

Determining the effectiveness of the FEPSim™ device for hand therapy

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| Submission date 02/06/2020 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 04/06/2020 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 09/07/2025 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Impairments of the upper limb affects functioning in everyday life and are correlated with a low quality of life. Impairments of the forearm, wrist, and hand represent a health-related problem that affects a sizable proportion of Albertans and represents a significant economic burden for Alberta's Health System. The FEPSim™ (flexion, extension, pronation, and supination), developed by Karma Machining & Manufacturing Ltd. (KM&M), an Alberta-based small-medium sized enterprises (SME), is a medical device for hand and wrist rehabilitation. The FEPSim™ has not yet been tested in a healthcare setting, as result whether FEPSim™ is effective, remains an open question

The purpose of this study is to test the research protocol so we can improve it. We also want to look for any changes in your active range of motion (AROM), passive range of motion (PROM), grip strength, pinch grip force and performance in activities of daily living.

Who can participate?

Potential participants (patients) are adults (18 years of age and older) with limitations in their forearm, wrist, or hand function due to distal radial/ulnar fractures, stroke, or osteoarthritis (e.g. patients who have undergone a Wrist Salvage Procedure). Hand therapists from the hand therapy services who used the FEPSim™ device are potential participants in our study as well.

What does the study involve?

Some participants (patients) in this project will not have sessions with the FEPSim™ (Group A). They will have all the regular intervention that patients in the outpatient clinic at the Royal Alexandra Hospital and Glenrose Rehabilitation Hospital usually receive.

In the FEPSim™ group (Group B), the participants will receive time using the FEPSim™ as part of their therapy. In week two, four, and eight; research assistants of the University of Alberta will administer tests to measure changes in your hand function. They will also administer the Patient-Rated Wrist Evaluation Questionnaire (PRWE). Each assessment session will take a maximum of 60 minutes. We will provide breaks if you feel you need them.

The participants (therapists) will be asked to record the therapeutic supplies, equipment (including the FEPSim™ configuration), and consumables you have used, and the time you spent

with a participant during regular therapy sessions. It will not take more than 3 minutes each session. For those therapists who use the FFEPSim™ device we will be asked them to participate in one interview that will take a maximum of 30 minutes regarding the usability of the FFEPSim™ device.

What are the possible benefits and risks of participating?

The benefits of participating are:

Participants (patients) in the intervention group may have improvement of active and passive range of motion (AROM and PROM) of wrist flexion and extension, and forearm pronation and supination, grip strength and pinch grip force greater than with the standard care. Participants in the intervention group may also experience lower wrist pain and more independence in activities of daily living.

Participants (Therapists) may find the FEPSim™ an easy and useful way to treat patients.

The risk participating in this study is minimal, meaning the participants may feel some discomfort and/or pain during the therapeutic sessions using the FEPSim™ or the standard care. It is normal to feel some pain or discomfort during therapeutic intervention during hand rehabilitation.

Where is the study run from?

University of Alberta (Canada)

When is the study starting and how long is it expected to run for?

November 2019 to April 2021

Who is funding the study?

Alberta Innovates - Health Solutions (Canada)

Who is the main contact?

Prof. Miguel Cruz, miguelcr@ualberta.ca

Contact information

Type(s)

Scientific

Contact name

Prof Antonio Miguel Cruz

ORCID ID

<https://orcid.org/0000-0003-1618-8733>

Contact details

8205 114 Street
3-48 Corbett Hall
Edmonton
Canada
T6G 2G4
7802246641
miguelcr@ualberta.ca

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Pro00095587

Study information

Scientific Title

Determining the effectiveness of a new device for hand therapy: the FEPSim™ device

Acronym

FEPSim™ Trial

Study objectives

The primary objective of this proposed study is to assess the feasibility of conducting a definitive trial in terms of recruitment, eligibility criteria, the type and number of diagnoses included, the length and dosage of the intervention, and the data collection methods.

This study also aims to gather clinical and statistical information, as well as information related to the costs and usability (adoption) of the new technology used in this study. Thus, this study has six secondary objectives as follows:

1. To explore the clinical effectiveness of adding the FEPSim™ device (Flexion, Extension, Pronation, and Supination) to standard care for patients with injuries and clinical conditions of the forearm, wrist, and hand
2. To assess the outcome measures for measuring changes in the dependent variables
3. To gather and synthesize the data, from which the sample size of a definitive Randomized Controlled Trial (RCT) can be estimated
4. To measure the key outcome domains (for the completion rates, missing data, estimates, variances, and 95% confidence intervals for the differences between the intervention groups) for patients with injuries and clinical conditions of the forearm, wrist, and hand
5. To examine the total and component costs associated with the FEPSim™ device and with standard care interventions for patients with injuries and clinical conditions of the forearm, wrist, and hand from an institutional perspective (i.e. the hospitals)
6. To investigate the usability of the FEPSim™ device by therapists

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/12/2020, University of Alberta Ethics Committee (308 Campus Tower 8625 - 112 Street Edmonton, Alberta, Canada T6G 1K8; +1 780-492-0459; reoffice@ualberta.ca), ref: Pro00095587

Study design

Feasibility parallel-group randomized controlled trial with economic evaluation and qualitative description

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Limitations in forearm, wrist, or hand function due to distal radial/ulnar fractures, stroke, or osteoarthritis

Interventions

The intervention group will receive the same standard care as the control group at each hospital, which consists of immobilization for 7-8 weeks after the time of the injury or surgery, followed by hand therapy sessions for 10 weeks to manage scar tissue, sensory alterations, and edema. The experimental group will use the FEPSim™ device for the therapeutic activities to increase strength, range of motion, resistance, and dexterity. The sessions' length and frequency will depend on the patients' needs and diagnoses. The length of each session will be between 30 and 45 min, and they will be carried out once or twice per week.

Randomization: The participants will be randomly assigned 1:1 either to the experimental group or to the control group using probability sampling stratified according to their medical condition (fractures, stroke, or osteoarthritis) at each of the hospitals. This allocation will be carried out using a stratified permuted block design. This allocation design allows the participants to be randomized within sequential blocks, which improves both the balance in the number of treatment assignments throughout the study period and the balance in the strata.

Participant (therapists) qualitative data collection: Once the data collection for primary objective one is finished, the interviews with the hand therapists will be conducted with those therapists who agreed to participate and signed a consent form. Semi-structured questions (topic guided) will examine the usability of the FEPSim™ device.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

FEPSim™

Primary outcome(s)

At week 0 and after the intervention (week 10), and during weeks 4 and 8:

1. Angles of active range of motion (AROM) and passive range of motion (PROM) of wrist flexion and extension, and forearm pronation and supination, measured using a goniometer
2. Grip strength measured using a grip dynamometer
3. Pinch grip force is measured using a pinch gauge or pinch meter

Key secondary outcome(s)

At week 0 and after the intervention (week 10), and during weeks 4 and 8:
Patients' perceived wrist pain and disability in activities of daily living measured using the Patient-Rated Wrist Evaluation (PRWE)

Completion date

30/04/2021

Eligibility**Key inclusion criteria**

Patients:

1. Wrist fractures, acquired brain injuries, burns or osteoarthritis (e.g. patients who have undergone a Wrist Salvage Procedure), causing limitation in hand movement
2. 18 years of age and older

Therapists:

3. The therapists need to have used the FEPSim™ to be able to provide feedback about the usability of the device during the interview

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

38

Key exclusion criteria

1. Chronic Regional Pain Syndrome
2. Subjective/patient-reported limitation to participate (e.g. excessive pain, edema)
3. Limitations in reading and listening comprehension of language that prohibits to understand the PRWE questionnaire
4. Limitation in following instructions due to cognitive impairment

Date of first enrolment

01/04/2020

Date of final enrolment

31/01/2021

Locations

Countries of recruitment

Canada

Study participating centre

Glenrose Rehabilitation Hospital

10230 111 Ave NW

Edmonton

Canada

T5G 0B7

Study participating centre

Royal Alexandra Hospital

10240 Kingsway NW

Edmonton

Canada

T5H 3V9

Sponsor information

Organisation

University of Alberta

ROR

<https://ror.org/0160cpw27>

Funder(s)

Funder type

Industry

Funder Name

Alberta Innovates - Health Solutions

Alternative Name(s)

AIHS

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of permission to do so.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | | 27/01/2025 | 09/07/2025 | Yes | No |
| Protocol article | | 27/05/2021 | 28/05/2021 | Yes | No |
| Interim results article | Qualitative study | 10/11/2022 | 11/11/2022 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |