

# PHOENIX-Feasibility: picking up hidden osteoporosis effectively during normal CT imaging without additional x-rays

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<b>Registration date</b> 15/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/07/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Osteoporosis is a condition that weakens bones, making them fragile and more likely to break. It is a condition that develops slowly over several years and is often only diagnosed when a minor fall or sudden impact causes a bone break (or fracture). Osteoporosis particularly affects the spine and hips, resulting in breaks of the bone in these areas. Whilst treatment of osteoporosis is now quite straightforward, detection is difficult. In the UK, osteoporosis causes 200,000 fractures of the spine yearly in women and men. The pain of a small spine fracture can feel like ordinary backache, and as a result patients are often left undiagnosed, so many small fractures are common. This eventually leads to poorer mobility and increased pain for the sufferer. The aim of this study is to find out whether it is possible to identify osteoporosis earlier, leading to improved treatment and better outcomes. To do this the researchers will be looking at special scans called CT scans (computerised tomography) that patients are already having for various reasons, and using some new software that has been developed to make more accurate diagnosis of osteoporosis and bone fractures. A CT scan uses x-rays and a computer to create images of the inside of the body; two million are performed each year in the UK, often for abdominal or pelvic problems. In this study, CT images are reviewed using a new software to identify osteoporosis enabling early treatment and potentially preventing future fractures. This new technology makes it simple to measure a patient's bone density quickly and identify vertebral fractures from CT images of a patient's torso or pelvis. Bone density measurements of the spine and hips are performed on images acquired from any CT scanner. This study is a feasibility study to see if it is realistic to develop into a national trial, so the researchers will be looking at how well they can recruit participants to the study, and as they hope to follow up with a questionnaire after one year, they will also be looking at how many people stay in the study, or drop out.

### Who can participate?

Women aged 65 - 90 and men aged 75 - 90 years who are undergoing a CT scan that includes the pelvis

### What does the study involve?

If someone is attending a CT Department for a scan in a participating hospital and is eligible to be part of the study (that is, within the correct age range and having a scan that includes the pelvis), they will be approached by a member of the research team at the local hospital and asked if they would like to be part of the study. If they are interested in being part of the study the patient will be asked to complete a Bone Health Questionnaire and sign a consent form. The patient will also be asked for their contact details so that the researchers can post out a questionnaire in about 2 months' time, and later at about 1 year. The answers of the Bone Health Questionnaire will be used to calculate the chance of that patient breaking a bone during the next 10 years. If the answers suggest an increased risk, they will be randomly allocated to one of four study groups. In all four groups, bone density is measured and the scans are studied for evidence of small fractures; in some cases this will happen immediately and in others in 12 months' time (there will not be a difference in long-term outcomes for the patient if they are in the group with delayed review of the scan). The groups will be chosen at random (like tossing a coin to make a decision) and NOT by the doctor. If answers suggest that the chances of breaking a bone are low, there will be no need to check bone health straight away. Once the CT scans are looked at by the specialist team in Cambridge, a report will be sent to GPs with results and guidance as to any treatment. Two questionnaires are sent out to participants – one after about 2 months, and one at one year. These will ask about any medication that may be prescribed for bone health and how participants are managing in their day to day life; they should take about 15 minutes to complete. A small number of patients will be asked if they would agree to telling us about their experience of the study; this can be by face to face discussion, or over the phone.

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

Possible benefits are that patients may receive earlier diagnosis and treatment of osteoporosis. There are no risks to being part of this study.

### Where is the study run from?

The study is run jointly by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge. Scans will be looked at in Cambridge, and all co-ordination of the study will be from there. There are other sites participating in this study: Addenbrooke's Hospital, Peterborough City Hospital, Lister Hospital, West Suffolk Hospital and Bedford Hospital.

