Reliability of the FCE-OH, and its relation with musculoskeletal complaints.

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29561

Source
Nationaal Trial Register

Health condition

Upper limb amputation, functional capacity evaluation, physical capacity, musculoskeletal complaints.

Sponsors and support

Primary sponsor: No sponsors.
Source(s) of monetary or material Support: This research is paid for by the bench fee of the researcher (PhD-candidate)

Intervention

Outcome measures

Primary outcome

- FCE-tests results (Each test is analysed separately, no total score is computed)

- Outcomes of the compensatory movement scale (per item, and one total score)

- Presence of MSC during the previous four weeks and last year

- Occurrence of pain response and serious adverse events

Secondary outcome

- Borg CR10 scale outcomes

- Difference in heart rate measured before and after each test or trial (computed as [heart rate after test/trial divided by heart rate before test/trial multiplied by 100%)]

- Gender, age, and work status

- Prosthesis use (yes/no, type of prosthesis, and years of experience with a prosthesis)

- General health (subscale of the SF-36)

Study description

Background summary

This study assesses the test-retest reliability of the Functional Capacity Evaluation –One-Handed (FCE-OH), which is an FCE developed for individuals with Upper Limb Absence (ULA) due to a congenital reduction deficiency (RD) or an acquired amputation (AA). The FCE-OH was developed as we saw a need for an instrument that assesses the physical capacity of these individuals, as these individuals are prone to development of MSC. The study will be performed at the INAIL centro protesi, at Vigorso di Budrio, in Italy. For test-retest reliability assessment of the FCE-OH we aim to include 25 individuals. Inclusion criteria are age between 18 and 62 years (official retirement age in Italy), presence of unilateral ULA at or more proximal of the carpal level, and good function of the nonaffected hand. Furthermore, the Physical Activity Readiness – Questionnaire (PAR-Q) is administered, to assess fitness for physical activity. Patients who visit the clinic for several days are asked to participate in this study. Information is given, and informed consent is obtained before the start of the first session. Two sessions are performed, with minimally 24 hours in between, but preferably two to three days in between. The FCE-OH consists of six tests: overhead lifting with a container, overhead lifting with a 2kg weight, overhead working test, repetitive reaching test with the nonaffected limb and the prosthesis, fingertip dexterity test with the nonaffected limb and the prosthesis, and hand grip strength of the nonaffected hand. The tests are performed in a set order. Furthermore, the participants answer two questionnaires. The first questionnaire inquires after general data, prosthesis use, general health, and presence of overuse complaints. This data will be used to assess the relationship between test results and presence of overuse complaints. The second questionnaire assesses the pain response after the first testing session, which is administered to assess safety of the FCE-OH.

Study design

Not relevant.

Intervention

Patients perfrom a functional capacity evaluation test twice, with approximately two/three days in between. Furthermore patients answer a questionnaire on musculoskeletal complaints and one on pain response after the testing. Video recordings will be made, in order to assess compensatory movements during performance of the functional capacity evaluation tests.

General treatment of patients is not affected by this research.

Contacts

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Eligibility criteria

Inclusion criteria

- 18-62 years of age

- Transversal reduction deficiency or ampupation of the upper limb at or proximal to the level of the wrist

- Normal hand function of the unaffected hand

Exclusion criteria

- Invalidating or serious pulmonary or cardiac health problems

- Balance problems

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	06-03-2016
Enrollment:	50
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5511
NTR-old	NTR5807
Other	Comitato Etico Interaziendale Bologna-Imola (CE-BI) : 15137

Study results