Development of a clinical assessment tool as instrument to monitor physical fitness

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24945

Source
Nationaal Trial Register

Brief title
Responsiveness of FitMáx©

Health condition

Oncologic patients

Sponsors and support

Primary sponsor: To be announced
Source(s) of monetary or material Support: National Foundation Against Cancer

Intervention

Outcome measures

Primary outcome

The criterion responsiveness of the FitMáx© questionnaire to measure individual changes inaerobic capacity. In other words: the level of agreement between the estimated change in VO2-peak by the FitMáx© and the actual measured change in VO2-peak by the CPET.

Secondary outcome

- Is the FitMáx© questionnaire a more valid instrument to monitor physical fitness compared to existing/validated international questionnaires?
- Is the FitMáx© questionnaire without the maximum cycling capacity, still a valid instrument to monitor physical fitness? (cultural adaptation for international use)

Study description

Background summary

The Máxima Medical Center developed a questionnaire as a clinical assessment tool for aerobic capacity in several patient groups. The questionnaire consists of three questions about the maximum capacity for walking/running, cycling and stairclimbing. These are recognisable activities for the general Dutch population.

To improve the clinical applicability of the questionnaire we want to study the internal responsiveness of the FitMáx© questionnaire, to determine the application as an instrument for monitoring aerobic capacity over time.

Patients who are expected to have a substantial change in aerobic capacity (due to rehabilitation/exercise intervention) and perform a cardiopulmonary exercise test in the beginning of the intervention and at the end of the intervention. The results of the FitMáx© questionnaire before and after the intervention, will be compared with the results of the cardiopulmonary exercise test (CPET) before and after the intervention in the same patients. After receiving signed informed consent and completed questionnaire, the data from the CPET are retrospectively obtained from the electronic patients files.

In the same research population existing and validated physical activity questionnaires are used to compare results of the FitMáx© questionnaire with. These questionnaires are; the veterans specific activity questionnaire (VSAQ), the duke activity status index (DASI), the physical fitness questions of the EORTC-QLQ C30 and a questionnaire used for preoperative screening in the Netherlands (validation of the preoperative questionnaire was not found in literature).

Study objective

It is hypothesized that the FitMáx questionnaire is a valid clinical instrument to monitor aerobic capacity compared to the gold standard, a cardiopulmonary exercise test.

Study design

- Maastricht UMC+ T0= after zero weeks of exercise/rehabilitation, T1= after ten weeks of exercise/rehabilitation.

Intervention

Beside the exercise intervention which is part of the usual care, no interventions are used in this trial.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients who are participating in a rehabilitation programme or exercise intervention and who perform a cardiopulmonary exercise test before and after the intervention in Maastricht UMC+
- Signed informed consent is received

Exclusion criteria

- Patients younger than 18 years
- (subjective) Submaximal exercise test due to early abortion of the test
- Incomplete questionnaire

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	66
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-04-2020
Application type:	First submission

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	NL8568
Other	METC Máxima MC and METC MUMC+ : to be announced

Study results