Peer mentorship in osteoarthritis

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
08/05/2017		[X] Protocol		
Registration date 22/05/2017	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category Musculoskeletal Diseases	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is the most common form of arthritis. It occurs when the protective cartilage on the end of bones wears away, causing the bones to rub against one another, which can cause stiffness, pain and a reduction in a person's range of movement. The physical symptoms can greatly reduce quality of life in sufferers, even leading to social isolation. The government has highlighted the need for individuals to manage their long-term condition themselves by providing the support for people to take care of their own health. There is evidence that 'peer support' can assist with improving management of long-term conditions. A peer mentor is usually someone who has the condition but has undergone training to be able to provide focused assistance and mentorship to someone who also has the condition. Peer mentorship appears to work well with supporting individuals with other conditions such as diabetes and in mental health but it hasn't been developed or tested for individuals with osteoarthritis, only for inflammatory arthritis. The aim of this study is to develop and evaluate the feasibility of a peer support model (OA mentor) to improve self-management of individuals with OA.

Who can participate?

Adults aged 55 and over who have confirmed OA of the knee or hip.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive an information booklet, and a researcher will visit the participants to guide them through this which provides useful tips on how to manage the symptoms of osteoarthritis. Those in the second group receive weekly visits for eight weeks from a trained volunteer (known as a 'peer mentor') who works with participants to help them manage their osteoarthritis more effectively. This involves visiting the participant at home for up to one hour each week over eight weeks. For whichever type of support the participants receive, a questionnaire is completed to collect information about length of time with OA, medication, pain, mobility, mood and quality of life initially, at eight weeks and then again six months later. The participants are visited by a member of the research team for questionnaire completion at eight weeks; and at six months the participants receive the questionnaire by post to complete.

In order to assess the acceptability and feasibility of the peer mentor programme, a sample of participants take part in face to face interviews six months after the end of the study. In addition, a selection of the peer mentors are also interviewed after delivering the eight week programme.

What are the possible benefits and risks of participating?

Participants may find that there are no direct benefits to taking part in this research. However, this research will be helping to try out these different types of support and to see whether these are of any benefit. If it is found that one type of support is showing positive benefits over the other, it will be the intention to develop this further to see what exactly the benefits are in receiving the booklet as compared to having a volunteer mentor to support individuals with their osteoarthritis. There are no notable risks involved with participating.

Where is the study run from? Chapel Allerton Hospital (UK)

When is the study starting and how long is it expected to run for? May 2017 to February 2020 (updated 05/03/2020, previously: January 2020)

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

Who is the main contact? Professor Gretl McHugh q.a.mchugh@leeds.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Gretl McHugh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Developing peer Mentorship to Improve self-management of Osteoarthritis: A feasibility study (aMIgO)

Acronym

aMlgO

Study objectives

Study aim:

The aim of this research is to develop and evaluate a peer support model (OA mentor) to improve self-management of individuals with osteoarthritis through a feasibility study.

Hypothesis:

A peer mentorship intervention can be delivered at home and is acceptable to individuals with osteoarthritis; and the protocol for a definitive randomised controlled trial is feasible in terms of recruitment and retention and collection of relevant outcome data.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West - Greater Manchester South Research Ethics Committee, 18/05/2017, ref: 17/NW /0238

Study design

Randomised; Interventional; Design type: Process of Care, Education or Self-Management, Complex Intervention

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Osteoarthritis of the hip or knee

Interventions

Feasibility study:

Patients recruited to the study will be randomised into one of two arms, standard care or the intervention package. Random allocation sequences with varying block length stratified by educational level will be generated by the statistician using nQuery Advisor 6.0.

Control group: Participants receive standard care. This involves receiving usual advice and follow-up for their osteoarthritis (OA) with a leaflet provided about their OA.

