ISRCTN18000119 https://doi.org/10.1186/ISRCTN18000119

What is the feasibility of testing a vertebral fracture screening tool in a real-world primary care setting?

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
01/03/2022

Overall study status
Completed

Last Edited
22/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoporosis (weak bones) is one of the most common musculoskeletal conditions in older women. Osteoporotic vertebral fractures (broken bones in the back due to osteoporosis) are particularly important because they identify people at high risk of breaking more bones. However, less than a third of people with vertebral fractures are correctly diagnosed and treated. The main reason for this failure is difficulty understanding who should have spinal x-rays. The Vfrac tool is a simple questionnaire developed carefully by research involving women with and without osteoporotic vertebral fractures. Vfrac is for healthcare professionals in GP practices to complete for women aged over 65 years with back pain. The output of Vfrac indicates whether or not they should have a spinal x-ray.
Vfrac has never been tested in a real-world situation to find out if it works and is likely to be cost-effective for the NHS. This real-world testing will be a large study involving many GP practices and will look at whether Vfrac improves the treatment of older people with osteoporosis.
Before they can design this study, the researchers need information to plan:
1. The size and process of the study, based on information including numbers of women who attend their GP with back pain and the average time it takes for X-ray results to get back to the GP
2. IT requirements, based on what different IT systems GP practices use
3. How Vfrac is used, based on which healthcare professionals see older people with back pain in primary care
4. Whether the tool needs to be changed based on understanding patient and healthcare professionals' views and experiences of using Vfrac

Who can participate?
Women aged over 65 years at the participating general practices

What does the study involve?
The researchers will:
1. Use a database that collects patient data from GP practices across the UK to calculate the size and design of the large study.

2. Ask six GP practices to be involved in this study, and get half of them to use Vfrac for 12 months. This will help the researchers understand the IT requirements. They will ask patients and healthcare professionals about their views of Vfrac and identify factors that make it easier or more difficult to use.
3. Do a nationwide survey of GP practices to describe which type of healthcare professionals see older people with back pain.

What are the possible benefits and risks of participating?
The main risk relates to the COVID-19 pandemic. Before any face-to-face interview about patients' views and experiences of using Vfrac, a risk assessment will be done to minimse the risk of exposure to COVID-19 by both the patient and researcher. There be no direct benefits of taking part in this study.

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

When is the study starting and how long is it expected to run for?
March 2022 to January 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Emma Clark, emma.clark@bristol.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Emma Clark

ORCID ID
https://orcid.org/0000-0001-8332-9052

Contact details
Musculoskeletal Research Unit, Level 1, L&R Building
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)1174147841
emma.clark@bristol.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
313632

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 313632, NIHR203026

Study information

Scientific Title
Vertebral fracture clinical decision tool for older women with back pain (Vfrac) - a feasibility study

Acronym
Vfrac feasibility

Study objectives
Researchers 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 and therefore requires a spinal radiograph to confirm the diagnosis. Vfrac 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". Statistical modelling suggests it is valid (AUC of 0.802, 95%CI 0.764-0.840), and pre-trial health economic modelling suggests a future trial to reduce uncertainties is justified.

Before they plan the future trial the researchers need more information to ensure the trial is adequately powered, that Vfrac is acceptable to patients and healthcare professionals, and that the length of follow-up is appropriate. They also need to understand what usual care is for older people with back pain, as this will be the comparator in any future trial.

This feasibility study aims to
1. Optimise the use of the Vfrac decision tool within a real-world clinical situation in primary care by (a) assessing the acceptability of Vfrac, and (b) identifying factors that impact on its implementation, including barriers and facilitators to delivery. Findings will be used to develop a series of recommendations to modify Vfrac and improve delivery in the future randomised controlled trial (RCT).
2. Quantify required trial parameters including (a) final design of the intervention and (b) length of time needed for trial follow up by assessment of UK-wide variability in length of time between initial consultation for back pain and eventual management implementation.
3. Identify processes required to collect accurate and comprehensive data on resource use as a result of Vfrac utilisation through a pilot study.
4. Contribute to the final decision as to whether a future definitive evaluation of Vfrac is warranted.
5. Describe 'usual care' through analysis of control general practices in the pilot study, and through a national survey

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/06/2022, Yorkshire & The Humber- Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 22/YH/0135

Study design
Pilot interventional non-randomized study with nested qualitative evaluation

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Osteoporotic vertebral fractures

Interventions
Work Package 1 (WP1): Pilot Vfrac implementation within primary care
Six general practices will be recruited purposively to include large/small practices, practices within different PCNs/clusters and practices that use different IT systems (EMISWeb/SystmOne for example). General practices will be identified and approached by the Bristol Primary Care CRN. Baseline data will be collected from all recruited practices. A clinical update on osteoporosis will be offered to all. Three practices will then be assigned to the implementation arm and three to the control. Those in the implementation arm will be trained in the use of Vfrac and will have it made accessible from their IT systems (through the provision of a URL via pop-ups on typing relevant words such as back pain). Use of the Vfrac tool will be encouraged within their clinical pathways for the management of older women who consult with back pain. The use of the tool in a manner that fits each practice's service delivery model will be facilitated by the research team in discussion with the clinical team. The control practices will use standard clinical processes for older women consulting with back pain. Regular data will then be collected on consultations by older women with back pain from all six general practices every 3 months for 12 months.

