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Musculoskeletal (MSK) Pathways Study

Submission date
17/05/2023

Recruitment status
No longer recruiting

Registration date
25/09/2023

Overall study status
Completed

Last Edited
20/05/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Musculoskeletal pain (affecting bones, joints, ligaments, tendons or muscles) is very common, accounting for a large number of GP appointments. NHS staff often have to make assessment and treatment decisions for these conditions in short consultations. Whilst national guidelines for MSK conditions are available, they are complex and cover many different conditions separately. Therefore, there is often variability in the care patients receive. Orthopathway is a system that is installed onto GP practice computers for use in appointments to help clinicians make these decisions. Pathways are built for each pain site that contain best practice national guidelines adapted by local experts. This means that all clinicians in the local area follow the same high-quality guidance. The aim of this study is to find out whether using Orthopathway in primary care has an effect on patient outcomes, clinical decision-making, is cost-effective, and reduces carbon emissions.

Who can participate?
Patients aged 18 years and over who consult for neck, shoulder, elbow, wrist/hand, back, hip, knee, or foot pain

What does the study involve?
Participating GP practices are randomly allocated to one of two groups. GPs in the intervention group will use the Orthopathway system in eligible consultations, while GPs in the control group will continue delivering care as usual. After the consultation, patients will be asked to complete questionnaires at the start of the study and after 6 weeks and 3 months to monitor their outcomes. Consent will be sought to review the medical records of participants to see what healthcare usage there was after the consultation. Some clinicians and patients from the intervention arm will be asked to take part in interviews to talk more in-depth about their experiences.

What are the possible risks and benefits of participating?
There are no direct benefits to taking part in this study. This is considered a low-risk study; no new treatments are being tested.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
February 2023 to March 2024

Who is funding the study?
SBRI Healthcare Grant (UK)

Who is the main contact?
Dr Hollie Birkinshaw and Pro. Jonathan Hill, research.mskpathways@keele.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326002

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 326002, CPMS 56279

Study information

Scientific Title
Comparing usual care vs CrossCover Orthopathway clincial decision support system in primary care: a non-inferiority cluster randomized control trial

Study objectives
That the intervention (Orthopathway) does not cause worse outcomes for patients' health and wellbeing (measured using the MSK-HQ) than usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2023, Yorkshire & The Humber – Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8388; sheffield.rec@hra.nhs.uk), ref: 23/YH/0105

Study design
Non-inferiority cluster randomized controlled trial with embedded health economic, carbon reduction, and qualitative analyses

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Diagnostic, Other, Treatment, Safety

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

Health condition(s) or problem(s) studied
Painful musculoskeletal conditions

Interventions
Orthopathway is a clinician decision support system to be used by clinicians in consultations with patients to reduce variability in care. Orthopathway enables patient-facing clinical staff to follow best practice national guidelines adapted by local experts. The platform facilitates clinical experts to edit existing pathways, or build new easy pathways to follow, with fully illustrated interactive flowcharts and relevant clinical information. The innovation is designed to standardise decision-making among front-line clinicians and follow best-practice patient care.

Participating GP practices are randomly allocated to one of two groups. GPs in the intervention group will use the Orthopathway system in eligible consultations, while GPs in the control group will continue delivering care as usual. After the consultation, patients will be asked to complete questionnaires at the start of the study and after 6 weeks and 3 months to monitor their outcomes. Consent will be sought to review the medical records of participants to see what healthcare usage there was after the consultation. Some clinicians and patients from the intervention arm will be asked to take part in interviews to talk more in-depth about their experiences.

Practices will be randomized in a ratio of 1:1 to intervention or control using stratified block randomization based on practice patient list size using a computer-generated random sequence and concealment by ensuring that each practice has an anonymized code. The randomization sequence and stratification will be carried out by the senior trial statistician. The block randomization will follow Keele CTU’s randomization SOP, and the data sequence will be held on a secure server.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

CrossCover Orthopathway Clinician Decision Support System

Primary outcome measure
Musculoskeletal health, as measured by the Musculoskeletal Health Questionnaire (MSK-HQ) at baseline and 3 months

Secondary outcome measures
1. Clinician confidence in MSK decision-making as measured by a clinician survey at baseline, 6 weeks and 3 months
2. Participant pain intensity as measured by 0-10 visual analogue score (VAS) at baseline, 6 weeks and 3 months
3. Participant quality of life as measured by the EQ5D at baseline, 6 weeks and 3 months
4. Participant experience of consultation and care as measured by Keele Patient Experience Measures at baseline
5. Participant ability to work as measured by modified Work Productivity and Activity Impairment (WPAI) at baseline and 3 months
6. Participant healthcare utilisation measured using self-reported questionnaire data at 3 months, and medical record review data at 3 months
7. Acceptability and experience of Orthopathway explored using qualitative interviews with patient participants and clinicians at 3 months
8. Health economic and carbon reduction analyses using self-reported healthcare utilisation questions and medical record review data at 3 months

Overall study start date
01/02/2023

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Registered with a participating GP practice during the study period
3. Clinician determined suitability at the point-of-care for trial inclusion
4. Presenting with an MSK problem and a pain intensity score of ≥4 on a 0 to 10 numerical rating scale at the index consultation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Patients considered vulnerable by their GP (including those on the severe and enduring mental health register, with a diagnosis of dementia, with a recent diagnosis of a terminal illness, who have experienced recent trauma or bereavement, and nearing the end of their life)
2. Patients unable to communicate in English (both in reading and speaking)

Date of first enrolment
01/10/2023

Date of final enrolment
01/02/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Birmingham and Solihull Icb - 15e
First Floor
Wesleyan
Colmore Circus Queensway
Birmingham
United Kingdom
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Sponsor information

Organisation
Keele University

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Sponsor type
University/education

Website
https://www.keele.ac.uk/research/raise/governanceintegrityandethics/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Research organisation

Funder Name
SBRI Healthcare

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal, dissemination to GPs.

Intention to publish date
01/05/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			20/05/2025	No	No
Statistical Analysis Plan		23/09/2024	20/05/2025	No	No