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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24945

Bron
NTR

Verkorte titel
Responsiveness of FitMáx©

Aandoening

Oncologic patients

Ondersteuning

Primaire sponsor: To be announced
Overige ondersteuning: National Foundation Against Cancer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

this trial.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	66
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8568
Ander register	METC Máxima MC and METC MUMC+ : to be announced

Resultaten