LIfelong Fitness Testing: The Steep Ramp Test in Dutch adults and elderly: age- and sex-related normative values and the investigation of reproducibility, validity, and underlying physiological responses.

Published: 21-12-2021
Last updated: 30-01-2025

Primary objective:o To create a set of sex- and age-specific normative values (graphs and tables) for SRT performance (WRpeak) for healthy Dutch adults, including elderly (aged 25-85 years) (group 1). Secondary objectives:o To determine the test-...

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

Summary

ID

NL-OMON54149

Source
ToetsingOnline

Brief title
LIFT - Normative values for the Steep Ramp Test in adults and elderly

Condition

- Other condition

Synonym
nvt

Health condition

geen, het betreft gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Health Holland;de Nederlandse Brandwondenstichting

Intervention

Keyword: Adults, Normative values, Physical fitness, Steep Ramp Test

Outcome measures

Primary outcome

WRpeak (in W en W/kg) attained at the SRT

Secondary outcome

For all subjects:

- Age (years)

- Sex (male/female)

- Body height (cm)

- Body mass (kg)

- Lean body mass (kg)

- Fat percentage (%)

- Waist and hip circumference (cm)

- Habitual physical activity (score on the SQUASH)

- Overall health status (score on the EQ5D+C)

- Heart rate in rest (bpm)

- Heart rate at peak exercise (bpm)

- Duration of the test (s)

Additionally, for group 2:

- WRpeak (W en W/kg) attained at an additional SRT performed within one to two weeks after the initial SRT

Additionally, for group 3:

- Maximal isokinetic upper leg muscle strength (peak torque in Nm)

- Upper leg muscular endurance

o % decline between first and last repetition

o Time (number of repetitions) to x% decline

o Area under the curve (to assess the course of the decline in strength)

- Parameters for CPET and SRT with respiratory gas analysis, electrocardiography and blood pressure assessment:

o Absolute oxygen uptake (ml/min) at rest and at peak exercise

o Relative oxygen uptake (ml/min/kg) at rest and at peak exercise

o Minute ventilation (VE) (L/min) at rest and at peak exercise

o Breathing frequency (breaths/min) at rest and at peak exercise

o Tidal volume (Vt) at rest and at peak exercise

o Oxygen pulse (ml/beat) at peak exercise

o Absolute work rate (W) at peak exercise

o Relative work rate (W/kg) at peak exercise

o Heart rate (bpm) in rest and at peak exercise

o Blood pressure (mm/Hg) at rest and throughout progressive exercise

o Oxygen saturation (SpO2) (%) at rest and at peak exercise

o Respiratory exchange ratio (RER) at peak exercise

o Test duration (s)

o Ventilatory anaerobic threshold (VAT)

o Oxygen uptake efficiency slope (OUES)

o Minute ventilation/carbon dioxide production slope (VE/VCO2) up to the

respiratory compensation point

o Ratio of the increase in oxygen uptake to the increase in work rate

o Rate of perceived extension (RPE) at rest and at peak exercise

o Stop reason

For CPET only, the forced expiratory volume (FEV1) will also be measured.

Aditionally, for group 4:

- Predicted VO2peak (ml/min/kg) based on Åstrand test performance using the

Åstrand-Rhyming-nomogram

- Parameters for SRT and Åstrand with respiratory gas analysis at rest

and/or at peak exercise (SRT) / the end of the test protocol (Åstrand):

o Absolute oxygen uptake (ml/min)

o Relative oxygen uptake (ml/min/kg)

o Minute ventilation (VE) (L/min)

o Breathing frequency (breaths/min)

o Tidal volume (Vt)

o Oxygen pulse (ml/beat)

o Absolute work rate (W)

o Relative work rate (W/kg)

o Heart rate (bpm)

o Blood pressure (mm/Hg)

o Oxygen saturation (SpO2) (%)

o Respiratory exchange ratio (RER)

o Test duration (s)

o Rate of perceived extension (RPE)

o Stop reason

Study description

Background summary

Although cardiorespiratory fitness (CRF) is increasingly recognized as an important marker of health and functioning, it is not (yet) structurally assessed in daily (clinical) practice. This is mainly due to the fact that the gold standard for assessing CRF, the standard cardiopulmonary exercise test (CPET) with determination of the maximal oxygen uptake capacity (VO2peak), is expensive and time-consuming. Advanced equipment and specialized knowledge are required to perform the test correctly and interpret its results correctly. Moreover, the test is relatively burdensome for the participant, especially for people with a (chronic) condition.

From (clinical) practice there is an urgent need for a short and simple exercise test to validly and reliably estimate someone's CRF. The Steep Ramp Test (SRT) is such a practical short exercise test on a bicycle ergometer (the work rate is increased by 25 W/10 sec, so the test phase lasts maximal 4 minutes), that does not require expensive equipment or specialized knowledge.

The main outcome parameter of the SRT - peak work rate (WRpeak) - is strongly correlated with VO2 peak measured with a standard CPET (r values **ranging from 0.822 to 0.958) in different patient populations (De Backer et al. 2007; Stuiver et al. 2017; Weemaes et al. 2021; Rozenberg et al. 2015; Bongers et

al., 2015) and in healthy children (Bongers et al. 2013).

Although the SRT is already widely used in the Netherlands to evaluate CRF, sex and age-specific reference values **for adults and the elderly are lacking thus far. This severely limits the interpretation of test results. With this study we therefore aim to collect sex- and age-specific norm values **for the SRT in adults and elderly (aged 25-85 years).

These normative values will definitely increase the usefulness of the SRT in daily (clinical) practice and research, enabling frequent determination of CRF. See also pages 11-13 of the protocol.

Study objective

Primary objective:
o To create a set of sex- and age-specific normative values (graphs and tables) for SRT performance (WRpeak) for healthy Dutch adults, including elderly (aged 25-85 years) (group 1).

Secondary objectives:
o To determine the test-retest reliability of WRpeak achieved at the SRT in healthy Dutch adults, including elderly. With this information, the minimal detectable change of the SRT in healthy adults, including elderly, will also be determined (group 2).

o To determine the criterion and construct validity of WRpeak achieved at the SRT in healthy Dutch adults, including elderly, by investigating the correlation between WRpeak achieved at the SRT and the VO2peak (and other measures like oxygen uptake at the ventilatory anaerobic threshold and the oxygen uptake efficiency slope) attained at the CPET. Moreover, the ability of the SRT to predict VO2peak will be investigated, including the development of a prediction equation to estimate VO2peak from SRT performance and other subject-related variables (group 3).

o To investigate the association between maximal upper leg muscle strength and upper leg muscular endurance and the WRpeak achieved at the SRT (group 3).

o To explore the underlying physiology of the SRT, by assessing cardiovascular, pulmonary, and metabolic responses using respiratory gas analysis, electrocardiography, and blood pressure assessment during SRT performance, as well as during CPET performance (group 3).

o To investigate the association between the WRpeak achieved at the SRT and the estimated VO2peak provided by the Åstrand test (group 4).

Study design

This is a large multicenter observational study, in which 540healthy Dutch adults and elderly aged between 25 and 85 years will be invited to perform the SRT.

In addition, three representative subgroups of subjects (60 for each group) will be invited to perform some additional tests, next to the SRT:

- An additional SRT within one to two weeks after the initial SRT (group 2).
- Isokinetic dynamometry, a SRT with respiratory gas analysis, electrocardiography, and blood pressure assessment, and a standard CPET, with a break of minimal 30 minutes between each test (group 3).
- A SRT and the submaximal Åstrand test, both with respiratory gas analysis, and with a break of minimal 30 minutes between both tests (group 4).

Study burden and risks

The burden is low (approx. 45 minutes) for the largest group of subjects (group 1, n=540).
The burden for group 2, 3 and 4is somewhat higher, 75 minutes, 3 hours and 90 minutes respectively (excluding eventual traveling time).
All tests are non-invasive and the risks associated with participation can be considered small to negligible.
All subjects are screened for contraindications to maximum physical exercise using the PAR-Q.

The SRT is very short and the participant continues to cycle until he/she can no longer sustain the pedaling rate. The load on the cardiopulmonary system is lower compared to the standard CPET.
Isokinetic dynamometers are designed in a way that a participant's maximum strength levels cannot be exceeded. In addition, the device is adjusted to the body size of the participant, which allows only movements within a safe range of motion.
The Åstrand test is also a relatively short exercise test and because the participant exercises on a submaximal level, the cardiopulmonary load is lower compared to the standard CPET.

The risks of the standard CPET are small. The incidence of a complication requiring hospitalization is <2 per 1,000 exercise tests (Myers et al. 2009). The incidence of serious cardiac complications is 1.2 per 10,000 exercise tests (Balady et al. 2010; Myers & Bellin, 2000) and the incidence of death is 2-5 per 100,000 exercise tests (ATS/ACCP 2003; Myers et al. 2009) . These numbers are mainly based on research in patient populations, while the current study will measure healthy subjects without known contraindications for maximal exercise. Moreover, all test subjects have reported that they meet the Dutch physical activity guideline, which means that they are used to regular (moderate) intensive exercise. The CPET will be performed under controlled conditions by trained test operators under professional supervision.

Expanding the existing reference values for SRT performance in children, adolescents, and young adults (8-25 years of age) with reference values for adults and elderly (25-85 years of age), will definitely improve the applicability of the SRT and allow for frequent estimation of CRF in daily (clinical) practice and research. Knowledge regarding the clinimetrics and physiological response to SRT performance in healthy adults and elderly is essential to better understand and interpret test results and justify its use in both scientific research and daily (clinical) practice.

Contacts

Public
Martini Ziekenhuis

Van Swietenplein 1
Groningen 9728 NT
NL
Scientific
Martini Ziekenhuis

Van Swietenplein 1
Groningen 9728 NT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy Dutch (living in the Netherlands and/or having a Dutch passport)

adults, including elderly, aged between 25-85 years.

Exclusion criteria

Subjects who meet any of the following criteria will be excluded: - A medical status (physically or mentally) that contraindicates maximal exercise, based on the PAR-Q (all questions need to be answered with); - Not compliant with the Dutch physical activity guidelines (a minimum of 5 days a week, 30 minutes a day moderate-to-vigorous physical activity), based on the SQUASH; - The use of medication affecting exercise capacity; - Evident health conditions affecting exercise capacity; - Impaired motor development; - Obesity (body mass index >30 kg/m2); - Unable to cooperate with the testing procedures (e.g. insufficient understanding of the Dutch language); - Being an elite athlete (>= 10 hours a week high physically active); - Pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2022
Enrollment:	720
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-04-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-01-2025
Application type:	Amendment
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	NL78670.100.21
Other	OND1370305