Study Protocol

Developing peer **M**entorship to **I**mprove self-management of **O**steoarthritis: A feasibility study **(aMIgO study)**

Aims and objectives

The overall aim of this research is to develop and trial a peer support intervention (OA mentor) to improve self-management of osteoarthritis (OA).

The specific objectives of the research are:

1) To develop peer mentorship training for the OA mentors;
2) To train volunteers to deliver peer-to-peer support to individuals with OA;
3) To assess the feasibility of delivering peer mentorship (OA mentor providing 8 weekly sessions) at home;
4) To assess the acceptability of this intervention to individuals with OA;
5) To assess the feasibility and acceptability of the key trial components (timing for delivering the intervention; recruitment process; and outcome measurement tools);
6) To understand eligibility, consent, recruitment and retention rates and rate of recruitment;
7) To estimate completion rates for proposed effect outcome measurement tools and resource use instruments at baseline and follow up;
8) To determine the sample size needed for a definitive randomised control trial;
9) To estimate the cost of delivering the intervention;
10) To provide a descriptive report on the types of resources used (and the number of contacts) and the impact on HRqOL.

Background to Research

The prevalence of osteoarthritis (OA) is high with over 30% of people aged 45 years or older having OA.[1] General Practitioners (GPs) manage most OA in primary care and a third of people over the age of 45 years have sought treatment from their GPs for OA.[1] Therefore, the cost burden and impact on primary health care is high and will continue to be so unless we find alternative approaches to management. The main symptoms associated with OA include high levels of pain, stiffness and reduced physical functioning.[2,3] Quality of life is also adversely affected in individuals with OA.[3,4]

The development and implementation of guidelines on OA from the National Institute for Health and Care Excellence (NICE)[2] has provided some guidance towards improving the management of OA. However, research evidence still indicates that the management of OA requires improvement.[2,4] Our previous research has revealed that pain is poorly managed in individuals with osteoarthritis.[3,6,7] Individuals did not appear to be taking appropriate levels of analgesia in relation to levels of pain with reluctance to discuss pain or their

OA with their general practitioner.[3] Their knowledge and skills regarding how to effectively manage their pain was also poor.[6] Patients identified the need for information and the opportunity to speak to someone in order to provide them with the knowledge and information to help them manage more effectively the symptoms associated with their osteoarthritis.[7]

A meta-analysis of 16 studies found that both patient education and exercise regimes for patients with OA of the knee had a modest yet clinically important influence on individuals' well-being.[8] In terms of the cost-effectiveness of self-care support interventions, a systematic review found little evidence to support these interventions, though the quality of studies was frequently poor and further research is required.[9] There has been considerable investment in the '*Expert Patient Programme*'[10], which focuses on empowering and educating patients to take a lead in managing their chronic disease. A national evaluation found some positive impact on self-efficacy from attending this programme and that the intervention was likely to be cost-effective.[11]

Evidence from other self-care intervention programmes suggest the need to focus on increasing knowledge including patients' experience of managing their condition.[12] Findings from the applicants' research on OA highlight the need to improve knowledge, confidence and skills in the area of pain, exercise and weight management.[2,6]

Peer support models to improve self-management of long-term conditions have grown considerably and are seen to be effective interventions.[13-15] These peer support interventions usually involve building and sharing the knowledge and experience that their peers with the same condition can offer.[16] Examples of peer support models include: face-to-face self-management programmes led by peer leaders who have the condition; peer coaching usually focusing on communication; and peer mentoring where the mentor assumes more of the health professional role.[16] Telephone based peer support and web and email based self-management[17] are also popular ways of providing support.[18] The social support side of peer support interventions cannot be underestimated and there is evidence that higher levels of social support especially those that are geared specifically for the long-term condition are associated with better self-management.[13] Peer mentoring has been embedded in an exercise programme for older adults and the findings were indicative of greater exercise programme adherence.[19] Other peer support models have been shown to effectively deliver pain self-management strategies in a study of veterans with chronic pain.[15] However, from this peer support intervention, there were a number of identified barriers such as motivation and engagement in the intervention with the facilitators being having someone who has the condition and having a shared identity.[20] It is also important that peer support interventions have clear and realistic goals and the training and support for peers is adequate.[18] These aspects all need to be considered when developing future peer support interventions.

