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Prevalence of knee pain and knee osteoarthritis in southern Sweden and the proportion that seeks medical care

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Knee OA prevalence and consultation in Sweden

Keywords: knee osteoarthritis; knee pain; prevalence; radiography

Abstract

Objectives: To estimate the prevalence of frequent knee pain, radiographic, symptomatic

and clinically-defined knee osteoarthritis (OA) in middle-aged and elderly, and the proportion

that seeks medical care.

Methods: The population-based Malmö Osteoarthritis Study; in 2007 a random sample of

n=10 000 56-84-year old residents of Malmö, Sweden were guestioned about knee pain. We

classified subjects reporting knee pain with duration of at least four weeks as having frequent

knee pain. A random sample of n=1300 with frequent knee pain and n=650 without were

invited for assessment of the American College of Rheumatology clinical knee OA criteria

and for bilateral weight-bearing knee radiography. We considered Kellgren and Lawrence

grade ≥2 as radiographic knee OA and that in combination with frequent knee pain as

symptomatic knee OA. By linkage with the Skåne Healthcare Register, we determined the

proportion of subjects that had consulted for knee OA or pain.

Results: The 10 000 subjects had mean (SD) age of 70 (7.6) years, mean body mass index

was 27.1 kg/m² and 62% were women. The prevalence of frequent knee pain was 25.1%

(95%CI:24.1-26.1), higher in women and similar across age groups. The prevalence of

radiographic knee OA was 25.4% while 15.4% had either symptomatic or clinically-defined

knee OA. Of these, 68.9% consulted a physician for knee OA or pain during 2004-2011.

Conclusions: Fifteen per cent of middle-aged or elderly have knee OA and symptoms.

About 1 in 3 of those do not consult physician. Inefficient care of OA and self-coping may be

an explanation.

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Introduction

Osteoarthritis (OA) is one of the most common causes of pain and functional impairment among the elderly and among adults of working age.[1-8] OA is mainly a clinical diagnosis, but findings on radiographs, including joint space narrowing, subchondral sclerosis and osteophyte formation, are commonly used for epidemiologic study purposes, even though there is often a discrepancy between radiographic changes and symptoms.[9] Asymptomatic radiographic OA is common and so is knee pain due to knee OA not yet detectable on plain radiographs as these changes may appear relatively late in the natural course of the disease. Hence, to obtain estimates of the occurrence of OA in the society is challenging as the definitions are plentiful and often ambiguous.[10, 11]

The knee is one of the most common sites affected. The first presenting symptom of knee OA is often pain in the joint, and in patients over the age of 55 years, knee pain is often attributable to OA.[12] The disease is expected to become increasingly common due to ageing and increasingly obese populations in many countries.[13] Hence, updated estimates reflecting the beginning of 21st century are highly needed. Evidence from morbidity surveys in primary care of England and Wales confirms that OA and joint pain contribute substantially to the workload of general practice.[14] The proportion of older adults with knee pain that consults a physician varies from 15 to 50 per cent depending on the knee pain definition and time period studied.[12, 15-17] However, there is also a substantial lack of information on what proportion of subjects with symptomatic or clinically defined knee OA that consults a physician.

We used a combination of questionnaire, clinical examination, interviews by trained personnel and radiography in a random sample of residents of the Malmö region located in southern Sweden to determine the current prevalence of knee pain, radiographic and symptomatic knee OA. Additionally, using healthcare register data covering all levels of

healthcare in the entire region, we assessed the proportion of subjects with symptomatic or clinically defined knee OA that consulted a physician for their knee symptoms.

