

# A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of screening for osteoporosis in older women for the prevention of fractures

<b>Submission date</b> 14/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/02/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Osteoporosis is a condition that weakens the bones, making them fragile and more likely to break (fracture). Osteoporotic fractures – in particular hip fractures – have major adverse effects on quality of life in terms of pain and disability. Around 50% of hip fracture patients lose the ability to live independently and 20% die within a year of their fracture. The aim of this study is to investigate whether a community-based screening programme for osteoporosis reduces the incidence of fractures, and is cost effective, in older women (aged 70 - 85 years).

### Who can participate?

Women aged 70 to 85 who are not currently on prescription medication to prevent osteoporotic fractures.

### What does the study involve?

Participants are randomly allocated to either the screening group or the control group. Those in the screening group have their risk of fracture calculated using data from a questionnaire and, for some participants, results from a DXA (x-ray) scan. Participants above an age-dependent threshold are recommended for treatment (typically bisphosphonate tablets), and to continue treatment for the duration of the study. The risk of fracture is not calculated for participants in the control group, who receive usual care. Participants are followed-up 6 months later and then annually by postal questionnaires and checking of medical records. The proportion of participants sustaining fractures is measured for each group, along with hip fracture rate. Cost-effectiveness is also assessed, as well as the acceptability of the DXA scanning and risk assessment process.

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

Participants in the screening group have the opportunity to discuss treatment with their GP that would reduce their fracture risk. In addition, everyone taking part in the study will be helping to determine whether screening would be beneficial in older women. Taking part in this study will

involve some time to complete questionnaires. If a participant in the screening group is invited to have a DXA bone density scan this would involve a single appointment lasting about 15 to 30 minutes with the DXA provider (usually at an NHS hospital trust). The DXA scanner uses much less radiation than a normal x-ray, such as a chest x-ray, and is equivalent to a few days of natural background radiation.

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

When is the study starting and how long is it expected to run for?  
February 2007 to December 2015

Who is funding the study?  
1. Medical Research Council (MRC) (UK)  
2. Arthritis Research Campaign (UK)

Who is the main contact?  
Prof. Lee Shepstone  
l.shepstone@uea.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Lee Shepstone

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## Additional identifiers

**Protocol serial number**  
MRC ref: G0601019

## Study information

**Scientific Title**  
A pragmatic randomised controlled trial of the effectiveness and cost-effectiveness of Screening for Osteoporosis in Older women for the Prevention of fractures (SCOOP)

**Acronym**  
SCOOP

## **Study objectives**

To investigate whether a community-based screening programme for osteoporosis reduces the incidence of fractures, and is cost effective, in older women (aged 70 - 85 years).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The North West Research Ethics Committee, 20/09/2007

## **Study design**

Two-group pragmatic randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

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

Musculoskeletal Diseases: Osteoporosis

## **Interventions**

Intervention subjects will have a 10-year absolute risk of fracture calculated from a World Health Organization (WHO) risk algorithm based on data from a screening questionnaire and, for some subjects, results from a Dual energy X-ray Absorptiometry (DXA) scan. GPs will be advised of those at high risk and whether to consider treatment.

The control group will have usual care.

Both intervention and control groups will be provided with lifestyle advice through an Arthritis Research Campaign (ARC) booklet on osteoporosis.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

All osteoporosis-related fractures (excluding those of hands, feet, nose and skull), assessed at the annual follow-up visits for 5 years post randomisation.

## **Key secondary outcome(s)**

1. All clinical fractures (including hip fractures)
2. Quality of life, assessed by the European Quality of life (EQ-5D) and Short Form 12 (SF-12) questionnaires at baseline (immediately prior to randomisation), 6 and 12 months and then annually for 5 years post randomisation

3. Psychological anxiety, assessed by the State-Trait Anxiety Index at baseline, 6 and 12 months and then annually for 5 years post randomisation

4. Mortality (assessed annually for 5 years post randomisation)

A process measure will be treatment adherence as ascertained by an ad-hoc questionnaire at follow-up visits.

**Completion date**

30/12/2015

## Eligibility

**Key inclusion criteria**

1. Female
2. Aged 70 to 85 years
3. Able to provide informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

Female

**Key exclusion criteria**

1. Currently known to be on treatment for osteoporosis (other than calcium and vitamin D)
2. Any known co-morbidity that would make entry to the trial inadvisable, in GP's opinion

**Date of first enrolment**

01/02/2007

**Date of final enrolment**

01/07/2009

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University of East Anglia**  
Norwich  
United Kingdom  
NR4 7TJ

**Study participating centre**  
**University of Birmingham**  
United Kingdom  
B15 2TH

**Study participating centre**  
**University of Bristol**  
United Kingdom  
BS2 8DZ

**Study participating centre**  
**University of Manchester**  
United Kingdom  
M13 9PT

**Study participating centre**  
**University of Sheffield**  
United Kingdom  
S57 7AU

**Study participating centre**  
**University of Southampton**  
United Kingdom  
SO16 6YD

**Study participating centre**  
**University of York**  
United Kingdom  
YO10 5DD

**Sponsor information**

**Organisation**

University of East Anglia (UK)

**ROR**

<https://ror.org/026k5mg93>

**Funder(s)****Funder type**

Government

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Arthritis Research Campaign (UK)

**Results and Publications****Individual participant data (IPD) sharing plan**

The trialists plan to make data available on request, subject to terms of data sharing agreement drawn up by University of East Anglia.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

<a href="#">Results article</a>		24/02/2018		Yes	No
<a href="#">Protocol article</a>	protocol	01/10/2012		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes