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Can a vertebral fracture screening tool be used remotely as well as face-to-face?

Submission date
06/01/2022

Recruitment status
No longer recruiting

Registration date
10/01/2022

Overall study status
Completed

Last Edited
24/07/2025

Condition category
Musculoskeletal Diseases

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

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 that medical staff find it difficult to know who should have a spinal X-ray.
To help medical staff decide, researchers have carried out a study that has resulted in the Vfrac tool. They now want to look at whether Vfrac can be completed by people at home or whether it needs to be done face-to-face (F2F) by a nurse or doctor.
There are three stages to this study:
1. Inviting men to complete the Vfrac questionnaire and simple physical examination at home. They will then attend a research clinic where the researchers will do the same F2F. They will be asked which they prefer and why.
2. Inviting women who have already had Vfrac done F2F as part of another study to complete the Vfrac questionnaire and simple physical examination at home. They will also be asked which they prefer and why.
3. Looking at the agreement between F2F and home completion of Vfrac by men and women to see if it can be completed by people at home.

Who can participate?
Men and women with back pain. For stage 1, men must be aged 65+ years and have had a spine X-ray recently. For stage 2, women must have already had Vfrac done F2F as part of another study.

What does the study involve?
Participants complete a questionnaire at home and send their answers back to the research team. For stage 1, participants will attend a research clinic for a 15-minute appointment to have the same questionnaire done F2F.

What are the possible benefits and risks of participating?
Completing the questionnaire at home as part of the study will take up a little time. Those participants who take part in stage 1 will also need to attend a research clinic in a hospital for a F2F assessment. Although this study will not benefit participants directly, it is hoped that this study will make it easier to identify people 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?
January 2022 to April 2024

Who is funding the study?
Stage 1: University of Bristol Elizabeth Blackwell Institute MRC Confidence in Concept (CiC) award (ref: 410) (UK)
Stage 2: National Institute for Health Research (ref: NIHR 203026) (UK)

Who is the main contact?
Vfrac study team
Vfrac-study@bristol.ac.uk

Study website
https://tinyurl.com/yw2dspcx

Contact information

Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309446

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 309446

Study information

Scientific Title
Testing an osteoporotic vertebral fracture screening tool (Vfrac): remote vs face-to-face data collection

Study objectives
Researchers have developed the Vfrac clinical tool using the MRC framework for the 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".

Currently no testing of Vfrac has been undertaken within a real-world clinical setting. Discussions with primary care colleagues have highlighted how much the model of consultation /service delivery has changed in the pandemic, and it is highly unlikely that there will be a full-scale return to face-to-face (F2F) consultations with GPs as the primary mode of clinical assessment. The Vfrac tool was originally planned to be used by practice nurses (all research data were collected by research nurses trained to the level of a practice nurse). However, there is an important question about whether Vfrac could be used fully remotely, with patients self-completing all questions and carrying out a self-assessment of the physical characteristics (height, weight and wall-to-tragus distance) themselves.

Published data on self-assessment of the wall-to-tragus distance, and work with our experienced in-house musculoskeletal PPI group have allowed us to produce easy to use instructions for completion of the Vfrac tool at home. Instructions are on a single side of A4 as the patient partners did not want it spread over two sides of paper. However, there is a concern that people with vertebral fractures may find it difficult to measure their wall-to-tragus distance due to difficulty raising their arms above head height. Remote use therefore needs to be tested in a group of older people with and without vertebral fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2022, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0) 207104828, +44 (0)2071048272; bloomsbury.rec@hra.nhs.uk), ref: 22/PR/0378

Study design
Testing of agreement

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Home

Study type(s)
Screening

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: Testing agreement between remote vs face-to-face (F2F) Vfrac in men
Men aged over 65 years (65+) who have had a spinal radiograph will be invited to take part in this study. All those recruited will be sent the Vfrac questionnaire and supporting documentation to complete at home with return of the completed documents to the study team. All participants will then be invited to a research clinic to have Vfrac completed F2F. Satisfaction and ease of use of remote Vfrac compared to F2F assessment will be investigated using a questionnaire. Outputs of the remote Vfrac (high risk vs low risk) will be compared to the F2F Vfrac (high risk vs low risk) and agreement assessed using Cohen's kappa. Outputs of the satisfaction and ease of use questionnaire will be used to modify the tool if necessary prior to Stage 2.

Stage 2: Testing agreement between remote vs face-to-face (F2F) Vfrac in women
As part of a separate feasibility study aiming to optimise Vfrac within a real-world clinical setting in primary care, women will be recruited for a nested study to assess agreement between remote vs face-to-face (F2F) use of Vfrac. This separate recruitment strategy is being used for women for efficiency. Women within three general practices where the Vfrac tool was used during a consultation for back pain will be recruited to Stage 2. They will already have had a F2F assessment with Vfrac as part of the feasibility study and those recruited to Stage 2 of this project will be sent the Vfrac questionnaire and supporting documentation to complete at home with return of the completed documents to the study team. Satisfaction and ease of use of remote Vfrac compared to F2F assessment will be investigated using the same questionnaire as Stage 1. Outputs of the remote Vfrac (high risk vs low risk) will be compared to the F2F Vfrac (high risk vs low risk) and agreement assessed using Cohen's kappa.

Stage 3: Decision as to whether Vfrac can be used remotely
Decision will be based on (1) size of agreement identified in Stages 1 and 2; and (2) patient satisfaction and ease of use of the self-completion questionnaire and written instructions. If Cohen's kappa is <0.6 (substantial agreement) remote use (self-completion) will not be incorporated into any future trial. If Cohen's kappa is ≥0.6, data from the satisfaction questionnaire will be used to make any further necessary modifications to facilitate remote use (self-completion) of Vfrac in any future RCT or implementation study.

Intervention Type
Other

Primary outcome measure
Measures taken once in each stage:

Stages 1 and 2:
1. Risk of having an osteoporotic vertebral fracture (OVF) as calculated by the self-completed Vfrac tool
2. Risk of having an OVF as calculated by the face-to-face Vfrac tool

Stage 3:
Assessment of agreement between remote vs F2F use of the Vfrac tool using Cohen's kappa. Standard classifications of Cohen's kappa will be used with 0.6 indicating substantial agreement

Secondary outcome measures
Satisfaction and ease of use of remote vs F2F Vfrac questionnaire collected during Stages 1 and 2. Questions based on the framework on Quality in Healthcare developed by Huycke et al. to cover process, interpersonal and technical attributes, plus relevant questions from the validated question on remote consultations by Mekhjian et al.

Overall study start date
01/01/2022

Completion date
01/04/2024

Eligibility

Key inclusion criteria
Stage 1:
1. Patient is willing and able to give informed consent for participation in the study
2. Male aged 65+ years
3. Spinal radiograph in the previous 3 to 6 months

Stage 2:
1. Patient is willing and able to give informed consent for participation in the study
2. Patient had a previous F2F use of Vfrac when consulting in primary care with back pain

Participant type(s)
Patient

Age group
Adult

Lower age limit
65 Years

Sex
Both

Target number of participants
Stage 1: 60; Stage 2: 60

Key exclusion criteria
Stage 1:
1. Female
2. Aged under 65 years
3. Has not had a spinal radiograph in the previous 3 to 6 months
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 member 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 2:
1. Not had a previous F2F use of Vfrac
2. Spinal malignancy
3. 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 member 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/)
4. Participants who are unwilling to provide informed consent

Date of first enrolment
01/05/2022

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
NHS Bristol CCG Hq
South Plaza
Marlborough Street
Bristol
United Kingdom
BS1 3NX

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
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BS1 3NU

Study participating centre
University of Bristol
Senate House
Tyndall Avenue
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BS8 1TH

Sponsor information

Organisation
University of Bristol

Sponsor details
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Sponsor type
University/education

Website

http://bristol.ac.uk/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
University/education

Funder Name
University of Bristol Elizabeth Blackwell Institute MRC Confidence in Concept (CiC) award

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The protocol and all other documents will be available after ethics approval. On completion of the study, a report will be prepared for the funders. The results will be published in peer-reviewed journals and presented at scientific meetings. The NIHR and the University of Bristol open access policies for the 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. The authors will acknowledge that the study was funded by the Elizabeth Blackwell Institute and the NIHR RfPB. 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.

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 the researchers' 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 the researchers use to 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

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	25/05/2022	17/11/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		07/02/2024	07/02/2024	Yes	No
Results article		23/07/2025	24/07/2025	Yes	No