within a certain time. Additionally, we will compare the survival of the joint for those patients with the reference cohort using relative survival.³³

Patient and public involvement

Patients were not involved in the development of the research question or the design of this study. Patients were however involved in the creation of the supported self-management programme and contributed with the key content of the programme and the mode of delivery from the patient perspective. If possible, a trained OA communicator is also participating in the education-part during the standardised core treatments to teach about the experience of living with OA, as well as his or her personal experience of non-surgical interventions.¹⁵

ETHICS AND DISSEMINATION

Storage and management of data

The anonymised research database with data for the study and reference cohorts that only uses serial

numbers will be administered by the Center of Registers Västra Götaland, Gothenburg, Sweden. Data will be stored on encrypted servers at Gothenburg University, and will only be accessible by researchers involved in the study. A statistician at the Center of Registers Västra Götaland will structure the data. The structured data will then be uploaded to a virtual computer (Secure On-line Data Access) by the researchers involved. The researchers can obtain remote access to the research database after double identification, but exporting or downloading of individual data is not possible. The process of linkage, storage and management of data, the role of informed consent in register-based research and safeguarding the integrity of study participants follows the legal and ethical frameworks as described by Swedish law and ethical boards. This has previously been described by Ludvigsson *et al.*²⁷

Dissemination of results

The results from this study will be published in peer-reviewed journals and at suitable national and international meetings. The results will also be disseminated through the relevant quality registers.

DISCUSSION

This study will provide unique data on patients with hip and/or knee OA throughout the progression of their disease. By merging data from the BOA Register with data from other Swedish health and socioeconomic data sources, we will be able to identify factors that influence the development of OA and factors that affect long-term outcomes, such as the need for replacement surgery and perceived function after surgery in patients with OA. To our knowledge, this study will represent the largest collection of data from a national OA population, and provide a unique opportunity to study a range of factors that may influence the progression of OA. In Sweden, the PIN and the various disorder-focused health data registers allow linking data from different sources, thereby allowing large populations to be followed over several years. All aspects that are affecting individuals with OA are however difficult to collect in the same research database. For example, we cannot capture OA-related items such as range of motion and eventual joint deformities, and we have no data from primary healthcare in Sweden, since this is not collected on a national basis. These are examples of weaknesses in the database and these limitations will be highlighted and discussed in relation to our results in the coming papers.

To optimise core treatment in OA and design treatment according to prognosis, it is important to identify patients that have a good prognosis and those who will need more interventions or future replacement surgery early in the course of disease. Knowledge about the progression of OA in different individuals and

their differing needs for healthcare interventions is important to manage this growing disease in future.

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Contributors All authors have substantially contributed to the conception and design of the study. KG wrote the first draft of the paper, which was critically revised by the other authors. All authors approved the final version of the manuscript.

Funding The study is financially supported by AFA Insurance, Sweden (160176). The preparation of the study has been financially supported by Futurum—Academy for Health and Care, Region Jönköping County, Sweden (559951,557821).

Competing interests None declared.

Patient consent Not required.

Ethics approval Ethical approval for this study has been granted by the Regional Ethical Review Board in Gothenburg, Sweden (dnr 1059–16).

Provenance and peer review Not commissioned; externally peer reviewed.

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