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Feasibility of the use of a 'barometer of foot health' for arthritis

Submission date
13/01/2020

Recruitment status
Stopped

Registration date
22/01/2020

Overall study status
Stopped

Last Edited
05/10/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
20 million people in the UK have some form of arthritis. Walking is encouraged for healthy lifestyles, however debilitating foot pain (linked with falling, tripping, weight gain and social isolation) may result in patients 'walking through foot pain' to manage problems such as arthritis or heart disease. Confusion exists over accessing foot-care services as there are no recommendations to show what foot care people with arthritis need. Some patients report that "doctors only refer people with diabetes". As a result many people with arthritis don’t receive foot care which may inhibit a healthy and active lifestyle because they have trouble walking. This study forms the final stage of a programme of work in which Professor Bowen has led a team of researchers undertaking extensive research to find out the best way of treating foot problems for people who have arthritis. The team has analysed all previous work published about foot health and analysed a UK wide NHS doctor database to understand where doctors refer patients and what services are available to support good foot health for people who have arthritis. In addition, the team has analysed patient, podiatrist, doctor and commissioner experiences of management of foot pain for people who arthritis. From this work, the researchers discovered that there is a general lack of understanding of how to access treatment for foot problems and a limited understanding of what podiatry services can provide from both patients and doctors. The researchers have therefore developed a guide to foot health services to be used by doctors and patients to support their management of foot health. Within this study, the researchers now wish to test whether our guide to foot health services would improve management of foot pain, specifically for people who have arthritis.

Who can participate?
Adults in the Wessex region who have visited their doctor (General Practitioner) / Practice nurse about foot pain and have arthritis are eligible to participate. the researchers also require people who take part to be able to complete a questionnaire and be happy to do this just after their doctor’s appointment, again four weeks after that appointment and a final questionnaire twelve weeks after the appointment.

What does the study involve?
In this study the researchers will ask participants to complete a questionnaire. They may also be given a leaflet or a booklet that has additional information about foot health management.

The questionnaire focuses on their foot symptoms, the advice that their doctor or practice nurse gave them and if or where/who they were referred to. Other questions that the researchers will ask will be about age, gender, shoes, walking ability and their arthritis. These questions will help us understand more about the characteristics that may link with foot pain. By completing and returning the questionnaire participants will be indicating their consent to continue to participate in this research. Participants will be required to initial some boxes on the consent form confirming this.
Four weeks after participants have completed and returned the questionnaire, a member of the research team will send them a second questionnaire to complete. The questions will be focussed on their foot symptoms and be very similar to the first questionnaire that they completed as the researchers want to know if there are any changes since they visited your doctor or practice nurse.

Eight weeks after they have completed the second questionnaire, a member of the research team will send a third questionnaire to complete. The questions will again be focused on their foot symptoms and be very similar to the first and second questionnaires that they completed as the researchers want to continue to know if there are any changes since they visited your doctor or practice nurse.

At the end of this feasibility trial the researchers do wish to know more about our participants' thoughts on the process of participation. The researchers plan to contact one to two individuals to ask if they would be willing to participate in a final interview about the trial. If their answer is yes, at the end of the final questionnaire there will be a tick box that will ask them if they would be willing to be contacted by telephone for a final end of study interview.

The end of study telephone interview will be more like a conversation than a set of questions with fixed responses. It will last for around 30 minutes to an hour and will take place at a time and place that is convenient for them. With their permission, the researchers would like to make an audio recording of the interview. This is because the researchers want to get an accurate account of what is said and the researcher can concentrate on what they say without being distracted by having too many notes.

What are the possible benefits and risks of participating?
Taking part in this study may not directly benefit participants. The information that the researchers get from this study, however, will help us make recommendations to the National Institute for Health Research and the College of Podiatry UK for the development of a future trial of an optimal foot health intervention pack to help doctors/practice nurses and patients who have arthritis manage foot pain and foot health.
There will be no risk or discomfort to participants as a result from participating in this research. They will be only required to complete three postal questionnaires. Participation will cost them nothing.

Where is the study run from?
The study is sponsored by the University of Southampton and is organised by investigators from the Universities of Southampton and Oxford.

When is the study starting and how long is it expected to run for?
October 2019 to September 2020

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
Prof. Catherine Bowen
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2020-000059-11

IRAS number
265543

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43497, IRAS 265543

Study information

Scientific Title
Acceptability and feasibility of the use of a 'barometer of foot health needs' in primary care to signpost people who have arthritis towards appropriate foot health management.

Study objectives
1. A primary care-led 'optimal foot health service information pack' will provide acceptable personalised choices of foot care and timelier referral to the most appropriately trained clinicians

2. The implementation of a larger scale UK wide trial of the 'optimal foot health services information pack' is feasible to be delivered as intended

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/12/2019, London - London Bridge Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8124; NRESCommittee.London-LondonBridge@nhs.net), ref: 19/LO/1587

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Osteoarthritis

Interventions
The OptiFooT study is a feasibility study for a future multi-centred parallel-group randomised superiority trial with 3-month follow-up. The feasibility study has been designed through findings from the two previous OptiFooT study phases that indicated better signposting was required at 'first contact' for access to foot health services for people who have arthritis.

For each ’willing’ GP practice recruitment site an invitation will be sent out to arrange a half-day workshop/training session on the OptiFooT project and reasons for the feasibility trial. During the session, they will receive further d training on the trial procedures and delivery of the intervention, the ‘optimal foot health services information pack’.

30 participants will be recruited over a 6-month period from three GP practices in Solent NHS Trust. 15 will receive an ‘optimal foot health service information pack’ and 15 will receive a ‘usual care foot health leaflet'.

Intervention acceptability and use will be measured at baseline and at follow up at 4 weeks and 12 weeks using postal questionnaires plus study closeout follow up telephone interviews with a small subgroup of participants (n=2-3).

Patients who have arthritis foot symptoms will be identified from participating GP practices by the Practice and/or research staff. Eligible patients will be sent a questionnaire along with a leaflet or a booklet that has additional information about foot health management. The questionnaire focuses on foot symptoms, the advice that their GP or practice nurse gave and if or where/who they were referred to. In completing this questionnaire participants will indicate their consent to continue to participate in this research. In addition, they will be required to initial some boxes on the consent form confirming this. Once participants have completed the questionnaire they will be required to put it into the Free Post envelope and send it back to the research team by Royal Mail. the researchers anticipate that response to these questions will not take participants more than 30 minutes.

A follow-up questionnaire will be sent to willing participants four weeks and twelve weeks after they have completed the first. The follow-up questions will be focussed on their foot symptoms and be very similar to the first questionnaire that they completed as the researchers want to know if there are any changes since they visited their GP or practice nurse.

When the researchers have received all the questionnaires, our research assistant will review the responses. At the end of this feasibility trial, the researchers do wish to know more about our participants' thoughts on the process of participation. the researchers plan to contact two to three participants to ask if they would be willing to participate in a telephone interview about the trial (if participants answer is yes, at the end of the final questionnaire).

At the closeout of the feasibility trial, an evaluation debrief will be held by the research team with clinicians (GPs/practice nurses) and general practice managers from each of the participating general practice sites.

Intervention Type
Other

Primary outcome measure
1. Referral rates and patterns assessed by the total number of referrals, where/who the referrals were to and tests related to foot pain requested by GPs/practice staff throughout the study period.
2. The measurement properties (responsiveness, minimal important difference) of different candidate outcome measures for foot pain, to identify and select the most suitable primary outcome measure for the main trial. Measured using participant self-report questionnaires
3. The acceptability of the 'optimal foot health services information pack' intervention, assessed by telephone interview with a subsample (n=2-3) of participants at 6 months (i.e. end of study period)
4. The acceptability of participating GPs delivering the 'optimal foot health services information pack' intervention as intended, assessed by debrief study evaluation at end of study period
5. The length of time to run the trial will be evaluated. Three-month follow-up was chosen in this feasibility study to allow sufficient time for referrals to be established, however it may be that 3-months is not long enough to assess clinically meaningful change in foot pain

Secondary outcome measures
1. The effect of an 'optimal foot health services information pack' on foot symptom reduction measured by a self-reported questionnaire at baseline, four weeks and twelve weeks
2. Foot pain and disability measured using the Manchester Foot Pain and Disability Index (MFPDI) at baseline, four weeks and twelve weeks
3. Referral to other clinicians, referral time to be seen, self-reported early life and current foot

and knee alignment, footwear type and footwear habits assessed by self-reported questionnaire at baseline, four weeks and twelve weeks
4. Levels of physical activity, effect of osteoarthritis (joint site/s, history, surgical history, and current medications), and any other medical conditions assessed by self-reported questionnaire at baseline, four weeks and twelve weeks

Overall study start date
01/10/2019

Completion date
30/09/2020

Reason abandoned (if study stopped)
due to the COVID pandemic and lockdown this study was unable to continue and had to be shut down in April 2020 after only the baseline data was collected.

Eligibility

Key inclusion criteria
1. Aged 18 or older
2. Accessing their GP practice with an episode of foot pain
3. Have clinician diagnosed OA (ie OA documented as a medical condition affecting their knees, hips, hands or feet).
4. Be literate in English and able to complete the questionnaires and pain diary used in this study
5. Be willing to complete follow up questionnaires at 3 months
6. Living in the Wessex region

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment
18

Key exclusion criteria
1. Inflammatory arthritis (e.g. rheumatoid arthritis)
2. Foot and/or ankle ulceration
3. Currently under the care of a foot and ankle surgeon or awaiting foot and ankle surgery

Date of first enrolment
22/01/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road
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United Kingdom
SO19 8BR

Sponsor information

Organisation
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Sponsor type
University/education

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http://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: CDF-2015-08-032

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
HRA research summary			28/06/2023	No	No