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Rehabilitation enhancing support for therapeutic orthosis and rehabilitation efforts

Submission date
29/06/2026

Recruitment status
Recruiting

Registration date
01/07/2026

Overall study status
Ongoing

Last Edited
30/06/2026

Condition category
Other

[ ] 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
The study is exploring the use of a new wrist-hand device to support hand and wrist function. We are interested in understanding how the device affects movement, comfort and the ability to carry out every day tasks, as well as gathering your feedback to help improve the design.

Who can participate?
You can participate if you are between 18 and 79 years old, are a registrant of the SHARE database and if you meet the criteria needed for our study and are part of the people in the community who have been prescribed a wrist hand orthosis, with or without a thumb brace to reduce pain and/or help with their activities of daily living.

What does the study involve?
If you decide to take part, you would be asked to attend two laboratory sessions, each lasting approximately 3.5 hours, and a group discussion (focus group).
Test Session Day 1: During your first visit, you will be asked to complete a series of hand movements and strength tests under three conditions:
1. Without wearing a Wrist-hand orthosis/device/brace
2. Wearing your current device
3. Wearing a new study device
We will ask about your comfort, any pain or discomfort, and how easy or difficult you find the tasks.
Test Session Day 2: During your second visit, you will complete everyday tasks (such as writing or simple food-related tasks), again under the same three conditions.
Focus Groups: You will also be invited to take part in a group discussion to share your experiences using the device. As part of the study, we may also capture images of your hand during tasks to help us understand movement. This is optional, and you can still take part if you prefer not to have images taken. The device being tested is new and has not yet been approved for clinical use. Some participants may experience mild discomfort, irritation or temporary changes in how they move while getting used to the device. You are free to stop taking part at any time. Participants will receive payment for taking part in each stage of the study, and reasonable travel costs (such as public transport or taxi fares) will be reimbursed.

What are the possible benefits and risks of participating?
We do not expect that taking part will benefit you directly. However, your involvement will help us better understand how this type of device may affect people with wrist or hand conditions or injuries, and this could help improve care for others in the future. We have designed this study to be as safe as possible, but there are some potential risks to be aware of:
Skin irritation (low risk). Wearing the device may cause redness, pressure marks or irritation, especially if you have sensitive skin. We will show you how to fit it properly and will check in with you during the study. Any skin problems will be recorded and monitored as part of the study's safety procedures. If symptoms persist or worsen, we will advise you to seek appropriate medical care (e.g., your GP).
Increased pain or discomfort (low to moderate risk)
The device may feel uncomfortable at first, and you notice increased pain or stiffness when using it. We will guide you on how to use it safely. You should stop using it if the pain becomes worse. Unknown effects on recovery (low risk). As this is a new device, we do not fully know how it may affect your recovery. In some cases, it could slow recovery or place too much strain on the wrist (for example, if the wrist is overstretched). We will provide guidance on safe use and monitor you during the study sessions. You can always stop the study if your symptoms worsen.
Adjusting to a new way of moving (muscle memory) (low to moderate risk). Your body may be used to moving your wrist and hand in a certain way. Using the device may change how you move, which can feel unfamiliar at first. This may lead to mild discomfort, awkward movements, or temporary difficulty completing tasks. Most people adjust over time. We will support you during testing, and you can stop at any time if you feel uncomfortable.
The device may not suit you (low risk). We may find that the device does not work well for your specific condition or needs. If this happens, we will address any concerns and may ask you to stop taking part.
Frustration or tiredness (moderate risk)
The device may not meet your expectations, and some of the testing tasks may feel tiring or frustrating. We will explain what to expect and support you throughout the study. Device problems (low risk)
As this is a new device, it may occasionally break or not work as expected. If this happens, we will deal with it promptly and during the study session. Unexpected health findings (low risk). During testing, we may notice issues such as movement difficulties or weakness that you were not aware of. If this happens, we will discuss it with you sensitively and may suggest that you speak to your GP.

Where is the study run from?
The study is run from Tayside Orthopaedic and Rehabilitation Technology (TORT) Centre in Ninewells Hospital, Dundee (UK)

When is the study starting and how long is it expected to run for?
June 2026 to December 2027

Who is funding the study?
Tay Health Tech, a Place-Based Impact Acceleration Account funded by the Engineering and Physical Sciences Research Council (EPSRC) (UK)

Who is the main contact?
For any questions or additional information about the study, please contact the research team, Dr Martin Seyres, Dr Alejandra Aranceta-Garza or Karyn Ross, by one of the following methods:
Telephone: 01382 381634 (Monday – Friday, 9am – 5pm)

Email: mseyres001@dundee.ac.uk / aarancetagarza001@dundee.ac.uk / k.ross@strath.ac.uk
You can also contact the Chief/Principal investigator, Prof. Arpit Jariwala: Email: ajariwala@dundee.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
372629

Study information

Scientific Title
Rehabilitation Enhancing Support for Therapeutic Orthosis and Rehabilitation Efforts (RESTORE)

Acronym
RESTORE

Study objectives
To measure:
1. Maximum range of motion at the wrist.
2. Maximum active range of wrist motion and maximum strength during a grip and pinch strength tests.
3. Measure wrist motion that occurs during seven standardised tasks, following the Jebsen Taylor Hand Function Test (JTHFT): writing, card turning, small object picking, simulated feeding, stacking checkers, picking up a coin, and moving a light object.
4. Wrist motion during the above tests while wearing the wrist-hand orthosis prototype, while wearing their prescribed WHO, and without any device.
5. Levels of pain before, during and after testing.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 23/06/2026, West of Scotland REC 4 (West of Scotland Research Ethics Service, Research Ethics – Room 29, 2nd Floor Administration Building Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 211 3600; ggc.wosrec4@nhs.scot), ref: 372629

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
People in the community who have been prescribed a wrist hand-orthosis, with or without a thumb brace to reduce pain and/or help with their activities of daily living

Interventions
Participants will be split into two cohorts, those using wrist-hand orthoses and those using wrist-hand-thumb orthoses. The following measures, with and without WHO (own device/s and test device/s), will be obtained in a controlled environment:
1. Maximum range of motion at the wrist
2. Maximum active range of wrist motion and maximum strength during maximum grip and pinch strength tests
3. Movement of the wrist and time to complete standardised tasks following the Jebsen Taylor Hand Function Test: writing, card turning, small object picking, simulated feeding, stacking checkers, picking up a coin, and moving a light object
4. Patient reported outcome measures to be completed: the Michigan Hand Questionnaire (MHQ) is a comprehensive patient-reported outcome measure (PROM) assessing hand outcomes, including hand function, ADLs, pain, aesthetics, and patient satisfaction with hand performance. It is used as an assessment of general user satisfaction of an orthotic device
5. Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)
6. Perceived comfort and discomfort (using the Orthotics Prosthetics User Survey [OPUS] for the upper extremity)
7. Pain scores will be captured at three different timepoints during the testing periods (using the Numerical Pain Rating Scale [NPRS]): before, when there is a change of the intervention used, including without any device and after completing the tests

Intervention Type
Other

Primary outcome(s)
1. Range of motion measured using electronic goniometer at baseline and day 2

2. Grip and pinch strength measured using electronic dynamometer and pinch meter at baseline

3. Patient-reported perception of their hand and wrist function (activities of daily living, pain, aesthetics and satisfaction with hand performance) measured using the Michigan Hand Questionnaire (MHQ) at baseline

4. Patient satisfaction with a specific assistive device measured using the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) at baseline

5. Functional improvements, quality of life, and satisfaction with assistive devices measured using the Orthotics Prosthetics User Survey (OPUS) at baseline

6. Pain measured using the Numerical Pain Rating Scale (NPRS) at three timepoints in the baseline session

Key secondary outcome(s)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Must be currently using a prefabricated wrist-hand or wrist-hand-thumb orthosis/splint/brace due to disease listed in eligibility criteria
2. Between 18 and 79 years old
3. Right-hand dominant (confirmed by the Edinburgh handedness test)
4. Able to provide consent
5. Have at least one of the following with confirmation of wrist/hand/thumb involvement from the Scottish Health Research Register and Biobank (SHARE):
5.1. M05 seropositive rheumatoid arthritis
5.2. M06 other rheumatoid arthritis
5.3. M13 other arthritis
5.4. G56 mononeuropathies of upper limb
5.5. S62 fracture at wrist and hand level < 1 year
5.6. S64 injury of nerves at wrist and hand level
5.7. S66 injury of muscle and tendon at wrist and hand level <1 year
5.8. S69 other and unspecified injuries of wrist and hand <1 year
5.9. N0406 Rheumatoid arthritis of distal radioulnar joint
5.10. N0407 Rheumatoid arthritis of wrist

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
79 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Anyone under 18 years of age
2. Unable to provide informed consent
3. Not currently using a prefabricated wrist-hand/thumb orthosis/splint/brace
4. Anyone with any other unstable medical condition
5. Anyone having undergone wrist/hand/thumb surgery in the last 6 months
6. Anyone due to have surgery to the wrist/hand/thumb in the next three months
7. Individuals with skin conditions that may be aggravated by wearing study-related equipment or materials, or for whom wearing such items over affected areas would cause discomfort or harm, should not take part in the study.

Date of first enrolment
25/06/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Dundee's NeuroRehabilitation and Technology Laboratory, in Ninewells Hospital, located at the TORT Centre
TORT Centre, Ninewells Hospital
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Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type

Funder Name
Tay Health Tech

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available