

# Testing a vertebral fracture screening tool for use in older men with back pain

<b>Submission date</b> 20/12/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A vertebral fracture (broken bone in the back due to weak bones) increases the chance of more fractures, but only one in three patients are diagnosed. One reason for this is because medical staff find it difficult to know who should have a spinal X-ray.

To help medical staff decide, we have carried out a study that has resulted in the Vfrac tool. We now want to look at Vfrac in men.

There are three stages to this new study:

1. Interviewing men with vertebral fractures to see if they describe their back pain in a similar way to women, and listening to their views on the content and wording of the questions in Vfrac
2. Updating the Vfrac tool to be relevant to men
3. Testing the updated Vfrac tool to see if it works in men as well as it does in women. If so, men will be included in future research into Vfrac

### Who can participant?

Men aged 65+ years with back pain. For stage 1 men must have a vertebral fracture.

### What does the study involve?

Stage 1 involves talking to a researcher (an interview) for 60-90 minutes on the telephone, by video call or face-to-face about back pain symptoms and views on the current version of our Vfrac checklist.

Stage 3 involves completing a questionnaire at home and sending your answers back to the research team.

### What are the possible benefits and risks of participating?

Talking to us as part of the study will take up a little time, although we will try and keep interviews as short as possible. Participants are also free to take breaks during the interview. We will also try to make any adjustments needed to make it easier to take part.

It may also be distressing to talk about how it feels to break a spinal bone. Participants are free to stop or to decide not to answer any questions without giving a reason, at any time. We will also provide lists of contacts for support and advice.

Although this study will not benefit participants directly, we hope that this study will make it easier to identify men who have broken a bone in their back in the future.

Where is the study run from?  
The University of Bristol (UK)

When is the study starting and how long is it expected to run for?  
December 2020 to September 2024

Who is funding the study?  
Stages 1 and 2 are funded by a research grant from the Royal Osteoporosis Society (Ref 462).  
Stage 3 is funded by the Southmead Hospital Charity.

Who is the main contact?  
The Vfrac study team can be contacted using the email address [Vfrac-study@bristol.ac.uk](mailto:Vfrac-study@bristol.ac.uk)

**Study website**  
<https://tinyurl.com/yw2dspcx>

## Contact information

**Type(s)**  
Principal Investigator

**Contact name**  
Prof Emma Clark

**ORCID ID**  
<http://orcid.org/0000-0001-8332-9052>

**Contact details**  
Musculoskeletal Research Unit  
Translational Health Sciences  
Bristol Medical School  
University of Bristol  
Learning & Research Building  
Southmead Hospital  
Westbury-on-Trym  
Bristol  
United Kingdom  
BS10 5NB  
+44 117 414 7862  
[Vfrac-study@bristol.ac.uk](mailto:Vfrac-study@bristol.ac.uk)

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

301023

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 301023

## **Study information**

**Scientific Title**

Applicability of Vfrac In Men: An osteoporotic vertebral fracture screening tool for use in older people with back pain

**Acronym**

Vfrac

**Study objectives**

We have developed the Vfrac clinical tool using the MRC framework for development and evaluation of complex interventions. The intention of Vfrac is to help healthcare practitioners in primary care decide if an older woman with back pain is at high risk of an osteoporotic vertebral fracture (OVF) and therefore requires a spinal radiograph to confirm the diagnosis. It contains 15 simple components based on self-reported data and a physical examination. It takes less than 5 minutes to perform and produces a binary output of "Low risk - spinal X-ray is not recommended" or "High risk - spinal X-ray is recommended as may have a vertebral fracture".

All of our Vfrac tool developmental work has been carried out in women because of the higher background prevalence of OVF. We now wish to assess Vfrac in men. There is clear evidence that moderate and severe OVFs in men predict future hip fractures in a similar way to women. There is support for the assumption that the underlying biology of osteoporosis and OVFs is similar in men and women. Pharmaceutical studies show that bone protection therapies work equally well in men and women in protection against future OVFs. However, there remain questions around men's characterisation of back pain symptoms in the context of OVF. For example, pilot work with men suggests one phrase in particular is problematic in the current Vfrac tool: 'If I'm working in the kitchen like chopping vegetables or washing, my back pain gets worse and worse to reach a peak – then I have to sit down immediately'. A suggested modification to make it acceptable to men is to remove the word 'working'.

Therefore, we have designed a study to assess the applicability of Vfrac in men: (Stage 1) To understand and further characterise pain symptoms and experiences of men with OVF, and to evaluate the wording of the current Vfrac tool from men's perspective; (Stage 2) To modify the Vfrac tool (if necessary) to be more relevant to men (called m-Vfrac); and (Stage 3): To test the updated Vfrac tool to identify its predictive ability in men.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Qualitative study followed by case control study

### **Primary study design**

Observational

### **Secondary study design**

Case-control study

### **Study setting(s)**

Community

### **Study type(s)**

Other

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

### **Health condition(s) or problem(s) studied**

Osteoporotic vertebral fractures

### **Interventions**

Stage 1: Qualitative in-depth interviews

To understand and further characterise pain symptoms and experiences of men with OVF, and to evaluate the wording of the current Vfrac tool from men's perspective.

After providing self-completion written consent participants will be contacted to arrange an interview. They will then undertake a one-to-one interview with a researcher for 60-90 minutes based on a Topic Guide, The interview will take place face-to-face, online or by telephone depending on the participant's preference. There is no follow up.

Stage 2: Modification of the Vfrac decision tool

To modify the Vfrac tool (if necessary) to be more relevant to men (called m-Vfrac).

