Validation of a combined arm leg ergometer for assessing and training physical fitness

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

Summary

ID

NL-OMON53324

Source
ToetsingOnline

Brief title
Validation arm leg ergometer

Condition

- Other condition

Synonym
No deficit

Health condition

Geen aandoening

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ergometry, Exercise testing, Physical fitness

Outcome measures

Primary outcome

Mean oxygen consumption (VO2), Respiratory Exchange Ratio (RER:VCO2/VO2),

ventilation (VE), heart rate (HR), and rate of perceived exertion (RPE) at 50 W

and maximal load (peak power output).

Secondary outcome

Mean muscle activity (EMG) over the full cycle of 16 muscles:

Arm: m. brachioradialis, m. biceps caput longum, m. triceps caput longum, m.

deltoideus pars clavicularis & m. deltoideus pars spinata

Trunk: m. rectus abdominis, m. pectoralis major, m. erector spinea, m.

trapezius transversa & m. latissimus dorsi

Leg: m. gastrocnemius medialis, m. tibialis anterior, m. rectus femoris, m.

vastus lateralis, m. biceps femoris & m. semitendinosus

Kinematic description of the movement:

The mean joint angles over the full cycle of the following joints will be

described: Knee, Hip/Trunk, Elbow, and Shoulder

Study description

Background summary

For persons with balance problems, such as persons with a lower limb amputation, no suitable alternative for a bicycle ergometer test is available. Therefore, a prototype for a new arm leg ergometer was developed based on previous ergometer designs. We hypothesize that the physiological outcomes of an incremental exercise test (e.g. maximal oxygen uptake) are similar for a bicycle ergometer and the current prototype.

Study objective

Our first aim is to evaluate the validity of the developed arm leg ergometer prototype during an incremental exercise test by comparing the outcomes with a regular bicycle ergometer test. The second objective is to describe the movement of participant on this new device.

Study design

Observational study

Study burden and risks

This first experiment will be conducted with healthy participants. The participants visit the lab twice, once per incremental exercise test. This type of test requires maximal effort, but no additional health risks are to be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age >18 years
No medical contradictions on the physical activity readiness questionnaire (PAR-Q): All questions answered with no.

Exclusion criteria

Age < 18 years
Answered one of the questions on the PAR-Q with yes.
A body mass index of more than 30
Viral or bacterial infection for less than 10 days
Wounds on the arm or legs
Neurological or orthopedic conditions that affect exercise performance

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-10-2023
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	Corival ALT
Registration:	No

Ethics review

Approved WMO

Date:	26-07-2023
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	NL83731.042.23