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Determining the effectiveness of the FEPSim™ device for hand therapy

Submission date
02/06/2020

Recruitment status
No longer recruiting

Registration date
04/06/2020

Overall study status
Completed

Last Edited
11/11/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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 FEPSimTM 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 FFEPSim™ 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 participation information sheet

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 measure
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

Secondary outcome measures
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)

Overall study start date
01/11/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Patients: n = 104, Control Group: 47, Intervention Group: 47

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
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Canada
T5H 3V9

Sponsor information

Organisation
University of Alberta

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Sponsor type
University/education

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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

Publication and dissemination plan
We plan to present the interim results to Alberta-based health service organizations (including the Glenrose Rehabilitation and Royal Alexandra Hospitals), and the final results at provincial, national, and international conferences. We also plan to publish in peer-reviewed journals and gray literature. We will engage with policy makers and support the SME industry partner in commercializing the technology application. We intend to collaborate with occupational therapy education programs, such as the University of Alberta, to incorporate this technology into their curricula.

Intention to publish date

30/07/2021

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?
Protocol article		27/05/2021	28/05/2021	Yes	No
Interim results article	Qualitative study	10/11/2022	11/11/2022	Yes	No