Exploring Wellbeing for People with Osteoporosis and/or Broken Bones

SURVEY INFORMATION SHEET

Version 1.1, 09-10-2025, IRAS Project Ref: 356624, RG-0407-25

This information sheet explains why the research is being done, what is involved and how you can take part. Please read the following information carefully and discuss it with family or friends if you wish. This information will help you decide whether you want to take part. We welcome any questions if there anything is unclear or if you would like to know more.

What is the purpose of this study?

Osteoporosis is a common condition which can increase the chance of breaking a bone. This is because your bones become weaker and are likely to break more easily (for example, from a simple fall on flat ground).

Some people might not have been told that they have osteoporosis but have broken a bone easily before. In either case, having osteoporosis and/or broken bones can affect wellbeing, including impacts on:

Impact on Wellbeing	Examples (not limited to)
Long-term physical health	• Pain, limited mobility, changes in posture • Eating and breathing difficulties
Mental health	• Depression, anxiety, lower self confidence
Social life	• Loss of independence and social isolation • Restrictions to hobbies, work, relationships, housing and finances
Spiritual, cultural or religious beliefs and practices	• Questioning meaning or purpose of life • Faith as a coping mechanism • Disruptions to sense of self (often due to stigma around osteoporosis or no longer being able to fulfil previous roles) • Difficulty in prayer or hosting gatherings

Your views and experiences will help us to understand what care needs people with osteoporosis and/or broken bones have and how they can best be supported. We hope to improve the quality of osteoporosis care and improve peoples' wellbeing as a result.

Why have I been invited?

You have been invited to complete a survey for this study because you:

- Have been told by a healthcare professional (e.g. doctor or nurse) that **you have osteoporosis**, *and/or*
- Have been **offered osteoporosis medicines** (even if you do not take them), *and/or*
- Have **previously broken a bone easily** (e.g. from a simple fall on flat ground, turning or twisting, coughing etc.)
    - *To note:* broken bones from an injury such as a car accident or falling down stairs would not be considered relevant to this research (unless you have also been told you have osteoporosis).

What do we mean by 'osteoporosis medicines'?

Osteoporosis medicines include tablets, injections or an intravenous 'drip' (IV). Here are some examples of osteoporosis medicines below:

Medicine Type	Medicine Name	How Often
Tablet	**Alendronate** (alendronic acid)	Usually once per week
	Raloxifene	Daily
	Risedronate	Usually once per week
	Ibandronate (or ibandronic acid)	Usually once per month
Injection	**Romosozumab**	Usually once per month
	Denosumab	Usually every 6 months
	Ibandronate (ibandronic acid)	Usually every 3 months
	Teriparatide	Daily
	Abaloparatide	Daily
Intravenous 'drip'	**Zoledronate** (zoledronic acid)	Usually once per year

Do I have to take part?

No, taking part in this research is completely voluntary. It is up to you to decide if you want to volunteer to take part in the research or not. If you do decide to participate, you will be asked to sign and date a consent form. If you decide not to take part or withdraw from the study, your healthcare will not be affected in any way.

What will taking part involve?

- You will be asked to complete a **one-off short survey.** This takes about **10-15 minutes** to complete.
- Before doing the survey, you will be asked to sign a consent form.
- Everybody will be asked “about you” questions (for example about your age, ethnicity, gender).
- You will be asked various questions about how osteoporosis and/or broken bone(s) have impacted your wellbeing (if at all).
- You can complete the survey with a family member, friend or carer if you require support.

You may be provided with a QR code or a website link to complete the consent form and survey online using your own electronic device (e.g. smartphone, tablet, laptop). Alternatively, you can complete the these on paper if preferred, and either post them back to the research team (using the freepost envelope provided) or hand them back to the NHS staff member if completing at your hospital appointment.

If you are told about this study at a hospital appointment and wish to take part, the above options will be available to you, but in addition, you may be offered the opportunity to complete the survey online using a tablet whilst waiting for your appointment.

If you would like paper rather than online documents, please contact us.

The survey will ask you whether you would be happy to be contacted about doing an interview to further explore your views, as part of the same study. If you agree to this, you may be contacted by myself to ask if you are still interested in doing an interview. You will be under no obligation to take part in the interview, and it is fine to change your mind. Not everyone that has agreed to do an interview will be asked to do one; only a limited number of interviews are planned to take place.

What are the possible advantages of taking part?

There are not any direct benefits to you for taking part. However, by taking part, you will be contributing to research that has potential to improve the care and wellbeing of people with osteoporosis and/or broken bone(s). The research team have worked with people with lived experience of osteoporosis in designing the study, to make sure the survey asks questions that are important to them, in an appropriate way. Being involved in research helps to improve patient care.

What are the possible disadvantages of taking part?

It is not expected that there will be any risks to you taking part in the survey.

You may possibly find it distressing to talk about the impact of your osteoporosis and/or broken bone(s) on your wellbeing. Please remember that you are free to stop the survey at any time, without giving a reason. A list of contacts for support and advice can be found at the end of this information sheet in case you feel distressed, or we would encourage you to contact your GP.

What will happen if I don’t want to carry on with the research?

Even if you agree to take part and have given your consent, you are still free to change your mind or withdraw from the study without giving a reason. Your ongoing care will not be affected in any way. However, we will keep any information about you that we already have which will be included in the final study analysis.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you exit the survey part-way through completion, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at www.hra.nhs.uk.

Who is organising and funding the study?

The study is being conducted by researchers from Keele University and has been funded by the Haywood Foundation and Keele University as part of a PhD matched funding scheme. A committee reviewed this study as part of the funding process.

Who has approved the 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 South Central - Oxford C Research Ethics Committee (REF: 25/SC/0296).

What if something goes wrong?

If you have a concern or complaint about any aspect of this research project, in the first instance you should contact the researcher(s) who will do their best to answer your questions. Their contact details are found at the end of this document.

If you remain unhappy and wish to complain formally, you can do this by contacting the research Sponsor at research.governance@keele.ac.uk or 01782 732980. Alternatively, if you would feel more comfortable discussing your concern with someone else, you can contact NHS England on england.contactus@nhs.net or 03003112233.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

What will happen to the results of this research?

We will publish a summary of the results on the Keele University School of Medicine website (https://www.keele.ac.uk/medicine/), the Royal Osteoporosis Society website (https://theros.org.uk/), and the Midlands Partnership University NHS Foundation Trust website (https://www.mpft.nhs.uk/working-here/research-and-innovation/news). In addition, we will share the study's findings via social media, NHS networks and professional bodies, publish them in scientific journals, and present them at meetings and conferences. Any data that is publicly shared will be anonymous and will not identify you. Your anonymised data may be used in other relevant research studies, subject to appropriate approvals.

YOUR DATA INFORMATION

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, age, gender, postcode (to calculate the level of deprivation in your area), ethnicity, religion, details of any previous broken bones (if any) and contact details. People 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. Your data will have a code number instead.

Keele University is the sponsor of this research. Keele University is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Other universities
- Third-sector organisations (e.g. Royal Osteoporosis Society)
- National Health Service (NHS)

We will keep all information about you **safe and secure** by:

- Working in accordance with general data protection regulations (Data Protection Act 2018)
- Only using your anonymised data for analysis
- Only sharing anonymised data with other organisations or researchers
- Storing your consent form (which contains your personal information) separately to your anonymous survey data
- Storing any electronic data securely on Keele's networks which are approved by a government-backed cyber security scheme
- Storing any paper records in lockable filing cabinets at Keele University. For paper records that will be handed in at hospital appointments, these will be stored in the same manner and securely transferred to Keele University.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

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. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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
- at our website: www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/checkyourinformationisbeinghandledcorrectly/researchparticipants
- by contacting a member of the research team at c.kettle1@keele.ac.uk or **01782 731789**
- by emailing Keele University's Data Protection Officer at: dpo@keele.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer (dpo@keele.ac.uk) who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO, https://ico.org.uk/make-a-complaint/).

CONTACT DETAILS

If you would like to discuss the research in more detail, please contact Chelsea in the research team at Keele University by:

☎ **01782 731789**
Monday – Friday, 9am – 5pm

✉ **c.kettle1@keele.ac.uk**

List of contacts for support:

Royal Osteoporosis Society (if you have concerns about osteoporosis)	• Free helpline telephone: 0808 800 0035 • Email: nurses@theros.org.uk • Website: https://theros.org.uk/
Mind (if you feel distressed or are worried about yourself)	• Free helpline telephone: 0300 102 1234 • Website: https://www.mind.org.uk/
Samaritans (if you feel distressed or are worried about yourself)	• Free helpline telephone: 116 123 • Email: jo@samaritans.org • Website: https://www.samaritans.org/

Thank you very much for taking the time to consider taking part in the research.