STUDY SUMMARY

Title

Multicentre Pilot Feasibility Randomised Controlled Trial of Conservative Management Strategies for Thumb Carpometacarpal Osteoarthritis

Principal investigators:

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TBC

Background and Rationale

Thumb carpometacarpal (CMC) osteoarthritis is a common condition associated with pain, weakness, and functional limitation. Conservative management is recommended as first-line care and commonly includes education, joint protection, exercises, and orthotic management.
Despite widespread clinical use of orthoses, evidence guiding optimal orthotic approaches in routine practice remains limited, particularly regarding feasibility, acceptability, and adherence within real-world clinical settings.
Preliminary clinical observations have suggested that soft thumb strapping may provide perceived improvements in comfort, stability, and function in some patients. However, evidence regarding the feasibility and acceptability of soft thumb strapping approaches remains limited.

This pilot feasibility study will explore the use of a commercially available soft thumb strap (NRX soft strap) alongside usual conservative orthotic management in a pragmatic multicentre clinical context, to determine whether a future definitive multicentre RCT is feasible and acceptable to participants and clinicians.

Study Aim

To evaluate the feasibility, acceptability, and adherence associated with conducting a multicentre pilot randomised controlled trial investigating conservative orthotic management strategies for thumb carpometacarpal osteoarthritis.

Study Objectives

Primary (Feasibility) Objectives

- To evaluate recruitment and retention rates across participating centres
- To assess adherence to prescribed exercises and splint use
- To examine acceptability and usability of different conservative management approaches
- To assess completeness and responsiveness of patient-reported outcome measures

Secondary (Exploratory) Objectives

- To explore trends in patient-reported pain
- To explore trends in hand function
- To assess patient global impression of change

These secondary outcomes are exploratory only and will inform the selection of primary outcomes for a future definitive trial.

Study Design

This study is a multicentre, parallel-group, pilot feasibility randomised controlled trial. Participants will be randomly allocated to one of three intervention arms for a three-week intervention period:

- Exercise and joint protection advice alone
- Exercise and joint protection advice plus an NRX soft strap
- Exercise and joint protection advice plus a usual care orthosis routinely prescribed in participating clinics

The study is not powered to detect between-group differences in effectiveness.

Participants

Adults with a clinical diagnosis of thumb CMC osteoarthritis (early to moderate stage), with radiographic findings recorded where available, will be recruited from participating hand therapy services.

Key inclusion and exclusion criteria will focus on maintaining clinical relevance while ensuring participant safety.

Interventions

All participants will receive a standardised education programme including joint protection advice and a home exercise programme.

Participants allocated to splint groups will be provided with either an NRX soft strap or a usual care splint as per local clinical practice. Therapists will provide standardised guidance on splint application, wear, and care. Adherence will be monitored using self-reported logs.

Outcome Measures

Feasibility Outcomes

- Recruitment rate per site
- Retention at follow-up
- Intervention adherence
- Acceptability and usability
- Completeness of outcome data

Exploratory Clinical Outcomes

- Pain (patient-reported)
- Hand function (patient-reported)
- Patient Global Impression of Change (PGIC)

Sample Size

A target sample size of approximately 36–45 participants (12–15 per group) is proposed, consistent with guidance for pilot feasibility trials. This will allow estimation of feasibility parameters and identification of logistical challenges across participating sites.

Analysis

Data analysis will be primarily descriptive. Feasibility outcomes will be summarised using appropriate descriptive statistics. Exploratory clinical outcomes will be reported as change scores with confidence intervals. No formal hypothesis testing is planned.

Ethics and Governance

Ethical approval will be sought from appropriate Research Ethics Committees prior to participant recruitment. The study will be conducted in accordance with the Declaration of Helsinki and relevant national research governance frameworks.
The Principal Investigator is a distributor of the NRX strap in Ireland; this relationship will be transparently declared.
Neither the manufacturer (Mediroyal) nor the distributor company will have involvement in study design, participant care, data collection, analysis, or reporting.
Outcome assessment will be conducted by a blinded assessor.

Sponsorship and Roles

An academic institution (anticipated: University of Limerick) is being approached to act as study sponsor.
The Principal Investigator will be responsible for study development, coordination, site liaison, and data management.
Outcome assessment will be conducted by a blinded assessor. Potential conflicts of interest relating to the NRX strap will be transparently declared and managed in accordance with study governance procedures.
Additional clinical and academic collaborators will be invited to contribute to study development, recruitment, and oversight as the project progresses.

Dissemination

Findings will be disseminated through:

- National and international conference presentations
- Peer-reviewed journal publication
- Feedback to participating centres

Results will inform the design of a future fully powered randomised controlled trial.

Why This Study Matters

This pilot study will provide important evidence regarding the feasibility, acceptability, and practicality of conservative management strategies for thumb CMC osteoarthritis within routine clinical practice.

Findings will inform the design of a future definitive multicentre randomised controlled trial and contribute to evidence-based orthotic management. Future expansion to international collaborating sites may be considered following successful completion of the pilot study.