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

Submission date
20/12/2021

Recruitment status
No longer recruiting

Registration date
23/12/2021

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
301023

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
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 it's 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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
Male

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
United Kingdom

England

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
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BS8 1TH

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research organisation

Funder Name
Royal Osteoporosis Society

Alternative Name(s)
The Royal Osteoporosis Society (ROS), National Osteoporosis Society, ROS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Southmead Hospital Charity

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes