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Implementing improved fracture risk assessment in primary care: Enhancing capture and quality of self-reported risk factors in electronic health records in primary care

Submission date
04/12/2023

Recruitment status
No longer recruiting

Registration date
05/03/2024

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Good news! This study can identify patients at increased risk of broken bones (fractures) using simple questionnaire-based tools. Significant advances in osteoporosis treatment and care have occurred over the last two decades. There is now access to a range of relatively inexpensive and safe treatments to reduce the risk of fracture. These treatments work well. Bad news! 3 out of 4 people at increased risk of fracture don't receive treatment, largely because this risk goes unidentified. Sadly, a gap persists between fracture risk identification and the receiving of osteoporosis treatment. This could be due to high workloads and limited awareness of GP practices. There may also be a lack of information on some risk factors within GP electronic health records. A strategy that can raise awareness of increased fracture risk would lead to an improvement in the prescribing of osteoporosis treatments. This study (the SELF-FRAX study) will start to develop such a strategy. Patient-centred, interactive approaches, devised with the involvement of patients and the public, are believed can improve the quality of fracture risk information in GP electronic health records.
This is an era of increasing digital communications (e.g. emails, texting) and interaction with our health records (e.g. mobile health apps). The study team will explore opportunities provided by technology to enable patients to voluntarily complete a fracture risk factor assessment questionnaire. This study will also determine the most effective way(s) of doing this so that, in the future, patients can update their health records directly.

Who can participate?
Men and women aged 50 years and older registered with a participating GP practice from across England

What does the study involve?
Participants will be invited through their GP to tell us about their fracture risk factors using a

simple online questionnaire. They will also be asked if their questionnaire answers can be linked with the information held in their GP electronic health records. This will discern how well the information from the questionnaires agrees with their electronic health records.

What are the possible benefits and risks of participating?
This study will not help participants personally but the information that we collect will benefit patients, hospital doctors, GPs and the NHS in the future. Ultimately, this work will increase awareness of fracture risk factors and improvements in osteoporosis care. This will lead to a reduction in the number of patients suffering fractures and an improvement in their quality of life. Completing the questionnaire will involve some of the participant's time, but no other disadvantages are expected.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
September 2021 to June 2025

Who is funding the study?
The ROS - Royal Osteoporosis Society (UK)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334004

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 59066, IRAS 334004

Study information

Scientific Title
Implementing improved fracture risk assessment in primary care: Enhancing capture and quality of self-reported risk factors in electronic health records in primary care: The SELF-FRAX study

Acronym
The SELF-FRAX study

Study objectives
The study will investigate the prevalence of fracture risk factors in the primary care population ages ≥ 50 years, and the concordance between self-reported (patient-reported) risk factors and those captured within the electronic health records (EHRs) in general practice. It is hypothesised that there is a discordance between self-reported fracture risk factors and those derived from primary care EHRs. Any discordance may lead to those individuals at high fracture risk going unidentified and not receiving treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/12/2023, South Central – Oxford B (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8178; oxfordb.rec@hra.nhs.uk), ref: 23/SC/0383

Study design

Observational qualitative study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Musculoskeletal disorders

Interventions
STUDY DESIGN, SETTING AND RECRUITMENT PLAN
This is an observational study of women and men ages 50 years and older registered with a participating GP practice. We will use the SystmOne GP software system (TPP, Leeds, UK) during our study and include General Practitioner (GP) surgeries throughout England.

A total of 7,500 men and 7,500 women will be approached within each of the following age groupings, giving a total study population of 30,000.
(i) Patients aged 50-65 years
(ii) Patients aged over 65 years

In England, a typical GP surgery has 9538 registered patients. Assuming that 38% of the patients registered with each GP practice are aged 50 years or older, 3625 patients could be approached per practice. We propose to limit the patient sample to 500 patients per practice by using the age and gender groupings (as above). Assuming that 25% of the patients approached at each GP surgery agree to take part, a total of 240 GP surgeries would have to be approached to ensure that 60 surgeries were recruited to the study. This would enable us to achieve our total target population of 30,000 patients.
Given the electronic nature of the study, we expect to recruit all participants within a total, staggered period of 4-6 months.

STUDY AIMS
Our study aims are to:
(1) Explore opportunities provided by technology to enable patients to voluntarily complete a fracture risk factor assessment questionnaire.
(2) Determine the most effective way(s) of doing this so that, in the future, patients can update their health records directly.

WHAT WILL HAPPEN DURING THE STUDY?
(A) GP practice identification, invitation and recruitment A list of GP practices in England, currently using the SystmOne GP software system (TPP, Leeds, UK), will be generated. In the first instance, each practice will be approached via a short email message inviting them to participate in the SELF-FRAX study. A link to a GP invitation letter, GP practice information sheet and the study webpage will be provided within the initial email message. A medically qualified representative from the GP practice will follow the links which provide detailed information regarding the (i) study purpose and aims and (ii) what the study team will ask the practice to do if they agree to participate.

There are four possible outcomes following this initial invitation:
(1) The GP practice agrees to participate: A link is provided in the GP practice information sheet.

This will direct the practice to an electronic consent form. This should be completed by a medically qualified representative from the practice. The consent format cannot be altered by the GP practice and will be dated automatically by the web-based system for online completion. Responses will be collated on the University of Sheffield secure server. The study team will monitor this to identify those GP practices returning a positive response. The study team will then provide instructions, to each consenting GP practice, on how to extract the NHS numbers of potential study participants with an active mobile phone number which can receive text messages. Once this has been completed, the GP practice will send the list of NHS numbers to the study team. 500 potential participants will be randomly selected based on age and gender by the study team. This list of NHS numbers will be returned to the GP practice. The practice will send out invitations to these potential participants using their in-house text messaging service. The study team may re-approach the GP practice to ask them to participate in one more round of invitations. This will be dependent on the uptake at the practice. The GP practice will then be thanked for participating in the SELF-FRAX study.

(2) The GP practice declines to participate:
If GP practices decline to participate, they will receive an on-screen notification thanking them for considering participation in the SELF-FRAX study and explaining that they will not be contacted further by the study team.

(3) The GP practice is unsure whether to participate:
The practice should contact the study team for more information.

(4) The GP practice does not respond:
A reminder will be sent out to the practice after 4 weeks.

(B) Participant invitation and recruitment
In the first instance, each patient will receive a text message from their GP practice inviting them to participate in the SELF-FRAX study. A link to a patient invitation letter, participant information sheet and the study webpage will be provided within the initial message. The patient will follow the links which provide detailed information regarding the (i) study purpose and aims and (ii) what the study team will ask the patient to do if they agree to participate. The participant is thanked for taking part in the SELF-FRAX study.

There are four possible outcomes following this initial invitation:
(1) The patient agrees to participate:
A link is provided in the participant information sheet. This will direct the patient to an electronic consent form. This should be completed by the patient. A relative, friend or carer may help the patient to complete this. The consent format cannot be altered by the patient and will be dated automatically by the web-based system for online completion. Patients completing the online consent will be given the option to obtain a copy of the consent form by emailing the study team.

The participant will then be directed to an online fracture risk assessment questionnaire and asked to complete this. A relative, friend or carer can assist the participant with filling in the questionnaire but they should not answer for the participant. As part of the questionnaire, a minimal set of participant-identifiable data will be collected to ensure that each individual can be correctly identified. Responses will be collated on the University of Sheffield secure server.

(2) The patient declines to participate:
If potential participants declined to participate, they will receive an on-screen notification thanking them for considering participation and explaining that they will not be contacted further by the study team.

(3)The patient is unsure whether to participate:
The patient should contact the study team for more information.

(4) The patient does not respond:
A reminder SMS message will be sent out to the patient after 4 weeks.

(C) Extraction of electronic health data
Electronic health data will be extracted (using SystmOne GP software system (TPP, Leeds, UK)) for each participating patient. We will link the patients' data collected using the fracture risk questionnaire with that held in the patient's electronic health record.

Data will also be collected via paper questionnaires (on request by the participant). These data will be entered manually into the online platform by the study team. Docmail will be used when patients wish to complete paper-based documentation. Docmail is a standards-compliant mail service providing document management.

DATA ANALYSIS
We will:
(1) Calculate the percentage of patients who respond and compare the characteristics of these responders to all the patients contacted during the study. We will assess the impact of non-response on our results.

(2) Compare fracture risk information collected using the questionnaires with that held within the patient's electronic health record.

(3) Examine associations between risk factors and response rates.

(4) Compare risk factor prevalence with those in published literature.

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE)
The Mellanby Centre for Musculoskeletal Research has recruited a Lay Advisory Panel for Musculoskeletal Research. An outline of this project has been presented, reviewed and approved by the panel. They are pleased to support our project and feel that it is worthwhile research. The panel will be informed of our progress, be consulted on the dissemination of results and be asked to review a lay summary of the outcomes of this project. The SMC comprises members of the study team and includes PPIE representatives from the ROS. Regular meetings of the SMC will take place throughout the study. PPIE representatives on the SMC have reviewed all study documentation and have been actively involved in providing advice on necessary revisions.

PPIE representatives have/will:
(i) Contributed to discussions on how to maximise inclusion and diversity in this research study.
(ii) Contributed to and reviewed participant-facing study documents and materials used in the study.
(iii) Provided the patient perspective on the design of the online fracture risk factor questionnaire.
(iv) Reviewed the study recruitment figures and methods and provided advice on promoting and

advertising the study to patients.
(v) Contribute to study oversight.
(vi) Contribute to the interpretation and dissemination of the SELF-FRAX study findings.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Patient-reported fracture risk factor information measured using the SELF-FRAX questionnaire at one time point after the patient agrees to participate
2. GP practice recorded fracture risk factor information measured using data extracted from primary care electronic health records (EHRs). Fracture risk factors include prior fracture, parental hip fracture, glucocorticoid use, rheumatoid arthritis, alcohol intake, current smoking, current osteoporosis treatment, and recent falls (within the last year) and one time point

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Patients aged > = 50 years
2. Registered with a participating GP practice during the study period
3. Able to read/understand English with or without assistance
4. Able to provide informed consent

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Key exclusion criteria
1. Has indicated in the EHR that they do not consent to be approached about research studies
2. Bereavement

3. Mental health issues
4. Receiving palliative care
5. Diagnosed with dementia
6. Unable to provide informed consent

Date of first enrolment
01/02/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
Medical School, Beech Hill Road
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research organisation

Funder Name
Royal Osteoporosis Society

Alternative Name(s)

The Royal Osteoporosis Society (ROS), National Osteoporosis Society, ROS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Eugene McCloskey, e.v. mccloskey@sheffield.ac.uk.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	16/11/2023	22/12/2023	No	Yes
Participant information sheet	version 3.0	14/12/2023	22/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.025	25/09/2023	22/12/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes