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3D-printed wrist orthosis for carpal tunnel syndrome

Submission date
28/11/2025

Recruitment status
Recruiting

Registration date
28/11/2025

Overall study status
Ongoing

Last Edited
13/01/2026

Condition category
Nervous System 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
This study is exploring a new way to make orthoses using 3D printing technology. These supports are used to help people with a condition called carpal tunnel syndrome, which causes pain, numbness, and tingling in the hand and fingers due to pressure on the median nerve. Although 3D printing has many advantages over traditional methods, it's not yet commonly used in clinics. The aim of this study is to see how acceptable and useful 3D-printed orthoses are for patients and healthcare professionals.

Who can participate?
Adults aged 18 years and over who have a carpal tunnel syndrome can take part in the study. Both men and women will be included, and participants will be recruited from different healthcare centres.

What does the study involve?
Participants, if interested, will receive a phone call to verify their eligibility. If eligible, patients will meet with the research assistant, who will scan the affected upper limb. The research assistant will send the scanned data to Althera (Penelle and Adams). Althera will model the orthosis, which will then be 3D-printed and sent to the patient. The patients will be asked to fill out questionnaires about their pain and hand function at five different times: before wearing the orthosis, and then 24 hours, 1 week, 1 month, and 2 months after starting to wear it. All questionnaires can be completed from home using a phone or computer.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain and improved hand and wrist function thanks to the orthosis. However, wearing it might be uncomfortable and could cause skin irritation or pain due to limited wrist movement. The study also requires some time commitment—about 30 minutes online and around 15 minutes to complete questionnaires at each of the five time points.

Where is the study run from?
Université du Québec à Trois-Rivières (UQTR) (Canada)

When is the study starting and how long is it expected to run for?
The study started in June 2025 and is expected to run until December 2026.

Who is funding the study?
Université du Québec à Trois-Rivières (UQTR) (Canada)

Who is the main contact?
Tokiko Hamasaki, tokiko.hamasaki@uqtr.ca

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Proof of concept: confection wrist orthoses for carpal tunnel syndrome using 3D printing

Acronym
3DP

Study objectives
This project aims to evaluate whether 3D-printed orthosis is acceptable in a clinical setting, both for professionals and for patients with carpal tunnel syndrome. This technology, which is still rarely used in this field, could offer practical and clinical advantages over traditional methods.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, Comité d'éthique de la recherche du CIUSSS de la Mauricie-et-du-Centre-du-Québec (2700, boulevard des Forges, bureau 302, Trois-Rivières, G8Z 1V2, Canada; +1 (0)819 372-3133, poste 32303; 04ethiqueciusssmcq@ssss.gouv.qc.ca), ref: MP-29-2026-896, 1026

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Carpal tunnel syndrome of the wrist

Interventions
The study design is semi-experimental; thus, there is no randomization, and there is only one arm for which the treatment is a 3D-printed orthosis. Every participant will wear the 3D orthosis and the thermoformed orthosis (control). They will wear each orthosis for a total of 2 months. The participants will answer a questionnaire assessing their symptoms before wearing the orthosis and questionnaires about the orthosis 24 hours, 1 week, 1 month and 2 months after beginning to wear the orthosis. They will not wear the 3D orthosis and the thermoformed orthosis at the same time.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain and upper limb function measured using 0-10 rating scale for pain at at the start of the study and after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)

2. Upper limb function measured using QuickDASH questionnaire at at the start of the study and after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)

Key secondary outcome(s))
1. User satisfaction measured using QUEST 2.0 questionnaire at after beginning to wear the orthosis at multiple intervals (24 hours, 1 week, 1 month, 2 months)

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. The patient must be 18 years or older
2. The patient must have a carpal tunnel syndrome of the wrist
3. The patient must be able to read, write and answer the questionnaires

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The patient is already wearing an orthosis
2. The patient received a cortisone injection in the last 4 months
3. The patient received surgery for this condition

Date of first enrolment
05/12/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
Canada

Study participating centre
CHUM
1000 Saint Denis St
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Study participating centre
Clinique Multidisciplinaire en Santé de l'UQTR
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Study participating centre
CBI Santé - Trois-Rivières
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Study participating centre
Centre hospitalier affilié universitaire régional de Trois-Rivières
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Sponsor information

Organisation
Centre Hospitalier de l'Université de Montréal

ROR
https://ror.org/0410a8y51

Organisation
Université du Québec à Trois-Rivières

ROR
https://ror.org/02xrw9r68

Funder(s)

Funder type

Funder Name
Université du Québec à Trois-Rivières

Alternative Name(s)
Universidad de Quebec en Trois-Rivières, UQTR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available