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

Thomas Ibounig <sup>(1)</sup>, <sup>1,2</sup> Rachelle Buchbinder <sup>(1)</sup>, <sup>3</sup> Niko Sillanpää <sup>(1)</sup>, <sup>2,4</sup> Lasse Rämö <sup>(1)</sup>, <sup>1,2</sup> Pirjo Toivonen <sup>(1)</sup>, <sup>2</sup> Saara Raatikainen, <sup>1,2</sup> Seppo Koskinen <sup>(1)</sup>, <sup>5</sup> Tommi Härkänen <sup>(1)</sup>, <sup>5</sup> Harri Rissanen, <sup>5</sup> Tomasz Czuba <sup>(1)</sup>, <sup>6</sup> Mika Paavola <sup>(1)</sup>, <sup>1</sup> Teppo Jarvinen <sup>(1)</sup>, <sup>1,2</sup> Simo Taimela <sup>(1)</sup>, <sup>1,2</sup> for the FIMAGE investigators

#### ABSTRACT

**To cite:** Ibounig T, Buchbinder R, Sillanpää N, *et al.* Concordance of shoulder symptoms and imaging findings: a protocol for the Finnish Imaging of Shoulder (FIMAGE) study. *BMJ Open* 2023;**13**:e074457. doi:10.1136/ bmjopen-2023-074457

Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2023-074457).

Received 10 April 2023 Accepted 27 November 2023



© Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to Dr Thomas Ibounig;

thomas.ibounig@helsinki.fi

**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.
- $\Rightarrow$  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.<sup>12</sup> The shoulder is the third most commonly affected site with 27% of the Finnish population reporting pain in the previous month.<sup>3</sup> Shoulder complaints are also the third most common musculoskeletal presentation in general practice after back and neck complaints,<sup>45</sup> and are among the most common musculoskeletal causes of work absence.<sup>6</sup> While the natural history of shoulder complaints varies and is often selflimiting, up to 50% of people presenting for care, particularly the elderly, might have persisting symptoms after 12 months of follow-up.

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.<sup>10–14</sup> The prevalence of full-thickness rotator cuff tears and

BMJ

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	Shoulder symptom assessment*, shoulder	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%.<sup>15-18</sup> 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.<sup>19</sup>

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.<sup>20</sup>

## **Aims and objectives**

Finnish Imaging of Shoulder (FIMAGE) is a populationbased, 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 5year 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).<sup>21</sup> 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.<sup>3</sup> 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' guidelines<sup>22</sup> 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**

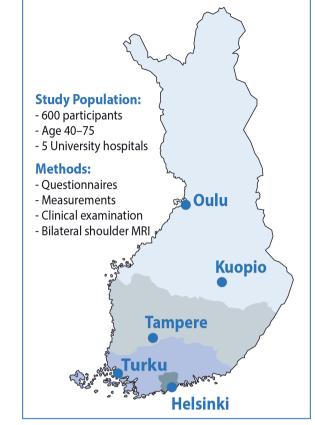
At the research visit, we will provide participants with detailed written and oral information about the study and ask them to sign a written consent form. Withdrawal from the study is possible at any time, in accordance with the latest version of the Declaration of Helsinki.<sup>23</sup>

#### **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

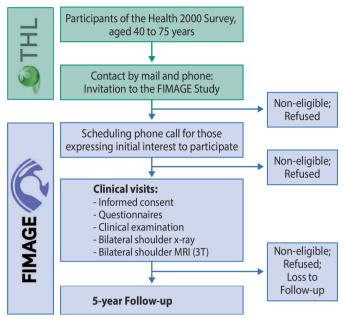


**Figure 1** Map showing the distribution of the Finnish population and the location of our recruitment centres. We will recruit participants living within a reasonable travelling distance of the five university hospitals. The marked areas represent where one-fourth of the population lives in Finland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



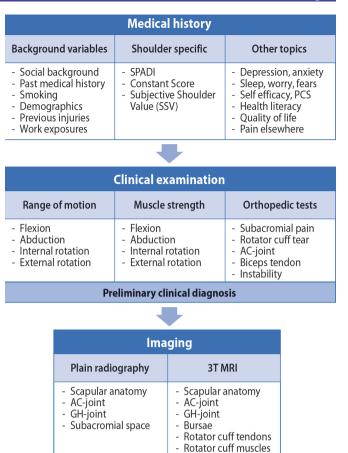
**Figure 2** Recruitment flow chart. FIMAGE, Finnish Imaging of Shoulder Study; THL, Finnish Institute for Health and Welfare.

quality of life will be assessed using the EuroQoL 5-Dimension 5-Level questionnaire<sup>24</sup> and psychological well-being will be assessed using the Hospital Anxiety and Depression Scale.<sup>25</sup>

Worry about shoulder pain will be assessed using a single-item question that has been used previously<sup>26</sup>: 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 previously<sup>26</sup>: 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.*<sup>26</sup> Pain self-efficacy and catastrophising will be measured using short forms of the Pain Self-Efficacy Questionnaire<sup>27</sup> and Pain Catastrophizing Scale,<sup>28</sup> respectively.

#### **Shoulder-specific questionnaires**

At the clinical visit, subjects will complete several questionnaires concerning shoulder symptoms. Shoulderspecific questionnaires will include the Shoulder Pain and Disability Index (SPADI),<sup>29 30</sup> the Constant Score (CS)<sup>31</sup> and Subjective Shoulder Value (SSV).<sup>32</sup> 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.<sup>33</sup> 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.

- Biceps tendon

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,<sup>34,35</sup> 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,<sup>36</sup> 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 classification<sup>37</sup> and the acromioclavicular joint as described by de Abreu *et al.*<sup>38</sup> 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 acromio-clavicular 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.*<sup>39</sup>

## 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.<sup>40</sup> 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.<sup>41 42</sup>

#### **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.<sup>43 44</sup> These methods are presented in table 2. For bilateral data outcomes we will used 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.<sup>45 46</sup>

#### Patient and public involvement

To achieve a participant-friendly design for our study,<sup>26</sup> 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 Outco	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	
			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.

#### Author affiliations

<sup>1</sup>Department of Orthopaedics and Traumatology, Helsinki University Central Hospital, Helsinki, Finland

<sup>2</sup>Finnish Centre for Evidence-Based Orthopaedics, University of Helsinki, Helsinki, Finland

<sup>3</sup>Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

<sup>4</sup>Tampere University Hospital, Tampere, Finland

<sup>5</sup>Population Health, National Institute for Health and Welfare, Helsinki, Finland <sup>6</sup>Department of Molecular and Clinical Medicine, University of Gothenburg, Goteborg, Sweden

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

Acknowledgements We thank the patient research panel of the Helsinki University Hospital for their valuable comments on improving the material we will send to the participants. We also thank the research personnel at all study sites for their invaluable contributions. We express our gratitude to Drs Juha Paloneva, Jaakko Niinimäki and Martin Englund for their initial comments on the study protocol.

**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.

**Funding** This work is supported by the Academy of Finland (316061), the Social Insurance Institution of Finland (KELA, 63/26/2018), the state funding for university-level health research in Finland (TYH2020213) and the Helsinki University Research Fund (WBS47087321). RB is supported by an Australian National Health and Medical Research Council (NHMRC) Leadership Fellowship (GNT1194483).

**Map disclaimer** The inclusion of any map (including the depiction of any boundaries therein), or of any geographic or locational reference, does not imply the expression of any opinion whatsoever on the part of BMJ concerning the legal status of any country, territory, jurisdiction or area or of its authorities. Any such expression remains solely that of the relevant source and is not endorsed by BMJ. Maps are provided without any warranty of any kind, either express or implied.

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.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

#### **ORCID** iDs

Thomas Ibounig http://orcid.org/0000-0001-9658-8571 Rachelle Buchbinder http://orcid.org/0000-0002-0597-0933 Niko Sillanpää http://orcid.org/0000-0003-0589-3648 Lasse Rämö http://orcid.org/0000-0003-4154-8462 Pirjo Toivonen http://orcid.org/0000-0002-1456-2093 Seppo Koskinen http://orcid.org/0000-0002-1456-2093 Tommi Härkänen http://orcid.org/0000-0002-4577-1808 Tomasz Czuba http://orcid.org/0009-0001-0232-0425 Mika Paavola http://orcid.org/0000-0002-2506-2115 Teppo Jarvinen http://orcid.org/0000-0003-3713-956X Simo Taimela http://orcid.org/0000-0001-6755-2983

#### REFERENCES

- 1 Kansaneläkelaitos. Kelan Tilastollinen Vuosikirja 2016; 2017.
- 2 GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the global burden of disease study 2016. *Lancet* 2017;390:1211–59.
- 3 Koskinen S, Lundqvist A, Ristiluoma N. Health, functional capacity and welfare in Finland in 2011, Report 68/2012. National Institute for Health and Welfare (THL); 2012.
- 4 Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Ann Rheum Dis 1998;57:649–55.
- 5 Adamson J, Ebrahim S, Dieppe P, *et al.* Prevalence and risk factors for joint pain among men and women in the west of Scotland Twenty-07 study. *Ann Rheum Dis* 2006;65:520–4.
- 6 US Department of Labor, Bureau of Labor Statistics. Lost-worktime injuries and illnesses: characteristics and resulting time away from work. Washington, DC: US Department of Labor, Bureau of Labor Statistics, 2005.
- 7 van der Heijden GJ. Shoulder disorders: a state-of-the-art review. Baillieres Best Pract Res Clin Rheumatol 1999;13:287–309.
- 8 Linsell L, Dawson J, Zondervan K, et al. Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology (Oxford*) 2006;45:215–21.
- 9 Whittle S, Buchbinder R. In the clinic. rotator cuff disease. *Ann Intern* Med 2015;162:ITC1–15.
- 10 Englund M, Guermazi A, Gale D, et al. Incidental meniscal findings on knee MRI in middle-aged and elderly persons. N Engl J Med 2008;359:1108–15.
- 11 Brinjikji W, Luetmer PH, Comstock B, et al. Systematic literature review of imaging features of spinal degeneration in asymptomatic populations. AJNR Am J Neuroradiol 2015;36:811–6.
- 12 Kasch R, Truthmann J, Hancock MJ, et al. Association of lumbar MRI findings with current and future back pain in a population-based cohort study. *Spine* 2022;47:201–11.
- 13 Chen L, Perera RS, Radojcic MR, et al. Association of lumbar spine radiographic changes with severity of back pain-related disability among middle-aged, community-dwelling women. JAMA Netw Open 2021;4:e2110715.
- 14 Culvenor AG, Øiestad BE, Hart HF, et al. Prevalence of knee osteoarthritis features on magnetic resonance imaging in asymptomatic uninjured adults: a systematic review and metaanalysis. *Br J Sports Med* 2019;53:1268–78.
- 15 Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic rotator cuff tears in the general population: from mass-screening in one village. J Orthop 2013;10:8–12.
- 16 Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff tear in the general population. J Shoulder Elbow Surg 2010;19:116–20.
- 17 Kobayashi T, Takagishi K, Shitara H, et al. Prevalence of and risk factors for shoulder osteoarthritis in Japanese middle-aged and elderly populations. J Shoulder Elbow Surg 2014;23:613–9.
- 18 Oh JH, Chung SW, Oh CH, et al. The prevalence of shoulder osteoarthritis in the elderly Korean population: association with risk factors and function. J Shoulder Elbow Surg 2011;20:756–63.
- 19 Wylie JD, Suter T, Potter MQ, et al. Mental health has a stronger association with patient-reported shoulder pain and function than tear size in patients with full-thickness rotator cuff tears. J Bone Joint Surg Am 2016;98:251–6.
- 20 Jaeschke R, Guyatt GH, Sackett DL. Users' guides to the medical literature. III. how to use an article about a diagnostic test. B. what are the results and will they help me in caring for my patients? The evidence-based medicine working group. *JAMA* 1994;271:703–7.
- 21 Kaila-Kangas L. Musculoskeletal disorders and diseases in Finland results of the health 2000 survey, (KTL B25/2007). Publications of the National Public Health Institute; 2007.
- 22 von Elm E, Altman DG, Egger M, *et al.* The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med* 2007;147:573.
- 23 World Medical Association. World Medical Association declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191–4.

## **Open access**

- 24 EuroQol G. Euroqol--a new facility for the measurement of healthrelated quality of life. *Health Policy* 1990;16:199–208.
- 25 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361–70.
- 26 Wynne-Jones G, Myers H, Hall A, et al. Predicting pain and function outcomes in people consulting with shoulder pain: the PANDA-S clinical cohort and qualitative study protocol. BMJ Open 2021;11:e052758.
- 27 Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain* 2007;11:153–63.
- 28 Walton DM, Wideman TH, Sullivan MJL. A Rasch analysis of the pain catastrophizing scale supports its use as an interval-level measure. *Clin J Pain* 2013;29:499–506.
- 29 Roach KE, Budiman-Mak E, Songsiridej N, et al. Development of a shoulder pain and disability index. Arthritis Care Res 1991;4:143–9.
- 30 Williams JW, Holleman DR, Simel DL. Measuring shoulder function with the shoulder pain and disability index. *J Rheumatol* 1995;22:727–32.
- 31 Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res* 1987;1987:160–4.
- 32 Gilbart MK, Gerber C. Comparison of the subjective shoulder value and the constant score. J Shoulder Elbow Surg 2007;16:717–21.
- 33 Angst F, Schwyzer HK, Aeschlimann A, et al. Measures of adult shoulder function: disabilities of the arm, shoulder, and hand questionnaire (DASH) and its short version (QuickDASH), shoulder pain and disability index (SPADI), American shoulder and elbow Surgeons (ASES) society standardized shoulder assessment form, constant (Murley) score (CS), simple shoulder test (SST), Oxford shoulder score (OSS), shoulder disability questionnaire (SDQ), and Western Ontario shoulder instability index (WOSI). Arthritis Care Res (Hoboken) 2011;63 Suppl 11:S174–88.
- 34 Green S, Buchbinder R, Forbes A, *et al.* A standardized protocol for measurement of range of movement of the shoulder using the Plurimeter-V inclinometer and assessment of its intrarater and interrater reliability. *Arthritis Care Res* 1998;11:43–52.

- 35 Hoving JL, Buchbinder R, Green S, et al. How reliably do rheumatologists measure shoulder movement? Ann Rheum Dis 2002;61:612–6.
- 36 Miranda H, Punnett L, Viikari-Juntura E, et al. Physical work and chronic shoulder disorder. Results of a prospective population-based study. Ann Rheum Dis 2008;67:218–23.
- 37 Allain J, Goutallier D, Glorion C. Long-term results of the Latarjet procedure for the treatment of anterior instability of the shoulder. *J Bone Joint Surg Am* 1998;80:841–52.
- 38 de Abreu MR, Chung CB, Wesselly M, et al. Acromioclavicular joint osteoarthritis: comparison of findings derived from MR imaging and conventional radiography. *Clin Imaging* 2005;29:273–7.
- 39 Gill TK, Shanahan EM, Allison D, et al. Prevalence of abnormalities on shoulder MRI in symptomatic and asymptomatic older adults. Int J Rheum Dis 2014;17:863–71.
- 40 Korn EL, Graubard BI. *Analysis of Health Surveys, 1st ed.* Wiley, 2011.
- 41 Bhatt DL, Mehta C. Adaptive designs for clinical trials. N Engl J Med 2016;375:65–74.
- 42 Pallmann P, Bedding AW, Choodari-Oskooei B, *et al*. Adaptive designs in clinical trials: why use them, and how to run and report them. *BMC Med* 2018;16:29.
- 43 Clayton D, Hills M. Statistical models in epidemiology. Oxford: Oxford University Press, 1996.
- 44 Rothman KJ, Greenland S. *Modern epidemiology*. Philadelphia: Lippincott Williams & Wilkins, 1998.
- 45 Harris PA, Taylor R, Thielke R, *et al.* Research electronic data capture (REDCap)--A metadata-driven methodology and workflow process for providing translational research Informatics support. *J Biomed Inform* 2009;42:377–81.
- 46 Harris PA, Taylor R, Minor BL, *et al*. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.

## Supplementary Table 1 – STROBE checklist

This protocol has been written according to the "Strengthening The Reporting of OBservational Studies in Epidemiology" (STROBE) guidelines. As there is no dedicated checklist for observational study protocols available (unlike the SPIRIT guidelines for clinical trials), we filled out the STROBE checklist below where applicable (leaving blank the results and discussion sections).

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary	2
		of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the	4-5
-		investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including	7
		periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of	7-8
		selection of participants	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	8-11
		confounders, and effect modifiers. Give diagnostic criteria, if	
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of	8-11
measurement		methods of assessment (measurement). Describe comparability	
		of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	8,12
Study size	10	Explain how the study size was arrived at	11
Quantitative variables	11	Explain how quantitative variables were handled in the analyses.	12
		If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to	11,12
		control for confounding	
		(b) Describe any methods used to examine subgroups and	11,12
		interactions	
		(c) Explain how missing data were addressed	11,12
		(d) If applicable, describe analytical methods taking account of sampling strategy	11,12
		(e) Describe any sensitivity analyses	11,12

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers	NA
		potentially eligible, examined for eligibility, confirmed eligible, included in the	
		study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social)	NA
data		and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	NA
		estimates and their precision (eg, 95% confidence interval). Make clear which	
		confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk	NA
		for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and	NA
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	NA
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	NA
		or imprecision. Discuss both direction and magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	NA
		limitations, multiplicity of analyses, results from similar studies, and other	
		relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other informati	on		
Funding	22	Give the source of funding and the role of the funders for the present study	16
-		and, if applicable, for the original study on which the present article is based	

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

# Supplementary Table 2 – Special Shoulder Tests

Special Shoulder Tests		
Stability	Apprehension	
	Relocation	
	Jerk test	
Subacromial shoulder pain	Painful arch	
	Neer	
	Hawkings-Kennedy	
Rotator cuff tests	Drop arm (SSP)	
	Full can (SSP)	
	Empty can/Jobe (SSP)	
	Starter sign/ zero-degree abduction test (SSP)	
	External rotation lag sign (SSP, ISP)	
	5 <sup>th</sup> finger test (ISP)	
	Resisted External Rotation Test (ISP)	
	Hornblower (TM)	
	Lift off (SSC)	
	Internal Rotation Lag Sign (SSC)	
	Belly-press (SSC)	
	Bear Hug (SSC)	
AC-joint	AC-joint pain in internal rotation	
	Finger sign	
	Cross-body adduction	
	O'Brian / Active compression test	
Long head of biceps and superior labrum	Speeds (LHB)	
	Yergason (LHB)	

SA=subacromial, SSP=supraspinatus, ISP=infraspinatus, TM=teres minor, SSC=subscapularis, AC= acromioclavicular, LHB= long head of biceps, SLAP= superior labrum from anterior to posterior

# Supplementary Table 3 – Radiography

Plain radiography	
AC Joint osteoarthritis	Abreu classification Grade 0 (No osteoarthritis) Grade 1 (Mild osteoarthritis) Grade 2 (Moderate osteoarthritis) Grade 3 (Severe osteoarthritis)
Subacromial space	Gill et al. Grade 1 (Normal) Grade 2 (Mild narrowing) Grade 3 (Moderate narrowing) Grade 4 (Severe narrowing / acetabularisation)
	SA space (minimum height in mm)
Calcific tendinosis	Bosworth classificiation Grade 0 (None) Grade 1 (Tiny, barely visible) Grade 2 (less than 15mm) Grade 3 (more than 15mm)
Scapula / acromion	Acromial spur (Yes/No)
	Os acromiale (Yes/No)
	Bigliani classification Type 1 Type 2 Type 3
	Critical shoulder angle
	Acromion index
	Acromion slope
	Lateral acromion angle
GH Joint osteoarthritis	Gill et al. Grade 1 (No arthritis) Grade 2 (Mild arthritis) Grade 3 (Moderate arthritis) Grade 4 (Severe arthritis)
	Samilson Prieto Allain Grade 0 (No osteoarthritis) Grade 1 (Inferior humeral exostosis 1-3 mm) Grade 2 (Inferior humeral exostosis 4-7 mm) Grade 3 (Inferior humeral exostosis > 7mm) Grade 4 (Narrowing of the GH joint and sclerosis)
Other	Hill Sachs (Yes/No)
	Previous proximal humerus fracture (Yes/No)
	Bony Bankart lesion (Yes/No)
	Osteonecrosis (Yes/No)