### When is the study starting and how long is it expected to run for?

September 2019 to December 2024

### Who is funding the study?

National Institute for Health Research (UK)

### Who is the main contact?

Karen Willoughby  
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## Contact information

### Type(s)

Public

### Contact name

Mrs Karen Willoughby

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

PB-PG-0816-2007; CPMS: 41112

**Study information****Scientific Title**

PHOENIX-f: a feasibility study for early identification of vertebral fractures and osteoporosis by opportunistically using CT scans undertaken for other purposes

**Acronym**

PHOENIX-f

**Study objectives**

It is hypothesised there will be value in early diagnosis and treatment of osteoporosis, through fractures prevented, societal and social burden and reduced health costs. The current usual care for case-finding osteoporosis in older people is for the GP to ask their patient to complete a FRAX questionnaire. The responses to these 11 questions regarding fracture risk factors are then entered by the GP into an online calculator which indicates whether a DXA scan should be requested. Uptake of case finding is low and there is no national mandate for screening. High-risk patients are referred for a DXA scan and treatment is offered if the bone mineral density (BMD) is low and/or fracture risk sufficiently high. Vertebral fractures are rarely detected in usual care even though they (alongside hip fractures) cause the biggest burden to patients and the health service. The expectation is that targeted screening will improve upon usual care and appropriately increase the diagnostic rate.

There are several reasons for opportunistic osteoporosis screening during a CT scan:

1. CT attenders are a high-risk population; >30% of these older adults have undiagnosed vertebral fractures or osteoporosis that can be effectively treated once identified
2. The PHOENIX pathway allows us to diagnose osteoporosis on scans already done, without additional x-rays/hospital visits
3. Opportunistic case-finding is recommended by NICE
4. Screening is effective at reducing hip fractures

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 28/07/2019, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)20 7104 8096; Email: nrescommittee.eastofengland-cambridgeeast@nhs.net), REC ref: 19/EE/0176

### **Study design**

Randomised controlled non-blinded multi-centre feasibility study

### **Primary study design**

Interventional

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

Diagnostic

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

Osteoporosis

### **Interventions**

Current intervention:

The intervention is a FRAX questionnaire and a review of CT scans repurposed to look for vertebral fractures and early osteoporosis using software developed for the diagnosis of osteoporosis and bone fractures. In Group 1, GPs will immediately be informed of the analysis, in Group 2 GPs will receive only FRAX calculation results, in Group 3 no results will be communicated with GPs and in Group 4, a referral to an Osteoporosis specialist will be made, rather than sending the results to the GP. To avoid any disadvantage, all CT scans of participating individuals will be analysed and results sent to GPs after one year if they are in Groups 2 and 3. Additionally, those on treatment after 1 year will be compared between Group 1 and Group 4.

### Previous intervention:

Intervention is FRAX questionnaire and review of CT scans repurposed to look at for vertebral fractures and early osteoporosis using software. GPs will be informed of analysis immediately in Group 1, in Group 2 GP will receive only FRAX calculation results and in group 3 no results will be communicated. To avoid any disadvantage, all CT scans of participating individuals will be analysed and results sent after one year to GPs if they are in Groups 2 & 3.

### Intervention Type

Other

### Primary outcome(s)

1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study in 10 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up one year after recruitment

### Key secondary outcome(s)

There are no secondary outcome measures

### Completion date

30/12/2024

## Eligibility

### Key inclusion criteria

1. Attend one of five participating radiology departments
2. Volunteers able to provide informed consent
3. Women aged  $\geq 65$  - 90 and men aged  $\geq 75$  - 90 years inclusive
4. Attending for CT, for any clinical reason, where the spine and/or hips are visible in the scan images

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

65 years

### Upper age limit

75 years

### Sex

All

### Key exclusion criteria

1. Aged > 90
2. Bilateral metalwork in hips
3. Unable to provide valid consent
4. Known to be receiving prescription treatment for osteoporosis other than calcium/vitamin D (i.e. bisphosphonate drug, strontium ranelate, denosumab, raloxifene or teriparatide)
5. Prone CT scan

**Date of first enrolment**

29/10/2019

**Date of final enrolment**

30/11/2024

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

**Study participating centre**

**North West Anglia NHS Trust**

Hinchingbrooke Hospital

Huntingdon

United Kingdom

PE29 6NT

**Study participating centre**

**East & N Herts NHS Trust**

Lister Hospital

Stevenage

United Kingdom

SG1 4AB

**Study participating centre**

**West Suffolk NHS Foundation Trust**  
West Suffolk Hospital  
Bury St Edmunds  
United Kingdom  
IP33 2QZ

**Study participating centre**  
**Bedford Hospital**  
Kempston Rd  
Bedford  
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MK42 9DJ

## Sponsor information

### Organisation

Cambridge University NHS Foundation Trust

### ROR

<https://ror.org/04v54gj93>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		24/05/2022	27/05/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version V1.2	01/07/2019	15/08/2019	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes