Physical demand and compensatory movements in Functional Capacity Evaluation tests in one-handed individuals.

Published: 09-04-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38598

Source
ToetsingOnline

Brief title
Functional Capacity Evaluation - One Handed (OH)

Condition

- Other condition
- Musculoskeletal and connective tissue disorders congenital
- Congenital and peripartum neurological conditions

Synonym
one-handedness

Health condition

amputaties van de bovenste extremiteit, plexus brachialis letsels

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brachial Plexus Injury, Functional Capacity Evaluation, Upper Limb Amputation, Upper Limb Reduction Deficiency

Outcome measures

Primary outcome

When performing FCE tests:

- Muscle tension of back, neck and shoulders

- Joint movement of the shoulder, elbow and wrist

- Heart rate

Secondary outcome

- FCE test results

- Compensatory movements

Study description

Background summary

One-handedness due to peripheral pathology can be caused by several conditions, such as Upper Limb Reduction Deficiency (ULRD), Upper Limb Amputations (ULA) and Brachial Plexus Injuries (BPI). Overuse and compensatory movements of the sound limb when performing daily and work related tasks might result in musculoskeletal complaints in this population. Musculoskeletal complaints are an important cause of disability and sick leave and possibly cause extra difficulty for individuals with ULRD, ULA or BPI to participate in society. Current international research shows higher rates of musculoskeletal complaints in people with ULA, compared to the general population. In order to diminish

the rate of musculoskeletal complaints in this population good assessment of functional and work capacity is necessary. Current Functional Capacity Evaluations (FCEs) are frequently used in rehabilitation medicine, but are developed for use in two-handed people. We wish to develop an FCE which can be used to assess functional capacity in one-handed individuals, based on physical demand and compensatory movements. In this study we examine physical demand when executing FCE tests by measuring muscle tension in the back, neck and shoulder, joint movements of the shoulder, elbow and wrist and heart rate. Furthermore, we wish to describe compensatory movements.

Study objective

The main objective of our research is to develop an FCE for use in one-handed individuals. The main objective of this part of the study is to gain descriptive data on muscle tension of the back, neck and shoulder, joint movements of the shoulder, elbow and wrist, heart rate and compensatory movements in order to develop this FCE.

Study design

This is an observational study.
We selected five Functional Capacity Evaluation (FCE) tests. Participants will have to perform each test two to four times, depending on the group they're in.

The five tests are:
- Overhead lifting
- Overhead working
- Repetitive reaching
- Hand grip strength
- Finger dexterity

During the tests the following measurements are performed:
- Muscle tension of the muscles of the back, neck and shoulders (using surface electromyography (SEMG))
- Joint movements of the shoulders, elbows and wrists (using Xsens, a motion analysis system)
- Heart rate (using a heart rate monitor)
Furthermore, videos are made, in order to analyse compensatory movements.

Each group has to perform the test 2 to 4 times:
Participants with ULRD or ULA:
- With the unaffected hand and a prosthesis on the affected side
- With the unaffected hand, without prosthesis on the affected side, but with the stump
- With the unaffected hand, but without prosthesis and stump (e.g. one-handed)

Participants with BPI:
- Two-handed, if they have any rest-function of the affected limb
- One-handed

Controls;
- Two-handed
- With a cast on the non-dominant hand, which mimics a below elbow prosthesis (with grasp function)
- With a cast on the non-dominant hand, which mimics an above elbow prosthesis
- One-handed (non-dominant hand is placed in a sling)

The order of the rounds and the tests in each round will be randomly decided.

Study burden and risks

Individuals participating to the study will have to come to the clinic once, for two hours, to perform FCE tests. FCEs are a safe and much used method to assess capacity. None of the performed measurements are invasive or pain-causing measurements. Participants might feel a bit of muscle soreness the next day. We believe that the overall burden for participants is minimal and the risks are negligible.

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

- Be between 18 and 67 years of age
- Good comprehension of the Dutch or English language (both written and spoken)
- Have a short arm, due a congenital reduction deficiency (ULRD) or amputation (ULA) or a non-functional hand due to brachial plexus injury (BPI)
- In case of ULA or BPI: the amputation or injury causing BPI must have taken place at least one year ago
- In case of ULRD or ULA: own a prosthesis and have experience using it
- Have normal hand function of the sound hand;Controls must have normal hand function of both hands.

Exclusion criteria

- Invalidating or serious pulmonary or cardiac health problems
- Other comorbidity that may influence the results of the FCE tests (like rheumatoid arthritis)

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	09-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43394.042.13