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A back pain checklist (Vfrac) for use in primary care to identify older women with back pain due to un-diagnosed broken bones in the back

Submission date
19/04/2018

Recruitment status
No longer recruiting

Registration date
24/05/2018

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis (brittle bones) is one of the most common musculoskeletal conditions in older women. Osteoporotic vertebral fractures (broken back) are of particular importance, as they identify people at one of the highest risks of future fracture. Despite this, less than a third of people with vertebral fractures are correctly diagnosed and managed. The main reason for this failure is lack of awareness by healthcare professionals over who should have spinal X-rays. We have carried out three relevant research studies in this area to identify triggers that could be used to identify who needs an X-ray.
The aims of this study are to answer the following questions: (1) Have we missed any important descriptions of back pain in people with vertebral fractures?; (2) Can we produce an accurate checklist for identifying older women with back pain who have undiagnosed vertebral fractures?; and (3) Is it likely that the use of this checklist in GP surgeries will save the NHS money, and improve quality of life in older women, by identifying which women with back pain have osteoporotic vertebral fractures?

Who can participate?
Women aged over 65 years who tell their GP about back pain they have had in the previous 4 months.

What does the study involve?
All of the participants will receive an invitation letter, information sheet, consent form and a baseline questionnaire in the post. If they will like to take part in the study, they need to fill in the questionnaire and the consent form before posting it back. We will then make an appointment for the participant to have a simple physical examination with a research nurse, who will also take consent face-to-face, and then the participant will have an X-ray of their back. The results of the back X-ray will be sent to the participant's GP as if the GP had ordered the X-ray. 3 months later the participant will receive a follow-up questionnaire and we will download their medical records from the GP practice (if we have permission for this).

What are the possible benefits and risks of participating?
By participating in this study, the participant 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. The radiation dose is similar to what one 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 the participant is found to have broken a bone in their back they will receive treatment from their GP and will get treatment for osteoporosis to prevent further broken bones.

Where is the study run from?
The study will be run from two sites: Bristol (the lead centre) and Stoke-on-Trent.

When is the study starting and how long is it expected to run for?
The study started on 1st January 2018 and will end on 30th June 2021.

How long will the study be recruiting participants for?
The study will be recruiting participants from 30th April 2018 to 30th March 2020. This study is funded by Arthritis Research UK.

Who is the main contact?
Dr Emma Clark: Emma.Clark@bristol.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2891

Study information

Scientific Title
Production and evaluation of an improved tool to screen older women with back pain for vertebral fractures (Vfrac)

Acronym
Vfrac

Study objectives
People with osteoporotic vertebral fractures (VFs) are important to identify, as they are at one of the highest risk of future fractures. Despite this, less than a third of people with osteoporotic VFs come to clinical attention due to a variety of reasons including lack of clear clinical triggers to identify who should have diagnostic spinal radiographs. The purpose of the Vfrac study is to produce and evaluate the improved tool (Vfrac) to screen older women with back pain for vertebral fractures. Vfrac is a screening tool for identifying older women with back pain who are likely to have vertebral fractures, based on investigation of vertebral fracture predictors identified from our previous studies in a de novo cohort of older women with back pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 19/04/2018, 18/WS/0061

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Screening

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

Interventions

After GP practice recruitment, participants will be recruited via the GP practice. They will be sent an invitation letter, two copies of the first consent form, the participant information sheet and the baseline questionnaire. After we receive the consent form and baseline questionnaire (which the participant will post back after completion), we will call to invite the participant to attend a research clinic and have a spinal radiograph. The research nurse will take consent face-to-face prior to research data collection and the X-ray, which will be carried out following NHS SOPs. The X-ray results will be sent back to the participant's GP as if the GP had ordered the X-ray. 3 months after the X-ray the participant will receive a follow-up questionnaire in the post and we will download their medical records from their GP practice. A copy of the X-ray will also be sent to the chief investigator for research analysis. The participant will be in the study for 9 months maximum.

Intervention Type
Other

Primary outcome(s)
The primary outcome measure will be the accuracy of the Vfrac tool as estimated by the sensitivity and specificity. We are aiming for a sensitivity and specificity of greater than 80% to justify subsequent exploration in a definitive trial. The method of measurement will be self-reported questionnaire data at recruitment followed by data collection in research clinic plus spinal radiograph as soon as possible after recruitment.

Key secondary outcome(s))
1. Cost effectiveness of Vfrac based upon follow-up of women from the primary outcome cohort to identify if a future definitive cluster randomised controlled trial is appropriate
2. Sources of variance that can be tested in a pilot as part of a future bid
3. Stopping rules for a future trial. The output of this will be a decision on whether a future definitive trial is warranted.

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Self-reported back pain in the previous 4 months
3. Aged over 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Female

Total final enrolment
1635

Key exclusion criteria
Current exclusion criteria as of 23/01/2019:
1. Aged 65 years or under
2. No self-reported back pain reported in the previous 4 months
3. Has already had a full spinal x-ray in the previous 4 months that is not available to the research team
4. Considered unsuitable to take part by their GP (e.g. cognitive impairment or near end of life)

Previous exclusion criteria:
1. Aged 65 years or under
2. No self-reported back pain reported in the previous 4 months
3. Has already had a full spinal x-ray in the previous 4 months
4. Considered unsuitable to take part by their GP (e.g. cognitive impairment or near end of life)

Date of first enrolment
20/04/2018

Date of final enrolment
10/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Stoke-on-Trent
United Kingdom
ST5 5BG

Study participating centre
Bristol
Vfrac Study Clinical Research Manager
Musculoskeletal Research Unit,
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Not defined

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participants 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 controlled data). A metadata record will be published openly by the repository and this record will clearly state how data can be accessed.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2022	19/06/2023	Yes	No
Protocol article	protocol	25/01/2019	25/03/2019	Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet		25/04/2018	24/05/2018	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes