

Vfrac Study

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**INFORMATION LEAFLET: Production and evaluation of an improved tool to screen older women with back pain for vertebral fractures (Vfrac).**

**Sponsor: University of Bristol**

**Funder: Arthritis Research UK**

**Introduction**

You are invited to take part in a study which aims to produce simple checklist for GPs to indicate whether someone is at risk of vertebral fracture and if they need an x-ray of their back. Before you decide, it is important for you to understand why this 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, such as family, friends or your GP. Ask the Vfrac study team (contact details above) 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.

***If you are older than 65 years and have had back pain in the past 4 months you can take part in the Vfrac study.***

**What is the purpose of this study?**

*Background*: Some women break a bone in their back (vertebral fracture) because of osteoporosis (brittle bones) but are never diagnosed. This is partly because back pain is so common that GPs do not know which people should have a back X-ray.

*Aim*: The Vfrac study aims to produce a simple checklist for GPs and other medical professionals to complete whenever a woman older than 65 years with back pain seeks healthcare. The checklist is likely to include questions for the patient (such as previous broken bones, or type of back pain), and a physical examination (such as measurement of height). The results of the checklist will indicate whether someone is at risk of having an osteoporotic vertebral fracture (broken bone in the back due to brittle bones) and if they should have an X-ray to diagnose the vertebral fracture.

**Why have you been invited?**

Your GP has forwarded this to you because you are a woman aged 65 or older and living within the Bristol area.

**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 are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from your GP or any hospital.

**What do I do now, if I am interested in taking part in Vfrac?**

We are specifically interested in women who have had back pain in the past 4 months. If you do decide you

are interested in taking part you should keep this information sheet, sign the enclosed consent forms

(keeping one copy for yourself) and complete the questionnaire. Please then send the completed questionnaire and one copy of the signed consent form back to us in the enclosed Freepost envelope. Once we receive your signed consent form and completed questionnaire we will make sure you are able to continue taking part.

**What happens if I can continue taking part?**

If you can continue taking part, a member of the Vfrac study team will call you to arrange an appointment for you at your local hospital. The hospital visit will involve a physical examination that will take 10 to 15 minutes. This examination will involve a few questions and simple measurements such as measuring your height, carried out in a private room by a clinical research nurse. You will not have to take off your clothes. You will then have an X-ray of your back to see if you have broken a bone. Your travel costs to the hospital will be refunded. The results of this X-ray will be sent to me and to your GP. Your GP will treat you for any broken bone found. Three months later we will send you another postal questionnaire, and we will look at your medical notes and X-ray reports for information on medications that have changed, how many hospital appointments you have had, and any other diseases.

**What are the risks or benefits of taking part in this study?**

By participating in Vfrac you will be helping improve the treatment of osteoporosis and back pain in the future for others. The slight risk of taking part is from the X-ray of your back. The radiation dose is similar to that you would get living in England or Wales for a year, i.e. is similar to the background radiation the average person receives over a year. However, there is the potential benefit that if you are found to have broken a bone in your back you will receive treatment from your GP, and you will get treatment for osteoporosis to prevent further broken bones. Occasionally, other abnormalities may be found on the x-ray. If this happens, your GP will treat you if needed. We think it is unlikely, but you might find some of the questionnaires upsetting. Please take your time when filling out the questionnaires and call us if you need to talk to someone. The physical examination is unlikely to cause distress as you do not need to undress, but we will be measuring your waist-line and how much your ribs expand when you breathe in and out. Please let the clinical research nurse know if you feel uncomfortable, but they will do everything they can to make this an easy and simple process for you.

**What data will we collect from you?**

Your name and contact details will be used to send the questionnaires to you and to make your hospital appointment. There is a possibility that we may need to contact you directly to clarify and cross-check some answers to the questionnaires.

Other information that we gather will have a unique Vfrac study number on it, not your name: Your date of birth, information you provide in the questionnaires, clinical research information from the X-ray and your physical examination, information from your medical records and X-ray reports. Your name and hospital number will be removed from the X-ray report before being sent to me. This means that when I look at the questionnaires or X-ray reports I will not know whose questionnaire or X-ray it is. If you consent to taking part in Vfrac, any of your medical records may be inspected by me, the Principal Investigator of this study for the purposes of clarification or cross-checks. They will be accessed using your NHS number and then anonymised. They may also be looked at by people from the NHS or University of Bristol or regulatory authorities to check the study is being carried out properly. Your name and other personal details such as your address, however, will not be disclosed. In the unlikely event you lose the capacity to give consent, you will be withdrawn from the study but any data you provided until then will be anonymised and kept. It is also our plan to share the research information collected as part of Vfrac with other researchers around the world, to maximise the benefits of collecting all this information. Any data shared will always be anonymous.

**Who has access to this information?**

The Vfrac study team, made up of Drs Emma Clark and Zoe Paskin, the research administrator and the clinical research manager.

**How long will we keep it for?**

Your name and contact details will be destroyed five years after the study ends. The study end date is 30th June 2021. Anonymised research data will be held for longer in the University of Bristol Research Data Repository.

**How can you find out what information we hold about you?**

You can contact us and ask. Our contact details are at the top of page 1 of this leaflet.

**Will all this information be kept confidential?**

Yes. Any information which is collected about you as part of Vfrac will be kept strictly confidential.

**What will happen to the results of this research study?**

A poster summarising the results of the study will be put up in your GP practice at the end of the study for you to look at. If you provide your email address, we will send you a copy of the poster. Results will also be published in professional journals and at conferences. You will not be identified in any report or publication.

**Who is organising and funding the research?**

This study is funded by the Arthritis Research UK and has been organised by Dr Emma Clark via the University of Bristol. This study was reviewed by the West of Scotland Research Ethics Committee and local research governance groups.

**Who do I need to contact if I want more information?**

If you would like to know more before deciding, please contact the Vfrac study team. The contact information is at the top of the first page of this leaflet.

**What if something goes wrong?**

In the unlikely event that you are harmed as a result of this study, there are no specific compensation arrangements.  If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. If you wish to talk to the patient advice and liaison service, their telephone number is 0117 414 4569. If you wish to make a complaint, please use these details: NHS complaints – 0117 4144569; complaints@nbt.nhs.uk

Thanks very much for taking the time to read this information.



Dr Emma Clark

Consultant Senior Lecturer

Vfrac study Chief Investigator

**Summary of Vfrac**

Read information leaflet

Decide whether or not you want to take part

No further action

No

Yes

No further action

No

Have you had back pain in the past 4 months?

Yes

1. Sign the enclosed consent forms (keep one copy for yourself)

2. Complete the enclosed questionnaire

3. Send back one copy of the consent form and the questionnaire using the Freepost envelope

We will call you to make an appointment for you to attend your local hospital

At your local hospital you will have a physical examination which will take 10 to 15 minutes, followed by an X-ray of your back

3 months later you will be sent another questionnaire

