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

Submission date
19/09/2018

Recruitment status
No longer recruiting

Registration date
21/09/2018

Overall study status
Completed

Last Edited
02/02/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Not defined

Funder Name
NIHR School for Primary Care Research

Results and Publications

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?
Results article		21/11/2021	02/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes