School of Healthcare

Research Protocol

FULL / LONG TITLE OF THE STUDY

Remote osteoarthritis peer-mentorship for socioeconomically underserved people

SHORT STUDY TITLE / ACRONYM: **R**emote peer-**M**entorship **I**n **O**steoarthritis (RaMIgO)

PROTOCOL VERSION NUMBER AND DATE: v1.0_19April2023

RESEARCH REFERENCE NUMBERS

IRAS Number:	326583
SPONSORS Number:	127064 (University of Leeds)
FUNDERS Number:	OBF/FR-000023819

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

Date:
19/04/2023

Name: (please print): **Professor Gretl McHugh**

ABBREVIATIONS

Abbreviation	Term
ADAPT	Adapting interventions to new contexts
CI	Chief Investigator
GDPR	General Data Protection Regulation
HRQoL	Health-related quality of life
IOs	Framework of Implementation Outcomes
MSK	Musculoskeletal
NIHR	National Institute for Health and Care Research
NPT	Normalization Process Theory
OA	Osteoarthritis
PAG	Project Advisory Group
PPI	Patient and Public Involvement
PPIE	Patient and Public Involvement and Engagement

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KEY STUDY CONTACTS

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Sponsor	University of Leeds
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	Nuffield Foundation in partnership with Versus Arthritis
Key Protocol Contributors	Professor Gretl McHugh
Committees	Project Advisory Group and Patient Public Involvement Group: Contact Elizabeth Lavender: email: e.c.lavender@leeds.ac.uk Phone number: 0113 3431346

STUDY SUMMARY

Study Title	Remote osteoarthritis peer-mentorship for socioeconomically underserved people
Internal ref. no. (or short title)	RaMIgO
Study Design	Pragmatic mixed-methods feasibility study with three phases: • Phase 1: intervention development (qualitative research and participatory approaches) • Phase 2: intervention set-up (recruiting and training volunteer peer mentors) • Phase 3: process evaluation (mixed methods study)
Study Participants	Phase 1: ~15 Participants who have hip and/or knee osteoarthritis and consider themselves to be experiencing socioeconomic disadvantage for focus groups/interviews; two participatory workshops each with approximately 3 lay people, 3 PPI members and 2-3 representatives from community groups for each workshop. Phase 2: 10-15 peer mentors to attend training course Phase 3: 30 participants with hip and/or knee osteoarthritis who consider themselves to be experiencing socioeconomic disadvantage to receive the remote peer-mentorship intervention from trained peer mentors. All 30 participants will be invited to participate in two semi-structured interviews (on completion of OA peer-mentorship intervention; and 6 months

	following completion). Peer mentor interviews: all peer mentors will be invited to participate in a single interview.
Planned Size of Sample (if applicable)	Phase 1: ~15 participants for focus groups (or if preferred interview); participatory workshop (public engagement activity) with ~15 people. Phase 2: Not applicable – training of 10-15 volunteers (to become peer mentors) Phase 3: 30 participants receiving peer-mentorship; all 10-15 peer mentors invited for an interview.
Follow up duration (if applicable)	Phase 3: 6-month follow-up through an additional interview.
Planned Study Period	01/02/2023 – 30/4/2025
Research Question/Aim(s)	To develop and assess the feasibility and perceived usefulness of a remote OA peer-mentorship intervention for people with hip and knee OA who are experiencing socioeconomic disadvantage.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Nuffield Foundation in partnership with Versus Arthritis	Financial

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor for the project is the University of Leeds who will take on overall responsibility for the study.

A representative for each of the funders will be invited to attend the Project Advisory Group Meetings. Any publications resulting from the study will be sent to Nuffield Foundation and Versus Arthritis for information and their record.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Project Team Group: All co-applicants will be involved in monthly project team meetings for the duration of the project and will be involved in the key decisions regarding the project.

The members of the Project Team include:

- University of Leeds: Professor Gretl McHugh, Professor Mark Conner, Dr Anna Anderson, Elizabeth Lavender;
- University of Aberdeen: Dr Heidi Gardner;
- Patient and Public Involvement (PPI): Susan Barry, Linda Eckersley.

Patient and Public Involvement (PPI) Group: This group will provide PPI into all stages of the project, including reviewing study documentation; advising on plans for recruitment and dissemination. Members will include approximately six lay representatives, including two PPI co-applicants as co-chairs of this group.

Project Advisory Group (PAG): The PAG consists of independent members who will operate to agreed ‘Terms of Reference’. The PAG will support/challenge decisions and provide feedback about communication and dissemination plans for project outputs. The membership may be adapted if required to accommodate changes in individuals' circumstances and the needs of the project.

PROTOCOL CONTRIBUTORS

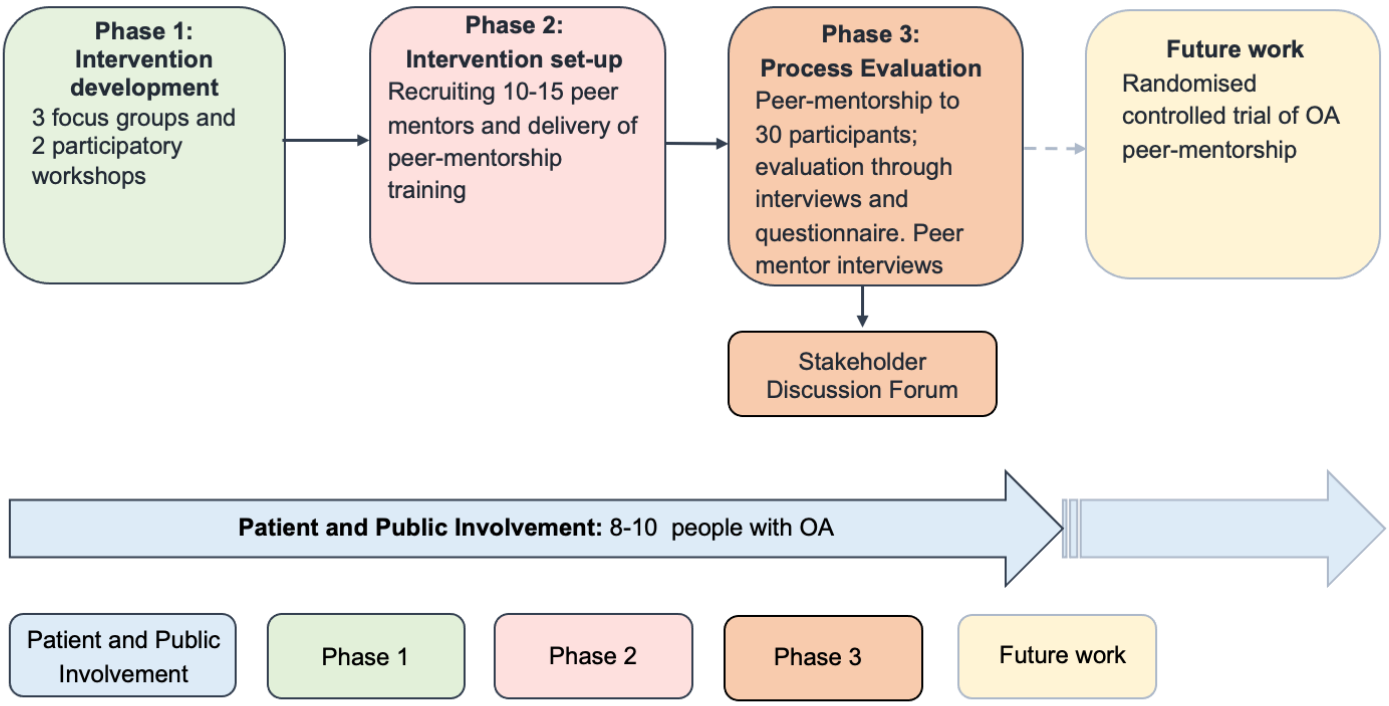
The Chief Investigator (CI, Professor Gretl McHugh), supported by Project Team Members (Dr Anna Anderson, Professor Mark Conner, Dr Heidi Gardner, Elizabeth Lavender) have contributed to this protocol. Two PPI co-applicants of the study have also helped with the design of the study and will be involved at all stages of the project. The funders will be acknowledged in any dissemination activities and publications.

KEY WORDS

Peer mentorship, self-management, osteoarthritis, complex intervention development, socioeconomic disadvantage, underserved groups

STUDY FLOW CHART

Study flow chart: Remote osteoarthritis peer-mentorship for socioeconomically underserved people



OA, osteoarthritis

STUDY PROTOCOL

Remote osteoarthritis peer-mentorship for socioeconomically underserved people

1 BACKGROUND

Osteoarthritis (OA) is a highly prevalent musculoskeletal condition (1). Rates of hip and knee OA are higher, and the impact is greater among neighbourhoods of high socioeconomic deprivation (2-4). Individuals with hip/knee OA may experience high levels of pain, reduced physical function, poor health-related quality of life (HRQoL), anxiety, depression and social isolation (5-9). HRQoL reduces in tandem with increasing socioeconomic disadvantage (10).

Managing OA is challenging for health professionals and patients. The National Institute for Health and Care Excellence (NICE) OA guidance recommends education, self-management, exercise and weight loss interventions (11). However, people often need guided support to manage OA. With pressures on the NHS, health professionals cannot always provide the required timely support.

People experiencing socioeconomic disadvantage can face barriers to accessing formal healthcare because of their social distance from health professionals (12); and NHS cuts disproportionately impact people living in rurality (13,14). Correspondingly, people living in neighbourhoods with higher levels of deprivation experience health inequalities, with many interventions/services causing or exacerbating health disparities (15,16). Other research has found intentions and/or self-efficacy to be less predictive of engagement in health-behaviours among people with lower socioeconomic status, highlighting their need for additional support (17,18). This aligns with OA research findings, which has demonstrated that interventions for OA may need to be targeted specifically for this group (3,10).

The NHS Long-Term Plan (2019) advocates improving support for patients with long-term conditions and working with volunteers to enhance self-management (19). Peer support interventions encouraging long-term condition self-management have been shown to be well-received and effective (20-22). Peer-mentorship is a type of peer support where people with a condition are trained to support those with the same condition.

The Project Team’s previous research developed a face-to-face peer-mentorship intervention to support OA self-management (23). The intervention was acceptable and feasible, helping people with hip and knee OA self-manage their condition more effectively (23,24). Additionally, peer mentors benefitted from their role (25). A key limitation of the study was that many participants were white, well-educated females (23). The impact of OA self-management education programmes may vary between white, educated women and other subgroups (26). In addition, peer support interventions may be more effective among people who are underserved, such as individuals experiencing socioeconomic disadvantage (27). The evidence and limitations of our previous study support the need to tailor our existing peer-mentorship intervention to people experiencing socioeconomic disadvantage.

2 RATIONALE

During the COVID-19 pandemic, many health services changed to using remote delivery approaches such as telephone/videoconferencing consultations. Remote approaches can help address the difficulties of delivering healthcare to a diverse and ageing population (28). The OA peer-mentorship intervention could be delivered remotely. However, people experiencing socioeconomic disadvantage may experience difficulties accessing remote services. Furthermore, as people with OA are typically older, they are more likely to have low digital literacy (29). Age UK (2021) reports an increase in internet usage since the start of the pandemic but 42% of those 75+years are not using the internet (30). Digital literacy is overlooked when developing digital health interventions targeted towards groups experiencing socioeconomic disadvantage (31). It is important that remote health interventions do not reinforce existing health inequalities (32).

The Project Team's research and consultation with PPI contributors indicate that peer support needs to be more inclusive and reach more diverse populations, in-line with NIHR 'INCLUDE' guidance (33). Building upon our OA peer-mentorship intervention, we will develop and evaluate remote peer-mentorship for and with people with hip and knee OA who are experiencing socioeconomic disadvantage. Delivery of mentorship for this group will help overcome the barriers presented by formal healthcare services.

This research is important as people experiencing socioeconomic disadvantage are underserved by health services/research and may benefit most from self-management support.

3 THEORETICAL FRAMEWORK

The logic model for the OA peer-mentorship intervention has been published (23) and will provide a foundation for the intervention being developed and evaluated in this project. Appropriate theory and input from multidisciplinary experts were incorporated when developing the face-to-face peer-mentorship intervention. The ADAPT guidance (34) will be followed for adapting the peer-mentorship intervention to be remote and for people with OA experiencing socioeconomic disadvantage.

The theoretical frameworks include:

Phase 1: The focus group (or if preferred interview) schedules are structured around the Theoretical Domains Framework (TDF) (35) to establish barriers and enablers to engagement with the peer-mentorship intervention among people experiencing socioeconomic disadvantage. The TDF provides a theoretical lens to view the various influences on behaviour, such as social and environmental factors.

Phase 3: The process evaluation will use the Framework of Implementation Outcomes (IOs) (36), to determine the success or failure of implementation of the remote peer-mentorship intervention. The constructs of the IO framework include: acceptability, adoption, appropriateness, feasibility and fidelity. The Normalization Process Theory (NPT) will also be used to examine implementation issues and solutions for health and social care delivery using the constructs of coherence, cognitive participation, collective action, and reflexive monitoring (37,38). In addition, the IOs and NPT will guide the interpretation of the thematic data analysis.

4 RESEARCH QUESTION / AIM(S)

4.1 Aim

To develop and assess the feasibility and perceived usefulness of a remote OA peer-mentorship intervention for people with hip and knee OA who are experiencing socioeconomic disadvantage.

4.2 Objectives

1. To explore barriers and enablers to engagement with a remote OA peer-mentorship intervention among people experiencing socioeconomic disadvantage.

2. To develop a remote OA peer-mentorship intervention with and for people with hip and knee OA who are experiencing socioeconomic disadvantage.
3. To estimate the costs of training volunteer peer mentors and delivering the OA peer-mentorship intervention.
4. To investigate the acceptability, appropriateness, adoption, feasibility and fidelity of a remote OA peer-mentorship intervention for supporting self-management of hip and/or knee OA among people experiencing socioeconomic disadvantage.
5. To investigate barriers and enablers to implementation of a remote OA peer-mentorship intervention.

4.3 Outcome

A remote peer-mentorship intervention, which is potentially more accessible, acceptable, and tailored to the needs of people experiencing socioeconomic disadvantage, will have been developed. All stakeholders are likely to benefit from the shared learning gained during this research, including by developing a better awareness of OA self-management among people experiencing socioeconomic disadvantage. This project will also generate information about the costs of the intervention, which will be valuable for informing potential commissioning and implementation of the intervention.

The future intention is to undertake a definitive RCT to determine the clinical- and cost-effectiveness of the remote OA peer-mentorship intervention. Working with people who are experiencing socioeconomic disadvantage and learning more about accessibility and inclusivity of a remote health intervention for this group is required before a RCT is undertaken.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

A pragmatic mixed-methods feasibility study will be conducted.

- Phase 1 will use qualitative and participatory approaches to address issues and uncertainties about remote OA peer-mentorship to develop and finalise the intervention.
- Phase 2 will involve recruiting and training peer mentors.
- Phase 3 will be a mixed methods process evaluation investigating the acceptability, appropriateness, feasibility, fidelity, and adoption of the intervention.

In this study, the ADAPT (Adapting interventions to new contexts) guidance (34) will be incorporated. The study involves adapting a previously developed and feasibility tested face-to-face, one-to-one peer-mentorship intervention for people with hip and knee osteoarthritis (OA) so that it can be delivered remotely and is tailored to the needs and preferences of people with OA experiencing socioeconomic disadvantage. Phase 1 will enable us to adapt the intervention for a new mode of delivery (that is, remote and group or one-to-one delivery); and tailor it specifically for people who identify as experiencing socioeconomic disadvantage. A process evaluation (Phase 3) will be conducted to assess whether remote OA peer-mentorship is acceptable to people with OA experiencing socioeconomic disadvantage.

5.1 Phase 1: Intervention Development

Focus groups or participant interviews (as preferred) will be conducted with people experiencing socioeconomic disadvantage. These will be structured around the Theoretical Domains Framework (TDF) (35) and will explore barriers and enablers to engagement with the peer-mentorship intervention.

5.1.1 Sample

The target sample are people with hip and/or knee OA experiencing socioeconomic disadvantage. These are people who:

- over 18 years of age;
- have been diagnosed with hip/knee OA by a health professional; and
- consider themselves to be experiencing socioeconomic disadvantage (assessed by the question *‘Do you consider yourself to be experiencing socioeconomic disadvantage?’*).

The socioeconomic disadvantage criterion is based upon research which has highlighted that patients and the public prefer terminology that emphasises the dynamic nature and potential transience of socioeconomic disadvantage. To ensure that the sample is diverse and specific characteristics are represented, purposive sampling will be used, based on joint affected (hip/knee), age, gender, and ethnicity (39). Three focus groups will be conducted with approximately five-six participants per group (n~15 total) (40,41). Recruitment of participants for the focus groups/interviews is described in section 7.3

5.1.2 Data collection

Data will be collected through focus groups where possible to enable discussions between participants. To promote inclusion, participants will be offered the opportunity to participate in an interview rather than a focus group if they prefer. Participants will be able to join their focus group/interview via videoconferencing, in person or via telephone according to their preference (and COVID-19-related restrictions if applicable).

The focus groups will be facilitated by an experienced facilitator with a co-moderator also present to assist with the group. If a one-to-one interview is preferred, this will be carried out by a researcher experienced in interviewing. A topic guide based on the TDF will be devised with input from our PPI members, and will include areas such as:

- factors affecting self-management (TDF: Beliefs about capabilities);
- information needs and support requirements (TDF: Skills);
- engagement with self-management support (TDF: Motivation and goals);
- engagement with a peer mentor (TDF: Social influence);
- format and accessibility of the peer-mentorship intervention.

5.1.3 Data Analysis

Focus groups and/or interviews will be recorded either using an encrypted digital recorder and transcribed verbatim or using MS Teams with built-in transcription. If using a digital recorder, a professional transcription company will be used to transcribe the focus groups and interviews. Pseudo- anonymisation will occur during the transcription process. Data will be analysed using reflexive thematic analysis by two researchers (42). Analysis will focus on identifying potential barriers, enablers, and intervention features in relation to the TDF Mechanisms of Action.

NVivo software will be used to assist with data analysis as appropriate. Once transcripts have been checked, the audio datafile will be deleted. Pseudo-anonymised transcripts will also be password protected and will be kept for up to five years; and stored on the CI's University one-drive and shared with relevant members of the research team; and then will be deleted.

5.1.4 Finalising the intervention

Building upon the findings from the focus groups/interviews, a participatory approach will be used (43) to finalise the intervention. This will involve carrying out engagement activities, including two interactive workshops with representatives of local community groups from different locations, people experiencing socioeconomic disadvantage, and members of our PPI Group.

The discussion framework for the public engagement activities will be developed from the findings of the focus groups/interviews. The workshops will be held remotely or in person according to the attendees' preferences (and COVID-19-related restrictions if applicable). People from relevant community groups will be invited and recruitment approaches as described in section 7.3 will be employed. The knowledge gained from these engagement activities will inform the development of the intervention. It will then be finalised for delivery in Phase 3.

5.2 Phase 2: Intervention set-up

This will involve the recruitment of volunteers to be trained as peer mentors (recruitment described in section 7.3).

5.2.1 Training delivery

A two-day training event will be delivered by study team members, an external collaborator (physiotherapist specialising in activity pacing) and our PPI co-applicants (LE and SB), who were peer mentors in a previous study (24). Other PPI members/previous peer mentors (e.g. digital champion) will also assist with aspects of the training as appropriate.

The training will be adapted from our previous study for remote /group delivery in collaboration with our PPI co-applicants. It will be delivered using presentations and interactive activities; and will include insights from previous peer mentors. Key topics will include:

Day 1: Overview of the study and peer mentor role (including how to make the most of remote technologies); OA key facts; and core and optional self-management topics such as goal setting, pacing, exercise, pain management, communication, healthy eating and sleep.

Day 2: Communication; professional boundaries; mentoring in practice (safeguarding, disclosures/confidentiality); delivering remote peer-mentorship; recording procedures; study data collection.

Additional topics may also be covered as depending on the requirements of the intervention developed in Phase 1.

Training will be delivered in person and/or via videoconferencing to account for peer mentors' preferences (and any potential COVID-19-related restrictions). To help guide the mentorship sessions, all peer mentors will receive an educational resource pack, which will be adapted from a pack developed during our previous study. The pack includes information/guidance on self-management topics, specific exercises, goal setting etc.

5.2.2 Training costs

To estimate the peer mentor training costs, information will be collected on the number of attendees and trainers at the events, and training-related expenses such as the cost of travel/digital connectivity, PPI input, resource packs and refreshments. This will enable us to estimate the peer mentor training costs.

5.3 Phase 3: Process Evaluation

A process evaluation will investigate the acceptability, appropriateness, adoption, feasibility and fidelity of remote OA peer-mentorship. Recruitment is described in section 7.3.

5.3.1 Intervention delivery

Participants will receive the remote OA peer-mentorship intervention approximately weekly over six to eight weeks. In the previous study participants received an average of six mentorship sessions (23). This supports the feasibility of this schedule and provides evidence that it could have a meaningful impact for participants and peer mentors. The peer-mentorship intervention will be finalised in Phase 1 but will involve a trained volunteer with hip and/or knee OA (known as a peer mentor) providing six mentorship sessions either individually or in a group for up to six to eight weeks remotely (using telephone and/or videoconferencing). The peer mentor's role is to provide self-management support through information and training; goal setting guidance; skill development and confidence building; motivation and social support as required. Peer mentors will cover core topics with all participants (e.g. pain management, goal setting, pacing, exercises). They may also cover optional topics that are specific to the participant's needs and preferences (e.g. healthy eating, communication, staying connected with family/friends). The classification of topics as core versus optional are based on the findings of the previous study (23) but may be adapted during Phase 1.

Educational resources (e.g. exercise sheets and pictures/videos demonstrations) will be posted/emailed to participants as required. After each remote session, the peer mentor will be helped as necessary to complete a standardised session summary form to record the topics covered during the session, goals set and the participant's progress towards their goals. This approach may be adapted if the mentorship is delivered in a group rather than one-to-one format.

5.3.2 Data collection

Quantitative

A structured questionnaire will be administered at baseline by telephone and will include questions on:

- participant characteristics/demographics
- confidence and capability to use digital technology
- level of pain
- overall impact of hip/knee OA on everyday life
- perception and adequacy of social support
- current exercise

Validated measures will include: Arthritis Self-Efficacy 8-item scale (44); EQ-5D-5L (measuring health status) (45). This questionnaire, included validated measures will be administered at baseline by post/online/telephone. Telephone reminders post-administration will be used to increase the response rate.

Longitudinal qualitative interviews

All participants will be invited to participate in two remote semi-structured interviews (via videoconferencing or telephone). One interview will be conducted immediately following the participant's completion of the OA peer-mentorship intervention at six weeks and the other will be conducted six months later. The semi-structured interviews will be directed by topic guides based on the Framework of Implementation Outcomes (IOs) (36) and NPT constructs (37,38) The IOs will be used to determine the success or failure of implementation of the remote peer-mentorship intervention with the following constructs: acceptability, adoption, appropriateness, feasibility, and fidelity. The NPT will also be used to look at implementation issues of the peer mentorship intervention and solutions for health and social care delivery using the constructs of coherence, cognitive participation, collection action and reflexive monitoring (37, 38).

The areas of questioning at the six-week interview will include:

- positive/negative experiences of remote OA peer-mentorship;
- health-related changes or decisions during/immediately following the intervention (adequate guidance/information to self-manage);
- benefits/challenges to receiving peer-mentorship/achieving goals.

The follow-up interview at six months will focus more on issues around sustained self-management such as:

- activities/changes sustained;
- perceptions of changes/improvements in symptoms;
- level of knowledge/confidence.

Peer mentor interviews

All peer mentors will be invited to participate in a remote semi-structured interview (via videoconferencing or telephone). The interviews based on previous research (24) and constructs of NPT and IOs will focus on:

- views of the training and support;

- delivery of remote peer-mentorship (including acceptability, appropriateness, adoption, feasibility and fidelity;
- motivation and engagement;
- experiences of being a peer mentor.

5.3.3 Data Analysis

Data from the questionnaire/outcome measures will be analysed using descriptive statistics and mainly used to contextualise participant health status. The qualitative interviews will be digitally recorded, transcribed verbatim and analysed using reflexive thematic analysis (42) with the IOs and NPT guiding interpretation. We will map themes and subthemes to the NPT constructs (coherence, cognitive participation, collective action and reflexive monitoring) and the IOs framework (appropriateness, acceptability, adoption). The session summaries will be content analysed (46). This will provide information on the number, frequency and types of goals set; range of topics discussed; and intervention fidelity issues.

6 STUDY SETTING

This is a community and primary care based study.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Phase 1

- Over 18 years of age;
- Diagnosed with hip/knee OA by a health professional;
- Consider themselves to be experiencing socioeconomic disadvantage (assessed by the question *'Do you consider yourself to be experiencing socioeconomic disadvantage?'*);
- Capacity to provide informed consent.

Phase 2 (Peer Mentors)

- Over 18 years of age;
- Diagnosed with hip/knee OA by a health professional;
- Consider themselves to be experiencing socioeconomic disadvantage (assessed by the question *'Do you consider yourself to be experiencing socioeconomic disadvantage?'*).

Phase 3

- Over 18 years of age;
- Diagnosed with hip/knee OA by a health professional;
- Pain on most days of the month for at least one of the previous three months;
- Moderate pain (≥4 on a Numerical Pain Rating Scale (NPRS) in the past week);
- Consider themselves to be experiencing socioeconomic disadvantage (as in Phase 1);
- Capacity to provide informed consent.

7.1.2 Exclusion criteria

Phase 1

- Unable to participate face-to-face due to geographical distance, and unable to participate remotely by videocall or telephone.

Phase 2

- Unable to obtain Disclosure and Barring Service (DBS) clearance
- Unable to attend the full training programme

Phase 3

- Inflammatory arthritis (including gout and rheumatoid arthritis);
- Serious health condition that would prevent participation.
- Unable to participate in remote (telephone, videocall) peer-mentorship

7.2 Sampling

7.2.1 Size of sample

Phase 1

Approximately 15 participants for up to three focus groups. Interviews with individual participants also will be accommodated.

Phase 2

Ten to 15 peer mentors to deliver the intervention.

Phase 3

30 participants to receive remote peer-mentorship (to allow for attrition). This sample size is deemed adequate to meet feasibility objectives. All the peer mentors (approximately 10 to 15) who deliver the intervention will be asked to participate in an interview following completion of the peer-mentorship intervention.

7.2.2 Sampling technique

Participants in Phases 1 and 3

Participants will be purposively sampled based on joint affected (hip/knee), age, gender and ethnicity.

PPIE representatives at the Phase 1 participatory engagement activity

To discuss findings of the focus groups/interviews and finalise the peer-mentorship intervention, two workshops will be held each consisting of approximately three community group representatives, six people experiencing socioeconomic disadvantage and four study PPI Group members.

Volunteers in Phase 2

There is no sampling involved as individuals will volunteer to be peer mentors and if they meet the eligibility criteria will be trained to deliver the peer-mentorship intervention. By tailoring the recruitment approach, a diverse range of volunteers and from different parts of the UK will try to be recruited.

7.3 Recruitment

7.3.1 Sample identification

Phases 1 and 3

For Phases 1 and 3 some participants will be recruited from NHS sites as indicated below. Collecting data remotely (via videoconferencing and/or telephone) will enable participants who live in any area of the UK to take part. People with hip and/or knee OA who identify themselves as experiencing socioeconomic disadvantage will be recruited. Participants who wish to take part in Phases 1 and 3, will be screened to ensure they meet the eligibility criteria.

To maximise diversity of participants, recruitment will be through engagement with:

- Primary care via NIHR Clinical Research Network Yorkshire & Humber and West Yorkshire Research & Development (on behalf of NHS West Yorkshire Integrated Care Board);*
- Leeds Community Healthcare NHS Trust Musculoskeletal Services;*
- Third sector organisations;
- Community organisations and networks;
- Egality (www.egality.health).
- Social media
- Public participation websites

(* for Phases 1 and 3 only)

To recruit participants who are experiencing socioeconomic disadvantage, we will target specific areas of the UK and recruit from neighbourhoods with high socioeconomic deprivation (20% most deprived) using the Index of Multiple Deprivation (IMD).

Participants who wish to volunteer to become peer mentors (Phase 2) will be recruited through engagement with community organisations and networks. In addition, we will use printed materials and social media advertising; and share information through the UK's National Innovation Centre for Ageing- VOICE®; Versus Arthritis; Egality Health and NIHR People in Research and other organisations as appropriate.

Potential participants will be identified from NHS sites by members of their direct care team. Identification of potential participants will be based on the following criteria:

- Diagnosed with hip and knee OA by a health professional; and
- Consider themselves to be experiencing socioeconomic disadvantage.

The member of the direct care team for any potential participant, i.e. either working in primary care and/or MSK and Rehabilitation services will be provided with information about the study to give to the patient. Anyone interested in participating will be asked complete a form giving their approval to be contacted by a researcher about the study.

Phase 2

Volunteers will self-identify as being interested in becoming a peer mentor. Advertising for volunteers will be through community organisations, public participation websites, social media and Egality Health. Appropriate Facebook and Twitter posts will be developed advertising for volunteers.

7.3.2 Consent

For Phase 1 (focus group/interview) and Phase 3 (peer-mentorship intervention), potential participants will be asked to provide electronic or written informed consent by completing the consent form for either Phase 1 or Phase 3. In Phase 3, peer mentors participating in an interview will be asked to provide or electronic written informed consent by completing a consent form. All Phase 1 and Phase 3 participants will be given the opportunity to ask questions about the study prior to giving consent.

7.4 Payments and reimbursements

Phase 1: Participants who attend the focus groups/interview will receive a recognition payment of 25 pounds. Travel expenses will be reimbursed for participants in Phase 1 who join an in-person focus group/interview at the University. Public participants who attend the participatory workshop will receive a recognition payment of 30 pounds. If the workshop is in-person, travel expenses will be reimbursed. Wi-fi replacement costs will also be provided.

Peer mentors will receive a recognition payment of 20 pounds for each peer-mentorship session delivered in Phase 3. This will be a maximum of six, one hour mentoring support sessions per participant.

Study participants in Phase 3 will not receive any payment for taking part. To ensure digital inclusivity and access, smart devices and dongles will be available to loan to peer mentors or participants. Wi-fi replacement costs and any out-of-pocket expenses incurred whilst delivering or receiving support sessions will be reimbursed.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

This study does not involve changing the routine care participants receive and all the risks will be minimal. In addition, we have planned various strategies to reduce all the identified risks as detailed below.

8.1.1 All phases

Most study activities will be conducted remotely. For any activities that are conducted in person, the latest government and University of Leeds guidance on COVID-19 will be followed.

Although there is a risk of breaching participant/peer mentor confidentiality in all the phases, this risk will be very low because we will follow the data protection procedures detailed in section 8.6.

Given this study involves discussing health-related issues, there is a possibility that participants and/or peer mentors may become distressed during their participation/peer mentor training. However, given the study is focused on OA self-management, rather than more sensitive health issues, the risk of participant/peer mentor distress will be very low. We will minimise this low risk further by:

- giving potential participants/peer mentors detailed information about the study and what it will involve;
- giving potential participants/peer mentors as long as they require to decide whether to participate/volunteer (until recruitment for the relevant phase closes);

- informing participants in Phases 1 and 3 that, if they do not want to answer any specific questions, they will be free to decline; they can take a break or leave at any point during their focus group/interview; and they may withdraw from the study at any time, without giving a reason.

