












BMJ Open Concordance of shoulder symptoms and imaging findings: a protocol for the Finnish Imaging of Shoulder (FIMAGE) study

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ABSTRACT

Introduction Shoulder pain is a substantial medical and socioeconomic problem in most societies, affecting the ability to work or carry out leisure time activities as well as subsequently influencing physical and psychological well-being. According to a nationwide survey in Finland, 27% of the population reported shoulder pain within the last 30 days. In clinical practice, imaging findings of structural abnormalities are typically thought to explain symptoms, even though such findings are also prevalent in asymptomatic individuals, particularly with increasing age. Overall, there is a paucity of high-quality evidence on the prevalence, clinical relevance and prognosis of ‘abnormal’ imaging findings of the shoulder.

The aim of the Finnish Imaging of Shoulder (FIMAGE) study is fourfold: to assess (1) the prevalence of shoulder symptoms and the most common anatomical variants and imaging abnormalities of the shoulder; (2) the concordance between shoulder symptoms, function and imaging abnormalities; (3) the most important determinants of symptoms, function and imaging abnormalities; and (4) the course of shoulder complaints over 5 years.

Methods The FIMAGE target population of 600 participants, aged 40–75 years, will be randomly selected from a nationally representative general population sample of 9922 individuals originally recruited for the Finnish Health 2000 Survey. On giving informed consent, the participants will be invited to a clinical visit that includes assessment of general health, shoulder symptoms, bilateral shoulder examination and imaging of both shoulders with plain radiography and MRI.

Ethics and dissemination The study has been approved by the Institutional Review Board of the Helsinki and Uusimaa Hospital District. The findings will be published according to the Strengthening the Reporting of Observational Studies in Epidemiology criteria.

Trial registration number NCT05641415.

INTRODUCTION

Background and rationale

Musculoskeletal disorders are the leading cause of chronic impairment and permanent

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A large general population sample to assess the prevalence of abnormal shoulder imaging findings and their concordance with shoulder symptoms.
- ⇒ Data on background variables from the year 2000 will enable a prospective analysis of possible determinants of shoulder symptoms and imaging findings.
- ⇒ Use of state-of-the-art shoulder imaging technology (plain radiography and 3.0T MRI).
- ⇒ Our study population is limited to individuals aged 40–75 years and the study results may not be generalisable to other age groups.

working disability in adults, putting an enormous burden on our health and social security systems.^{1,2} The shoulder is the third most commonly affected site with 27% of the Finnish population reporting pain in the previous month.³ Shoulder complaints are also the third most common musculoskeletal presentation in general practice after back and neck complaints,^{4,5} and are among the most common musculoskeletal causes of work absence.⁶ While the natural history of shoulder complaints varies and is often self-limiting, up to 50% of people presenting for care, particularly the elderly, might have persisting symptoms after 12 months of follow-up.^{7–9}

The origin of pain in degenerative musculoskeletal conditions is commonly attributed to imaging abnormalities. However, recent evidence has cast doubt on this reasoning, as imaging studies in other sites such as the lumbar spine and knee show a high prevalence of structural abnormalities even in asymptomatic individuals.^{10–14} The prevalence of full-thickness rotator cuff tears and

**Table 1** Overview of the FIMAGE study and its most important subprojects

Subproject	Prevalence	Concordance	Determinants	Longitudinal
Study question	Prevalence of shoulder symptoms, anatomical variants and imaging abnormalities	Concordance between shoulder symptoms, function and imaging abnormalities	Determinants of shoulder symptoms, function and imaging abnormalities	Course of shoulder complaints
Study design	Cross-sectional	Cross-sectional	Prospective	Prospective
Study population	Finnish population aged 40–75 years	Finnish population aged 40–75 years	Finnish population aged 40–75 years	Finnish population aged 45–80 years
Outcome measure(s)	Shoulder symptom assessment*, shoulder imaging†	Shoulder symptom assessment*, shoulder examination‡, shoulder imaging†	Shoulder symptom assessment*, shoulder examination‡, shoulder imaging†	Repeated outcome assessment at 5-year follow-up
Subproject	Function	Examination	Diagnostic labels	Quality
Study question	Age and gender-specific shoulder function in the Finnish population	The accuracy of clinical shoulder examination. Creating a clinical test battery for shoulder complaints.	Identification of shoulder disorder patterns. Are current diagnostic labels clinically valid?	Association between health-related quality of life and shoulder complaints
Study design	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional
Study population	Finnish population aged 40–75 years	Finnish population aged 40–75 years	Finnish population aged 40–75 years	Finnish population aged 40–75 years
Outcome measure(s)	Shoulder symptom assessment*, shoulder examination‡	Shoulder examination‡	Latent classes	EQ-5D-5L

