Being involved and informed: Improving appointments about your bone health
The **iFraP** study

PARTICIPANT INFORMATION SHEET

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- This information sheet explains in detail why this research is being carried out, what it involves and how you can take part. This information will help you decide whether you want to take part.
- If you choose to take part, you are free to withdraw at any time. If you choose not to take part, this will not affect the current or future health care you receive.
- This Participant Information Sheet is provided in English. Keele Clinical Trials Unit (CTU) can help with language translation if needed. Their contact information can be found on the last page.

KEY THINGS TO KNOW

- You have recently been identified as needing a Fracture Liaison Service appointment to discuss your bone health as part of your routine NHS care. This means you can also be invited to take part in the iFraP research study.
- Everyone who takes part in the study will receive best current NHS practice in their Fracture Liaison Service appointment.
- **The iFraP research study is testing the best way of sharing information in appointments. The study is not testing new medicines.**
- For **half of the people** who take part in the study the healthcare professional will have access to **extra resources** in the appointment. These include a computer tool that the healthcare professional will use which may help explain bone health and treatment options to you. We are looking to see if use of these resources, including the computer tool, helps you to understand your bone health and make decisions about treatments which are best suited to you and your situation.

- Even if you do not get to test the extra resources, you will still be providing information about your health and experiences which will be very useful for the research.

If you decide to take part in the iFraP study it will involve:

- Completing a consent form and baseline questionnaire [delete as appropriate: included in this pack / on the next page]. If you are happy to take part, you will need to complete these [delete as appropriate: and submit online / and return it using the freepost return envelope **(no stamp needed)**].

- Attending your Fracture Liaison Service appointment as part of your normal NHS care.
  This could be in person, via telephone or video. There will be a 50:50 chance of the healthcare professional having access to **extra resources** in the appointment including a computer tool which may help explain bone health and treatment options.

- Completing 2 further questionnaires at approximately 2 weeks and 3 months after your Fracture Liaison Service appointment.
  The questionnaires will ask about your health and experiences. Each questionnaire will take you approximately 20-30 minutes to complete. Questionnaires can be completed by post or online (based on your preference).

- We will also ask your agreement to
  - Researchers accessing your medical records.
  - Your Fracture Liaison Services appointment being recorded and transcribed (written up) afterwards for research purposes. (optional)
  - Being interviewed about your experiences (optional)

- **Taking part in the iFraP research study will not affect the medical treatment of your broken bone or bone health.**

If you think you might be interested in taking part, please now read the rest of the information sheet carefully.

If there is anything unclear or if you would like more information, please contact the iFraP study team during office hours on 01782 732950 or email ctu.ifrap@keele.ac.uk

If you decide to participate, your involvement would be extremely valued.

Why is the iFraP research study being carried out?

- The iFraP study is looking at a new way to help Fracture Liaison Service healthcare professionals to involve patients in discussions and inform them about their bone health. By informing and involving patients, the iFraP study hopes to help patients feel more confident in making decisions about their bone health.

- The results from this research study will help Fracture Liaison Service healthcare professionals find the best way to conduct appointments about bone health and about treatments for people who have broken a bone.

Why have I been invited?

You have been invited to take part in the iFraP research study because you have been identified as needing a Fracture Liaison Service appointment as part of your routine NHS care. This is to discuss your bone health, usually related to a recent broken bone (fracture).

Who is funding and organising this research?

This study is funded by a National Institute for Health Research (NIHR) Clinician Scientist Award: CS-2018-18-ST2-010, awarded to Dr Zoe Paskins (Chief Investigator). The study is being led by researchers in the School of Medicine at Keele University and managed by Keele Clinical Trials Unit.

What would taking part in this study involve?

If you agree to take part in the iFraP study, we will ask you to:

A. Complete the consent form

- A consent form is where you give your permission to take part in the research. You only need to do this once. If we find that key parts of the consent form are missing or unclear, we may contact you to complete this information.

B. Complete 3 questionnaires

- You will be asked to complete 3 questionnaires, one to be completed now, one 2 weeks after your Fracture Liaison Service appointment, and finally one 3 months after your Fracture Liaison Service appointment.

- If you would like to take part in the iFraP study, you will need to complete and return the first questionnaire **along with** the consent form. You can either do this [Delete as applicable**:** online, via the link given on the enclosed the invite

letter/ by completing paper copy enclosed and returning it to us, in the freepost return envelope provided **(no stamp needed)**].

- The questionnaires will ask about you, your health and your experiences. We would like to hear your thoughts before and after your appointment. It is therefore important to complete all the questionnaires even if your broken bone has healed. Even if you do not have an appointment which uses the iFraP resources, it will still be very helpful to understand your experience of the Fracture Liaison Service appointment.

- When going through your responses, if we find that key questions are unanswered or unclear, we may contact you by post, email or telephone, to see if we are able to help you complete the information. If we do not reach you the first time, we will not make any more than 2 more attempts to contact you.

- [online only] You can stop completing the questionnaire at any time, without giving a reason, but we would like to keep any answers that you have given to that point as a partially completed questionnaire. If you would like to opt out of us keeping those answers, please contact us on ctu.ifrap@keele.ac.uk or 01782 732950.

- If you do not return the questionnaires, we will send you a reminder and may try and contact you by telephone. If we do not reach you the first time, we will not make any more than 2 more attempts to call you. Following this, we will send you a shortened version of the questionnaire to complete.

- If you change your phone number, email or postal address during the study, please contact Keele CTU on 01782 732950 or via email ctu.ifrap@keele.ac.uk

C. Attend your Fracture Liaison Service (FLS) appointment as usual

- You will be invited to your Fracture Liaison Service appointment as usual. This could either be face to face or via telephone or video.

- Before your appointment, a computer will randomly decide whether you will have an appointment with or without the iFraP additional resources including the computer tool. There is a 50:50 chance, which means half of the people in the study will have an appointment which use the additional resources. If you have your appointment using iFraP resources, it may change how things are explained. For example, the iFraP computer tool uses images to explain bone health and your risk. The healthcare professionals using the additional resources and computer tool will also have had additional training, including how to use the tool. **The study is not testing treatments and being**

involved will not affect your medical treatment of your broken bone or bone health.

- If your appointment is on the phone, it may not be obvious to you whether the healthcare professional is using the iFraP resources such as the computer tool or not. At the end of the study, we will write to you about the results and confirm whether you had the iFraP resources or not.

- **Optional recording of your appointment.** We may ask if you consent to having your appointment audio or video recorded and transcribed (written-up) afterwards. **You can choose not to have your appointment recorded.** If the appointment is recorded, transcripts of the recordings will have your personal information removed for analysis. If your appointment is video recorded, the video will be analysed, however cannot be fully anonymised. Sections of the appointment recording may be used in future presentations, reports, publications and for training, but if this happens faces will be blurred, and any identifying information will be removed from the sound recording. Removing your identifiable information means that it cannot be traced back to you.

  Data you provide as part of this study may be used in other research studies. For recorded appointments, all written transcripts shared for other research will not contain your personal information. If your appointment is video recorded, it may not be possible to remove your identity from the video file. If the video files are used in other research, they would have to apply for separate ethical approval and data access from Keele, including the completion of a data sharing agreement. These agreements would state that the videos would only be available and could only be viewed by named researchers, time-limited to the period of data analysis and that participants' identity must be removed in outputs, so that it cannot be traced back to you.

D. Hospital medical record review

- We will need to use information from your medical records for this study. On the consent form at the front of the questionnaire, we ask your permission to review your hospital records. The hospital record review is only related to information we are collecting as part of the research study, for example, to confirm what medication, if any, you have been prescribed.

E. Optional interview

- If you decide to take part in the iFraP study, you may be contacted, at a later date, to ask if you would be willing to take part in an interview. The interviewer would want to find out what you thought of your Fracture Liaison Service appointment. Not everyone who takes part in the iFraP study will be asked to take part in an interview. If you are contacted about an interview, you can choose whether to take part.

We have provided detail on how the data you provide to us on the questionnaires and consent form is kept safe in this Information Sheet. Information you provide on questionnaires or in interviews during the study will not be shared with your healthcare team.

Do I have to take part?

Your participation is **voluntary.** We can assure you that whatever you decide to do, your healthcare will not be affected in any way, now or in the future.

If you do decide to take part, you will still be free to **withdraw** from the study at any time, without giving a reason and again your healthcare will not be affected in any way, now or in the future. If you do decide to take part a letter will be sent to your GP telling them that you are taking part in the study.

Am I able to take part?

As long as you do not know anyone else taking part in the study, you will be able to take part if you want to. This is because talking to other people about the iFraP resources may affect your questionnaire responses.

What shall I do if I do not want to take part?

If you have decided that you do not want to take part, please let us know by [Delete as applicable: completing the online reply slip/ completing the reply slip and returning it to us, in the freepost return envelope provided **(no stamp needed)**].
We realise that people are busy, and do not always have the time to complete and return the questionnaire. For this reason, if we do not receive the questionnaire or have any contact from you after 2 weeks, we will assume you do not wish to take part and you will receive the usual best practice appointment.

What are the possible benefits of taking part?

There may not be any immediate benefits for you, although some people find it rewarding to take part in health research. Your participation in this study may help to:

- improve future information for Fracture Liaison Service (FLS) patients about their bone health and when considering bone health treatments.
- help doctors, nurses and other health care professionals to better advise patients about what to do to reduce the chance of future broken bones.
- Help other healthcare professionals learn about the best ways of explaining new medicines

What are the possible risks of taking part?

We are not anticipating any risks in taking part in the iFraP research study. The care you receive from your NHS service will not be affected. You will need to spend some of your time completing the questionnaires.

What will happen to the results of the study?

At the end of the study, we will write to you about the results and confirm whether you had the iFraP resources or not. Key findings from the iFraP research study will be written in an easy to read summary and will be available to view on the iFraP study website www.ifrap.co.uk. The results will be published in medical journals and reports. You will not be personally identifiable in these presentations or publications.

Who has approved this study?

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by [*insert Ethics committee*] Research Ethics Committee (reference: XX/XX/XXXX). The study has also been reviewed by scientific experts on behalf of the National Institute of Health and Care Research (NIHR), who assessed it before awarding funding.

DATA INFORMATION

What will happen to the information collected about me during the study?

Keele University is the sponsor for this study which is based in the United Kingdom. Keele University will be using information from you to undertake this research and will act as the data controller for the data collected during this study.

If you decide to take part in this study, the information collected about you will be treated in strict confidence and in accordance with the general data protection regulations (Data Protection Act 2018).

This means that we are responsible for looking after your information and using it properly. Keele University will keep the information you provide for 10 years after the research has finished. This is normal in research of this nature.

Your identifiable data will be securely stored by Keele Clinical Trials Unit. Consent forms will be stored separately to the other data that you provide. Data shared to other researchers will be anonymised, with the exception of your video recorded appointment, as it might not be possible to remove your identity from the video.

How we will use information about you

We will need to use information from you and your medical records for this research project.

This information about you will include your name, date of birth, NHS number and contact details. The information from your medical records will include your medication prescribed for your bone health, if you have decided to have it, and your healthcare use (for example further appointments about your broken bone). Authorised individuals from Keele University and regulatory organisations will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. The data you provide will be anonymised which means your data will have a unique study ID number instead. If you agree to your appointment being audio or video recorded (optional), the audio from these recordings will be written up (called a 'transcript') which will be anonymised. However, it will not be possible to remove your identity from the video footage. Sections of the video recording may be used in future presentations, reports, publications and for training, but if this happens, your identity will be removed (by blurring your face).

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your healthcare use about your fracture from your hospital medical records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients
- our website available at www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/checkyourinformationisbeinghandledcorrectly/researchparticipants
- by asking one of the research team

- by sending an email to Keele University's Data Protection Officer at: dpo@keele.ac.uk
- by ringing us on 01782 732950

Our procedures for handling, processing, storage of and destruction of data

Our procedures for handling, processing, storage of and destruction of data are in line with relevant regulatory requirements. To ensure electronic data are stored securely, it will be held on networks approved by a government backed cyber security scheme. Paper records are stored securely within lockable filing cabinets and/or in strictly restricted access rooms. Keele Clinical Trials Unit also operates a key code entry system to ensure only appropriate persons have entrance to the Unit.

In accordance with Keele University, the Government's, and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoid duplication of research) and to understand the bigger picture in particular areas of research. Your anonymised data may be used in other research studies related to bone health subject to appropriate approvals.

CONTACT DETAILS

If you have any questions or would like any further information, please contact the iFraP Research Team at **Keele Clinical Trials Unit** on:

01782 732950

Office hours are Monday - Friday 9am - 5pm

E-mail:

ctu.ifrap@keele.ac.uk

Study website:

www.ifrap.co.uk

If you have any concerns or complaints, you can contact Keele University's Head of Project Assurance on email: research.governance@keele.ac.uk

Alternatively, you can contact NHS England on telephone: 0300 311 2233, email: england.contactus@nhs.net

Thank you for taking the time to read this information sheet and for considering taking part in this research study.

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