If a participant/peer mentor discloses anything that has the potential of any risk/harm, the risk management plan will be followed. This will include advising the participant/peer mentor to discuss the issue with their health professional and if necessary, asking their permission to disclose the issue to their health professional.

8.1.2 Phase 1

This phase will involve focus groups/interviews only, so will not involve any specific risks other than those detailed above. However if a participant wants to have a one to one in-person interview, at home, a risk assessment will be completed, and the lone-worker policy followed.

8.1.3 Phase 2

This phase will involve training the peer mentors in person and/or via videoconferencing. The risks involved in the training will be minimal because it will be largely educational. There will be two training sessions, with around 5-7 volunteers per training session.

8.1.4 Phase 3

This phase will involve participants receiving the remote peer mentorship intervention. The risks involved will be very low because:

- all the volunteers who act as peer mentors will have undergone a Disclosure and Barring Service Check and attended the full training programme prior to providing peer-mentorship;
- the sessions will be delivered remotely so there will be no lone working-related risks;
- the peer mentors will provide the participants appropriate education and support for all the intervention activities, such as guidance on how to exercise safely at home;
- peer mentors will receive support from study volunteer coordinator. This will include an opportunity to discuss any concerns they have about the participant's or their own wellbeing so that they can be signposted to appropriate sources of further support if required.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before starting the study, a favourable opinion will be sought from the NHS REC for the study protocol, informed consent and advertisements for study recruitment. Before any data collection involving study participants, each participant will complete the REC-approved consent form/statement for the relevant study phase. Participants are free to withdraw at any time from the study without giving reasons and without prejudicing any further care/treatment.

Any study amendments that require review by the NHS REC will not be implemented until that review has been completed. The CI will adhere to the NHS REC requirements in terms of progress reporting.

8.2.1 Regulatory Review & Compliance

Before any NHS site can enrol patients into the study, the CI/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations will be followed and comply with the relevant guidance.

8.2.2 Amendments

The study sponsor (University of Leeds) will make the decision whether any proposed amendment to the protocol is substantial or non-substantial, and the CI, on behalf of the sponsor, will submit a valid notice of amendment to the NHS REC for consideration.

Phases 1& 3: As some participants for these two phases will be recruited through the NHS, any amendment to the study, will be submitted by the CI or designee, in agreement with the sponsor. The CI or designee will submit information to the appropriate body for them to issue approval for the amendment. The CI or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment and confirm their support for the amended study.

Phase 2 is outside of the NHS and specifically doesn’t require NHS REC review, but is included in the NHS REC review. NHS management approval and amendments will be handled in line with the sponsors and site management organisation policies.

8.3 Peer review

The study has been independently reviewed by external reviewers and committee members of the funding organisation. Throughout the project, the independent Project Advisory Group will be providing support and guidance on aspects of the project as required.

8.4 Patient & Public Involvement

The study will have a PPI Group consisting of approximately six PPI members and will also include the two PPI co-applicants. PPI Group members will be involved in Phase 1 and Phase 2 study activities and will be consulted at key stages throughout the study.

8.4.1 Project Design

The concept of remote OA peer-mentorship and design of this study to focus on people experiencing socioeconomic disadvantage has been informed by input from public and patient participants. Two PPI members are co-applicants on this study and have been directly involved in the design of this study, specifically by contributing to design ideas and through reviewing application sections, including the Plain English Summary to ensure that it is accessible to lay people.

In addition, PPI members have contributed to the outline dissemination plan and will advise on communications and plans for final dissemination activities following Phase 3.

8.4.2 Delivery of project

This study has been designed to involve PPI members and engage key community groups and people experiencing socioeconomic disadvantage throughout. Phase 1 will involve a participatory approach to developing the intervention. In addition to the involvement of PPI members, Egality Health will assist us to engage new community groups, as well as using existing established community connections to recruit people who are experiencing socioeconomic disadvantage.

For Phase 2 members of the public with hip and/or knee OA will be recruited as volunteer peer mentors. The PPI co-applicants and other PPI members will be closely involved in peer mentor training and engaged for ongoing support of peer mentors and mentees during intervention delivery.

For Phase 3, PPI members will be involved in finalising the interview topic guides. Following completion of Phase 3 (process evaluation), two Stakeholder Discussion Forums will be undertaken to share findings and discuss any challenges and solutions to implementation with key stakeholders. PPI members will be invited to contribute to dissemination materials, review the final report and be given an opportunity to present the findings of the study as a co-presenter, if they wish.

8.5 Protocol compliance

If there are any deviations to the protocol, these will be documented and reported to the CI and Sponsor as required. A ‘serious breach’ is a breach which is likely to affect a significant degree:

a) the safety or physical mental integrity of the subjects of the trial; or
b) the scientific value of the trial.

Serious breaches will be reported to the sponsor by the CI within 1 working day of the breach to governance-ethics@leeds.ac.uk. Serious breaches will be reported to the REC within the REC specific timelines.

8.6 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (GDPR) and Data Protection Act 2018 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the GDPR and Act’s core principles. The performance of a task carried out in the public interest is the lawful basis for processing personal data and archiving in the public interest, scientific research purposes, as the additional basis for processing special category data.

Personal information, such as contact information (name, email address, telephone number) will be kept securely and, in a password, protected encrypted file. Any paper copies of consent forms will be scanned and then destroyed. Scanned copies will be kept securely on the University of Leeds’ Secure Server, encrypted and password protected. Questionnaire data will use ID numbers and will contain no identifiable information. The session summaries which will record the peer-mentorship sessions will have a participant ID number. The ID code will be stored separately in an encrypted folder on the University of Leeds secure server and kept separate to the other research data.

Data will be transcribed by a professional transcription service and a Data Processing Agreement (DPA) will be in place. The transcripts from the focus groups and qualitative interviews will be anonymised prior to storing on the University of Leeds secure server. The raw recording data will be destroyed once the transcripts have been anonymised.

The data will be held for five years following completion of the study before being destroyed.

8.7 Indemnity

The sponsor of the study is the University of Leeds who will provide insurance for liabilities and prospective liabilities arising from negligent harm.

8.8 Access to the final study dataset

Only the project CI and University of Leeds' co-applicants will have access to the full dataset. A summary of the findings will be discussed with the Project Advisory Group and PPI Group.

9 DISSEMINATION POLICY

9.1 Dissemination policy

On completion of the study, a final study report, including an executive summary will be prepared. The report, once approved by Nuffield Foundation, will be made available on their website and available on Versus Arthritis (the co-funder's) website. A communication plan developed for the study will be followed to ensure appropriate dissemination and communication throughout the duration of the study.

Any publications arising from this study will acknowledge the funders and a copy of the publication will be provided to the funding organisations.

Study participants who have indicated they would like to be made aware of the findings from the study, will received an accessible lay summary and/or infographic summary after the final study report has been compiled.

Some of the data from the study will be archived via the University of Leeds institutional research data repository ('Research Data Leeds). The formal repository deposit agreement set out by the University of Leeds for the long-term management of the digital material will be adhered to. Full and unrestricted sharing of interview transcripts will not be appropriate as even if personal identifiable data is removed, the transcript content may enable study participants and those providing or receiving peer-mentorship to be identified. Data that can be anonymised and does not pose a risk to maintaining participant confidentiality will be prepared for deposit to this data repository. The University of Leeds' guidelines for preparing the metadata will be followed and once data is uploaded to the centre, a DOI will be allocated and can be used for any subsequent publications.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The CI and co-applicants will have authorship on the final study report. For authorship on any publications from this study, the authorship criteria from 'The International Committee of Medical Journal Editors' will be followed.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

Recruitment Adverts

RecruitmentImages_P1_P2_P3_RaMIgO_V1.0_19April2023

Phase 1:

TwitterFlyerFGP1_RaMIgO_V1.0_19April2023

TwitterPostFGP1_RaMIgO_V1.0_19April2023

Phase2:

PosterPeerMentorP2_RaMIgO_V1.0_19April2023

Phase 3:

PosterParticipantP3_RaMIgO_V1.0_19April2023

TwitterPostParticipantP3_RaMIgO_V1.0_19April2023

Phase 1 documentation:

- ContactForm_Phase1_RaMIgo_V1.0_19April2023
- InvitationLetterFGInterviewP1_RaMIgO_V1.0_19April2023
- ConsentformFocusGroupInterviewP1_RaMIgO_V1.0_19April2023
- DemographicInformationFocusGroupP1_V1.0_19April2023
- PIS_ FGInterviewsP1_RaMIgO_V1.0_19April2023
- TopicGuideFocusGroupInterview_RaMIgO_V1.0_19April2023

Phase 3 documentation:

Peer-mentorship Intervention Evaluation

- ContactFormP3_RaMIgO_V1.0_19April2023
- ConsentFormEvaluationP3_RaMIgO_V1.0_19April2023
- InvitationLetterP3_RaMIgO_V1.0_19April2023
- BaselineParticipantQuestionnaireP3_RaMIgO_V1.0_19April2023
- PIS_EvaluationPhase3_RaMIgO_V1.0_19April2023
- SessionSummaryTable_RaMIgO_V1.0_19April2023
- SixWeekQualInterviewP3_RaMIgO_V1.0_19April2023

Participant Follow-up 6 months

- ConsentFormParticipantFollow-upInterviewP3_RaMIgO_V1.0_19April2023
- Follow-upQualInterviewP3_RaMIgO_V1.0_19April2023

Peer Mentors Interview

- PeerMentorsInterviewP3_RaMIgO_V1.0_19April2023

- PIS_PeerMentorPhase3_RaMIgO_V1.0_19April2023
- ConsentFormPeerMentorInterviewP3_RaMIgO_V1.0_19April23

Data Management Protocol

- DMP_RaMIgO_V.1.0_19April2023

Data Processing Agreement

- Lawson_Hardwick_Ltd_DPA_08032023

11.2 Appendix 2 – Schedule of Procedures

Procedures for Phase 1	**Visits**	
	Screening	**Baseline**
Screening	1	
Informed consent		1
Demographic Questionnaire		1
Focus Group (or interview)		1

Procedures for Phase 3	**Contacts**			
	Screening	**Baseline**	**Week 6**	**6 Months**
Screening	1			
Informed consent		1		
Questionnaire		1		
Peer-Mentorship		Weekly session of 1 hour for six weeks		
Interview			1	1

11.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**