AC= acromioclavicular, SA=subacromial, GH=glenohumeral

# Supplementary Table 4 – Magnetic resonance imaging

MRI	
AC Joint	Abreu classification Grade 0 (No osteoarthritis) Grade 1 (Mild osteoarthritis) Grade 2 (Moderate osteoarthritis) Grade 3 (Severe osteoarthritis)
	ACJ effusion / synovitis (Yes/No) ACJ bone edema (Yes/No)
GH Joint	Cartilage damage Grade 1 (Normal) Grade 2 (Cartilage damage) Grade 3 (Endstage osteoarthritis)
	Subchondral bone cyst (Yes/No)
	Bone edema (Yes/No)
	Posterior glenoid retroversion (degrees)
Subacromial space	SA bursitis Grade 1 (Normal) Grade 2 (Mild) Grade 3 (Moderate) Grade 4 (Severe)
Rotator cuff (SSC, SSP, ISP, TM seperately)	Zlatkin classification Grade 0 (Normal tendon) Grade 1 (Tendinopathy) Grade 2 (Partial thickness tear) Grade 3 (Full thickness tear)
	Tear size in mm (only if full thickness tear)
	Tendon retraction in mm (only if full thickness tear)
	Calcifications (Yes/No)
	Muscle atrophy (Goutallier/ Fuchs) Goutallier 0 (Normal muscle) Goutallier I (Some fatty streaks) Goutallier II (Less than 50% fatty muscle atrophy) Goutallier III (50% fatty muscle atrophy) Goutallier IV (greater than 50% fatty muscle atrophy)
	Traumatic muscle edema (Yes/No)
Nerves	Denervation edema (Yes/No)
	Subscapular notch entrapment (Yes/No)
GH Joint: bone and cartilage	Cartilage damage Grade 1 (Normal) Grade 2 (Cartilage damage) Grade 3 (Endstage osteoarthritis)
	Subchondral bone cyst (Yes/No)
	Bone edema (Yes/No)
	Posterior glenoid retroversion (degrees)
	Hill Sachs (Yes/No)
	Bony Bankart lesions (Yes/No)
	Other fractures (Yes/No)
	Osteonecrosis (Yes/No)

GH Joint: labrum and biceps	Anterior labrum Grade 1 (Normal) Grade 2 (Small/intrasubstance tear) Grade 3 (Large/complete tear) Anterior labral cysts (Yes/No)
	Posterior labrum (Grade I-III) Grade 1 (Normal) Grade 2 (Small tear) Grade 3 (Large tear)
	Posterior labral cysts (Yes/No)
	SLAP lesion (Snyder I-IV)
	Capsule thickness (Grade I-III)
	Long head of biceps (Grade I-IV) Grade 0 (Normal tendon) Grade 1 (Tendinopathy) Grade 2 (Partial thickness tear) Grade 3 (Full thickness tear)
GH Joint: anatomy and variants	Acromial spur (Yes/No)
	Bigliani classification Type 1 Type 2 Type 3
	Critical shoulder angle (degrees)
	Acromion index (scalar)
	Acromion slope (degrees)
	Lateral acromion angle (degrees)
	Sublabral recess (Yes/No)
	Sublabral hole (Yes/No)
	Bufort complex (Yes/No)
	Os acromiale (Yes/No)
	Bare area (Yes/No)
	Tubercle of Assaki (Yes/No)

AC= acromioclavicular, ACJ= acromioclavicular joint, GH=glenohumeral, SA=subacromial, SSC=subscapularis, SSP=supraspinatus, ISP=infraspinatus, TM=teres minor, SLAP= superior labrum from anterior to posterior