Accurate and consequent measurements of hand function for patients with hand and wrist problems using a mobile application with digital measuring equipment.

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To investigate if patients with a variety of hand and wrist problems can conduct measurements, using a mobile application integrated with the Manus VR glove and a digital dynamometer, as an alternative for conventional measurements conducted by a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON48387

Source
ToetsingOnline

Brief title
HandApp: accurate and consequent digital measurements of handfunction

Condition

- Fractures

Synonym
arthritis/joint degeneration, Fractures/broken bone

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Innovatiefonds zorgverzekeraars

Intervention

Keyword: digital measuring equipment, hand and wrist problems, Hand function

Outcome measures

Primary outcome

- Accuracy of range of motion is defined as the agreement between the ManusVR glove and the conventional goniometer, consisting of three repetitions per measuring method.

- Reliability of range of motion, measured with the ManusVR glove, is defined as the consistency of the measure with repeated observations. (time interval of 2 weeks)

- Feasibility of range of motion is defined as the percentage completely conducted measurements of all conducted measurements using the ManusVR glove

- Accuracy of grip/pinch strength is defined as the agreement between the digital dynamometer and a conventional dynamometer, consisting of three repetitions per measuring method.

- Reliability of grip/pinch strenght, measured with the digital dynamometer, is defined as the consistency of the measure with repeated observations. (time

interval of 2 weeks)

- Feasibility of grip/pinch strength is defined as the percentage completely conducted measurements of all conducted measurements using the digital dynamometer.

- duration of measurement in minutes.

Secondary outcome

geen

Study description

Background summary

In Holland, the incidence of hand and wrist problems is 12.5% of people aged 25 years or older. Hand and wrist diseases can have a great implication on the quality of life when not treated properly.1,2 Common hand and wrist problems include fractures, arthrosis and Dupuytren*s disease. During treatment, objective and consequent measurements of the hand function are important to evaluate progression and change treatment course if necessary. Examination of hand function consists of measuring joint range of motion (with a goniometer) , grip and pinch strength (with a dynamometer) and patient reported outcome measures (PROM*s). However, assessment of hand function is time consuming and inaccurate. Therefore, physicians often partially carry out or even totally skip these measurements during follow-up visits. Resulting in poor insights in treatment progression for physician and patient. Patients measuring hand function using a mobile application, integrated with a digital measuring glove and digital dynamometer, could result in more accurate and consequent measurements. This could prevent unnecessary operations and costly rehabilitation therapies. Thereby, physicians can spent more time conversating with their patient during visits.

Technical specifications
The Manus VR glove is a digital device that measures hand and wrist position and range of motion using a variety of sensors. The glove is made of antibacterial polyester and weighs only 65 grams. Therefore it is no burden to

wear for patients. The Manus VR glove is currently used in the prototyping industry and for gaming.
The mobile application will be developed by Synappz, a medical application developer who is certified in secure data storage. Clinical outcomes will be visable for physicians and patients in the application.

Study objective

To investigate if patients with a variety of hand and wrist problems can conduct measurements, using a mobile application integrated with the Manus VR glove and a digital dynamometer, as an alternative for conventional measurements conducted by a physician.

Study design

Prospective observational research

Study burden and risks

The burden experienced regarding time spent will most likely not exceed 20 minutes per visit. Approximately 10 minutes will be spent measuring patients using the conventional method (goniometer and dynamometer) and 10 minutes will be spent measuring with the Manus VR. These measurements are done every follow-up visit. On average a patient has 4 follow-up visits, which would cost the patient 80 minutes of extra time spend in the hospital when participating in this study.
Using the Manus VR glove to measure hundreds of patients could risk the transmission of micro-organism from patient to patients. Although, the glove is made of anti-bacterial polyester and even if bacteria are transmitted, the chance that patients will experience any physical discomfort by this is neglectable. However, we will use disposable latex gloves (if not allergic) to wear underneath the Manus VR glove to meet regular hygiene protocols.
Subjects could experience mild discomfort during physical examination and testing, but this will be no different from physical examination during routine follow-up. The Manus VR glove weighs only 65 grams, which does not influence hand movement. No serious events are expected to occur due to measuring with the Manus VR glove. Reduction of risks will be done according to inclusion and exclusion criteria. If complications arise, the treating physician will proportionate the adequate treatment according to the current protocols of treatment based on the published literature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

New patients of 18 years and older who present on the outpatient clinical of the traumatology or plastic surgery with either: 1. fracture of the hand or wrist, 2. artrosis of the hand or wrist, and 3. Dupuytren's disease.

Exclusion criteria

Non Dutch speaker

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2019
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Manus VR glove
Registration:	No

Ethics review

Approved WMO

Date:	22-07-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL69489.100.19