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Relative Motion Extension - Orthosis use in treating Trigger finger (ReMEx-OT) in the adult population – A multi-centre, randomised, superiority trial

Submission date
23/10/2024

Recruitment status
Recruiting

Registration date
14/11/2024

Overall study status
Ongoing

Last Edited
19/12/2024

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
Trigger Finger (TF), also known as stenosing tenosynovitis, is a condition that affects the movement of the fingers. People with TF often experience their finger snapping, locking, or getting stuck when they try to bend or straighten it. This happens because the tendon in the finger becomes thickened or its covering (called the tendon sheath) tightens, making it hard for the tendon to move smoothly. TF is estimated to affect about 2% of the general population but is more common in women, particularly in their 60s and 70s. While TF can happen on its own (idiopathic), it can also be linked to conditions like diabetes, rheumatoid arthritis, and hypothyroidism.

Treatment for TF can vary. Conservative options, such as wearing an orthosis (a custom-made splint) to reduce the movement of the tendon, are often tried first. Several types of orthoses can be used to treat TF. One of the most common is the metacarpophalangeal joint blocking orthosis (MCPJ-BO), which restricts movement in the affected finger to help reduce symptoms. Another option is the relative motion extension orthosis (RME-O), which has a lower profile and allows relatively easier hand use during daily activities. While both are used in clinical practice, there is limited research comparing their effectiveness.

This study aims to compare these two orthoses, the MCPJ-BO and the RME-O, in treating TF. The goal is to determine which orthosis is more effective in improving hand function and relieving pain, especially in patients with mild to moderate TF (graded 2-5 on the Stenosing Trigger Finger scale). The study will also look at patient satisfaction and how well they stick to wearing the orthosis as prescribed.

The aim of this study is to compare two types of orthoses used to treat TF: the metacarpophalangeal joint blocking orthosis (MCPJ-BO) and the relative motion extension orthosis (RME-O). The study will investigate which orthosis is more effective in relieving symptoms and improving hand function in people with TF.

Who can participate?
Participants in this study must be:
• Adults aged 18 or older
• Diagnosed with Trigger Finger in the index, middle, ring, or little finger, graded between 2 and 5 on the Stenosing Trigger Finger (SST) scale
• Able to speak English and give informed consent

People will not be able to participate if they:
• Have had previous orthotic treatment, corticosteroid injections, or surgery for their condition
• Have TF in multiple fingers or affecting the thumb
• Are pregnant or have any conditions that prevent them from using the orthoses or providing consent

What does the study involve?
This study will compare two types of splints (orthoses). Participants will be randomly assigned to receive either the MCPJ-BO or the RME-O during their occupational therapy sessions. These splints aim to reduce symptoms by limiting certain hand movements. Both orthoses will be worn full-time for six weeks, and participants will keep a diary to track how long they wear the splint.

The study will measure several outcomes at the start of the study and followed by 3, 6, 9, 12, and 16 weeks, including:
• Pain and hand function (using the Patient-Rated Wrist and Hand Evaluation)
• Grip strength
• Triggering severity and frequency
• Satisfaction with the splint

What are the possible benefits and risks of participating?
Participants may benefit from receiving a splint that could relieve their symptoms and improve hand function. However, there are rare but potential risks associated with wearing an orthosis, such as skin irritation or discomfort. These potential side effects will be monitored throughout the study.

Where is the study run from?
This study is run from a publicly funded university in Ireland (University of Galway, Ireland) and is being conducted in the occupational therapy departments of two publicly funded hospitals. One is a regional teaching hospital (University Hospital Limerick, Ireland), and the other is a general acute hospital (Our Lady's Hospital Navan, Ireland) that provides elective orthopaedic services.

When is the study starting and how long is it expected to run for?
March 2024 to December 2026

Who is funding the study?
The researchers are currently self-funding the study with appropriate support from the participating universities and HSE centres. However, funding from the Health Research Board, Ireland, the Elizabeth Casson Trust, UK, the Royal College of Occupational Therapists and the Federation of European Societies for Surgery of the Hand is being explored.

Who is the main contact?
For further information about the study, please contact Manigandan Chockalingam, the principal investigator, at Manigandan.Chockalingam@universityofgalway.ie

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HSE-MWR_REC Ref:0103

Study information

Scientific Title
A multi-centre, investigator-blinded, randomised, 6-week, parallel-group, superiority trial to compare the efficacy of using the Metacarpophalangeal Joint Blocking Orthosis (MCPJ-BO) versus the Relative Motion Extension - Orthosis (RME-O) in reducing pain and improving function of trigger finger in the adult population

Acronym
ReMEx-OT

Study objectives
The trial hypothesises that either the Relative Motion Extension Orthosis or the Metacarpophalangeal Blocking Orthosis will result in superior outcomes based on mean post-randomisation scores for self-reported wrist/hand pain and functional performance, with data collected at 3, 6, 9, 12, and 16 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/10/2024, HSE Mid-Western Area Research Ethics Committee (Secretary, Ethics Committee Mid-Western Regional Hospital, Dooradoyle, Limerick, V94 F858, Ireland; +353 (61) 482519; ULHGResearchEthicsandClinicalTrials@hse.ie), ref: 0103

2. Submitted 15/10/2024, HSE North East Area Research Ethics Committee (Secretary, HSE North East Area Research Ethics Committee, Bective Street, Kells, Co. Meath, A82 NX32, Ireland; +353 (46) 9251262; NorthEast.REC@hse.ie), ref: YET TO RECEIVE

Study design
Two-arm parallel-group assessor-blinded multi-centre individual participant randomized controlled trial

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
Improvement of self-reported wrist/hand pain and functioning outcomes in patients with trigger finger

Interventions
Participants will be randomly assigned to one of two intervention groups, relative motion extension orthosis (RME-O) or metacarpophalangeal joint blocking orthosis (MCPJ-BO), during their first occupational therapy appointment. An independent researcher will conduct baseline assessments. A trained hand therapist will fabricate the assigned orthosis per standardised protocols.

The MCPJ-BO restricts flexion at the metacarpophalangeal joint to prevent the triggering of the A1 pulley. The RME-O positions the affected digit in relative extension, potentially enhancing palmar sensitivity and functional hand use. Both orthoses will be prescribed for full-time use over six weeks, with patients documenting adherence in a diary. Removal will only be permitted for hygiene purposes. All participants will receive standardised educational materials and exercise instructions.

A 1:1 randomisation system will be used to allocate participants to either the MCPJ-BO or RME-O intervention arms after eligibility has been confirmed, consent has been obtained, and all baseline data have been collected. The computer-generated allocation schedule will be included in concealed, opaque, consecutively numbered envelopes by someone not otherwise involved in the study.

Due to the nature of the intervention, it is not possible to blind patients and their treating therapist to the allocation of treatment. The outcome assessor, however, will be blinded to the participant's allocation to avoid bias in the collection of primary and secondary outcomes.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Custom-fabricated orthosis will be used in the trial, namely, RME-O and MCPJ-BO

Primary outcome measure
Patient-Rated Wrist and Hand Evaluation (PRWHE), measured at 3, 6, 9, 12 and 16 weeks after randomisation, and is expressed as the mean total score

Secondary outcome measures
1. Grip strength measured using a handheld dynamometer according to standard protocols at 3 and 6 weeks post randomisation
2. Trigger Severity: Objectively assessed using the Stages of Stenosing Tenosynovitis (at 3 and 6 weeks post randomisation) and subjectively via a patient-reported severity scale (at 3, 6, 9, 12 and 16 weeks post randomisation)
3. Trigger Frequency: Measured by the number of trigger events during ten active fists (at 3 and 6 weeks post randomisation) and reported by participants (at 3, 6, 9,12 and 16 weeks post randomisation)
4. Orthosis Wear Time: Documented by patients in a daily diary, recorded on a 10 cm scale representing 10% increments for the entire duration of orthotic use (six weeks)
5. Orthosis Satisfaction: Assessed on a 0-10 scale, with 0 representing "strongly disagree" and 10 representing "strongly agree" with satisfaction-related statements (at 3 and 6 weeks)

Overall study start date
13/03/2024

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 and over with TF diagnosed by a hand therapist, general practitioner, orthopaedic, or rheumatology doctor, presenting with a grade between 2 and 5 SST of the index, middle, ring, or little finger
2. Able to communicate adequately in English and give informed consent
3. As TF is commonly observed among patients with musculoskeletal disorders and other associated diagnoses such as arthritis, diabetes and carpal tunnel syndrome, these will be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 100

Key exclusion criteria
1. Those who have previously failed with orthotic intervention, received corticosteroid injections or surgical release of A1 pulley for the symptomatic digit
2. Multiple-digit TF
3. Triggering of the thumb
4. Patients who are pregnant
5. Those patients who are unable to consent or adhere with the intervention for various reasons, such as cognitive, psychological, or physical impairments

Date of first enrolment
02/12/2024

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
Ireland

Study participating centre
Our Lady's Hospital Navan
Townparks, Navan, Meath
Navan
Ireland
C15 RK7Y

Study participating centre
University Hospital Limerick
St Nessan's Road, Dooradoyle, Limerick,
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Sponsor information

Organisation
University Hospital Limerick

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Sponsor type
Hospital/treatment centre

Website
http://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/ulh/hospitals/uhl/

ROR
https://ror.org/04y3ze847

Organisation
Health Service Executive

Sponsor details
Our Lady's Hospital Navan, Townparks, Navan, Meath
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C15 RK7Y
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Sponsor type
Hospital/treatment centre

Website
http://www.hse.ie/

ROR
https://ror.org/04zke5364

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
University Hospital Limerick

Funder Name
Our Lady's Hospital Navan

Funder Name
University of Galway

Alternative Name(s)
Coláiste na hOllscoile, Gaillimh, Ollscoil na hÉireann Gaillimh, Queen's College, Galway, University College, Galway, NUI Galway, National University of Ireland, Galway, National University of Ireland Galway, Ollscoil na Gaillimhe, National University of Ireland, Galway/NUI Galway, NUI Galway, OÉ Gaillimh

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Funder Name
University of Galway School of Health Sciences Early Career Researcher Bursaries, 2024

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Conference presentation
3. Submission to regulatory authorities

Intention to publish date
30/06/2027

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