Work Package 2 (WP2): Nested qualitative assessment of acceptability
16-24 older women who consulted with back pain and had Vfrac used during their clinical consultation within one of the three intervention practices will be recruited to take part in this work package. They will be identified by the unique code generated and embedded within their GP records at the time the result of Vfrac was recorded. They will be approached by the direct clinical care team in their general practice with an information pack about the study. The information pack will contain an introductory letter, a participant information booklet, a consent form and a pre-paid envelope for return to the research team. Those who reply by returning the completed Consent Form will be recruited. In addition, 16-24 healthcare professionals working within the intervention practices will also be recruited. The plan is to undertake approximately four focus group interviews with patients, and four focus groups with healthcare professionals, each focus group with an estimated 4-6 participants. The final sample size will be determined by data saturation. Focus groups will aim to understand and assess the perceived acceptability of Vfrac and identify factors that impact on implementation. To do this the researchers will address two key actions of intervention development: (1) understand and assess the acceptability of Vfrac to healthcare professionals (providers) and patients (recipients), and (2) identify factors that impact on implementation, including barriers and facilitators to delivery. These may include

patient-related factors and provider-related factors such as working practices, or service constraints such as time and resources.

Work Package 3 (WP3): Additional data collection to inform parameters for the trial through analysis of data from the CPRD (WP3A) and a national survey (WP3B) of CCGs, primary care managers and GPs.

Work package 4 (WP4): Decision as to whether a future definitive evaluation is warranted
Stop/Go criteria for any future trial are:
1. Accuracy of Vfrac tool – already completed and results are favourable (not part of this study)
2. Modelled cost-effectiveness - already completed and results are favourable (not part of this study)
3. Realistic proportion of older women with back pain identified with vertebral fractures by Vfrac - already completed and results are favourable (not part of this study)
4. Realistic required sample size based feasibility study (WP1) and on analyses of national data (WP3)
5. Realistic required length of follow-up for the future trial based on results of WP1 plus additional analyses of national data (WP3)
6. Evidence that the Vfrac tool is acceptable to healthcare professionals and patients based on results of WP2

Intervention Type
Other

Primary outcome(s)
WP1: Intervention and control practices
1. Descriptives of each practice, computer system, name of PCN/cluster, other demographic characteristics, number of registered patients, number of women aged ≥50 and ≥65 years, as reported by the Practice Manager at baseline
2. The type of healthcare professional carrying out initial consultation for back pain, the number and date of consultations by older women with back pain, resource use after initial consultation for back pain, new diagnoses since initial consultation for back pain, measured using a questionnaire at 3, 6, 9, 12, 15 and 18 months

WP1: Intervention practices only (in addition to the above)
The proportion of consultations for back pain where Vfrac was used, other consultations where Vfrac was used, results of the Vfrac tool completed in primary care, measured using a questionnaire at 3, 6, 9, 12, 15 and 18 months

WP2: nested qualitative assessment of acceptability
1. Understanding of acceptability to healthcare professionals and patients based on Topic Guide using the Theoretical Framework of Acceptability collected during focus groups at baseline
2. Identification of factors that impact on implementation, including barriers and facilitators to delivery based on a Topic Guide using Implementation Science, collected during focus groups at baseline

WP3: Additional data collection to inform parameters for the trial, all measured at baseline:
WP3A: Data from Clinical Practice Research Datalink (CPRD) will be used to quantify:
1. The range and relative frequencies of healthcare professionals who run the initial consultation for back pain across the UK
2. Levels of and variability in bisphosphonate prescribing and consultation rates for back pain by patient-level characteristics/general practices/regions

3. Variability in the length of time between initial consultation and eventual management implementation
4. Variation in size of general practices
WP3B: The researchers will utilise the primary care CRNs, NHS Digital and social media to cascade a survey to CCGs, primary care managers and healthcare professionals (mainly GPs) to:
1. Identify variation in the number of practices within each PCN
2. Sense-check the data obtained from CPRD around variation in initial contact healthcare practitioner
3. Identify the range of IT systems are in use around the UK (such as EMIS or SystmOne)

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

Completion date
31/01/2025

Eligibility

Key inclusion criteria
WP1: Recruitment of general practices only - no individual patients
1. General practices willing to take part in research within the Bristol area

WP2: nested qualitative assessment of acceptability - recruitment of patients and healthcare professionals
Inclusion criteria for patients:
1. Female aged >65 years
2. Had Vfrac used during a consultation for back pain
3. Patient is willing and able to give informed consent for participation in this nested evaluation

Inclusion criteria for healthcare professionals:
1. Used Vfrac during a consultation for back pain OR were involved in the implementation of Vfrac within IT systems or clinical pathways within one of the three intervention practices
2. Healthcare professional is willing and able to give informed consent for participation in this nested evaluation

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
Female

Key exclusion criteria
WP1: Recruitment of general practices only - no individual patients
Does not meet the inclusion criteria

WP2: nested qualitative assessment of acceptability - recruitment of patients and healthcare professionals
Exclusion criteria for patients:
1. Has not had Vfrac used during a consultation for back pain
2. Patients who do not have the capacity to provide informed consent. Capacity to consent will be assessed by the researcher, in consultation with 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/).
3. Participants who are unwilling to provide informed consent

Exclusion criteria for healthcare professionals:
1. Participants who are unwilling to provide informed consent

Date of first enrolment
01/06/2022

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol, North Somerset, South Gloucestershire CCG (or successor organisation)
360 Bristol (three six zero)
Marlborough Street
Bristol
United Kingdom
BS1 3NX

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

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

Individual participant data (IPD) sharing plan
Prof 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 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, Available on request

Study outputs

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

Study website	Study website	11/11/2025	11/11/2025	No	Yes