Steps to Recovery; Body weight-supported treadmill training for patients in the intensive care unit: a feasibility study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON43392

Source
ToetsingOnline

Brief title
Steps to Recovery

Condition

- Muscle disorders

Synonym
Intensive Care Unit-Acquired Weakness (ICU-AW)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Functional training, Intensive care, Recovery, Rehabilitation

Outcome measures

Primary outcome

The study parameters to evaluate feasibility are:

- Eligibility criteria, proportion of enrolled patients of those who are screened.

- Number and reasons of planned sessions that could not be executed;

- Number and reasons of sessions that could not be completed sessions;

- (Serious) Adverse Events ((S)AE*s); Adverse events: near falls, wounds, dislocation of tubes or lines and Serious adverse events ((S)AEs);

- Effort and costs: Number of staff needed; Treatment duration, including preparation time,

- Fatigue (measured with Borg score before and after BWSTT, as part of ususal physiotherapy care), Patient satisfaction; Pain (measured with the numeric raitng scale, before and after BWSTT, Anxiety measured with the numeric raitng scale before and after BWSTT).

Secondary outcome

The parameters to assess the effect size of potential outcome measures for the evaluation of BWSTT in ICU patients (future trial):

- Acceleration of the first time to ambulation in ICU patients: Number of enrolled patients provided with the intervention who should not be able to walk without the intervention BWSTT

- Walking capacity; Change in walking independence between start of BWSTT and at ICU /M-ICU discharge (measured with the De Morton Mobility Index (DEMMI) and Functional ambulation catergories (FAC) as part of usual physiotherapy care),

Change in walking duration between start of BWSST and at ICU /M-ICU discharge,

Body weight support (yes / no): change between first and last BWSTT

- General muscle strength (MRC sum-score); change between start of BWSST and at ICU /M-ICU discharge as part of usual physiotherapy care.

Study description

Background summary

Intensive Care Units (ICUs) in the Netherlands admit over 82,000 patients every year 1. The survival rate of critically ill patients admitted to the ICU has significantly increased through improvements in medical care. Approximately 50% of these critically ill patients are at risk of developing ICU-Acquired Weakness (ICU-AW) 2,3. ICU-AW results in difficult weaning from the ventilator and impedes recovery of muscle strength, muscular endurance and aerobic capacity and that contributes to a longer hospital stay, a decrease in functioning and a reduced quality of life after ICU admission.
There is increasing evidence that early mobilization, activation and ambulation of patients admitted to the ICU may influence or even prevent long term physical impairments.
In the AMC currently ICU patients are mobilized in several ways from standing and sitting, biking on a cycle ergometer with legs or arms while in bed or in a chair, and walking, whenever feasible. However, walking with ICU patients is difficult in practice, because of the reduced muscle strength, as well as the limited length of the infusion lines, drains and the tube of mechanical ventilation.
Body weight-supported treadmill training (BWSTT) has shown to be an effective modality for improving fitness, walking capacity and daily functioning in different rehabilitation populations with muscle weakness.
BWSTT has not been used in ICU patients before, but might be able to facilitate ambulation in an early phase, even before independent walking is attained. Moreover, ICU patients are attached to lines, drains and mechanical ventilation, which are necessary for monitoring and treatment. The premise is that early ambulation training in ICU patients supported by BWSTT will facilitate the first time to ambulation and improve functional status at ICU

discharge in critically ill patients.

Study objective

The aim of this study is to conduct a pilot study of weight-supported ambulation training in ICU patients and to assess its feasibility of the use in daily practice, and to obtain information for the development of a randomized clinical trial for the evaluation of the effect of BWSTT in ICU patients.

Study design

A pilot interventional single group design.

Intervention

A mobile treadmill with weight bearing utility will be used for BSTT in ICU patients. The body weight-supported treadmill enables early ambulation in patients with insufficient motor control or strength to fully bear weight.
For study participants, the BWSST intervention consists of walking on a treadmill while supported by a harness. The intervention will be conducted according to the standardized operating procedure (SOP) with respect to safety checks, transfers, bodyweight support, treadmill speed and ambulation duration. The training will be conducted by two experienced ICU physiotherapists involved in this study and trained and skilled for this intervention as described in the SOP. BWSTT is provided on a daily basis (5 times a week, not during the weekend) in the ICU or MICU.

Study burden and risks

Negelectable.
The burden and risks associated with the intervention BWSTT is comparable to that of usual physiotherapy treatment.
The majority of outcomes are currently measured and recorded as part of the current physiotherapy treatment (as described in the Evidence Statement for ICU physiotherapy; Sommers 2013).
Additional measurements are: patient satisfaction (numeric rating scale using symbols), pain, anxiety (numeric rating scale).

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

Medical and surgical adult patients (*18 years) admitted to the ICU or the MICU of the AMC who have been mechanically ventilated *48 hours

Exclusion criteria

Contra indications for physical therapy treatment according to the Evidence Statement for ICU physical therapy (Sommers. et. al. 2013):
o Recent myocardial ischemia
o Hart frequency < 40 or > 130
* Blood pressure:
o Map 110 mmHg
Pulse oxymetry: * 90%
Mechanical ventilation:
o FiO2 *0.6 (60%)
o PEEP* 10cm H2O
Breathing frequency:
o Frequency > 40 per minute
Low consciousness:

o RASS score: -4, -5, 3 or 4
Dose of inotropes:
o Dobutamine > 20 mcg/kg/min
o Dopamine > 10 mcg/kg/min
o Nor/adrenaline * 0.1 mcg/kg/min
Temperature:
o * 38.5 degrees Celsius
o *36 degrees
Other:
o Clinical observation by physical therapist: abnormal sweating, pain, fatigue
o Surgical contra-indications (i.e. instable fractures, bone flap, open abdomen or thorax)
o Presence of lines that prevent mobilization
* Imminent to death,
* Insufficient knowledge of the Dutch language,
* Neurological diseases and disorders as reason for ICU admission,
* One or more amputated lower extremities,
* Mental retardation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2016

Application type:	First submission
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	NL56342.018.16