Stage 3: Case control study

Cases are men aged 65+ with an osteoporotic vertebral fracture identified on a recent spinal radiograph. Controls are men aged 65+ without an osteoporotic vertebral fracture on a recent spinal radiograph. All cases and controls will self-complete the Vfrac questionnaire at home. Statistical analyses will then be undertaken based on our understanding of how the Vfrac questionnaire behaves in women. For this project in men, the Vfrac regression equation will be used to calculate the mean (SD) linear predictor in men with and without osteoporotic vertebral fractures. If the linear predictors show a similar difference in men with and without osteoporotic vertebral fracture to that in women (i.e., approximately 1 SD); and the linear predictors for men with and without osteoporotic vertebral fractures falls within the 95% CI of the original Vfrac work in women, then these results will provide support for use of Vfrac in men. Additionally, the sensitivity and specificity of the pre-determined cut-off of the Vfrac tool will be calculated for men, based on a simple two by two table for cases and controls. This will be compared to the sensitivity and specificity of the Vfrac tool for women (known to be 72.4% and 72.9% respectively).

### **Intervention Type**

Other

## **Primary outcome measure**

Measures taken once in each stage:

Stage 1:

1. Qualitative outcomes of characterisation of pain symptoms and experiences of men with osteoporotic vertebral fractures based on a Topic Guide previously developed with women, and collected during one-to-one interview
2. A list of problematic words, phrases or questions for men within the current Vfrac tool collected through think-aloud during one-to-one interview

Stage 3:

1. Risk of having an osteoporotic vertebral fracture ('High risk' or 'Low risk') based on the binary output of the modified Vfrac questionnaire using the pre-determined cut-off developed with women, collected through self-completion of the Vfrac questionnaire
2. The linear predictor based on the Vfrac regression equation, collected through self-completion of the Vfrac questionnaire

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

20/12/2021

## **Completion date**

30/09/2024

# **Eligibility**

## **Key inclusion criteria**

Stage 1

1. Patient is willing and able to give informed consent for participation in the study.
2. Male aged over 65 years
3. Spinal radiograph in the previous three months that shows an osteoporotic vertebral fracture
4. Aware that they have an osteoporotic vertebral fracture

Stage 3

1. Patient is willing and able to give informed consent for participation in the study.
2. Male aged over 65 years
3. Spinal radiograph in the previous three months

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

65 Years

## **Sex**

Male

**Target number of participants**

Stage 1: 12 Stage 3: 60

**Total final enrolment**

15

**Key exclusion criteria**

Stage 1

1. Female
2. Aged under 65 years
3. Potential participant is not aware they have a vertebral fracture
4. Spinal malignancy (cancer) mentioned in the radiology report
5. Patients who do not have the capacity to provide informed consent. Capacity to consent will be assessed by the researcher, in consultation with a clinical members of the study team (EC). This is in accordance with the Mental Capacity Act 2005 (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/>).
6. Participants who are unwilling to provide informed consent.

Stage 3:

1. Female
2. Aged under 65 years
3. Spinal malignancy (cancer) mentioned in the radiology report
4. Patients who do not have the capacity to provide informed consent. Capacity to consent will be assessed by the researcher, in consultation with a clinical members of the study team (EC). This is in accordance with the Mental Capacity Act 2005 (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/>).
5. Participants who are unwilling to provide informed consent.

**Date of first enrolment**

01/06/2022

**Date of final enrolment**

31/01/2024

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Southmead Hospital**

North Bristol NHS Trust

Southmead Road

Westbury-on-trym

Bristol

United Kingdom  
BS10 5NB

### **Study participating centre**

#### **University of Bristol**

Senate House  
Tyndall Avenue  
Bristol  
United Kingdom  
BS8 1TH

## **Sponsor information**

### **Organisation**

University of Bristol

### **Sponsor details**

Senate House  
Tyndall Avenue  
Bristol  
England  
United Kingdom  
BS8 1TH

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research-governance@bristol.ac.uk

### **Sponsor type**

University/education

### **Website**

<http://bristol.ac.uk/>

### **ROR**

<https://ror.org/0524sp257>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Royal Osteoporosis Society

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

**Funder Name**

Southmead Hospital Charity

## **Results and Publications**

**Publication and dissemination plan**

On completion of the study, a report will be prepared for the Funder.

The results will be published in peer-reviewed journals and presented at scientific meetings. The Royal Osteoporosis Society and the University of Bristol open access policies for publication of peer-reviewed papers will be followed.

The PI and Co-applicants will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the Royal Osteoporosis Society. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

The study progress and a lay summary of the results at the end of the study will be posted on the study webpage. At the end of Stage 1, we will provide participants with a brief summary of study findings. This summary will provide overall themes from all the interviews we have done.

**Intention to publish date**

01/09/2024

**Individual participant data (IPD) sharing plan**

Dr Emma Clark is the data custodian for this study. Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. It is our intention to share the underpinning research data to maximise reuse. Patients will be asked for permission to share anonymised data beyond the immediate project team. The data will be deposited at the University of Bristol Research Data Repository (as restricted data). A metadata record will be published openly by the repository and this record will clearly state how data can be accessed. The actual data is only made available to authenticated researchers upon application. The criteria we check applicants against is: the applicant has provided a verifiable institutional affiliation; the applicant has provided verifiable institutional contact details; the applicant has nominated an appropriate institutional signatory; the applicant has ethical approval in place (this may not be required, depending on the nature of the requested dataset). The request is referred to the University of



Bristol Data Access Committee (DAC) for approval before data can be released. Again, the applicant's host institution must agree to a Data Access Agreement.

### **IPD sharing plan summary**

Available on request