

PROTOCOL FOR A MULTICENTRE PILOT FEASIBILITY RANDOMISED CONTROLLED TRIAL OF CONSERVATIVE MANAGEMENT STRATEGIES FOR THUMB CARPOMETACARPAL OSTEOARTHRITIS

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INTRODUCTION

Thumb carpometacarpal (CMC) osteoarthritis commonly causes pain, weakness, and functional limitation. Although conservative management is recommended as first-line care, evidence guiding optimal orthotic approaches remains limited.

Preliminary clinical observations suggest that dynamic thumb strapping using NRX strap may improve comfort, stability, and function in some patients; however, evidence regarding feasibility, acceptability, and adherence remains limited.

Current clinical challenges:

- ✓ Variation in orthotic management across settings
- ✓ Limited evidence regarding feasibility and acceptability of different orthoses
- ✓ Uncertainty surrounding adherence and patient preference
- ✓ Need for multicentre feasibility data to inform future definitive trials

AIM

To evaluate the feasibility of conducting a multicentre pilot randomised controlled trial comparing conservative management strategies for thumb carpometacarpal osteoarthritis.

METHODOLOGY

Design
Multicentre parallel-group pilot feasibility RCT with a 6-week intervention period.

Participants
Adults with clinically diagnosed early-stage (Stage I-II) thumb carpometacarpal osteoarthritis will be recruited across participating clinical sites, with radiographic confirmation obtained where available.

Interventions
Participants will be randomised into 3 groups.

- 1 Exercise + Advice
- 2 Exercise + Advice + NRX soft strap orthosis
- 3 Exercise + Advice + usual care orthosis

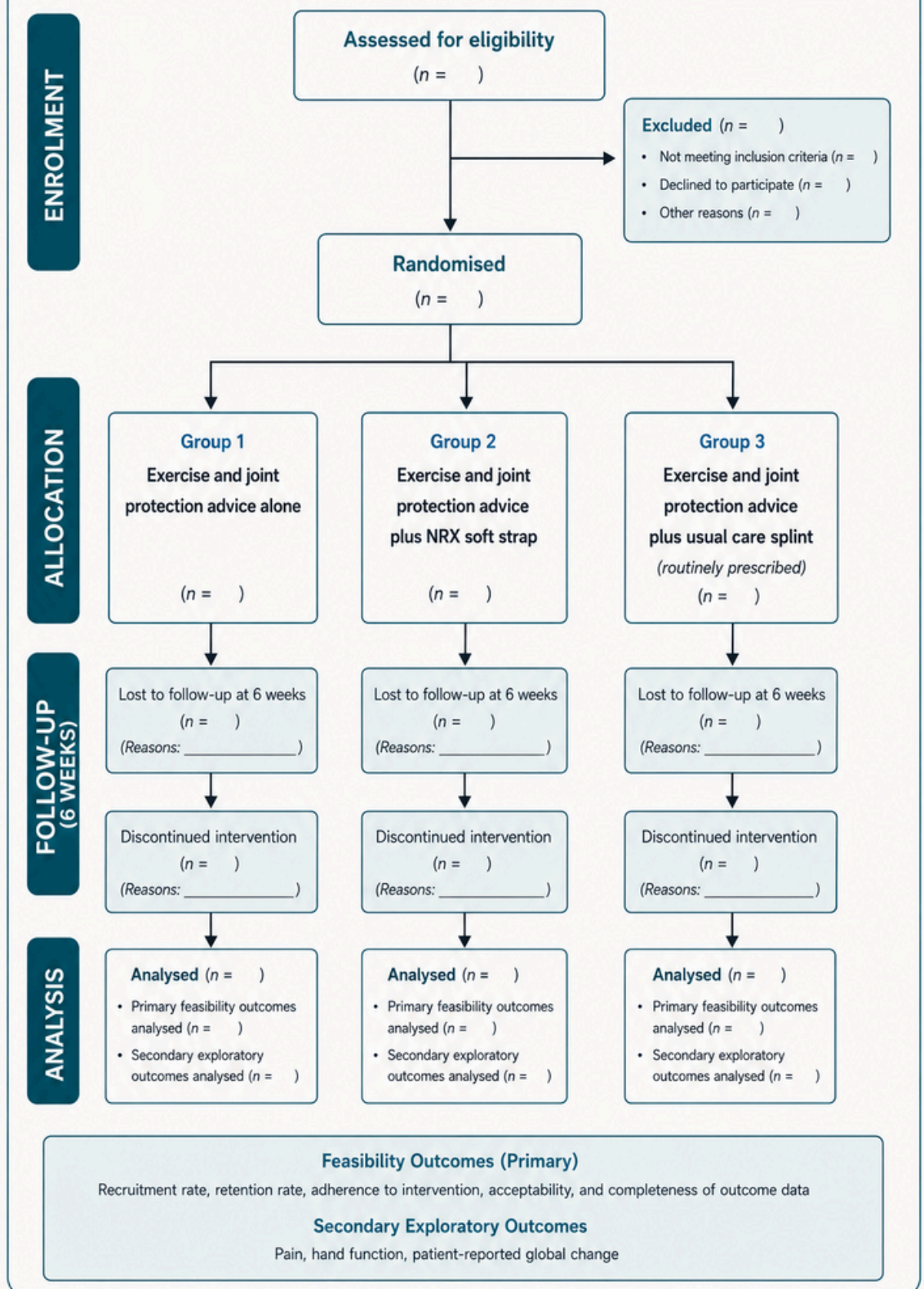
All groups will receive standardised exercise and joint protection advice.

Outcomes

Primary feasibility outcomes
Recruitment, retention, adherence, acceptability, completeness of outcome data

Secondary exploratory outcomes
Pain, hand function, patient-reported global change

STUDY FLOW: CONSORT DIAGRAM



PRIMARY FEASIBILITY OUTCOMES

- Recruitment rate
- Retention rate
- Intervention adherence
- Acceptability (participants and clinicians)
- Completeness of outcome data

SECONDARY EXPLORATORY OUTCOMES

- Pain
- Hand function
- Patient-reported global change (PGIC)



PROGRESSION CRITERIA

Progression to a definitive multicentre RCT will be considered if the following criteria are met:

- ✓ Recruitment and retention targets achieved
- ✓ ≥ 70% adherence to assigned interventions
- ✓ ≥ 80% completeness of outcome data
- ✓ Acceptability rated satisfactory by participants and clinicians

ETHICAL CONSIDERATIONS

- ✓ 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 governance frameworks
- ✓ The lead 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

EXPECTED IMPACT

Inform feasibility of conservative management, including soft strapping

Refine protocols, adherence monitoring, and outcomes for future RCTs

Support evidence-based conservative management for thumb CMC osteoarthritis

May improve patient outcomes, adherence, and resource utilisation