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BMJ Open Prevalence of self-reported knee symptoms and management strategies among elderly individuals from Frederiksberg municipality: protocol for a prospective and pragmatic Danish cohort study

Elisabeth Marie Ginnerup-Nielsen,¹ Marius Henriksen,^{1,2} Robin Christensen,^{1,3} Berit Lilienthal Heitmann,^{1,4} Roy Altman,⁵ Lyn March,⁶ Anthony Woolf,⁷ Hanne Karlsen,¹ Henning Bliddal¹

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For numbered affiliations see end of article.

Correspondence to

Professor Henning Bliddal;
Henning.Bliddal@regionh.dk

ABSTRACT

Introduction The Global Burden of Disease 2010 study ranked osteoarthritis (OA) as a leading cause of years lived with disability. With an ageing population, increasing body weight and sedentary lifestyle, a substantial increase especially in knee OA (KOA) is expected. Management strategies for KOA include non-pharmacological, pharmacological and surgical interventions. Meanwhile, over-the-counter pain medications have been discredited as they are associated with several risks with long-term usage. By consequence, the use of exercise and all sorts of complementary and alternative medicine (CAM) for joint pain has increased. The available self-management strategies are plenty, but there is no overview of their use at a population level and whether they are used along with doctors' prescriptions or replace these. The aim of this study is to estimate the population incidence of developing knee symptoms and analyse the association between (and impact of) the use of self-reported preventive measures and knee symptoms.

Methods and analysis This prospective cohort study pragmatically recruits individuals from the municipality of Frederiksberg, Denmark. All citizens aged 60–69 years old will be contacted annually for 10 years and asked to participate in a web-based survey. The major outcomes are self-reported knee symptoms and their association with use of various management strategies, including use of non-pharmacological treatments and CAM. Secondary outcomes include the influence of treatments on use of healthcare system and surgical procedures. Descriptive and analytic statistics (eg, logistic regression) will be used to provide summaries about the sample and observations made and the associations between self-management and development of knee symptoms.

Ethics and dissemination This study can be implemented without permission from the Health Research Ethics Committee. Permission has been obtained from the Danish Data Protection Agency. Study findings will be disseminated in peer-reviewed journals and presented at relevant conferences.

Strengths and limitations of this study

- This study will be based on a large pragmatically sampled cohort.
- The longitudinal design enables investigation in management strategies to treat knee problems and will reveal potential ways to prevent development of symptomatic knee osteoarthritis.
- This is the first study to explore patient-reported long-term use and effects of self-management strategies for knee symptoms.
- A limitation to the overall generalisation of study results is the selected population within a single community.

Trial registration number NCT03472300.

INTRODUCTION

The Global Burden of Disease 2010 study ranked hip and knee osteoarthritis (OA) as a leading cause of years lived with disability and the 38th highest contributor to years lost due to disability among 291 conditions.¹ In 2001, Peat *et al*² estimated that about 25% of adults >55 years of age experience significant knee pain, half of whom have abnormal X-rays (corresponding to OA) and a quarter have significant disability. As OA is linked to age and overweight,^{3 4} the prospected ageing population, increasing body weight and sedentary lifestyle head society towards a potentially explosive development in knee OA (KOA). This has significant importance for individuals, who experience reduced quality of life, and for the society with steeply increasing healthcare expenses,

including costly surgical procedures. Although knee pain is prevalent among community-dwelling older adults and frequently leads to consultation in primary care, little is known about how people in general self-manage their knee pain either in parallel to established healthcare or autonomously.

Recognised (by health authorities) treatments of KOA include a variety of non-pharmacological, pharmacological and surgical interventions with highly individual and inconsistent results. With the possible exception of a longer lasting weight reduction,⁵ non-surgical treatments have not been able to demonstrate long-lasting effect on pain or disability. Long-term usage of prescription medications and surgical procedures have several side effects and should be limited, if possible.

It is recognised that patient participation in disease management creates better compliance and satisfaction with pharmacological treatment in some diseases, while the possible importance in OA is debated.⁶ In line with this, a study exploring how illness perceptions of hand OA (based on the 'revised illness perception questionnaire'⁷) could affect the course of the disease found that perceived personal control of the disease did not show any association with disability, while perceptions of illness coherence (patients' understanding of their illness) was associated with less disability at 2-year follow-up in 384 patients with hand OA.⁸ Another study found that, compared with treatment as usual, an intervention aimed at enhancing perceived personal control led to significantly improved treatment satisfaction in 201 patients with low back pain.⁹ It is well known that non-pharmacological treatments with various kinds of exercise are advocated to a large number of patients, for example, the currently very popular Good Life with osteo Arthritis in Denmark (GLA:D) programme in Denmark (www.glaiddk.dk) which is being adopted internationally (eg, in Australia, Canada and China). In spite of successful results, the persistence in exercise programmes for low back pain has been weak.¹⁰ Long-term results for exercise in OA remain to be clarified.

Body weight is the most obvious, modifiable risk factor for the development of KOA,¹¹ and for many patients an option for self-management. Long-lasting weight reduction among overweight or obese patients has been demonstrated to substantially reduce symptoms in this patient group.^{5, 12} Difficulty with maintenance of weight loss, however, is well known and has led to the development of numerous intervention programmes for long-term weight management.¹³⁻¹⁵ Longitudinal evidence of the results of the efforts in the general population remains to be clarified, as well as how the weight management actions interact with other treatments.

Another option for taking active part in self-management is the use of complementary and alternative medicine (CAM), such as nutritional supplements, herbal medicine, acupuncture, various weight loss programmes, healthy lifestyle services and many more. The available CAM products and services are plenty and have during

decades been used consistently for different health purposes or specifically for chronic joint pain in the USA, European countries and Denmark.¹⁶⁻²³ Despite their popularity, there is currently no overview of the actual extent of CAMs used for knee pain and disability at the population level, and most CAMs remain to be studied scientifically for efficacy and safety. This has recently been emphasised by the James Lind Alliance (a British initiative where patients, carers and clinicians work together to set research priorities; www.jla.nihr.ac.uk), which has the identification of appropriate self-management options and their effectiveness as a top 10 research priority within OA research.

Previous studies have indicated that populations using CAMs seem willing to share their experiences with health authorities, for example, the general practitioner,²⁴ and hence important knowledge about the use of CAMs and symptoms development over time in populations may be gained by addressing target populations either with existing (or likely to develop) knee symptoms about the use of treatment and development over time in symptomology.

RATIONALE AND THEORETICAL CONSIDERATIONS

The incidence of KOA shows a steep increase at age above 60 years.²⁵ Furthermore, after this age, an increasing prevalence of disablement to knee symptoms is encountered.²⁶ To prevent this development, measures must be sought to alter the course of KOA. Compared with non-users, people consulting primary care, with knee pain or manifest KOA, have more severe disease and higher levels of disability and handicaps, with major consequences on their lives.¹⁶ Still, little is known about pain preventive initiatives (self-managed) among citizens without manifest OA leading to a need for medical care.

By asking people about how knee pain affects their lives, which treatments or self-management strategies they have chosen (or are being offered), and how these interact for the reduction of pain and maintenance of function, new knowledge will be gained about the preferences and perceived effectiveness of treatments at large. This information is of importance for the development of healthcare strategies in KOA and for the support of patient-sponsored preventive measures against the development of disability and disablement in the high-risk group of the elderly. The results of this longitudinal survey can be used by healthcare providers both in our local community and at the larger scale in the possible prevention of KOA. The information gained will enable the prioritisation of research on interventions to be tested and will align this with the primary concerns and interests of the population. It is anticipated that this will subsequently lead to better guidance of patients by the healthcare providers and will aid decision makers in choosing feasible healthcare policies and strategies.

Aims

The following are the aims of this study:

- ▶ To estimate the population incidence of knee symptoms and explore how these distribute across factors such as sex, socioeconomic status (SES) and lifestyle.
- ▶ To register and analyse the association between the use of self-reported preventive measures against knee symptoms and the incidence of knee symptoms.

Specific objectives

- ▶ To estimate the annual incidence rate of knee symptoms in elderly individuals from the Frederiksberg municipality in Copenhagen.
- ▶ To estimate the annual incidence rate of KOA in elderly individuals from the Frederiksberg municipality in Copenhagen.
- ▶ To explore how the use and durability of treatments of all kinds for knee symptoms may relate to sex, SES, illness perceptions and lifestyle factors.
- ▶ To explore the influence of self-management strategies on conventional care use, including downstream consequences such as surgical procedures.

METHODS

Study design

This study is a prospectively designed, observational study surveying individuals from the entire community of Frederiksberg. As we wish to follow a well-defined group with an anticipated high risk of developing knee symptoms, all citizens aged 60–69 years old have been contacted by secure email (e-Boks; see below) with an electronic, web-based self-report survey and a suggestion of participation in a cohort study concerning knee symptoms and treatments (any). People without access to e-Boks have not been contacted.

All participants have been assessed at baseline and will be assessed once per year for 10 years (until 2028). From September 2018 through October 2018, the first electronic survey was sent to all eligible individuals in the municipality. Among the respondents, everyone, whether with or without knee symptoms, will be asked each year if he/she agrees to receive an annual follow-up survey, thus initiating a prospective cohort to continue the pursuit of the above objectives.

e-Boks

The contact is made through the online free digital mail system ‘e-Boks’, linked to the individual’s personal identification number—a national identification number which is part of the personal information stored in the Civil Registration System. All public information in Denmark is sent electronically via e-Boks, and access to e-Boks is mandatory unless you have special needs. Hence, almost all Danish citizens have access to e-Boks. (According to e-Boks and numbers from Statistics Denmark,²⁷ approximately 90% of citizens aged 60–69 years old have access to e-Boks.)

Participants

Inclusion criteria

- ▶ Between 60 and 69 years.
- ▶ Living in the community of Frederiksberg.
- ▶ Ability to read and understand Danish.
- ▶ Access to e-Boks.
- ▶ Consents to participation in this survey.

Exclusion criteria

- ▶ No exclusion criteria.

Variables and outcome measures

The survey is designed by experts in OA (rheumatologists), population surveys and registries (epidemiologists), biostatistics, and rehabilitation (physical therapists), and the outcomes planned to be measured are described in [table 1](#). Although the questionnaire will be evaluated and adjusted annually, the main outline will be the same. The full baseline questionnaires (for people reporting, respectively, knee pain and no knee pain) are available in English in online supplementary appendix 1 and appendix 2. All questions have been translated from Danish to English by a native English speaker, but no formal validation (cultural or linguistic) has been performed.

Participants will not be able to review the whole questionnaire before responding but will be informed about the estimated response time of 15–45 min.

Parts of the survey questionnaire are based on other, already established but non-validated questionnaires used in other Danish cohorts. Any new question, drafted specifically for this survey, has been face-validated through cognitive interviewing²⁸ to test if the questions are subjectively viewed as covering the concept they purport to measure. Cognitive interviews have been performed using the ‘think-aloud’ technique and eventually followed by ‘verbal probing’ to describe patients’ thought process as they read each question and to clarify any sources of confusion.²⁸

Validated questionnaires used

EQ-5D (3L)

EuroQoL (EQ-5D) is a standardised measure of health status that provides a simple, generic measure of health. It is applicable to a wide range of health conditions. EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics and in face-to-face interviews, and takes only a few minutes to complete. The EQ-5D-3L essentially consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D-3L descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems and extreme problems. The EQ VAS records the respondent’s self-rated health on a vertical VAS, where the endpoints are labelled ‘Best imaginable health state’ and ‘Worst imaginable health state’. This information can

**Table 1** Questionnaire measures**Questionnaire**

| | |
|---|---|
| Knee symptoms: yes/no | ▶ One triage question: Have you experienced any pain/discomfort from your knee/knees during the last month? (both at work and rest). |
| Questions for people reporting knee symptoms | |
| Knee symptoms | ▶ Four questions concerning actual and earlier knee symptoms. ▶ Knee injury and Osteoarthritis Outcome Score (58 questions concerning knee symptoms). ▶ Three questions concerning effect of alcohol intake and/or weight change and/or physical activity on knee pain. |
| Self-management strategies: CAM and conventional treatments | ▶ Thirty-one questions concerning current and past treatments for knee pain. ▶ Eleven questions concerning current and past treatments for other reasons than knee pain. |
| Knee injuries and surgeries | ▶ Eight questions concerning current and past knee injuries and surgeries. |
| Illness perceptions | ▶ Brief Illness Perception Questionnaire (nine questions concerning perception on knee pain). |
| Lifestyle | ▶ Three questions concerning sleeping habits. |
| Eventual comments | |
| Questions for people reporting no knee pain | |
| Use of CAM | ▶ Eleven questions concerning current and past treatments. |
| Knee injuries and surgeries | ▶ Six questions concerning current and past knee injuries and surgeries. |
| Questions for all respondents | |
| Demographics | ▶ Six questions concerning weight, height, education, marital status and income. |
| Lifestyle | ▶ Eight questions concerning smoking and drinking habits. |
| Quality of life | ▶ EQ-5D-3L (six questions concerning health-related quality of life). |
| Musculoskeletal health | ▶ Twelve questions concerning diseases in bones and joints. ▶ One question concerning eventual knee pain in next of kin. |
| Health beliefs and attitudes | ▶ Six questions concerning beliefs towards use of CAM for knee pain. ▶ Eight questions concerning beliefs towards use of exercise for knee pain. |
| Fitness and physical function | ▶ Five questions concerning physical activity/fitness level. |
| Two questions concerning further contact and follow-up questionnaire. | |

CAM, complementary and alternative medicine.

be used as a quantitative measure of health outcome as judged by individual respondents.²⁹

Brief Illness Perception Questionnaire

The Brief Illness Perception Questionnaire is a generic questionnaire developed to measure illness perception in a variety of illnesses. The questionnaire is patient-reported and assesses perceptions on the following five dimensions: identity, cause, timeline, consequences and cure control. It contains eight numerical rating scale questions (0–10) and a memo field based on patients' own beliefs about their condition. In some circumstances it may be

possible to compute an overall score which represents the degree to which the illness is perceived as threatening or benign. To compute the score, scores on items 3, 4 and 7 are reversed and then added to scores on items 1, 2, 5, 6 and 8. A higher score reflects a more threatening view of the illness.³⁰

Knee injury and Osteoarthritis Outcome Score

The Knee injury and Osteoarthritis Outcome Score (KOOS) is developed as an instrument to assess patients' opinion about their knee and associated problems. It is patient-reported and can be used to assess groups and

Box 1 Patient and public involvement

Patient research partner (PRP) involvement according to the European League Against Rheumatism recommendations

- ▶ The PRPs have voluntarily participated in the process of designing and preparing the study protocol and survey. They have acknowledged the survey in its current form.
- ▶ The PRPs have acknowledged the idea and purpose of the study, and participated in discussions of ethics, design, relevance and feasibility of the content and investigation programme. They have revised all patient information prior to distribution. The PRPs and the primary investigator (EMG-N) will meet approximately every six months until the study is finalised to discuss the process and results.
- ▶ Two PRPs suffer from knee osteoarthritis, while two PRPs do not. They are all middle-aged.
- ▶ The PRPs were identified during routine care. Prior to their decision to participate, they received a written and oral task description that clarified their roles and expected contributions.
- ▶ The PRPs exhibited immense interest in the research collaboration and showed good communication skills.
- ▶ The primary investigator will continuously consider the specific needs of the PRPs, including educational aspects. A safe and respectful environment is highly prioritised and the PRPs may contact the research group whenever needed.
- ▶ The investigators provide information and appropriate training, including awareness of ethical issues, continuously throughout the study.
- ▶ The PRPs work voluntarily and will be offered coauthorship according to the International Committee of Medical Journal Editors criteria.

to monitor individuals. KOOS consists of five subscales: pain, other symptoms, function in daily living, function in sport and recreation, and knee-related quality of life. The last week is taken into consideration when answering the questions. Standardised answer options are given (5 Likert boxes), and each question gets a score from 0 to 4. A normalised score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.³¹

PATIENT AND PUBLIC INVOLVEMENT

The observational, real-world settings of the study should ensure a high degree of external validity. Furthermore, four patient research partners were involved in the designing process and will be involved during the study conduct. Collaboration between patients and professionals in developing and disseminating research projects is still relatively new. Nevertheless, this project follows the European League Against Rheumatism recommendations³² for the inclusion of patient representatives in the contemporary scientific process by adhering to eight important aspects as depicted in [box 1](#).

DATA MANAGEMENT

All data will be collected using self-report survey questionnaires and kept pseudonymised in a secure database

made in the dedicated online data capture and management system REDCap (<https://www.project-redcap.org/>) managed by the Capital Region of Denmark. If a participant does not answer the questionnaire within 2 weeks, up to two reminders will be sent to the participant via e-Boks. All respondents will be offered access to ongoing information about study results. Participants will stay in the study as long as they consent based on the intention to survey. Non-respondents will not be contacted any more according to the protocol and Danish legislation.

COHORT SIZE CONSIDERATIONS

The following have been estimated based on publicly available data on the Frederiksberg community population demographics:

- ▶ The health survey questionnaire will be forwarded to the e-Boks of all living citizens aged 60–69 years and living in the Frederiksberg municipality: 9086 individuals.
- ▶ During the mailing process, the number of obvious exclusions, such as deaths, departures from the municipality and not on e-Boks, will leave an eligible baseline population: approximately 8000 individuals.
- ▶ We expect about 40%–50% will respond and return the health survey questionnaires (ie, feedback): 3500 individuals.
- ▶ About 50% of the 3500 will accept participation in follow-up: 1750 individuals.

According to our estimates, of these 1750 participants, 1000 will have knee symptoms at entry. These two overlapping groups will then constitute the prospective cohort.

ANALYSES AND STATISTICS

Owing to the exploratory design, no formal statistical power estimation has been performed. This study is designed as a prospective cohort study following each participant annually for 10 years. As this study includes both cross-sectional and cohort study designs, the results will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology initiative developed recommendations on what should be included in an accurate and complete report of an observational study.³³ We will distinguish descriptive statistics from inferential statistics (or inductive statistics) in a way that descriptive statistics will summarise our sample rather than use the data to infer beyond the population that the sample of data is thought to represent. Analytic statistics will be used to explore associations between self-management and knee symptoms.

For each data collection wave, potentially eligible participants, partial responses and dropouts will be reported in a flow diagram. For each variable of interest, the number of participants with missing data will be reported.

Annual incidence rates will be analysed using logistic regression analyses with the presence of knee symptoms as dependent variable. The independent variables initially

included in the exploratory univariate analyses are all the covariates collected at baseline, for instance whether participants were taking prescription drugs, using CAMs or doing exercise. Following univariate logistic regression analyses, some of the independent variables will appear statistically significantly associated with clinically important knee symptoms after 1 year. For these variables (covariates assessed at baseline), the OR will indicate the strength of the association. Subsequently, we will construct multiple logistic regression models to explore how many of the independent variables remain statistically significantly and independently associated with the development of clinical knee symptoms.

Other analyses

During data collection and analyses, new and important hypotheses may emerge that can be tested in the data set. While the current study may not be designed to answer such hypotheses, we may do ad-hoc analyses on the cohort. For example, participants whose knee pain disappears are interesting, as this may be due to treatment (self-management or conventional). This will be explored in the longitudinal analyses.

DISSEMINATION

The study findings will be disseminated in peer-reviewed journals and presented at national and international conferences. Baseline variables will be described for all participants and in relevant subgroups.

DISCUSSION

About 12% of adults aged >55 years have KOA (corresponding to OA), and a quarter of these have significant pain-related impairment.² With an ageing population, increasing body weight and sedentary lifestyle, a considerable increase in the incidence of KOA is expected, with increasing healthcare expenses and severely reduced quality of life for the individual. Although knee pain and OA frequently lead to consultation in primary care, little is known about how people in general self-manage their knee pain. The aim of this project is to estimate the population incidence of knee symptoms, explore self-disclosed measures against this and how they influence on the incidence of knee symptoms.

Investigating how people with knee symptoms (or KOA) choose to manage their condition in the very early stage will eventually guide us in prioritising research areas within self-management of KOA and ultimately help decision makers in setting the appropriate healthcare and prevention policy.

The strengths of this study include its prospective design, enabling us to explore the associations between the use of self-management strategies for general health or specifically for knee symptoms with the incidence of knee symptoms in a large study population, with the possibility to merge the survey information at the individual

level with historical data on disease and use of medicine from Danish registries. Furthermore, our study population lives in Frederiksberg, a relatively wealthy municipality, with citizens that generally do not move from the area when first settled. This will probably enable us to reach a relatively high response rate and to follow a large part of the cohort throughout the planned 10 years.

Data collection is based on self-report, making it possible to explore the effects of different pain treatment strategies from peoples' point of view. Moreover, the survey will be sent via e-Boks, ensuring that questionnaires will reach the targeted population.

Some limitations to the study should be noted as well. In general, to minimise the survey load, the questionnaires for participants with/without knee symptoms (based on triage question) are not identical (see [table 1](#)).

Even though the questionnaires have been face-validated in a relevant population, we cannot know if all participants will interpret the questions as we want them to. Second, citizens from the wealthy Frederiksberg, in the middle of Copenhagen, may not be representative of the whole Danish population, which may limit the generalisability of study results.

Third, as the study questionnaire will be sent electronically, there may be a selection bias among study participants. Even though e-Boks is popular among people aged 60–69, some citizens are not signed up for the use of e-Boks. Hence, we approximate that 10% of the population will not be reached with this survey. Further, poor e-literacy may be a barrier to some people (eg, due to dementia or cognitive problems).

Author affiliations

¹The Parker Institute, Bispebjerg and Frederiksberg Hospital, Copenhagen, Denmark

²Department of Physical and Occupational Therapy, Copenhagen University Hospital Bispebjerg-Frederiksberg, Copenhagen, Denmark

³Department of Rheumatology, Odense University Hospital, Odense, Denmark

⁴Department of Public Health, Section for General Practice, Copenhagen University, Copenhagen, Denmark

⁵Division of Rheumatology and Immunology, University of California, Los Angeles, California, USA

⁶Department of Rheumatology, Institute of Bone and Joint Research, University of Sydney, Royal North Shore Hospital, Sydney, New South Wales, Australia

⁷Bone and Joint Research Group, Royal Cornwall Hospital, Truro, UK

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Contributors HB has conceived the study and is the grant holder. EMG-N, BLH, RC and MH have provided expertise in planning of surveys and studies involving patients with knee osteoarthritis. LM, AW, RA and HK have, in line with the other authors, contributed to the refinement of the study protocol and approved the current version.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Regional Health Research Ethics Committee of the Capital Region of Denmark has reviewed the outline of this cohort study. The committee

has accepted the study as exempt from approval (reference no: 17024697) as this study is only based on questionnaires. Such studies can be implemented without permission from the Health Research Ethics Committee according to Danish legislation (Committee Act § 1, paragraph 1). However, we will conduct the study with the highest research ethics standards possible.

Provenance and peer review Not commissioned; externally peer reviewed.

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