# Visual incentivised and monitored rehabilitation for early mobilisation in the Intensive Care Unit.

Published: 06-10-2022 Last updated: 05-04-2024

To develop an exergame system which helps patients, ICU staff (including physiotherapists), in ameliorating early mobilisation exercises (frequency, intensity and patient and staff experience), finally aiming to accelerated rehabilitation and reduce...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

# Summary

### ID

NL-OMON52312

**Source** ToetsingOnline

Brief title IC-MOVE

### Condition

• Other condition

**Synonym** Intensive Care Acquired weakness, muscle weakness

#### **Health condition**

Patienten die langer dan 24 uur zijn opgenomen op de Intensive Care

#### **Research involving**

Human

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### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** EuroStars

### Intervention

Keyword: Early mobilisation, Exergame device, Intensive Care Unit, Physical Therapy

### **Outcome measures**

#### **Primary outcome**

The main study parameter is the feasibility of the exergame device to be

developed.

#### Secondary outcome

Experience of patients and ICU staff with the exergame device to be developed.

# **Study description**

#### **Background summary**

Healthcare expenditures keep rising. One particularly costly and important aspect is the Intensive Care Unit (ICU). On the ICU the most fragile and critical patients are admitted. In ICU patients bed rest and prolonged immobility commonly occur, increasing the risk of ICU-acquired weakness (ICU-AW) and other complications. Early mobilization of ICU patients, both (guided) active exercise therapy and mobilization in a chair, is recommended, as soon as justified, as it leads to improved muscle strength and functional independence. It has also been associated with a shorter duration of delirium, mechanical ventilation, and ICU length of stay. Despite the safety and feasibility of early mobilisation, most ICU patients remain immobilized for long periods of time and the number of daily activities is low and limited to contact moments with the physiotherapist and/or the nursing staff. Intelligent systems to support data-driven early mobilisation while supporting the ICU staff are an unmet need. Exergaming, or active video gaming, might be useful in adding extra exercise moments in supporting early mobilisation. However, current exergaming devices are not yet suitable for early mobilisation in ICU patients.

#### **Study objective**

To develop an exergame system which helps patients, ICU staff (including physiotherapists), in ameliorating early mobilisation exercises (frequency, intensity and patient and staff experience), finally aiming to accelerated rehabilitation and reduce healthcare costs.

### Study design

This is a multicentre feasibility study in which an existing exergaming device for use in the ICU will be further developed, and evaluated on its feasibility and validity. Two sites, Erasmus Medical Centre (Erasmus MC) Rotterdam and Stichting Gelre Hospitals Apeldoorn, are involved in this study.

#### Study burden and risks

Early mobilisation is shown to be safe and considerated as standard of care. Early mobilisation exists of kinesiotherapy, transfer and locomotion training, cycle ergometry as well as neuromuscular electro stimulation. In this process, the physiotherapist encourages the patient to perform movements and activities. The exergame device to be developed will be supportive in the early mobilisation process and will evoke the patient to perform these movements and activities by means of an interactive video game.

# Contacts

**Public** Erasmus MC, Universitair Medisch Centrum Rotterdam

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# **Trial sites**

# **Listed location countries**

Netherlands

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# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- \* 18 years of age
- ICU admission \*24 hours
- The ability to sign an informed consent or by a designated family member;
- Being awake, defined as a Richmond Agitation and Sedation Scale (RASS) score of -1 to 1 (i.e. not sedated or agitated) [41]

- At least Moderate cooperative / some cooperation is possible defined as Standardized 5 questions; S5Q > 3 [41]

- Absence of delirium, defined as a negative score on the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) or \*4 on the Intensive Care Delirium Screening Checklist (ICDSC) [52]

# **Exclusion criteria**

- Haemodynamic instability in which physical exercise is advised against by the attending physician or attending ICU nurse;

- Impaired sight or hearing that is expected to considerably influence the ability to play or evaluate the game;

- Language barrier or mentally incapacitated;

- Delirium, defined as a positive score on the CAM-ICU scale (CAM-ICU positive)>= 3 or >4 on the ICDSC;

- Loss of one or more limbs due to amputations or genetic defects.

# Study design

### Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

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# Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	30
Туре:	Anticipated

### Medical products/devices used

Generic name:	SilverFit IC-MOVE
Registration:	No

# **Ethics review**

Not approved	
Date:	06-10-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

# **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 CCMO **ID** NL78997.078.22