**Nottingham Spinal Health (NoSH) Study:** **A cohort study of vertebral fragility fractures admitted to hospital**

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**Participant Information Sheet**

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**INVITATION**

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

**BRIEF SUMMARY**

Vertebral fractures are broken bones affecting bones of the spinal column, called vertebras. In those over the age of 50, it is commonly due to the loss of density in bones causing it to become brittle and breaking in the event of a low-impact injury. These broken bones in the spine are usually managed without needing to be admitted into hospital. However, there are cases that need to be admitted.

There is not much information about why this particular group of patients need to be admitted to hospital for treatment of their broken spine; and how it affects them in the long term. Hence, this study aims to address this gap in knowledge and learn more about patients and their broken spine.

You are being invited to participate as you are currently being investigated for; or have been diagnosed with a broken bone of the spine (a vertebral fragility fracture).

***At this stage, if you are not keen to participate, we would like to thank you for taking the time to speak to us and briefly read this patient information sheet. Your treatment in hospital is not affected by your decision to not participate in this research study.***

***If you are keen to find our more, please carry on reading as further sections will go into further detail about the research study. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.***

**Nottingham Spinal Health (NoSH) Study:** **A cohort study of vertebral fragility fractures admitted to hospital**

**Participant Information Sheet**

**1. What is the purpose of the study?**

Vertebral fractures are broken bones of the back. Specifically it affects the bones of the spine, called vertebras. Over the age of 50, it is most commonly caused by brittleness of the bone making it susceptible to breaking even in the event of a low-impact injury, e.g. after falling off a chair. Sometimes, the brittleness can be serious enough for the bones to break during coughing, sneezing or bending forwards. Breaking a bone in the spine has been shown to increase the risk of further broken bones and potentially leading to ill-health in the future.

Most broken bones of the spine do not need to be treated in hospital. However, some people do still need to be admitted into hospital for treatment. This group of patients have not been well studied and information is lacking about why they needed to be admitted, the type of broken back they have sustained, what happens to them in hospital and what their general health is like when they leave hospital.

This study aims to address this lack of information so that we can learn more about the condition and the group of patients that unfortunately sustained it

**2. Why have I been chosen?**

You have been invited to participate as you have presented to hospital with symptoms (e.g. back pain) suggestive of a broken bone of your back.

**3. Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you do decide to take part, you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, information collected up until then will be kept for analysis as this is valuable to the study. If you want it removing, let us know and it will be done.

A decision to withdraw at any time, or a decision not to take part, will not affect your hospital treatment.

**4. What will happen to me if I take part?**

If you agree to take part, a researcher will obtain information about you and your hospital admission. This will involve an interview with you to gather the relevant information about your clinical condition, your ability to look after yourself, your mobility and memory. As this process can be tiring having just been admitted into hospital, we will be happy to proceed at a pace that is suitable for you. Also with your consent, we will obtain information about your hospital admission from a combination of your medical notes and hospital computer records. If during your hospital stay, further tests reveal that a broken bone of your back is not the cause of your symptoms, or reason you are poorly, the research team will not collect further information from you beyond what has been collected so far. Within the remit of the researchers’ role, we will not be able to provide any information about your hospital diagnosis or treatment. However, we are happy to assist as best as we can if you have any questions about your diagnosis and future treatment plan with your medical team.

When you are ready to leave hospital, a researcher will visit you on the ward to conduct an interview to gather further information which involves repeating some of the initial assessment and tests. Your medical notes and hospital records will be assessed to identify the care you received while in hospital.

After 6 months from your admission into hospital, a researcher would like to visit you in your own home or invite you back to hospital (whichever is convenient) to see how you are doing and conduct a further interview regarding your general health status. The research team will be in touch by phone or postal letter to confirm the date and time of the interview.

Your participation in this research study will not affect the treatment you will receive or the duration of your stay in hospital. It will also not affect your medical care when you leave hospital.

**5. What will happen if I don’t want to carry on with the study?**

If you do not want to carry on with the study, you may ask to be withdrawn. Unless you object, data and records that we have obtained up until your withdrawal will be anonymised and kept for analysis as this is valuable to the study. If you want it removing, do let us know. A decision to withdraw can be done at any time and will not affect the quality of care you will receive on the ward.

**6. What are other possible disadvantages and risks of taking part?**

We do not anticipate any problems or risks if you choose to participate in the study. If at any point during the interview you find the process tiring, let the researcher know and we will be happy to proceed with the interview at a pace that suits you.

**7. What are the possible benefits of taking part?**

Participating in this study is unlikely to benefit you. However, your participation will hopefully help us understand the condition better and therefore help to improve the care we provide to patients with broken bones in the spine in the future.

**8. What happens when the research study stops?**

Your participation in the study stops after your 6 month follow up interview. If you would like to receive a summary of the study results at the end of the study please let us know.

**9. What if there is a problem?**

If you have concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. Contact details are at the end of this patient information sheet. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact PALS (Patient Advice and Liaison Service) telephone 0800 183 0204

**10. Will my taking part in this study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential under the provisions of the Data Protection Act 1998. Any personal details will be kept secured in the research office. You will be identified in any study related documents by your unique study number only. Your details will only be passed to other members of the research team, and to the people overseeing the study (called the “sponsor”), the Research & Innovation department, Nottingham University Hospitals NHS Trust. Your records may also be made available to people authorised to work on the study on behalf of the sponsor, such as auditors, who are ensuring that the study is being carried out correctly. .

***The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.***

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

**11. What will happen to the results of this study?**

The results of the study will be available after it finishes and will be published in medical journals and be presented at scientific conferences. The data will be anonymous and none of the participants involved in the study will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask the research team.

**12. Who is organising and funding this study?**

The daily running of the study will be led by the study’s research team. Nottingham University Hospitals NHS Trust will act as “sponsor” for the research and will take responsibility to ensure that the study is carried out correctly. Funding for this study has been provided by the Dunhill Medical Trust.

**13. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS by the East of England Research Ethics Committee (Cambridge Central).

The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust as well as the Health Research Authority.

**Contact Details**

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*If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and you will be given a copy to keep.*

*You can have more time to think this over if you are at all unsure.*

*Thank you for taking the time to read this information sheet and to consider this study.*