Methods

Study sample

The Malmö Osteoarthritis (MOA) study was carried out between 2007 and 2008 and originated from the Malmö Diet and Cancer Study (MDCS) cohort established between 1991 and 1996.[18-22]

The first part of the MOA study consisted of knee pain questionnaire sent to a random sample of 10 000 subjects from the MDCS cohort who were still alive and residents in the Malmö area at the beginning of 2007. Respondents answered a question about whether having knee pain during the last 12 months and its duration (less than one week, one to four weeks, one to three months, longer than three months). We classified subjects with pain in one or both knees in the last 12 months and duration of at least 4 weeks as having *frequent knee pain*. In the second part of the study a random sample of 1300 subjects with frequent knee pain and 650 subjects without were invited to a clinical visit and radiographic examination. (Figure 1)

At the clinical visit the trained study nurse performed a physical examination where weight and height were measured, subjects were asked if having a previous knee arthroplasty and answered a questionnaire assessing, among others, pain in the whole body and its location. Data on education and body mass index (BMI) from MDCS examination in 1991-1996 were available for the whole study sample.

Knee pain

As a main knee pain outcome measure, we used the question from the first part of the study about frequent knee pain (see above). Additionally, we used the knee pain question from the American College of Rheumatology (ACR) clinical criteria at the clinical assessment: "Have Knee OA prevalence and consultation in Sweden

you had pain in knee on most days of the previous month?" This question was used to determine clinically defined knee OA (see below).

Knee OA

Both knees were radiographed in weight-bearing and semi flexed position (knees in 10-15 degrees of flexion) using a posterior-anterior beam direction (film focus distance 110 cm, 60 kV and 10 mA) with the aid of fluoroscopy to optimally align the tibia plateau. We also obtained patella axial images with knees in 30 to 40 degrees of flexion. An independent senior radiologist specialized in musculoskeletal conditions who was blinded to clinical data assessed joint space narrowing and osteophytes according to the atlas from Osteoarthritis Research Society International (OARSI).[23] We classified a knee as having *radiographic knee OA* if one or more of the following criteria were fulfilled in either the medial, lateral or patellofemoral compartment: joint space narrowing grade 2 or worse, the sum of marginal osteophyte grades in the same compartment 2 or worse, joint space narrowing grade 1 and osteophyte grade 1 in the same compartment (approximating Kellgren & Lawrence [KL] grade 2 or worse).[24] We considered those having radiographic knee OA and frequent knee pain to have *symptomatic knee OA*.

Clinically defined knee OA status was determined by the study nurse blinded to radiographic status using the ACR clinical criteria according to the recursive positioning method.[25]

Subjects who had a history of knee replacement or osteotomy were considered as fulfilling all three knee OA definitions.

Healthcare consultations

The Skåne Health Care Register (SHR) contains information about every healthcare visit made in the region and includes data on healthcare provider, the profession (physician, physical therapist, etc.), type of visit (e.g. primary/specialist care, in- or out-patient visit, clinic and others) and date of visit. The register contains the publicly practicing physicians' diagnostic codes according to the International Classification of Diseases (ICD) 10 system. Knee OA prevalence and consultation in Sweden

Using the MOA subjects' unique personal identification number we retrieved data on all doctor visits for MOA subjects in years 2004 to 2011. We identified subjects that received the diagnosis of knee OA (ICD-10 code M17) or pain in joint (joint unspecified, ICD-10 code M25.5) during that time.

Statistical analysis

We used weighting to adjust for a possible selection bias that could arise from nonresponse that arose in the first and second part or the MOA study.[26] A logistic regression model with sex, age at 1st Jan 2007 and BMI as well as the highest education level measured at the baseline MDCS examination as covariates was used to estimate the probability of response in the survey and the reciprocal was used as a weight. Covariate list in models for willingness to participate as well as for attendance to the clinical examination included knee pain status (from part I) as well. The sampling weights (the reciprocal of the sampling probability for those with and without frequent knee pain) were multiplied with the weights for non-response and willingness to construct the final weights used in analyses. Thus, presented estimates are representative for the original 10 000 study sample. For the prevalence of knee pain based on questions from the first part of the study only weights for nonresponse in that part were used. Due to the survey design where subjects had different sampling probability depending on their knee pain status, we used the robust variance estimator. We presented prevalence proportions as percentages and we used the Poisson regression model to calculate adjusted prevalence ratios.[27]

We used the multiple imputation technique to account for the missing diagnostic codes in the SHR.[28, 29] As diagnosis of knee OA or pain in joint was set in primary care, orthopaedic clinic or emergency in over 98% of cases, we used only visits to those clinics in the model. Of all visits, 45% were made within the private care and thus had no ICD-10 code assigned. In the public care 9% of doctor visits had a missing ICD-10 code. A multivariate normal model with random intercept was used to impute 20 datasets. Variables included in the model were: the diagnosis, age, sex, clinic, BMI, if having knee pain, if having radiographic Knee OA prevalence and consultation in Sweden

knee OA, if having symptomatic knee OA, if having clinically defined knee OA, year of health care visit, if visited a physiotherapist and income. The correlation between visits made by the same person was accounted for through including the random effect in the model.[30] The imputed values were rounded using cut-off values determined by simulation.[31] We used STATA 12.0 and the R programming environment version 2.15.2, *package pan*, for the analyses.

The study was approved by the Regional Ethics Committee in Lund and informed consent was obtained from all participants in accordance with the declaration of Helsinki.

Results

Study sample

The 10 000 MOA subjects were 56 to 84 years old (mean [SD]: 70 [7.6]), 62% were women and the mean (SD) BMI was 27.2 (5.0) kg/m². The response rate to the mailed survey was 77.4%, and 72.0% of the responders were willing to participate in the clinical examination. Further, 1527 of 1950 sampled subjects (78.3%) attended the clinical visit. Of those, 42 subjects had missing information from the radiographic examination (41 did not attend and 1 could not participate due to Parkinson's disease) (Figure 1).

Prevalence of knee pain

The prevalence of frequent knee pain in one or both knees during the last 12 months was 25.1% (95% confidence intervals [95%CI]: 24.1%, 26.1%), 20.8% in men and 27.7% in women. The prevalence of knee pain on most days of the previous month was 20.3% (95%CI: 18.2%, 22.6%), 17.9% in men and 21.7% in women, respectively. The prevalence remained stable across age groups (Figure 2).

Prevalence of knee OA

The prevalence of radiographic knee OA was 25.6% (95%CI: 22.7%, 28.6%); 24.3% in men and 26.4% in women using the definition approximating the KL grade 2 or more in medial, Knee OA prevalence and consultation in Sweden

lateral or patellofemoral compartment (Table 1). The prevalence increased with increasing age and was 21.0% when the patellofemoral compartment was excluded (Figure 2).

The prevalence of the symptomatic knee OA was 10.5% (95%CI: 9.8%, 11.3%), 9.7% in men and 11.0% in women. For the clinically defined knee OA corresponding percentages were 9.0% (95%CI: 7.9%, 10.3%), 8.0% and 9.6% respectively (Table 1).

The prevalence of those fulfilling either the clinically defined knee OA criteria or symptomatic knee OA definition was 15.4% (95%CI: 14.2%, 16.7%), 13.6% in men and 16.5% in women.

Relation between knee pain and radiographic knee OA

The prevalence of frequent knee pain in subjects with radiographic knee OA was 41.5% (95%CI: 36.5, 46.7), similar in men and women (Figure 3). The prevalence ratio of frequent knee pain in subjects with and without radiographic knee OA, adjusted for age, sex, current BMI and having pain other than knee pain, was 2.3 (95%CI: 1.9, 2.7). The prevalence of radiographic knee OA in the population with frequent knee pain was 43.2% (95%CI: 40.1, 46.4), 47.5% in men and 41.3% in women. In the study sample 11.8% of subjects reported frequent knee pain but did not fulfil OA criteria, neither for clinical ACR nor radiographic knee OA.

Healthcare consultations

Between 2004 and 2011 74.7% (95%CI: 70.0%, 79.3%) of the subjects classified as having symptomatic knee OA consulted a physician and received a diagnosis of either knee OA or pain in joint while 63.0% (95%CI: 57.8%, 68.2%) were diagnosed with knee OA specifically. The corresponding percentages for the subjects fulfilling the clinical knee OA criteria were 66.8% (95% CI: 59.1, 74.6) and 49.9% (95% CI: 41.8, 58.1) (Table 2). Of those with either symptomatic or clinically defined knee OA 53.3% (95% CI: 47.6, 58.9) consulted a physician for knee OA during an 8 year time period, while 68.9% (95%CI: 63.8-74.0) consulted for either knee OA or pain in joint. Generally, the proportion that consulted was similar in men and women, irrespective of the OA definition used (Table 2). In 98% of consultations the Knee OA prevalence and consultation in Sweden

diagnosis of knee OA or pain in joint was set in primary care or by a specialist (or physician under specialty training) in orthopaedics or emergency medicine.

Discussion

We found that in the Swedish population aged 56 to 84 years one in four reported frequent knee pain and the same fraction had radiographic knee OA approximating KL grade 2 or more. The criteria for symptomatic OA or clinically defined (according to ACR criteria) OA were fulfilled by 15.4% whereof 69% had consulted a physician for knee complaints during an 8-year time frame.

In 1982, some 25 years prior to our study, a population-based study from the city of Gothenburg, Sweden, reported a prevalence of knee complaints (pain, stiffness or swelling) in those aged 79 years (25% in women and 11% in men) that was lower than the prevalence of frequent knee pain in those 78-80 age group in our study (30% in women and 14% in men).[32] Methodological differences, nonresponse and survival bias, and different knee pain questions make comparisons challenging. While the prevalence of radiographic knee OA in our study is in line with numbers from a Danish study in population aged 55 to 79 years, it is much lower than the prevalence in United States (US).[33-36] The higher prevalence of obesity in the US than in Sweden is a probable explanation as well as the different age and ethnic structure of the populations. For instance, in our sample the mean BMI was 27 compared to 31 reported from Johnston County study participants of similar age.[37] In spite of the differences in the prevalence of radiographic knee OA, the prevalence of symptomatic knee OA is similar in our study and in the studies from US. In the age group of 60 to 79 the US prevalence ranges from 9.3% to 11.8%, with our estimate in the middle of this range (10.9%).[35, 36] This holds even for sex-specific estimates, with women having slightly higher prevalence than men. The prevalence of frequent knee pain was higher in our study than in studies from US which may be one explanation of the similar prevalence of symptomatic knee OA. Our estimate of the prevalence of frequent knee pain, 25%, is in line Knee OA prevalence and consultation in Sweden

with estimates from England for population aged 55 or older, while studies from US and the Netherlands reported lower numbers.[12, 38-40] However, slightly different knee pain questions, composition of study groups and methods of data collection may explain variation in the prevalence of knee pain.

The estimated prevalence of symptomatic knee OA and clinically defined knee OA according to ACR criteria were similar, but the overlap between subjects fulfilling those two definitions was relatively low. The low overlap was found even by Peat et al in patients 50 years of age or older and with knee pain during the previous 12 months.[41] In this group the prevalence of symptomatic knee OA was 32.9% and the prevalence of knee OA according to the ACR clinical criteria was 30.2%. Our estimates in subjects with knee pain in the last 12 months were lower, 20.4 % and 18.5%, respectively. It is somewhat counterintuitive that the prevalence of ACR defined OA did not increase with age and it may be explained by that crepitus and stiffness was less frequently found and reported by elderly in our cohort, perhaps part of adaption, i.e. these symptoms are more and more considered as normal and are not reported even if they are present.

