

# Long-term follow-up of foot pain and osteoarthritis in older people: The Clinical Assessment Study of the Foot (CASF) 7-year follow-up

<b>Submission date</b> 19/09/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Foot pain is common and causes poor balance, falls and difficulty performing everyday activities. Our previous research shows that patients are often frustrated when they see their GP about their feet; 'They say "well, it's just arthritis and old age and just keep popping the pills"'. Foot pain is commonly caused by osteoarthritis (OA) in older people, yet compared with other commonly affected joints such as the knee, hip and hand, there has been much less research on the foot. Most existing foot OA research is limited by focussing on the big toe, ignoring symptoms such as pain, and being undertaken in hospital settings. In our previous study, we sent questionnaires to everyone aged over 50 years registered with four general practices, ensuring our findings are relevant to the majority of people living in the community with painful foot OA. We provided the first estimate of how common painful foot OA affecting the big toe and midfoot is. However, it is not known how often painful foot OA gets worse over time, who is likely to do well or badly, or whether seeing a GP or having treatment such as physiotherapy reduces foot pain and improves function over time. Seven-year follow-up of our existing study of foot pain and OA using questionnaires will: (i) describe for the first time how often foot pain and OA get worse over time, (ii) identify which people are going to do well and understand better why some people get worse and (iii) examine whether seeing a GP or having treatments affects foot pain and function over time. This will help understand how to avoid, slow and treat progressive foot OA, understand which patients might respond to treatment, show us new directions for treatment, and improve health services for people with painful foot OA.

### Who can participate?

This study is a follow-up of participants who have taken part at previous stages. The participants who will be invited to take part will be individuals who completed a postal Health Questionnaire at baseline, who provided written informed consent to further contact at baseline and at 3 years, who provided further written informed consent to further contact and who have not subsequently withdrawn this consent.

What does the study involve?

Participants will be mailed a study information pack containing an invitation letter, a Patient Information Sheet, a Questionnaire and a pre-paid addressed envelope. We will invite participants to complete the questionnaire and return it to us in the pre-paid envelope.

What are the possible benefits and risks of participating?

Although direct benefit for participants is unlikely, we hope that what we learn from the study will lead to better management and patient care and help to inform how best to treat people with joint pain in the future. We do not envisage there to be any significant risks.

Where is the study run from?

The Research Institute for Primary Care and Health Sciences, Keele University

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

October 2018 to March 2019

Who is funding the study?

The National Institute for Health Research - School for Primary Care Research

Who is the main contact?

Michelle Marshall, Research Institute for Primary Care and Health Sciences, Keele University m.marshall@keele.ac.uk

### **Study website**

<https://www.keele.ac.uk/pchs/research/osteoarthritisisandosteoporosis/casf/>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Michelle Marshall

### **ORCID ID**

<http://orcid.org/0000-0001-8163-6948>

### **Contact details**

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

RG-0278-18 v1.0 25-Jul-2018

## **Study information**

### **Scientific Title**

Long-term outcome of foot pain and osteoarthritis in older people. A prospective observational study of foot pain and foot osteoarthritis in the general population: The Clinical Assessment Study of the Foot (CASF) seven-year follow-up.

### **Acronym**

CASF 7-year follow-up

### **Study objectives**

The overall aim of this study is to investigate the long-term course of foot pain and foot osteoarthritis over 7 years in community-dwelling adults aged 50 years and over.

The main objectives of the 7-year follow-up of foot pain and OA in a community-dwelling population are:

1. to describe how often foot pain and OA get worse over time
2. to identify which people are going to do well and understand better why some people get worse
3. to examine whether seeing a GP or having treatments affects foot pain and function over time

### **Ethics approval required**

Old ethics approval format

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

East Midlands - Leicester South Research Ethics Committee; 21/08/2018, 18/EM/0249

### **Study design**

Single-centre observational cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

GP practice

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

Quality of life

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Foot pain, foot osteoarthritis

## **Interventions**

A follow-up postal questionnaire at 7 years for all participants. The questionnaire content will be similar to that used in the CASF study at baseline and 3 years and will be divided into four main sections:

1. General health, psychosocial factors, and social participation
2. Specific health problems including comorbidities
3. Musculoskeletal problems and the presence, duration, location, severity, and impact of foot pain
4. Demographic and socioeconomic characteristics, current employment status and self-reported consultation of GP, and NHS and private physiotherapy, podiatry and chiropody services.

