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JOINT SUPPORT: Can we perform a trial to test a caregiver intervention for people with chronic pain?

Submission date
16/12/2021

Recruitment status
No longer recruiting

Registration date
11/04/2022

Overall study status
Completed

Last Edited
16/04/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Long-term (chronic) bone, joint, and muscle (musculoskeletal) pain causes disability whilst reducing quality of life and independence. People with chronic musculoskeletal pain often rely on family members or friends to take on roles as caregivers, helping in tasks such as washing, dressing, cooking, eating, and shopping. Unfortunately, caregivers are often under-prepared to do this. They are left to work out what to do themselves, and so ask the patient to do less than they could do for fear of causing harm. We suggest that a training programme to support caregivers in how to support people with chronic musculoskeletal pain could solve many of these problems, to improve patient health and well-being.

Who can participate?
In this study, people who have chronic (3 months or longer) bone, joint or muscle pain, and one of their friend/family members who will be the patient's caregiver is able to participate.

Who does the study involve?
Whilst attending a hospital appointment with the physiotherapy, occupational therapy, rheumatology, orthopaedic, or pain management services, people who have chronic (3 months or longer) musculoskeletal (bone, joint or muscle) pain will be introduced to the study and provided with an information pack to take home. They will be called on the telephone a couple of days later to provide an opportunity to ask any questions they or their caregiver may have about the study. After this, if they wish to participate in the study, both the patient and caregiver will be asked to sign a consent form. If both sign their consent forms, they will join the study and will be asked to complete some questionnaires on their health and wellbeing. This should take about 30 minutes.

A researcher will enter the patient's details into a computer and a computer program will make a decision about which group they will be in whilst in the study. Patients will be allocated to a Usual Care group or the JOINT SUPPORT group. This allocation is made by chance, rather like the toss of a coin. This is important because it ensures that the treatments are tested fairly and no one can guess the group the computer puts you into.

For patients who are in the JOINT SUPPORT group, a member of the JOINT SUPPORT team will arrange a time convenient for the patient, caregiver, and themselves to start the skills and support training. The JOINT SUPPORT programme involves 5, 1- hour group sessions with a patient and their main caregiver. This will be run by a trained physiotherapist or occupational therapist. They will discuss and 'up-skill' the caregiver and patient on topics including: exercise, lifestyle modification, problem-solving everyday tasks, education on pain, coping strategies and medication use. After the group sessions, they will be supported with 3 telephone calls, and a workbook. These calls will allow the patient and caregiver to explore their progress, provide advice on any difficulties in problem-solving and to create future goals. Each session will be done within the hospital, within the therapy department. Each session will last no longer than 1 hour.

Usual NHS Care Group
Patients who are allocated to the Usual Care group will be provided with standard NHS care delivered by physiotherapy or occupational therapy departments, consisting of patient-focused treatments such as exercise, medication prescription and advice/education.

Three months after the participants have joined the study, both the patient and the caregiver will be sent some questionnaires in the post. These will take about 30 minutes to complete. Once the assessments have been completed that is the end of the study for them.

To understand more about people’s experiences of being involved in this study, we will invite some participants (patients and caregivers) to have an interview with a researcher. This will involve a discussion with one of the study researchers to ask about their experiences of being in the study including the assessments and treatments. This will help work out if a bigger study could be improved on. These meetings will last a maximum of 1 hour and will be in a location convenient to the patient and caregiver participants. Only 15 patients are required for the interviews. Taking part in this part of the study is entirely optional.

What are the possible benefits and risks of participating?
It is not known what the results of the study will be. This is why this study is being conducted.

The study will find out if it is possible to do a large trial investigating caregiving skills and training treatment for people with chronic musculoskeletal pain and their friends and family who may support (caregivers) them. If this study indicates that a larger study would be feasible, then this larger study will be planned. The results of that larger study would then be able to inform healthcare professionals if the JOINT SUPPORT programme is effective or not.

There may not be any benefit in taking part in this study. However, research like this helps to continually improve the treatments and care provided to all patients now and in the future by collecting information on what may or may not help.

There are only minimal risks involved in this research. There is a possible risk of patients feeling a little sore after exercising with the JOINT SUPPORT health professionals support and guidance. However patients will be guided by their health professionals and will be able to seek their opinions about bone, joint and muscle soreness recovering so they will be able to modify patient activities if needed.

Where is the study run from?
Norwich Clinical Trials Unit within the University of East Anglia (UK) and 5 NHS hospitals across England.

When is the study starting and how long is it expected to run for?
September 2021 to May 2024

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

Who is the main contact?
Dr Toby Smith
toby.smith@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Toby Smith

ORCID ID
http://orcid.org/0000-0003-1673-2954

Contact details
School of Health Sciences
Queen's Building
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 1603 593086
toby.smith@uea.ac.uk

Type(s)
Scientific

Contact name
Dr Toby Smith

Contact details
School of Health Sciences
Queen's Building
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 1603 593086
toby.smith@uea.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
310020

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 310020, CPMS 51789

Study information

Scientific Title
A feasibility study to assess the design of a multi-centre randomised controlled trial of the clinical and cost-effectiveness of a caregiving intervention for people with chronic musculoskeletal pain.