*Shoulder symptom assessment includes the Shoulder Pain and Disability Index (SPADI), Constant Score, various shoulder pain and disability questions (eg, 1-month prevalence, pain, impairment NRS, etc).
†Shoulder imaging shows radiography and MRI of both shoulders.
‡Shoulder examination demonstrates range of motion and strength measurements, special shoulder tests.
EQ-5D-5L, EuroQoL 5-Dimension 5-Level questionnaire; FIMAGE, Finnish Imaging of Shoulder; NRS, Numerical Rating Scale.

radiographic signs of shoulder osteoarthritis (OA) in middle-aged and elderly populations has been reported to range from 17% to 22%.^{15–18} However, the validity of these estimates is open to question due to the imaging modalities used in these studies as well as the representativeness of their study participants to the general population. As well, mental health has been found to have a stronger association with symptoms than structural abnormalities.¹⁹

Precise valid age-specific prevalence estimates of shoulder imaging abnormalities in the general population, and an understanding of their connection with symptoms, are needed to optimally interpret shoulder imaging findings in patients who present for care with shoulder pain.²⁰

Aims and objectives

Finnish Imaging of Shoulder (FIMAGE) is a population-based, longitudinal, observational study aiming to improve our understanding of the aetiology, epidemiology and diagnostic utility of imaging of shoulder complaints (table 1).

The four main objectives of the FIMAGE study are to:

1. Determine the prevalence of shoulder symptoms, anatomical variants and imaging abnormalities of the shoulder in the general population aged 40–75 years.
2. Determine the concordance between shoulder symptoms, function and imaging abnormalities.
3. Explore the determinants of shoulder symptoms, function and imaging abnormalities.
4. Investigate the course of shoulder complaints at a 5-year follow-up.

METHODS AND ANALYSIS

Overview of study design

Participants for this observational study will be drawn from the sample of a nationwide, population-based health survey performed in Finland from August 2000 to June 2001 (Health 2000 Survey).²¹ The Health 2000 Survey is one of the most comprehensive nationwide health surveys with well-refined study protocols and a high participation rate. The survey consisted of several questionnaires, an extensive interview, laboratory and functional capacity tests and a clinical examination. A nationally representative two-stage stratified cluster sample was drawn by stratifying Finland into 20 strata consisting of the 15 biggest

cities and five university hospital districts. A total of 9922 persons aged 18 years or older were sampled from these clusters.⁵ Most of them took part in the follow-up survey 11 years later (Health 2011 Survey).

This protocol has been written according to the 'Strengthening The Reporting of OBServational Studies in Epidemiology' guidelines²² where applicable; the checklist is available as online supplemental table 1.

Study settings and participant selection

For the FIMAGE study, we will recruit a random, population-based subsample of Health 2000 Survey participants. To be included in the study, participants have to be ambulatory, aged between 40 and 75 years, capable of communicating in Finnish or Swedish and be participants in the Health 2000 Survey. In total, 2368 participants fulfilled these criteria on 1 December 2022, and will serve as the baseline for our random subsample of 600 participants. Participants with dementia, terminal cancer, previous shoulder replacement surgery and contraindications to MRI will be excluded.

The random sampling process will be performed using the SAS/STAT software v9.4 M7 (SAS Institute, Cary, North Carolina, USA) developed for statistical analysis of variance and predictive modelling. For feasibility reasons, that is, availability of 3T MRI, we will only recruit participants living within a reasonable travelling distance of the five university hospitals and not the whole of Finland. The distribution of the Finnish population can be seen in figure 1, showing that most of the Finnish population lives in the proximity of the five university hospitals. The recruitment areas do include rural areas in addition to metropolitan areas.

Informed consent

At the research visit, we will provide participants with detailed written and oral information about the study and ask them to sign a written consent form. Withdrawal from the study is possible at any time, in accordance with the latest version of the Declaration of Helsinki.²³

Data collection and case definitions

Our data collection is based on methods developed and validated for the Health 2000 and Health 2011 Surveys, as it ensures reliable data and provides a unique opportunity to implement a prospective design for investigating possible determinants of shoulder symptoms and imaging findings, including general health parameters and work-related exposures. We would then have detailed background data from two to three different time points (2000, 2011 (some of the participants) and 2023–2024).

Recruitment

The first contact with potential participants will be established by the Finnish Institute for Health and Welfare, which was responsible for the planning and execution of the Health 2000 and Health 2011 Surveys. The contact letter will include an information leaflet explaining the study protocol. Individuals who fail to respond will

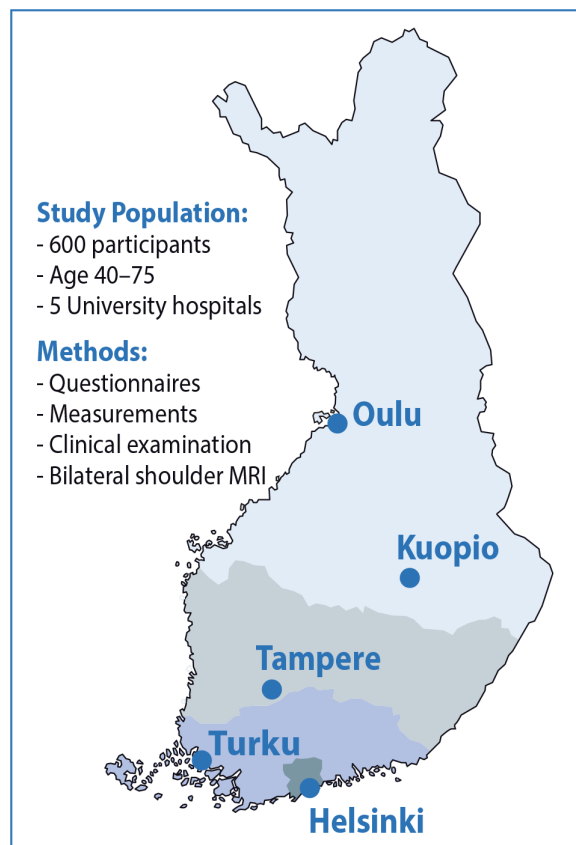


Figure 1 Map showing the distribution of the Finnish population and the location of our recruitment centres. We will recruit participants living within a reasonable travelling distance of the five university hospitals. The marked areas represent where one-fourth of the population lives in Finland with the majority living in the southern part.

be contacted via phone by Statistics Finland to increase participation rates and minimise selection bias. We will attempt to minimise potential recruitment bias by not specifically emphasising the presence of shoulder symptoms and stressing the fact that participation is important regardless of symptom status. Study participants will be invited to a research visit, where they will undergo an extensive health interview and clinical shoulder examination. Shoulder imaging (plain radiography and MRI) of both shoulders will be taken during the same visit or scheduled for a second visit depending on the participant's preference (figure 2).

Medical history

A detailed medical history will be obtained in a face-to-face health interview. A standardised questionnaire will collect data on social background, medical history and demographic variables (figure 3). The interview will determine presence of past and present shoulder symptoms, history of shoulder trauma and general health status, including smoking, alcohol consumption, comorbidities, physical and psychosocial work exposures, overhead activities and pain elsewhere (pain at multiple body sites). General health-related

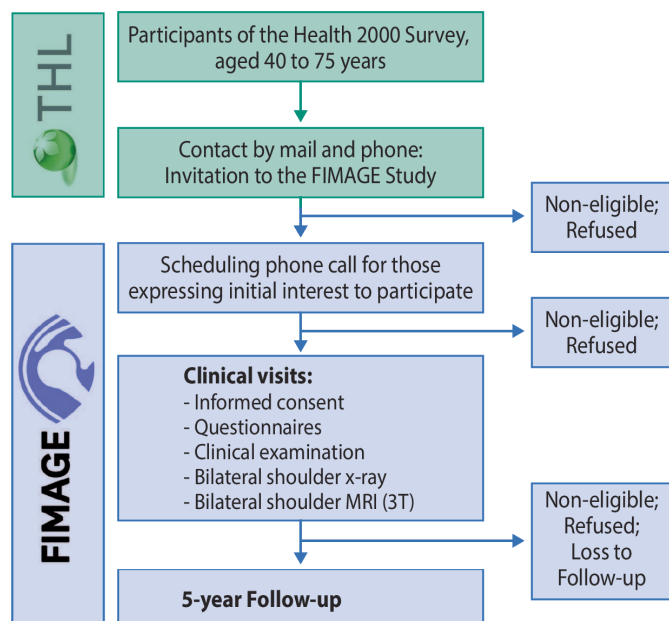


Figure 2 Recruitment flow chart. FIMAGE, Finnish Imaging of Shoulder Study; THL, Finnish Institute for Health and Welfare.

quality of life will be assessed using the EuroQoL 5-Dimension 5-Level questionnaire²⁴ and psychological well-being will be assessed using the Hospital Anxiety and Depression Scale.²⁵

Worry about shoulder pain will be assessed using a single-item question that has been used previously²⁶: how worried have you felt about your shoulder pain in the past week? (possible responses: not this week, often, sometimes, every day). Self-reported health literacy will also be assessed using a single-item question used previously²⁶: how often do you need to have someone help you read written instructions, pamphlets or other written material from your doctor or pharmacy? (response options: never, rarely, sometimes, often, always). Fear avoidance beliefs will be assessed using two single-item questions previously published by Wynne-Jones *et al.*²⁶ Pain self-efficacy and catastrophizing will be measured using short forms of the Pain Self-Efficacy Questionnaire²⁷ and Pain Catastrophizing Scale,²⁸ respectively.

Shoulder-specific questionnaires

At the clinical visit, subjects will complete several questionnaires concerning shoulder symptoms. Shoulder-specific questionnaires will include the Shoulder Pain and Disability Index (SPADI),^{29 30} the Constant Score (CS)³¹ and Subjective Shoulder Value (SSV).³² The SPADI is a self-administered questionnaire designed to measure shoulder pain and disability associated with shoulder pathology. The means of the pain and disability subscales are averaged to produce a total score ranging from 0 (best) to 100 (worst). It has been validated for different clinical settings and populations and has been widely used.³³ The CS is a

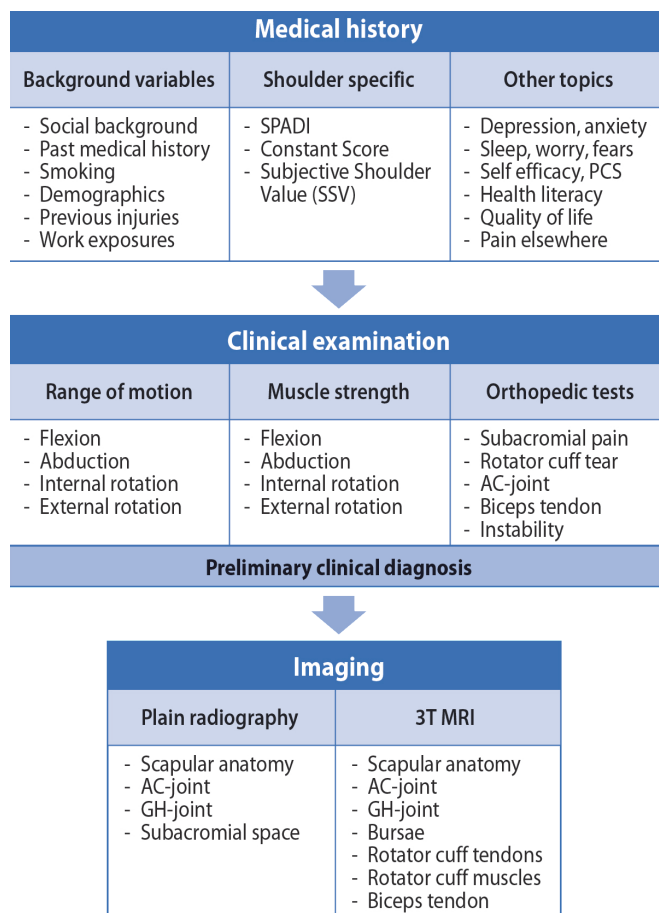


Figure 3 Data collection and outcomes. Constant Score indicates functional shoulder assessment. Work exposures characterise physical and psychosocial. 3T MRI, 3 Tesla MRI; AC, acromioclavicular; GH, glenohumeral; PCS, Pain Catastrophizing Scale; SPADI, Shoulder Pain and Disability Index.

combined self-based and examiner-based tool divided into four subscales (pain, activities of daily living, range of motion (ROM) and strength). The higher the score, the higher is the quality of function (minimum 0, maximum 100). The SSV is a participant's subjective shoulder assessment scored as a percentage from 0% to 100%, with 100% representing a completely normal shoulder.

Clinical examination

Active and passive ROM of both shoulders will be measured using an inclinometer using a standardised protocol,^{34 35} and isometric muscle strength of shoulder abduction, internal and external rotation will be measured using a handheld dynamometer. In addition, we will perform special shoulder tests (online supplemental table 2) following a structured assessment protocol. Similar to a previous study,³⁶ investigators will attend a prestudy training course that includes quality control measures such as

observation, feedback on examination technique and repeated and parallel measurements.

