Validation of the modified FixMáx© questionnaire

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Ethical review	Not available
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57530

Source
Onderzoeksportaal

Brief title
Validation of the modified FitMáx© questionnaire as a measurement instrument for cardiorespiratory fitness.

Condition

- Other condition

Synonym
Healthy Subjects, Cardiac, Pulmonary and Oncologic patients

Research involving
Human

Sponsors and support

Primary sponsor: Máxima MC
Source(s) of monetary or material Support: MMC COI en NFTK

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

Physical fitness is assessed through the FitMáx©, VSAQ, and DASI and compared to the gold standard—a maximal exertion test with breath gas analysis.

Secondary outcome

Different subgroups

Study description

Background summary

Physical fitness is an important factor for health and quality of life. For patients, physical fitness can partially determine the risk of complications from surgeries or other intensive treatments. To estimate physical fitness—expressed as maximal oxygen uptake (VO2max)—in a simple and cost-effective way, the Sports Medicine Department at Máxima MC developed the FitMáx©. The FitMáx© is a questionnaire consisting of three questions about patients' maximum walking, cycling, and stair-climbing capacity. The questionnaire has been validated against the gold standard (an exertion test with breath gas analysis). The calculated FitMáx© score correlates at r=0.95 (0.93-0.96) with measured VO2max during an exertion test in both patients and healthy individuals.

One component of the FitMáx© for making an adequate estimation is the question about maximum cycling capacity. Internationally, this may be a weak point in the questionnaire, as cycling is not as common in every country as it is in the Netherlands. Even though the FitMáx©, without the maximum cycling capacity question, still reaches a correlation of r=0.92 (0.90-0.94) with measured VO2max during an exertion test, we aim to develop and validate a new question as part of the FitMáx© to enhance its international applicability. To achieve this, we plan to add a question about daily functioning. This question could be used as a supplement to the FitMáx© questionnaire or as a replacement for the cycling capacity question.

In the original validation study of the FitMáx©, we also administered the Duke Activity Status Index (DASI) and the Veterans Specific Activity Questionnaire (VSAQ) to the same patients for comparison.

Study objective

In a previous study, the validity of the FitMáx© in measuring physical condition was examined in comparison to the gold standard—an exertion test with breath gas analysis**.** The aim of the current follow-up study is to improve the international applicability of the FitMáx© by validating a modified version of the FitMáx© against the gold standard.

Additionally, we want to compare the FitMáx© results with questionnaires from the literature to investigate whether the FitMáx© can provide a better estimate of the VO2max in patients and healthy individuals. For comparison, VSAQ and DASI will also be administered and included in the analyses.

Study design

Study participants will be recruited at Máxima MC in the Cardio-Pulmonary-Sports department. Individuals scheduled for an exertion test with breath gas analysis will be approached to participate in the study and complete the questionnaires. Additionally, consent will be requested to access the results of the exertion test to allow for comparison.

Participants from the validation study primarily came from the following specialties:

- Sports Medicine (mainly involving fitness assessments, meaning they were healthy)
- Cardiology
- Pulmonology
- Oncology (patients who visited the sports physician and underwent a CPET)

Intervention

- Modified FitMáx©
- VSAQ
- DASI

Study burden and risks

Neglectible

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

- Patients or clients over 18 years old
- Treated at Máxima MC and undergo an exertion test

Exclusion criteria

- Submaximal exercise test
- Incomplete questionnaire(s)

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	1200
Duration:	1 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Not available

Date:	13-05-2025
Application type:	First submission
Review commission:	Validatie nWMO registratie door CCMO

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
Research portal	NL-010004