Your invitation to participate in a research study
Can you help?

PARTICIPANT INFORMATION SHEET

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

We would like to invite you to take part in our research study. Before you decide, it is important for you to understand why the study is being done and what it will involve. Please take time to read this information sheet carefully and discuss it with your family or friends if you wish. Ask us if there is anything that is not clear or if you would like help with completing the forms – our contact details are given at the end of this information sheet. You can keep this information sheet.

- **PART 1** - tells you about the purpose of this study and what will happen to you if you take part.
- **PART 2** – gives you more detailed information about the way the study is being carried out.

~~~~~~~~~~~~~~~~

PART 1

What is the purpose of the study?

Osteoporosis is a relatively common condition. It causes a 'weakening' of bones and makes them prone to break (fracture) easily.

Good news! – we can identify patients at increased risk of fractures using a simple questionnaire. Significant advances in osteoporosis treatment and care have occurred over the last two decades. We now have 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.
~~~~~~~~~~~~~~~~

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. We believe that patient-centred, interactive approaches, designed with the involvement of patients and the public, can improve the quality of fracture risk information in GP care records.

This is an era of increasing digital communications (e.g emails, texting) and interaction with our own health records (e.g. mobile health apps). We will explore opportunities provided by technology to enable patients to voluntarily complete a fracture risk assessment questionnaire. We will determine the most effective way(s) for doing this so that, in the future, patients could update their health records directly.

The SELF-FRAX study will increase awareness of fracture risk factors and improvements in osteoporosis care. This will, in turn, benefit patients as it will reduce the number of fractures that occur and improve their quality of life.

Why have I been approached?

A number of GP practices are supporting this study by writing to patients (men and women) aged 50 years and older who are registered with their practice. The majority of patients in this age group will be eligible to take part in the SELF-FRAX study. We plan to approach and collect fracture risk information from up to 30,000 patients in England. Your GP practice has agreed to help us with this study.

Do I have to take part?

No.

It is up to you to decide whether you want to take part or not. Taking part in the SELF-FRAX study is completely voluntary. If you do, decide to participate, you are still free to change your mind at any time and without giving a reason. If you decide not to take part the medical care you receive in the future will not be affected.

What will happen to me if I take part?

If you decide to take part, we will ask you:

1. To give consent (electronically) to say that you would like to take part in the SELF-FRAX study.

2. To fill in a simple online questionnaire (Figure 1.). This is a based on a fully tested fracture risk assessment tool (https://frax.shef.ac.uk/FRAX/) used by the NHS to inform patient care. It will include questions about your health and helps us to identify those patients at increased risk of fractures.
3. If we can link your questionnaire answers with the information held in your GP electronic health record. This will help us to see how well the information from the questionnaires agrees with your GP health record.
4. If you are willing to be contacted about other studies in the future. You can decline to be contacted and this will not affect your participation in the SELF-FRAX study.

What are the possible benefits of taking part in the study?

This study will not help you personally but the information that we collect will benefit patients, hospital doctors, GPs and the NHS in the future.

What are the possible disadvantages of taking part in the study?

Completing the questionnaire will involve some of your time. We cannot think of any other disadvantages.

Will I receive any expenses or payments?

Unfortunately, you will not receive any expenses or payments for taking part in the SELF-FRAX study. Despite this, we hope that you will still agree to take part.

What happens when the study ends?

When the research study ends, we will put a summary of the results onto the SELF-FRAX webpage [INSERT LINK].

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. More detailed information can be found in Part 2 of this information sheet. If you have a complaint please firstly contact Professor Eugene McCloskey (Chief Investigator) on 0114 215 9695.

Please answer the following questions:

ABOUT YOU

(1)	Did a relative, friend or carer help you to fill in this questionnaire? (Please choose 'yes' or 'no')	Yes	No	
(2)	Do you live in a care or residential home? (Please choose 'yes' or 'no')	Yes	No	
(3)	To which of these ethnic groups do you consider you belong? (Please choose one answer, or state 'other' and describe below): _____	White	Asian or Asian British	Black or Black British

FRACTURE RISKS

(1)	Your age (in years)? [age – FRAX Q1]	years		
(2)	Are you male or female? (Please choose 'male' or female') [sex – FRAX Q2]	Male	Female	
(3)	Your weight (in kilograms) [weight – FRAX Q3]	kilograms		
(4)	Your height (in centimetres) [height – FRAX Q4]	centimetres		
(5)	Have you broken (fractured) a bone in adult life? (Please choose 'yes' or 'no') [previous fracture – FRAX Q5]	Yes	No	
(6)	Has your mother of father ever broken a hip? (Please choose 'yes' or 'no') [parent fractured hip – FRAX Q6]	Yes	No	
(7)	Do you smoke? (Please choose 'yes' or 'no') [current smoking – Q7]	Yes	No	
(8)	Do you take steroid tablets now or have you taken them for more than 3 months in the past? (Please choose 'yes', or 'no')	Yes	No	
(9)	Do you have rheumatoid arthritis? (Please choose 'yes', or 'no') [rheumatoid arthritis – FRAX Q9]	Yes	No	
(10)	Do you have/or have had any of the following? (Please choose 'yes', or 'no') [secondary osteoporosis – FRAX Q10] a) Type 1 diabetes (you use insulin), b) Osteogenesis imperfect c) untreated long-standing hyperthyroidism (over active thyroid) d) hypogonadism (low testosterone - men or low oestrogen/progesterone - women) e) premature menopause (menopause before 45 years old) f) chronic (longstanding) malnutrition (poor nutrition) g) malabsorption (inability to absorb some nutrients) h) chronic (long-standing) kidney disease	Yes	No	
(11)	Do you drink 3 or more units of alcohol daily? (A unit = half a pint of beer or larger, a single measure of spirits, or a medium-sized glass of wine) (Please choose 'yes', or 'no') [alcohol 3 or more units/day – FRAX Q11]	Yes	No	
(12)	Longstanding poor mobility (e.g. following a stroke, Parkinson's disease, or spinal injury)? (Please choose 'yes', or 'no')	Yes	No	
(13)	Have you had one or more falls in the last 12 months? (Please choose 'yes', or 'no') If 'yes' please state how many here: _____	Yes	No	

Figure 1. An example of the SELF-FRAX questionnaire (for reference only).

Will my taking part be kept confidential?

Yes.

All the information about your participation in this study will be kept confidential. The details of how this is done are included in Part 2 of this document.

What do I need to do now?

- Yes, I would like to take part.

Thank you. Please click on the click provided here: [INSERT LINK]

This will take you to the online consent form and the questionnaire. Please complete both of these. We can provide you with a copy of your consent form.

If you do not have a computer or smartphone but you still wish to participate, we can send paper forms out to you. In this case, please contact the **Bone Research Team** by telephone on [INSERT PHONE NUMBER].

- I am not sure about taking part. Where can I get more information about the study?

We would be very pleased to answer any questions you may have. Please contact the **Bone Research Team** by telephone on [INSERT PHONE NUMBER].

- No, I do not wish to take part.

No problem. You do not need to do anything else. Thank you for taking time to read this information sheet.

THIS COMPLETES PART 1 OF THE INFORMATION SHEET.

If the information in PART 1 has interested you and you are considering taking part in the study, please continue to read the additional information in PART 2 before making any decision.

~~~~~~~~~~~~~~~~~

PART 2

What will happen if I don't want to carry on with the study?

You are free to voluntarily withdraw from the study at any time. Your decision to withdraw will not affect the standard of care you receive at the time of the study withdrawal or in the future. Any data collected up to the point of withdrawal from the study will be retained.

What if there is a problem?

Complaints: If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. You can contact Professor Eugene McCloskey (Chief Investigator) on 0114 215 9695 in the first instance.
If you remain unhappy and wish to complain formally, you can do this through the Head of the Division of Clinical Medicine at the University of Sheffield [NAME; CONTACT DETAILS].

If the complaint relates to how your personal data has been handled, you can find information about how to raise a complaint in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

Harm: In the unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the University of Sheffield but you may have to pay your legal costs. In addition, the University of Sheffield holds insurance against risk of claims against the University and its staff relating to clinical trials/research studies they design and undertake in their University employment.

Safeguarding: If you wish to make a report of a concern or incident relating to potential exploitation, abuse or harm resulting from your involvement in this project, please contact the project's Designated Safeguarding Contact [NAME; CONTACT DETAILS]. If the concern or incident relates to the Designated Safeguarding Contact, or if you feel a report you have made to this Contact has not been handled in a satisfactory way, please contact the Head of the of the Division of Clinical Medicine at the University of Sheffield [NAME; CONTACT DETAILS] and/or the University's Research Ethics and Integrity Manager (Lindsay Unwin (l.v.unwin@sheffield.ac.uk, 0114 222 1443).

Will my taking part be kept confidential?

Yes.
The University of Sheffield is the Sponsor for this study. We will be using information from you and from your medical records in order to undertake the SELF-FRAX study. The University of Sheffield is the Sponsor and it will act as the data controller for this

study. This means that we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, each participant will be given a unique study number which will be added to the study database. The database will be analysed by the study team at the University of Sheffield.

The University of Sheffield will not contact you directly about the SELF-FRAX study unless you contact the Bone Research Team for further information or for paper versions of the consent form and questionnaire.
Any other form of contact about this research study will be made through your GP practice.

Your personal details will not be passed on to any other parties. Individuals from the University of Sheffield and other regulatory organisations may need to look at your medical and research records to ensure that this research is being carried out properly.

The funder of the study (the Royal Osteoporosis Society) will not receive the study database or your contact details. They will be provided with a summary report at the end of the study.

The University of Sheffield will keep the information collected about you and essential documents from the SELF-FRAX study for 15 years after the research has finished.

You can find out more about how The University of Sheffield use research participant's information at https://www.sheffield.ac.uk/govern/data-protection or by contacting Luke Thompson (Head of Data Protection and Legal Services) via email (dataprotection@sheffield.ac.uk) or by phone 0114 222 1117.

All participant information handling processes are compliant with General Data Protection Regulations 2018 at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/.

Involvement of your GP/Family doctor?

Your GP will already know about your participation in the SELF-FRAX study. With your permission, we will let your GP know about your future risk of fracture.

What will happen to the results of the SELF-FRAX study?

The results of this research will be used to inform future clinical studies we are aiming to undertake. Results may be presented at scientific meetings in the UK and overseas and it will not be possible to identify you in any data presented. The data from the study may be published in medical and scientific journals. You will not be identified in any report or publication.

Who is organising and funding the study?

The University of Sheffield is responsible for the SELF-FRAX study (the 'Sponsor').
The Faculty of Health, Division of Clinical Medicine, School of Medicine & Population Health, University of Sheffield is running the study.
The Royal Osteoporosis Society UK is funding the study.

Who has reviewed the study?

The SELF-FRAX study has been reviewed by an appropriate Research Ethics Committee and the Health Research Authority. Research ethics committees protect the rights, safety, dignity and wellbeing of participants in research studies. The study has also been reviewed by the Sheffield Lay Advisory Panel for Musculoskeletal Research and the Royal Osteoporosis Society.

Contact details

If you require any further information please contact us. A friend or relative may contact us on your behalf if you wish. The SELF-FRAX study also has a website at [INSERT LINK].

Contact details:
The Bone Research Team [INSERT PHONE NUMBER]
Dr Margaret Paggiosi (Project Manager). Email address: m.a.pagiosi@sheffield.ac.uk
Postal address: Sheffield NIHR Clinical Research Facility, Northern General Hospital, Herries Road, Sheffield S5 7AU

THIS COMPLETES PART 2 OF THE INFORMATION SHEET.

~~~~~~~~~~~~~~~~

Thank you for taking the time to read this information sheet and for considering taking part in the SELF-FRAX study.
~~~~~~~~~~~~~~~~