Intervention group: Participants receive the peer mentor intervention. This involves weekly visits by the OA mentor for 8 weeks, providing guided support which will focus on: exercises for OA; information about OA, healthy eating, pacing; pain management and learning about goal setting. The individual will be assessed by the peer mentor on the first visit and will work with the mentor to ensure support and mentorship is tailored.

Follow up involves participants to complete a questionnaire at 8 weeks with support from the member of the research team visiting the participant at home; the participant will then received the final follow-up questionnaire at six months and asked to return the completed questionnaire by post or email.

Nested Qualitative study:

To assess the acceptability and feasibility of this peer-mentorship intervention, a qualitative study will be undertaken and will interview a purposive sample of the intervention participants (n~15) after completion of the 6-month feasibility trial follow-up. Face-to-face interviews will be conducted with the sample of participants and will gather data on the usefulness and how acceptable has been and whether the support sessions were done at the right intervals and using an appropriate approach. We will also interview the 7 volunteer peer Osteoarthritis mentors using semi-strutted interview to get information on the mentorship and training provide. These interviews will be undertaken after the 8 week mentorship programme they deliver.

Intervention Type

Other

Primary outcome measure

The primary outcome will be informed by the results of the feasibility study. Candidate variables for the primary outcome will be:

- 1. Self-management as measured by the Partners in Health Scale Questionnaire at baseline, 8 weeks and 6 months
- 2. Physical function as measured by the Western Ontario and McMaster's University (WOMAC) Osteoarthritis Index questionnaire at baseline, 8 weeks and 6 months
- 3. Pain as measured by the Western Ontario and McMaster's University (WOMAC) Osteoarthritis Index questionnaire at baseline, 8 weeks and 6 months
- 4. Health status as measured by the EQ-5D-5L (EuroQoL Group) at baseline, 8 weeks and 6 months
- 5. Social support as measured by the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline, 8 weeks and 6 months
- 6. Self-efficacy as measured by the Arthritis Self-Efficacy Scale at baseline, 8 weeks and 6 months
- 7. Anxiety as measured by the Hospital Anxiety and Depression Scale (HADS) at baseline 8 weeks and 6 months

Secondary outcome measures

Other feasibility outcomes

- 1. Recruitment rate will be recorded as the number of eligible participants who consent to participate in the study
- 2. attrition rate will be recorded as the number of participants who consent to participate who remain in the study until the end of follow-up at six months
- 3. Health-related resource use will be recorded as mean health related resource use collected using questions pertaining to health and social care usage at 8 weeks and 6 months

Qualitative study:

Evaluation of the acceptability peer-mentorship intervention as explored by the qualitative interviews of intervention participants after completion of the 6-month feasibility trial follow-up.

Overall study start date

01/05/2017

Completion date

24/02/2020

Eligibility

Key inclusion criteria

- 1. Aged 55 years or over
- 2. Male and female
- 3. Confirmed osteoarthritis of the hip or knee

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment

50

Key exclusion criteria

- 1. Patients who are experiencing other rheumatologic conditions
- 2. Other serious health conditions that prevent participation
- 3. On the waiting list for a hip or knee replacement

Date of first enrolment

01/09/2017

Date of final enrolment

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Chapel Allerton Hospital

Chapeltown Road Leeds United Kingdom LS7 4SA

Study participating centre Leeds Community Healthcare NHS Trust

Wortley Leeds United Kingdom LS12 5SG

Sponsor information

Organisation

University of Leeds

Sponsor details

Faculty of Medicine & Health Research Office Level 9 Room 9.29 Worsley Building Leeds England United Kingdom LS2 9JT +44 113 343 4897 governance-ethics@leeds.ac.uk

Sponsor type

University/education

ROR

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

Publication and dissemination plan

Planned publication in a high-impact peer review journals and this will be during late 2020. In addition, there are plans which include working with Associated Charities, the public, health professionals and policy makers to work with them in developing a strategy for wider community engagement.

Intention to publish date

30/05/2021

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/07/2021	26/07/2021	Yes	No
Protocol file		15/05/2019	12/08/2022	No	No