Acronym
JOINT SUPPORT

Study objectives
The aim of this study is to assess the feasibility of conducting a pragmatic, multi-centre randomised controlled trial (RCT) to test the clinical and cost-effectiveness of an informal caregiver training programme to support people with chronic musculoskeletal pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2022, North West - Preston Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048290; preston.rec@hra.nhs.uk), ref: 22/NW/0015

Study design
Mixed-methods feasibility study comprising of a parallel multicentre pragmatic interventional randomized controlled trial and embedded qualitative study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Management of pain and associated symptoms for people with chronic musculoskeletal (bone, joint, muscle).

Interventions
Experimental Group
This consists of standard NHS care PLUS The JOINT SUPPORT programme which involves 5, 1-hour group sessions with a patient and their main caregiver. This will be run by a trained physiotherapist or occupational therapist. They will discuss and 'up-skill' the caregiver and patient on topics including: exercise, lifestyle modification, problem-solving everyday tasks, education on pain, coping strategies and medication use. After the group sessions, they will be supported with 3 telephone calls, and a workbook. These calls will allow the patient and caregiver to explore their progress, provide advice on any difficulties in problem-solving and to create future goals. Each session will be done within the hospital, within the therapy department. Each session will last no longer than 1 hour.

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Randomisation
Randomisation to treatment arm will take place once patient and caregiver participant consent forms and baseline questionnaire packs have been completed and received. The randomisation scheme will be generated by the Norwich Clinical Trials Unit data manager and notified by email to the trial team. Randomisation will be stratified at the individual dyad level (approximately 2:1) by:
• Site
• Age of patient (< or > and equal to 65 years).
The allocation is computer generated so will not be known prior to the patient participant being randomised. Allocation is concealed prior to randomisation to prevent treatment bias.

Intervention Type
Other

Primary outcome measure

1. Ability to screen and identify potential participants (patients and caregivers) across the 5 sites measured using screening log data at baseline and 3 months follow-up
2. Willingness of eligible participants to consent and be randomised to intervention measured using semi-structured interviews at baseline and 3 months follow-up
3. Fidelity of healthcare professionals to deliver the experimental intervention and caregivers to adopt these post-group sessions measured using semi-structured telephone interviews at baseline and 3 months follow-up
4. Risk of intervention contamination measured using semi-structured interviews at baseline and 3 months follow-up

Secondary outcome measures
1. Patients will be assessed for the following at baseline and 3 months follow-up:
1.1. Health resource use using a study-specific health resource use questionnaire
1.2 Health-related quality of life using the 5-level EuroQol 5-Dimension (EQ-5D-5L)
1.3 Disease-specific function using the Musculoskeletal-Health Questionnaire (MSK-HQ)
1.4 Perceived self-efficacy using the General Self-Efficacy questionnaire
1.5 Depression symptoms using the Center for Epidemiologic Studies Depression Scale (CES-D)
1.6 Pain using the Numerical rating scale (NRS) for pain
1.7 Fatigue using the Numerical rating scale (NRS) for fatigue
1.8 Complications and adverse events including a study-specific questionnaire
2. Caregivers will be assessed for the following at baseline and 3 months follow-up:
2.1 Health resource use using a study-specific health resource use questionnaire
2.2 Health-related quality of life using the 5-level EuroQol 5-Dimension (EQ-5D-5L)
2.3. Depression symptoms using the Center for Epidemiologic Studies Depression Scale (CES-D)
2.4. Caregiver burden using the Short Sense of Competence Questionnaire (SSCQ)
2.5 Social and personal time quality of life using the Leisure Time Satisfaction questionnaire (LTS);
2.6 Complications and adverse events including a study-specific questionnaire

Overall study start date
01/09/2021

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over with a history (6 weeks or more) of pain from a musculoskeletal (bone, joint or muscle) origin.
2. Patient currently has a secondary care referral or is attending physiotherapy, rheumatology, orthopaedic, occupational therapy or pain management services.
3. Patients able to nominate an individual who is an informal caregiver. An informal caregiver is defined as someone who has done or is expected to provide unpaid care, assistance, support or supervision in activities of daily living for at least three hours per week over two or more personal contacts.
4. Patients and caregivers willing and able to provide consent.
5. Patients and caregivers who can engage in a group-based intervention currently delivered in English.

6. If the participating hospital appointment is routinely an online or virtual appointment rather than an in-person face-to-face appointment, patient and caregiver participants must have access to a computer or tablet and internet services to receive a video consultation call.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Total final enrolment
76

Key exclusion criteria
1. Patients or caregivers with acute (requiring hospitalisation) or terminal illness (life expectancy <6 weeks), which would make participation in the rehabilitation strategies contraindicated and /or impractical.

Date of first enrolment
15/09/2022

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Pinderfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
University of East Anglia

Sponsor details
Registry and Council House
Norwich
England
United Kingdom
NR4 7TJ
+44 1603 591482
t.moulton@uea.ac.uk

Sponsor type
University/education

Website
https://www.uea.ac.uk

ROR
https://ror.org/026k5mg93

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
Results will be provided to health professionals and patients through published articles in a peer-reviewed journal, conference presentations, social media blogs and newsletters. This will help the design of a larger trial to test the JOINT SUPPORT programme in a wider population.

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the potential for these data to contribute to a definitive trial

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		15/04/2025	16/04/2025	Yes	No