Imaging

Plain radiography

Radiographic examination of both shoulders by plain radiography (three views: anterior posterior in internal and external rotations and a lateral view of the scapula) will be carried out to evaluate scapular anatomy and degenerative changes of the glenohumeral and acromioclavicular joints (online supplemental table 3). OA of the glenohumeral joint will be graded according to the Allain modification of the Samilson-Prieto classification³⁷ and the acromioclavicular joint as described by de Abreu *et al.*³⁸ The radiographs will be read independently using structured assessment forms by two musculoskeletal radiologists who will be blinded to the information gathered by history, clinical examination and MRI.

MRI and grading of structural changes

Bilateral MRI scans of the shoulders will be obtained with the use of a 3 Tesla scanner with a phased-array shoulder coil. The MRI scans will be read independently using structured assessment forms by two musculoskeletal radiologists who will be blinded to the information gathered by history, clinical examination and radiography findings. For cases in which the findings are not consistent, consensus will be obtained. Structures that will be evaluated will include the glenohumeral and acromioclavicular joints, subacromial-subdeltoid bursa, rotator cuff tendons and muscles, biceps tendon, scapular morphology and nerves (online supplemental table 4). Grading of imaging findings will be performed according to the procedure by Gill *et al.*³⁹

Sample size

Given the wide range of prevalence estimates of imaging abnormalities in the published literature, we have focused instead on what precision we can achieve for such a sample size for a range of potential true prevalence values. With 600 participants, 95% CI widths would range from 2.4% units (for a prevalence of 2%) to a maximum of 8%-units (for a prevalence of 50%).

Our recruitment target is 600 participants, which is divided into an initial sample of 200 participants and a secondary sample of 400 participants. After the first 200 participants have completed their baseline assessment, we will perform an interim analysis to assess the need to adjust the sampling probabilities of the secondary sample to sample more individuals in those subgroups where the participation rates are low. This way, the coefficient of variation of the sample weights and therefore the inefficiency will be smaller.⁴⁰ We will use age, sex and other variables, which are associated with the non-response, for the comparison of the participants of the initial sample and the Health 2000 participants. If needed, we will modify the number of participants to achieve higher precision of the estimates for our main outcomes of

interest, if the preliminary CIs appear to be considerably wider (accounting for the smaller number of participants in the initial sample) than those anticipated in our power analyses above. This adaptive study design will ensure that our results regarding our key study questions are sufficiently precise and valid, and it will guarantee the most economic use of our resources.^{41 42}

Statistical analyses

To ensure that our sample will be representative of the Finnish population, in interim analyses, we will compare both the demographic variables and the symptom and risk factor variables collected in the Health 2000 and Health 2011 Surveys of study participants to the general Finnish population, and the Health 2000 and Health 2011 Surveys, respectively, aged 40–75 years to assess the representativeness of our participants. Important comparisons will be, for example, with respect to the non-participants, who participated in the Health 2000 or Health 2011 Survey, and with respect to the rural population, which will be under-represented in our data. If deemed necessary, we will adjust the weights of our random sampling for certain subgroups, especially age, to improve representativeness to the general population. We will also assess for potential recruitment bias by comparing shoulder symptom prevalence in study participants with people who decline participation.

We will employ standard epidemiological statistical analysis methods applicable to each study question.^{43 44} These methods are presented in table 2. For bilateral data outcomes we will use mixed-effects regression models.

Quality assurance

Prior to study launch, we will create a written standard operating procedures file and perform a pilot study training and standardising shoulder measurements and the clinical examination protocol. The radiologists will read both separately and together a 10-patient random sample cohort to calibrate their scoring practices and delineation of anatomical regions before the definite readings. Study data will be collected and managed using REDCap electronic data capture tools hosted at the University of Helsinki.^{45 46}

Patient and public involvement

To achieve a participant-friendly design for our study,²⁶ we recruited patient experts from the patient research panel of the Helsinki University Hospital. They reviewed and provided feedback on the following documents: (a) the clarity and comprehensibility of the Finnish version of the study protocol, the patient consent form and the General Data Protection Regulation form, (b) the burden (time amount needed) related to filling out the numerous questionnaires (to assess if the amount of questionnaires is feasible and finalise the time schedule for the research visit) and (c) the clarity and understandability of our questionnaires. After the study is completed,

**Table 2** Outcome measures, variable types and statistical analysis methods in the FIMAGE study

Subproject	Prevalence	Concordance	Determinants	Longitudinal
Study question	Prevalence of anatomical variants and imaging abnormalities	Concordance between imaging abnormalities, shoulder symptoms and shoulder function	Determinants for imaging abnormalities, shoulder symptoms and function	Course of shoulder complaints
Outcome measure(s)	Shoulder symptom assessment*, shoulder imaging†	Shoulder symptom assessment*, shoulder examination‡, shoulder imaging†	Shoulder symptom assessment*, shoulder examination‡, shoulder imaging†	Repeated outcome assessment at 5-year follow-up
Variable type(s)	Continuous, categorical, binary	Continuous, categorical, binary	Continuous, categorical, binary	Continuous, categorical, binary
Analysis	Descriptive analysis	Mixed regression model	Mixed regression model	Mixed regression model
Subproject	Function	Examination	Diagnostic labels	Quality
Study question	Age and gender specific in the Finnish population	The accuracy of clinical shoulder examination. Creating a clinical test battery for shoulder complaints.	Identification of shoulder disorder patterns. Do phenotypes match with current diagnostic classifications?	Association between health-related quality of life and shoulder disorders
Outcome measure(s)	Shoulder symptom assessment*, shoulder examination‡	Shoulder examination‡	Latent classes	EQ-5D-5L
Variable type(s)	Continuous	Continuous, categorical, binary	Categorical	Continuous
Analysis	Descriptive analysis	Mixed regression model	Latent class analysis	Mixed regression model

*Shoulder symptom assessment includes the Shoulder Pain and Disability Index (SPADI), Constant Score, various shoulder pain and disability questions (eg, 1-month prevalence, pain, impairment NRS, etc).
†Shoulder imaging shows radiography and MRI of both shoulders.
‡Shoulder examination demonstrates range of motion and strength measurements, special shoulder tests.
EQ-5D-5L, EuroQoL 5-Dimension 5-Level questionnaire; FIMAGE, Finnish Imaging of Shoulder; NRS, Numerical Rating Scale.

we will contemplate together with patient experts on how to best share the study results to the public.

Time schedule

Recruitment of our study started in February 2023 in Helsinki and gradually expanded to first Tampere (April 2023), Turku (August 2023), Kuopio (September 2023) and Oulu (September 2023). Our scheduled average enrolment rate per week is 14 and at the current pace we aim to have completed the baseline data collection in early 2024. Thus, the 5-year follow-up should be completed in 2029.

ETHICS AND DISSEMINATION

This study will be conducted according to the Helsinki Declaration. The protocol has been approved by the Institutional Review Board of the Helsinki and Uusimaa Hospital District (HUS/13564/2022), and the study is registered at www.ClinicalTrials.gov (NCT05641415). All modifications to the study protocol will be communicated by updating the study registry. Before recruitment, oral and written explanations will be provided to all eligible patients, and informed consent will be obtained at the participating centre.

All participating centres will obtain local institutional research approvals before start of recruitment. Information about the study participants will be kept confidential and will be managed in accordance with the following rules: (1) all study-related information is stored securely at the research sites, (2) all possible study participant information in paper form is stored in locked file cabinets and is accessible only to study personnel, (3) all case report forms are identified only by a coded participant number, (4) all records that contain participant names or other identifying information are stored separately from the study records that are identified only by the coded participant number and (5) all local databases are password protected.

The findings of this study will be published through peer-reviewed journals and conference presentations and disseminated to the public through newspapers and social media. Study participants will be provided with a summary of the results after the research visit is completed.

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Correction notice This article has been corrected since it was published. Incorrect ORCID of Tomasz Czuba has been corrected.

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Collaborators FIMAGE investigators: Robert Björkenheim, Markku Heliövaara, Roope Kalske, Kari Kanto, Eira Viikari-Juntura, Danielle van der Windt.

Contributors TI, ST, TJ and RB conceptualised the study idea and contributed to the overall design of the study. TI, ST, TJ, PT and SR will implement the study at all study sites. ST, TJ, TI and TC planned the statistical analyses. All authors (TI, RB, NS, LR, PT, SR, SK, TH, HR, TC, MP, TJ, ST) contributed to the design of the study and revised and approved the final manuscript. All collaborators (FIMAGE investigators: RB, MH, RK, KK, EV-J, DvdW) provided feedback on drafts and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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