During an eight-year period, 2004 to 2011, only two of three patients with clinically defined knee OA or symptomatic knee OA consulted healthcare and received a diagnosis of knee OA or pain in joint. In a study on performance of ACR clinical criteria in the general population Peat et al found that among subjects with knee pain and fulfilling the ACR clinical criteria for knee OA 29.8% consulted for knee OA or knee pain during the 18 months preceding the study examination, while 37.1% of those with symptomatic knee OA consulted during the same time period.[41] In the corresponding MOA study sample subgroup (knee pain during the last year, consultations within 18 months before the first MOA survey) 27.8% of subjects fulfilling the clinical ACR knee OA criteria and 33.5% of those with symptomatic knee OA consulted for knee OA or pain in joint. Both results suggest that only a minority of knee OA patients with knee pain actually consult healthcare.[3] Self-management or coping strategies as well as over-the-counter pain treatments may explain that partly. Another Knee OA prevalence and consultation in Sweden

explanation may be the perception of knee pain in the general population or among physicians. Older people may often view chronic joint pain and other symptoms of OA as a part of normal aging and are more likely to consult when symptoms come on suddenly and severely or disturb sleep, or when having mobility problems.[6, 42] Both international and Swedish national guidelines for treatment of OA of the knee recommend in the first place non-drug treatments. However, only a minority of knee OA patients are referred to a physical therapist.[43] In a questionnaire only about half of UK-based physical therapist agreed that knee problems are improved by exercise and adherence was seen as the patient's responsibility.[44] On the other hand patients delay seeking medical care for musculoskeletal pain and many do not take treatment and/or lack information about their disease.[45] Physical activity guidelines and recommended daily steps are met by less than half of people with knee OA.[46] Only less than half of obese patients with knee OA in a study from US have been advised by a health care professional to lose weight and people with knee pain continue to have persistent problems regardless of whether they consult or not.[4, 47] Better management of patients with OA in primary care and improved awareness of non-drug treatments in society could result in more symptomatic subjects seeking healthcare. [48, 49] Non-response is common in surveys and could result in selection bias if participants are systematically different than non-participants.[50] The non-response rate in the MOA postal questionnaire was relatively low at 22.6%, as was the dropout from the MOA clinical examination (21.7% of all invited). The baseline variables available for the whole study sample were age, sex, BMI and education level. All of them were associated with the nonresponse and thus used in the calculation of weighs, which, together with the sampling weights, were used in the analyses to account for a possible selection bias. However, the results might still be affected by selection bias due to factors we could not account for (such as knee pain status in non-responders in part I of the study). Using multiple imputation we accounted for the missing diagnostic codes in the SHR, but we cannot rule out that the missing data in the MOA study or in the register depended on unobserved factors which Knee OA prevalence and consultation in Sweden

would introduce bias in our results. However, the majority of missing diagnostic codes in SHR was due to the administrative routines, as the codes from private healthcare providers are not forwarded to the register. In Sweden both types of healthcare are equally accessible and financed through the same tax-based system and thus missing data from private providers can be considered as missing and random and would not introduce bias in our estimates. The 10 000 subjects in the MOA study were a random sample from the Malmö Cancer and Diet cohort. This cohort has been shown to have slightly lower mortality rates than the background population suggesting a healthy selection bias in persons willing to participate.[18] Between 2004 and 2006 (3 years preceding the MOA examination) 7.3% of 10 000 MOA subjects consulted health care and received diagnosis of knee OA while the corresponding number for the whole Skåne population aged 56 to 84 was 6.8%, which suggests that with respect to knee OA the MOA study sample is fairly representative of the background population. For the definition of symptomatic knee OA we required knee pain for at least 4 weeks to exclude persons with milder symptoms. However, for 37 persons we didn't have the information if the pain was in the knee with radiographic changes. In conclusion we found the first decade of the 21st century prevalence of symptomatic or clinically defined knee OA in the Swedish population aged 56 to 84 years to be 15.4% whereof two of three of those subjects saw a physician during an 8-year time period and was diagnosed with knee pain or knee OA. The prevalence of radiographic knee OA, irrespective of symptoms, was 25.4%. Our findings show that there is a large group of people with symptomatic knee OA not seeking healthcare. This group could potentially benefit from OA education and training.

Key messages

- Knee OA prevalence in middle-aged and elderly in Sweden ranges from 9% to 25%
- One in three with knee OA and symptoms do not consult a physician
- Inefficient care of OA and self-coping strategies may be an explanation

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Conflict of interest statement

LSL, ME, AT and PN report no potential conflict of interest.

MGdV has been employed by AstraZeneca and is an owner of some AstraZeneca shares as a part of the bonus system. CM has been employed by AstraZeneca. GE was employed by AstraZeneca at the time of the study conduct.

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AstraZeneca was involved in the overall MOA study design and approved the manuscript for publication, but was not involved in the collection, analysis, and interpretation of data, in the writing of the report, or in the decision to submit the paper for publication. The other funders had no role in study design, collection, analysis, and interpretation of data, in the writing of the report, or in the decision to submit the paper for publication.

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Table 1. The 2008 prevalence (%) of knee pain and knee osteoarthritis (OA) in population aged 54-86 southern Sweden.

	Age group and sex								
	56-64		65-74			75-84			
	Men	Women	All	Men	Women	All	Men	Women	All
Number	130	381	511	256	346	602	164	250	414
Frequent knee pain ^a	21.1	28.2	26.2	21.2	26.1	24.0	20.3	29.0	25.4
Radiographic knee OA ^a	18.8	16.7	17.3	19.8	20.3	20.1	31.7	42.5	40.0
Symptomatic knee OA ^a	9.6	8.1	8.5	10.6	9.7	10.1	8.9	15.5	12.7
Clinically defined knee OA ^a	10.4	9.8	10.0	8.0	9.7	9.0	6.7	9.3	8.3
Symptomatic or clinically defined knee	14.6	14.4	14.5	14.1	15.7	15.1	12.5	19.6	16.6
OAa									

^aFrequent knee pain – knee pain in one or both knees in last 12 months with duration of at least 4 weeks; Radiographic knee OA –changes on x-ray approximating Kellgren-Lawrence grade 2 or worse; Clinically defined knee OA –OA according to the American College of Rheumatology clinical criteria, recursive positioning method; Symptomatic knee OA – knee pain as defined above in combination with radiographic OA as defined above.

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Table 2. The percentage of 2008 prevalent subjects with knee osteoarthritis (OA) who received a diagnosis of knee OA or pain in joint, respectively, set by a physician during 2004 to 2011.

	OA definition	Diagnosis of knee	Diagnosis of knee	Diagnosis of pain	
		OA or pain in joint	OA	in joint	
		% (95%CI) ^a	% (95%CI) ^a	% (95%CI) ^a	
All	Radiographic knee OAb	56.8 (49.1-64.5)	43.4 (36.5-50.4)	31.3 (23.7-38.9)	
	Clinically defined knee OAb	66.8 (59.1-74.6)	49.9 (41.8-58.1)	39.7 (30.9-48.4)	
	Symptomatic knee OAb	74.7 (70.0-79.3)	63.0 (57.8-68.2)	40.8 (35.3-46.4)	
	Symptomatic or clinically				
	defined knee OAb	68.9 (63.8-74.0)	53.3 (47.6-58.9)	40.1 (34.3-45.9)	
Men	Radiographic knee OAb	60.8 (48.6-72.9)	50.8 (39.2-62.4)	30.9 (20.0-41.8)	
	Clinically defined knee OAb	67.2 (56.4-78.0)	51.7 (38.8-64.6)	41.4 (27.6-55.3)	
	Symptomatic knee OAb	76.1 (68.4-83.8)	66.3 (57.5-75.2)	39.3 (30.1-48.6)	
	Symptomatic or clinically				
	defined knee OAb	71.3 (63.8-78.8)	58.5 (49.5-67.6)	39.4 (30.2-48.6)	
Women	Radiographic knee OAb	54.5 (44.7-64.4)	39.4 (30.5-48.2)	31.6 (21.6-41.5)	
	Clinically defined knee OAb	66.7 (56.5-76.8)	49.1 (38.6-59.6)	38.9 (27.4-50.3)	
	Symptomatic knee OAb	73.9 (67.9-79.9)	61.2 (54.6-67.8)	41.6 (34.6-48.6)	
	Symptomatic or clinically				
	defined knee OAb	67.7 (61.0-74.4)	50.7 (43.4-58.1)	40.5 (32.8-48.1)	

^a 95%CI: 95% confidence intervals

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^b Radiographic knee OA –changes on x-ray approximating Kellgren-Lawrence grade 2 or worse; Clinically defined knee OA – OA according to the American College of Rheumatology clinical criteria, recursive positioning method; Symptomatic knee OA – knee pain of duration at least 4 weeks in the last 12 months in combination with radiographic OA as defined above

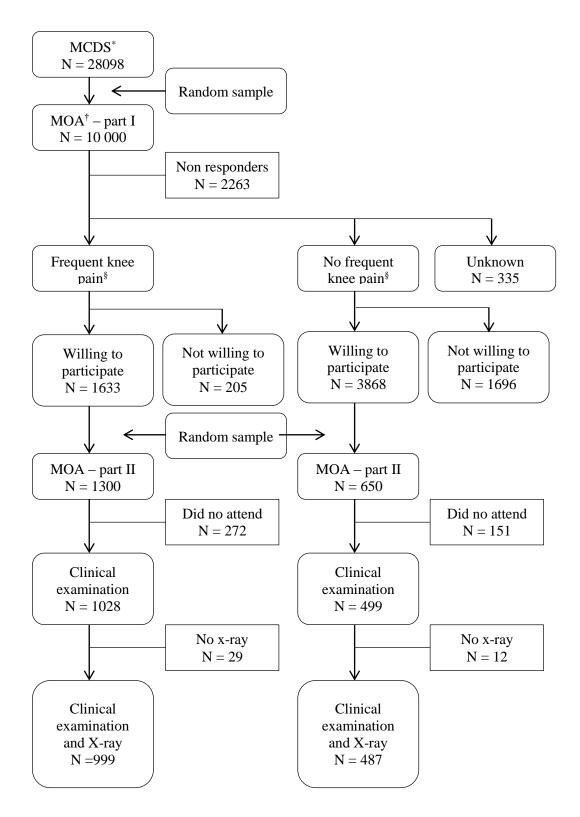


Figure 1. Study sample.

*MDCS – Malmö Diet and Cancer Study; †MOA – Malmö Osteoarthritis Study; §Frequent knee pain – knee pain in the last 12 months with duration of at least 4 weeks, no frequent knee pain – no knee pain or knee pain with duration of less than 4 weeks during the last 12 months.

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Figure 2. The 2008 prevalence of frequent knee pain and knee osteoarthritis (OA) in Swedish adults 56-84 years old.

Frequent knee pain – knee pain in one or both knees in last 12 months with duration of at least 4 weeks; Radiographic knee OA –changes on x-ray approximating Kellgren-Lawrence grade 2 or worse; Clinically defined knee OA –knee OA according to the American College of Rheumatology clinical criteria, recursive positioning method; Symptomatic knee OA – frequent knee pain as defined above in combination with radiographic knee OA as defined above.

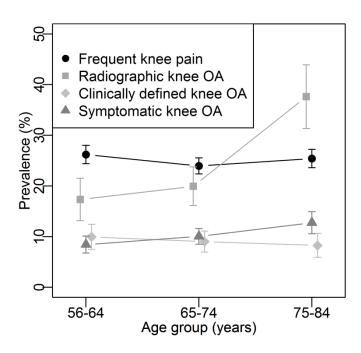


Figure 3. The 2008 prevalence and overlap of frequent knee pain and knee osteoarthritis (OA) in Swedish adults 56-84 years old.

Numbers are percentages describing the prevalence of knee OA or knee pain and their combinations. Radiographic knee OA –changes on x-ray approximating Kellgren-Lawrence grade 2 or worse; Clinically defined knee OA –knee OA according to the American College of Rheumatology clinical criteria; Frequent knee pain – knee pain in one or both knees in last 12 months with duration of at least 4 weeks.

