ISRCTN13131384 https://doi.org/10.1186/ISRCTN13131384

Testing a new digital program to help reduce arm pain and improve movement in people with upper limb disorders

Submission date
09/10/2024

Recruitment status
Recruiting

Registration date
25/10/2024

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Distal upper limb (DUL) musculoskeletal disorders (MSDs) affecting the elbow, forearm, wrist /hand are highly prevalent and cause distressing levels of pain, swelling, loss of function and disability. The effects of living with a DUL- MSD are considerable in terms of personal and socioeconomic consequences. Recently it was shown that advising people to remain active reduced the risk of disability in the DUL at 6 months compared to people advised to rest or just have immediate physiotherapy. Current NHS challenges including increased costs, overburdened musculoskeletal services and an unwarranted variation in service provision, all call for innovative ways of providing care, including the delivery of rehabilitation remotely. Supporting self-management and personalising treatments, including the use of digital technology are NHS priority areas.
This trial is part of a larger programme that aims to develop and evaluate an evidence-based digitally delivered self-management rehabilitation programme (called Digital-My Arm Pain Programme [D-MAPP]) to address deficiencies in treatment and healthcare support for people with DUL-MSDs in order to optimise recovery, improve long-term function and reduce pain

Who can participate?
Adults aged 18 years or over with a clinician diagnosed distal upper limb-musculoskeletal disorder (DUL-MSD) who meet the eligibility criteria.

Please note that as recruitment can be completely remotely and no site visits are required, participants can be from anywhere in the country, not just where there are recruiting centres.

What does the study involve? (for participants)
Eligible participants with a clinically diagnosed DUL-MSD will be randomly assigned to either continue with their usual care (control group) or receive the D-MAPP package-of-care in addition to usual care (intervention group). The intervention period is 12 weeks and all participants will be followed for 12 months. Participants will be asked to complete a questionnaire booklet at baseline and then at 3, 6, 9 and 12 months after joining the study.
D-MAPP is a progressive web-app that includes an exercise programme tailored to the type of

DUL condition and the patients' functional ability. It also provides guided support and education to enable self-management.
A sub-sample of participants who complete D-MAPP will be invited to take part in an in-depth interview to gain further information about participants' experiences of using D-MAPP.

What are the possible benefits and risks of participating?
Taking part in this study may or may not directly benefit participants, although the information might help the treatment of future patients with DUL-MSDs.
There is minimal risk involved with this trial, however, some participants could experience a temporary increase in pain from the exercises which is to be expected with a new exercise regimen. There is the slight inconvenience of being asked to complete the study questionnaires.

Where is the study run from?
The trial is coordinated by the Leeds Clinical Trials Research Unit (CTRU), which is based at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
June 2023 to February 2028

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

Who is the main contact?
CTRU.D-MAPP@leeds.ac.uk

Study website
https://ctru.leeds.ac.uk/d-mapp

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Kingsbury

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
-
CTRU.D-MAPP@leeds.ac.uk

Type(s)
Scientific

Contact name
Dr Sarah Kingsbury

Contact details
LIRMM
Level 2 Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA
+44 (0)113-39-24878
S.R.Kingsbury@leeds.ac.uk

Type(s)
Public

Contact name
Dr Dawn Groves-Williams

Contact details
Clinical Trials Research Unit
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT
-
CTRU.D-MAPP@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
330550

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59076, NIHR201612

Study information

Scientific Title
Development and evaluation of the Digital-My Arm Pain Programme for improving painful distal upper limb musculoskeletal disorders

Acronym
D-MAPP

Study objectives
The overall aim of this research programme is to develop and evaluate a digital rehabilitation programme (Digital- My Arm Pain Programme, D-MAPP) to be prescribed by healthcare professionals. This will include an exercise programme tailored to the type of DUL condition and the patients' functional ability and will provide guided support and education to enable self-management.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2024, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8340; edgbaston.rec@hra.nhs.uk), ref: 24/WM/0212

Study design
Interventional randomized controlled trial with mixed methods evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://ctru.leeds.ac.uk/d-mapp/for-patients/patient-information-sheets/

Health condition(s) or problem(s) studied
Painful distal upper limb musculoskeletal disorders

Interventions
Participants will be asked to complete a questionnaire booklet at baseline, prior to randomisation, and then follow-up questionnaires at 3-, 6-, 9- and finally 12-months post randomisation. Consent to access patient medical notes as required will be requested, for example if needed to investigate a reported event of interest during the 12-month follow-up period. Questionnaire booklets will be provided electronically via REDCap, but participants can choose to complete paper versions. The CTRU will be responsible for managing the electronic databases/questionnaire platforms and collection of paper questionnaires. Participants will be sent an electronic, followed by postal reminder if questionnaires are not completed. If required, a third reminder will be used where the participant will be asked to complete the questionnaire over the phone. The primary outcome measure is the participant reported QuickDASH at 6 months post randomisation. QuickDASH reports functional disability, symptoms, and participation levels experienced by people with upper limb disorders. Full details of the trial data analysis will be specified in a predetermined, approved, version-controlled statistical analysis plan.

Participants allocated to the intervention arm (D-MAPP) will be sent instructions about how to download the web-app and will be asked to use D-MAPP for at least 12 weeks and to continue using the app during the 12 month follow up. The app contains accessible self-management resources (information/guidance), a symptoms diary, and a guided exercise programme tailored to the individual's distal upper limb condition. As part of the D-MAPP intervention participants will receive equipment (stress ball and resistance band) where required. The healthcare professional registering the participant will assign the user type based on their diagnosis and this will ensure they have access to resources and exercises relevant for their condition.

The primary feature of the D-MAPP intervention is a tailored and progressive exercise programme. Participants will be asked to log information such as their perceived exertion (using a modified OMNI Exertion Scale) and based on pre-defined thresholds, this will trigger a recommendation to make the exercise programme either easier or harder to ensure the recommended exercises are appropriate for the participant. Logged information will not be used for remote monitoring by a healthcare professional. The exercise programme will also automatically progress at weeks four and eight of the 12-week programme. All exercise programmes have been developed in consultation with clinical experts. Participants can choose which additional features to utilise to support their individual self-management. Participants will be encouraged to access D-MAPP daily for a minimum of 12 weeks to complete their exercise sessions but can choose how long they engage with the intervention afterwards.

The intervention includes in-app and out-of-app notifications to encourage adherence. In-app notifications will be triggered by the participant's use of the intervention. Out-of-app notifications are optional, and the participant can set the frequency and mode (email or SMS) of these.

Participants allocated to the D-MAPP arm can continue to use D-MAPP until 3 months after the end of follow up for the last participant remaining in the study. Participants allocated to the control arm may also be given access to D-MAPP after the end of their 12 month follow up period until 3 months after the end of trial.

The usual care that trial participants will be receiving will differ and will largely depend on their upper limb condition and the type of healthcare professional treating them. Usual care for some participants may mean continuing with their normal self-management regime, which might involve doing prescribed exercises, taking pain medication and/or using splints or braces. Some participants who are no longer under the care of a clinical team may not have any specific treatment. The control group will be asked to continue with whatever 'usual care' they are doing without the addition of the D-MAPP intervention.

A sub-set of approximately 25 participants, purposively sampled based on sex, age, ethnicity, type of DUL-MSD and varying confidence in using the Internet, will be invited to take part in the mixed methods evaluation component. Consenting participants will be asked to complete two additional questionnaires (approx. 10 mins) and an in-depth qualitative interview (approx. 45 mins), which will be conducted remotely and audio-recorded (with permission). This component will explore participants' experiences of using the D-MAPP digital intervention. A combination of descriptive statistics and thematic analysis of the transcribed interview data will be used.

Due to the nature of the intervention, participants and the attending clinical team/research team will not be blinded to treatment group allocation.

Intervention Type

Other

Primary outcome measure
Functional disability/symptoms are measured using QuickDASH (Disabilities of the Arm, Shoulder and Hand) at 6-months

Secondary outcome measures
1. Functional disability/symptoms are measured using QuickDASH (Disabilities of the Arm, Shoulder and Hand) at baseline, 3, 6, 9 and 12-months.
2. Pain is measured using a multi-joint pain questionnaire at baseline and the Numerical Pain Rating Scale (NPRS) at baseline, 3, 6, 9 and 12-months.
3. Anxiety and depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline.
4. Health-related quality-of-life is measured using EQ-5D-5L and a Patient Global Assessment question at baseline, 3, 6, 9 and 12-months.
5. Work limitation is measured using a Work Ability Numerical Rating Scale (NRS), the Work Productivity and Activity Impairment Questionnaire: General Health (WPAI:GH) and 3 questions from the iProductivity Cost Questionnaire (iPCQ).
6. Resource use and cost data will be measured using the Modified Client Service Receipt Inventory (CSRI) at baseline, 3, 6, 9 and 12-months.
7. Process outcomes will be measured using the Discrete Choice Experiment (DCE) at baseline, 3, 6, 9 and 12-months.
8. Confidence using the internet will be measured using a 5-point Likert scale at baseline.
9. Motivation to do exercises will be measured using a Numerical Rating Scale (NRS) at baseline, 3, 6, 9 and 12-months.
10. Data relating to the longer term usage of/adherence to D-MAPP will be collected over 12 months from routine monitoring of web-based exercise views & material downloads (intervention group only).

Overall study start date
01/06/2023

Completion date
28/02/2028

Eligibility

Key inclusion criteria
1. Age >=18 years
2. Clinician-diagnosed DUL-MSD
3. DUL-MSD symptom duration of at least 6 weeks
4. Ability to provide informed consent
5. At least moderate pain (> = 4 on numeric rating scale where 0=no pain and 10=pain as bad as it could be) for most days of the prior 4 weeks
6. No changes to patient’s usual use or type of analgesia taken for the DUL-MSD during the previous 4 weeks

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 356; UK Sample Size: 356

Key exclusion criteria
1. A patient who has distal upper limb pain/symptoms due to any of the following conditions:
1.1. Referred pain from the neck/spine
1.2. Systemic inflammatory conditions or inflammatory arthritis, including (but not limited to) gout, rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, or polymyalgia rheumatica
1.3. Traumatic peripheral nerve injury or peripheral neuropathy due to systemic illness (e.g., diabetes). Mild carpal tunnel syndrome is NOT to be excluded
1.4. Neurological conditions (e.g., stroke, multiple sclerosis)
1.5. Ulnar nerve entrapment or trigger finger
2. Any upper limb fracture in the last 12 months
3. Diagnosis of complex regional pain syndrome
4. Any widespread body pain syndrome that in the view of the investigator would interfere with the assessment of upper limb pain
5. Any DUL condition (e.g., moderate to severe carpal tunnel syndrome) that in the opinion of the investigator warrants referral to surgery
6. Surgical intervention for any condition in either arm/shoulder in the previous six months
7. Any planned surgical intervention for any condition likely to take place in the next three months
8. Steroid injection in either arm/shoulder in the previous eight weeks or planned in the next 12 weeks
9. Any condition (e.g., moderate/severe asthma, inflammatory bowel disease, chronic obstructive pulmonary disease) where the participant has required the use of steroids in the last two years
10. Cancer within the last 3 years or currently receiving treatment for cancer
11. Unable to follow the study protocol and/or comply with or adhere to the intervention
12. Previously randomised to the D-MAPP trial
13. Currently pregnant or has given birth in the last 3 months
14. Ongoing litigation or work disputes relating to their DUL condition

Date of first enrolment
24/02/2025

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Community Healthcare NHS Trust
3 White Rose Office Park
Millshaw Park Lane
Leeds
United Kingdom
LS11 0DL

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds

Sponsor details
Woodhouse Lane
Leeds
England
United Kingdom
LS2 9JT
+44 1133431992
governance-ethics@leeds.ac.uk

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/03/2029

Individual participant data (IPD) sharing plan
De-identified data generated during and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds by contacting ctru-reception@leeds.ac.uk in the first instance.

IPD sharing plan summary
Available on request