The prosup app ; a reliable application for measuring prosupination of the lower arm

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Primary objective; To asses the accuracy and precision, the criterion validity of the app compared to the goniometer and the inter and intra observer reliability Secondary objective; To evaluate the applicability of the PROSUP mobile phone...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON48486

Source
ToetsingOnline

Brief title
the prosup app

Condition

- Bone disorders (excl congenital and fractures)

Synonym
movement, rotation

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: via afdeling orthopedie erasmus mc/ reinier de graaf gasthuis

Intervention

Keyword: application, lower arm, prosup, prosupination

Outcome measures

Primary outcome

The main study parameter is the pro- and supination range of motion of the arm as measured by the PROSUP mobile phone application (index) and the goniometer (reference). The outcome will be expressed as degrees.

Accuracy; Criterion validity: correlation between *smartphone with app and casing* and goniometer, expressed by Pearson*s correlation coefficient

Precision ; Reliability: ICC for intra and inter-rater reliability and

Standard Error of Measurement/ Smallest Detectable Change / Limits of agreement (Bland & Altman plot)

Secondary outcome

Baseline parameters like age, sex, affected arm, and trauma mechanism will be collected.

Study description

Background summary

Decrease in supination and pronation is a well-known phenomenon after both-bone ante-brachii forearm fractures. A fracture might lead to a limitation of the rotation of the forearm, resulting in decreased pronation and supination. This decreased function is often precluded. It is desirable to maintain a full range of motion to allow for daily activities. Currently the clinical golden standerd for prosupination is a visual estimation with the Universal Goniometer (UG). The most accurate measure device is a mechanical goniometer in the motionlab in the Technical University of Delft, the biometrics ltd. apparatus. This machine gives the most reliable measurements, but it applicable in the clinical setting. This golden standard can be used to validate the application. Pitfalls

of the current method are; visual malestimation, by wrong execution of the test by the patient, or wrong execution of the test by the physician (Behnoush, et al. 2016). Smartphones are being implemented in medial care more and more. Therefore we conducted a search of literature for smartphones as a tool for accurate measurement of angles. A study of Behnoush et al, showed different methods of measuring ROM of the shoulder. They compared the smartphone to the UG and we compared and they found that the use of a found that the smartphone was at least as accurate as the UG. The purpose our study was determine if our prosup application is as reliable as the currently applied UG or the technical golden standard goniometer for measuring pronation and supination of the forearm as well in adults as in children.
First we designed an application for android smartphones. This application was compared to the golden standard the biometrics ltd. apparatus. Than followed by designing a prototype wristband. The ideal position of the wristband on the wrist was determined, with the most stable position on the lowerarm, and the lowest measurements error. This was done by positioning the wristband on different positions on the lower arm, flexing the muscles and register how much this affected the measured values. The best position was on the radial side of the wrist. The prototype was tested on three test persons to determine the accuracy of the measurements of the application. Finally an inter observer reliability was conducted to determine if our application is a reliable replacement for the current goniometer and the biometrics ltd. apparatus golden standard .
The next aim of our study is to test our application and wristband on 100 test persons, on the affected arm and the non-affected contra-lateral arm. And compare these measurements to the currently used UG measurements. All done in triple and by two investigators. Validating our application and preparing It for clinical use.

Study objective

Primary objective; To asses the accuracy and precision, the criterion validity of the app compared to the goniometer and the inter and intra observer reliability
Secondary objective; To evaluate the applicability of the PROSUP mobile phone application for children with a lower arm injury with evaluation forms.

Study design

Clinical research in which patients will undergo a prosupination measurement during their normal follow-up after trauma to the forearm. Patients can be included after plaster removal / pressure bandage.
Involved arm; 2 researchers / 3x measurement with the application and the goniometer. Unaffected arm; 1 researchers / 1x measurement with the application 1x the goniometer.

Order of measurements will be randomized using a computer application.
A total of 9 measurements. This way we can calculate the intra- and interobserver reliability.
And compare this app with the currently used golden standard the goniometer.
Evaluate the user friendlyness of the PROSUP mobile application with evaluation forms.

Study burden and risks

none, low burden

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- all patients in the outbound clinic of trauma/ orthopedics after lower arm trauma after the cast has been removed
- patients approval for inclusion in the clinical study
- sufficient command of the Dutch language
- Age >4yr-16yr

Exclusion criteria

- arm still in cast/ pressure band aid

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	prosup application
Registration:	No

Ethics review

Approved WMO Date:	22-12-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL67861.098.18