There is considerable evidence of peer support models for improving self-management of chronic pain and conditions such as heart failure.[15, 21] For arthritis sufferers, there was only study (in North America) identified, which examined the feasibility and potential benefits of early peer-to peer mentoring to improve health and quality of life in individuals with early inflammatory arthritis. This study found some positive results, concluding that peer-to-peer mentoring (face-to-face or telephone) had a place in supplementing rheumatology care.[22] There have been no studies identified where '*peer mentorship'* was used for supporting self-management of individuals with OA, although there are other valuable programmes such as '*Expert Patient*' programmes.[10-11] There has also been some recent initiatives by Arthritis Care UK such as, '*Arthritis Champion'* pilot schemes which have been implemented in a few locations in the UK. The aim of the '*Arthritis Champion*' is to increase the awareness of arthritis and self-management of OA. These have a focus on personal goal setting and care planning using an arthritis champion to provide either face-to-face, telephone support or group telephone support with individuals who also suffer from arthritis.[23] The goal of these are to assist with providing self-management support in terms of information provision. Evaluation of these pilot sites is still taking place using observational methods. In Northern Ireland, a lottery-funded initiative, '*Staying Connected*' provides social support to the over 60's, who have arthritis and/or other long-term conditions. These volunteers are trained to provide support and advice using a person-centred approach to goal setting with similar sessions to Arthritis Care. Anecdotal evidence suggests a value in this service, with a small-scaled evaluation still under way. However, these schemes don't follow a peer mentorship model and do not address some key self-management requirements in individuals with OA.

With our ageing population, increasing prevalence of OA and the over-burden on GPs, we need to develop robust and sustainable interventions, with a focus on improving self-management so individuals can manage effectively their OA. The development and evaluation of a peer-mentorship model for OA is necessary to determine whether this is a way forward in achieving better outcomes for individuals with OA, which this project aims to address.

Research Plan

This study is designed as a feasibility study using the MRC complex framework as the theoretical basis.[24] A literature review of peer support interventions and training packages and interviews with patients and healthcare professionals and individuals representing arthritis organisations will guide the development of the peer mentor programme. Peer mentors will be trained and will be paired up with a mentee who will receive face-to-face support over 8 weeks. An exploratory feasibility trial will be conducted which will involve both qualitative and quantitative data collection. This will test the feasibility and acceptability of this intervention; to assess the potential of this peer mentoring intervention for OA patients at home; and to refine the intervention and trial procedures for a definitive RCT.

The study has been developed as two phases: Phase 1 will be developing the intervention and delivering the peer mentorship training; and Phase 2 will be the feasibility study to inform the Randomised Controlled Trial (RCT).

Phase 1a: Developing the peer mentorship training (objective 1):
A review of the literature using systematic approaches to searching and synthesising the literature of peer-support mentorship in existence for musculoskeletal conditions will be undertaken. An analysis of the types of peer-mentorship models and also training packages will be undertaken using a meta-synthesis approach.[25] We have already done a scoping search and identified relevant approaches to peer support and also the recommended training of peer support for supporting long term conditions.[26,27] In addition, there is currently national training by Arthritis Care UK and close contact has already been established and we have the knowledge about what type of training programme they deliver and may incorporate elements of this training; but we will also follow NICE guidance[2] for the evidence base around core treatments in managing OA, so will ensure that topics and information around exercises, weight management; and medication support is provided. 'Pacing' is an important aspect for individuals who suffer from osteoarthritis therefore, this will be important for the OA mentors to be trained in and will be one of the areas in the training programme. One of the applicants, an NHS Physiotherapist, has expertise in 'pacing' techniques and will support this element and will also provide the training in gentle exercising with OA. We will then hold 'expert review' sessions and present our proposed training programme to a number of patients with OA (n=5), health professionals (n=5) and the key arthritis organisations (n=2) to discuss the proposed peer mentorship training, so refinements and adjustments can be made to the training programme.

Phase 1b: Delivering the peer mentorship training (objective 2)
Once the training package is finalised in Phase 1a, a qualified trainer, supported by our clinical co-applicants who have expertise in pain management, exercise and pacing, will deliver the two-day training programme to volunteer peers mentors (Phase 1b). To recruit volunteer peer mentors, we will work with our PPI group in Leeds Musculoskeletal Biomedical Research Unit (LMBRU) and local arthritis groups to recruit the 7 volunteers needed to do the training and to support Phase 2 -the delivery of the intervention. We will ensure that the OA mentors have full Disclosure Barring Service (DBS) checks and this will be done prior to attending the training programme. We envisage the peer mentors to have osteoarthritis. Findings from a study exploring peer support found that having a peer mentor who has the long-term condition and is managing their condition was a necessary element for success.[26] We will also use the excellent guidance and support available from the Mental Health Foundation who run courses for peer support workers which develops the knowledge and skills and confidence in delivering peer support.[27] We will also have a peer co-ordinator who will provide support to the peer mentors, provide co-ordination of the volunteer peer mentors and ensure safeguards are in place.

Phase 2a: Feasibility trial of peer mentorship for individuals with osteoarthritis:

Hypothesis for future definitive RCT: Peer mentorship (OA mentor) will enable better self-management of osteoarthritis, resulting in improvements in self-management ability, self-efficacy, anxiety, social support and health-related quality of life as well as potential reductions in health related resource use.

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

Aim: To evaluate a peer mentorship intervention for individuals with OA .
The specific objectives (as above) to be achieved will be*:* assessing the feasibility of delivering the intervention (OA mentor providing 8 visits) at home (objective 3); assessing the feasibility and acceptability of the key trial components (timing for delivering intervention; recruitment process; outcome measurement tools) (objective. 5); understanding eligibility, consent, recruitment and retention rates and speed of recruitment (objective. 6); estimating completion rates for proposed effect outcomes measurement tools at baseline and follow up (objective 7) and determining the sample size needed for the definitive randomised control trial (objective. 8). We will estimate the cost of the intervention (objective 9) and provide a description of the impact on resource use and HRQoL (objective 10).

Study Design: Feasiblity RCT with nested qualitative study*.*

Sample: Individuals 55 years and over with confirmed OA of the hip or knee will be recruited. Assuming an attrition rate of 20%, a starting figure of 25 per arm will be sufficient to have 20 participants in each arm by the end of the trial, and this has been recommended as acceptable for a feasibility or pilot trial assuming at worst a medium effect size (Cohen’s d=0.2) for a continous outcome and 80% power.[28] Patients with OA who have a confirmed diagnosis of lower limb OA will be recruited for the study. One large NHS acute Trust (Leeds Teaching Hospitals NHS Trust) and one large NHS community trust (Leeds Community Healthcare NHS Trust) will be involved in the study. Based on the applicants’ experience from previous studies of OA, we will need to identify 110 patients, and following exclusions/refusals, this will ensure an adequate number of patients to be randomised to receive usual care (n=25) and patients to receive the peer mentoring intervention (n=25). To reduce costs, random allocation sequences with varying block length stratified by educational level will be generated.

Exclusion criteria: Patients who are experiencing other rheumatologic conditions; other serious health conditions that prevent participation; and who are on the waiting list for a hip or knee replacement will be excluded from the study.

Method of data collection: Patients recruited to the study will be randomised into one of two arms, standard care only or standard care plus the intervention package. As there is an educatonal/information aspect to the intervention, stratified randomisation on the basis of educational level assessed at baseline, will be undertaken to test out the feasibility of this process for the definitive RCT.

Details of the Intervention: Standard care will be the usual advice and follow-up for their OA with a leaflet provided about osteoarthritis published by Arthritis Research UK and information about local support groups. The peer mentor intervention (to be finalised in Phase 1a), but is envisaged to be weekly visits by the OA mentor for 8 weeks, providing guided support, which will focus on: exercises for OA; information; healthy eating, pacing; pain management; and learning about peer support techniques, such as goal setting. The individual will be assessed by the peer mentor on the first visit and will be able to work with their OA mentor to ensure their support and mentorship is tailored.

The specific role of the OA mentor will be to provide:

- social support (encouragement and help with social isolation);
- information and training (developing individual's self-management skills and guidance on exercises for OA; pacing; healthy eating; pain management); and goal setting.

From preliminary discussions with PPI, a key issue was that face-to-face home visits (or convenient location to the participant) would be the most appropriate way to deliver the intervention for this group of individuals as many will be older adults with OA and have restrictions with mobility.

Data Collection: Data will be collected by self-completed questionnaires. The data collection process will be standardised between participants in the intervention and control groups. The researcher will visit all participants at baseline to provide the baseline questionnaire, Arthritis Research UK leaflet and information about local support groups. Participants will be asked to complete the baseline questionnaire and return it to the researcher at that visit. Participants will not be informed of their group allocation until after they have completed and returned the baseline questionnaire. All participants will receive follow-up questionnaires by post at 8 weeks and 6 months and will be asked to return them in the stamped addressed envelopes provided. A second reminder by post two weeks later for non-responders will be undertaken. In addition, we will also follow-up by telephoning those not returning the questionnaires to further increase our response rate.

A structured questionnaire will be used to collect information on demographics (including education level), pain medication, consultation episodes, and service usage and provision. Validated tools will be used to assess biomedical and psychosocial outcomes. The following validated tools will be used:

- Self-management: Partners in Health Scale;[29]

- Social Support: Multidimensional Scale of Perceived Social Support (MSPSS);[30]
- Severity of OA: Western Ontario and McMaster's University (WOMAC) Osteoarthritis Index[31] a specific tool for patients with osteoarthritis measuring pain, physical functioning and degree of stiffness;
- Self Efficacy: Arthritis Self-Efficacy Scale (ASES);[32]
- Anxiety and Depression: Hospital Anxiety and Depression Scale (HADS);[33]
- Health status: EQ-5D-5L (EuroQoL Group)[34]- a standardised measure of health providing a simple, generic measure of health status for clinical and economic appraisal;

The chosen measurement tools have been selected for their validity, reliability and responsiveness to detect change. They also do not take long to complete and this was a key aspect to take into account following PPI feedback. The provisional primary outcome measure will be self-management as measured by the Partners in Health Scale.[29] Secondary outcomes will be the MSPSS, WOMAC physical function, pain and stiffness subscales, the Arthritis Self-Efficacy Scale, the EQ-5D-5L scale, and the HADS anxiety scale. We will also collect data on the number of contacts made and the duration of these contacts to generate an estimate of the cost of delivering the intervention.

Phase 2b: Nested qualitative study*:* To assess the acceptability and feasibility of this peer-mentorship intervention (Objectives 3 & 4), we will undertake a nested qualitative study and will interview a purposive sample of the intervention participants (n~15) following completion of the peer mentor intervention. This qualitative work is essential for the evaluation of the peer mentorship intervention before the development of the definitive RCT. Face-to-face interviews will be conducted with the sample of the participants and will gather data on the usefulness and how acceptable the intervention 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 OA mentors using semi-structured interviews to get information on the mentorship and training provided. This will be undertaken after the 8 week mentorship programme they delivered.

Data Analysis*:*

Phase 2a: Feasibility RCT: Quantitative responses to the questionnaires at baseline, 8 weeks and 6 months will be analysed using IBM SPSS Statistics and will provide the evidence on potential effectiveness of the intervention. Data will be double-entered and compared within SPSS to check for data entry errors. Attrition will be examined at 8 weeks and 6 months to see if there are factors that may be systematically affecting drop-out. The feasibility RCT will also provide the data to estimate recruitment and retention rates and the sample size needed for a definitive RCT. The observed change in the feasibility study will be taken into account along with differences reported in other studies when deciding what difference will be clinically important for a main trial. We will also have data on when is the best time to deliver the intervention and whether the peer-mentorship sessions have the potential to have an impact. The primary analysis will tentatively assess the difference in self-management scores between arms at six months using analysis of covariance to adjust for baseline scores. Secondary outcomes will be analysed in a similar manner. From the 6 month data, the magnitude of changes from 8 weeks in outcomes will be computed with 95% confidence limits to assess, in the treatment arm, to what extent the effect persists. As the feasibility trial will not be powered to detect statistically significant effects, the main analyses will be descriptive and involve estimation of confidence intervals and effect sizes for differences between groups adjusted for baseline values.[35] Similarly, for the health economic analysis we will provide a description of the impact of the intervention on HRQoL and mean health related resource use as well as uncertainty around these estimates.

Phase 2b: Nested Qualitative Study: Interviews will be digitally recorded (with permission from participants), transcribed and data managed using NVivo, a qualitative software programme to assist with the organisation and coding of data. Data will be analysed using Framework Analysis.[36] Framework analysis provides a systematic approach to sifting, charting and sorting material using the key themes and issues. To ensure trustworthiness and rigour of the analysis, this will be assured by double coding of data as a validity check and exploring alternative interpretations of the data and by discussion with members of the advisory group.

Research timetable

This is a 33-month project. We will ensure that ethical approval and research governance arrangements are in place prior to the start of this project.
The study is designed in two phases.
Phase 1a – Intervention Development (months 1 to 8). We have allowed sufficient time for the expert reviews and refinements to the intervention.
Phase 1b -Recruitment and training of volunteers (months 8 to 14). As we need to recruit and DBS check our peer volunteer mentors, we have allocated 7 months for this given that DBS checks can take 3 to 4 months. We will then be in a position to provide the 2-day training.
Phase 2: Feasibility study (months 14 to 27). We will recruit the patients for the study and deliver the intervention (over 8 weeks), with a follow-up questionnaire at 6 months post-intervention. As this feasibility study requires a small number of participants, this is achievable in our timeframe.
The qualitative interviews (including analysis) will be undertaken months 22 to 30. Data analysis for the feasibility study will be undertaken months 27 to 30.
Write-up & Dissemination (months 31-33): We have allowed two months for final write-up and dissemination.

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