Physical recovery of Intensive Care Unit survivors.

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Primary Objective: (1) To determine the feasibility of the measurement protocol of a large prospective longitudinal study to describe the exercise capacity and physical functioning of critical illness survivors up to 5 years after discharge from the...

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

Summary

ID

NL-OMON48487

Source
ToetsingOnline

Brief title
Physical recovery of ICU survivors.

Condition

- Other condition

Synonym
Critical illness, Post-intensive care syndrome (PICS)

Health condition

Variabel (Intensive Care)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Critical illness, Exercise test, Intensive care units, Rehabilitation

Outcome measures

Primary outcome

(1) Maximal exercise capacity

The primary outcome measure is the peak oxygen uptake (VO2peak) assessed through CPET. This measure is considered the gold standard for exercise capacity, and provides a standardized, objective, and integrated assessment of the cardiac, respiratory, and musculoskeletal system.

(2) Perceived physical functioning

Measured as the Physical Component Score (PCS) of the Dutch version of the Short Form 36-item Health Survey (SF-36 survey).

Secondary outcome

(3) Muscle function

For muscle function we will assess measures of muscle strength, muscle quantity and physical performance. The Medical Research Council score will be used to assess strength in upper and lower extremity muscle groups. In addition, the maximal voluntary contraction (MVC) of the knee extensor muscles will be assessed using a fixed dynamometer. Bioelectrical impedance analysis (BIA) will be used to estimate the muscle mass as a measure of muscle quantity, and 3d

ultrasound as a measure of muscle quality. As a measure of physical performance, the 4-m usual walking speed test will be performed. Together these measures also allow to assess the presence of sarcopenia.

(4) Daily activity

Activity monitors will be used to determine the total step count, and to establish the total time spent in different individual intensity zones (e.g. low, moderate and vigorous) during 7 consecutive days. Subjects will also be asked to keep an activity diary.

(5) Health-related quality of life

Assessed using the Dutch version of the Short Form 36-item Health Survey (SF36). The physical health component scores and mental health component scores will be calculated, using age-correlated means and standard deviations of a healthy Dutch population.

(6) Fatigue

The level of fatigue will be measured using the MFI-20 (Multidimensional Fatigue Inventory). The MFI-20 is a self-reported instrument to measure fatigue that was validated in patients with a variety of chronic conditions and has been used in ICU survivors before.

(7) Endurance capacity.

Endurance capacity will be assessed with the 6 minute walking test (6MWT). The

6MWT provides an integrated assessment of the cardiac, respiratory and musculoskeletal system during walking. In addition the 2 minute step test (TMST) will be conducted. There are norm values available for this validated test for the population of 60 and older, and it is considered an alternative test for determination of the endurance capacity for participants who are unable to complete the 6 MWT.

(8) Dietary intake.

Subjects will be asked to keep a dietary intake diary.

(9) Return to work

Information about the manner in which the participant was able to return to work will be obtained through a self-developed questionnaire.

(10) Mental functioning

Mental functioning will be assessed using the Hospital Anxiety and Depression Scale (HADS) and The Global Psychotrauma Screen (GPS). The HADS is the most often used questionnaire to measure symptoms of anxiety and depression in ICU survivors. The GPS is adapted from the Primary Care PTSD screen (PC-PTSD) and was recently validated by researchers from the AMC psychiatry department (Dr M. Olff, publication in progress). The questionnaire consists of 22 items (yes/no answers) aiming to screen for the presence of psychological trauma as a result of the critical illness and ICU admission.

(11) Cognitive functioning

ICU survivors experience long-term cognitive impairment. Cognitive functioning

will be measured using the validated abbreviated 14-item Cognitive Failure

Questionnaire (CFQ-14).

Study description

Background summary

Several studies evaluated the deleterious effect of critical illness on physical functioning, with exercise limitations and neuromuscular abnormalities, during and shortly after hospital discharge. As survival rates improve among critically ill patients, there is a growing need to also understand the long-term effects. This information is currently lacking, but crucial for the development of optimal rehabilitation strategies for critical illness survivors after hospital discharge. Therefore, we aim to set up a large prospective longitudinal study to describe the exercise capacity and physical functioning of critical illness survivors up to 5 years after discharge from the Intensive Care Unit (ICU) and to explore potential determinants. To determine the feasibility of the measurement protocol, we will first conduct a cross-sectional feasibility study, including critical illness survivors in different phases of their recovery.

Study objective

Primary Objective:
(1) To determine the feasibility of the measurement protocol of a large prospective longitudinal study to describe the exercise capacity and physical functioning of critical illness survivors up to 5 years after discharge from the ICU.

Secondary Objective(s):
(2) To describe the exercise capacity and physical functioning of critical illness survivors.
(3) To determine potential determinants for exercise capacity and physical functioning in critical illness survivors.
(4) To describe the relative contribution of cardiac, respiratory, and musculoskeletal impairment to exercise limitations in critical illness survivors.

Study design

A cross-sectional feasibility study will be conducted at the outpatient clinic of the Department of Rehabilitation of the Amsterdam UMC, location AMC.

Study burden and risks

A physician assistant with advanced life support skills will be present during the exercise tests, minimizing the risk associated with the study procedures. Subjects will not benefit directly from participation in the study. The group of mechanically ventilated ICU patients may in the future benefit from the results as it will increase our understanding of the long-term effects on daily physical functioning. This will contribute to better rehabilitation strategies for critical illness survivors after hospital discharge. Therewith the potential (future) benefits outweigh the burden and minimal risk associated with the study.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
(1) Admitted to an ICU.
(2) Mechanically ventilated >= 24 hours.
(3) Discharged alive from the ICU.
(4) Minimum age of 18 years.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
(1) Contraindication for being physically active (according to the guidelines by the American College of Sports Medicine).
(2) Documented history of neurologic disease or psychiatric disease or significant cognitive impairment.
(3) Unable to follow verbal or written instructions.
(4) Insufficient mastery of the Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL71725.018.19