## **Intervention Type**

Other

## **Primary outcome measure**

Impact of foot pain assessed using Manchester Foot Pain and Disability Index at 7 years

## **Secondary outcome measures**

1. Foot pain location identified using the Garrow foot manikin
2. Foot pain duration
3. Foot pain intensity assessed using a numerical rating scale (NRS)
4. Foot pain persistence assessed using number of days with pain
5. Foot pain severity assessed using the Chronic Pain Grade Scale (CPGS)
6. Symptom satisfaction using questions adapted from the instrument by Cherkin 1996.
7. Self-reported consultations for foot pain in past 7 years
8. Self-reported treatments and service for foot pain in past 7 years
9. General health assessed using the Short Form-12 (SF-12) health survey
10. Physical functioning assessed using the Short Form-36 (SF-36) health survey
11. Participation restriction assessed using the Keele Assessment of Participation questionnaire
12. Anxiety and depression using the Hospital Anxiety and Depression Scale
13. Body pain location identified using a manikin
14. Self-reported co-morbidities
15. Presence, side and duration of hand, knee and hip pain assessed using single-item questions in the questionnaire

All outcomes will be assessed at 7 years.

## **Overall study start date**

01/04/2018

## **Completion date**

31/03/2019

# Eligibility

## Key inclusion criteria

1. Registered with one of the four participating local general practices
2. Aged 50 years and over at the time of baseline survey
3. Member of the cohort who completed a postal Health Questionnaire at baseline and provided written informed consent to further contact at baseline
4. At 3 years provided further written informed consent to further contact and has not subsequently withdrawn this consent.

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

2212

## Total final enrolment

560

## Key exclusion criteria

1. Died since last follow-up (3 years for survey cohort participants or 54 months for clinic cohort participants)
2. Departures since the last follow-up (survey cohort only, 3 years for survey cohort)
3. Became unable to complete brief questionnaire or inappropriate to invite to take part – e.g. significant cognitive impairment, dementia, severe/terminal illness, as judged by their GP prior to mailing.

## Date of first enrolment

01/10/2018

## Date of final enrolment

04/01/2019

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Research Institute for Primary Care & Health Sciences**  
Keele University  
Keele, Staffordshire  
United Kingdom  
ST5 5BG

## Sponsor information

### Organisation

Keele University

### Sponsor details

Directorate of Engagement & Partnerships, Innovation Centre 2, Keele University  
Keele, Staffordshire  
England  
United Kingdom  
ST5 5NH

### Sponsor type

University/education

### ROR

<https://ror.org/00340yn33>

## Funder(s)

### Funder type

Not defined

### Funder Name

NIHR School for Primary Care Research

## Results and Publications

### Publication and dissemination plan

The results of this study will be disseminated at high profile national (British Geriatrics Society, UK College of Podiatry) and international (e.g. American College of Rheumatology (ACR), Osteoarthritis Research Society International (OARSI)) conferences and through publication in high-quality peer-review journals (e.g. Journal of Gerontology, Annals of the Rheumatic Diseases). In addition, the Arthritis Research UK Primary Care Centre has a commitment to local dissemination through formal reports, presentations, social media use and newsletters to clinical commissioners, practices and participants. Other forms of dissemination include national

Best Practice Days held at the Centre at Keele University annually, articles on the Research Institute's website, leaflets and posters for general practices, podiatry and physiotherapy clinics, and presentations to community groups and health service commissioners and providers.

We also want to work with our existing Advisory Research User Group to consider additional ways of disseminating findings beyond the traditional academic routes including more patient-focused outlets such as through local radio or newspapers, Twitter, Blogs and Podcasts.

### **Intention to publish date**

01/08/2021

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request through liaison with Michelle Marshall; Research Institute for Primary Care and Health Sciences, Keele University; m.marshall@keele.ac.uk. The Research Institute for Primary Care & Health Sciences, in collaborations with Keele CTU, has established data sharing arrangements to support joint publications and other research collaborations. Applications for access to anonymised research datasets are reviewed by the centre's Data Custodian and Academic (DCAP) Committee to new analysis being proposed. A decision regarding access to the data is made subject to Health Research (HRA) approval first provided for the study, the permissions set by the study sponsor, study funder and in accordance with Data Protection and Research Governance procedures.

### **IPD sharing plan summary**

Available on request

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		21/11/2021	02/02/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No