

Rehabilitation of HAND and arm function using a Meta QUEST-based virtual reality game in ICU patients

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Primary: To investigate the effect of a 4-week VR-exergame intervention on handgrip strength in patients staying in the ICU for 48 hours or longer compared to standard rehabilitation practices. Secondary: To investigate the longer term effect of a 4-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56582

Source

ToetsingOnline

Brief title

HANDQUEST

Condition

- Other condition

Synonym

Intensive Care Unit-Acquired Weakness, recovery after critical illness

Health condition

Post-Intensive Care Syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden

Source(s) of monetary or material Support: MCL Wetenschapsfonds

Intervention

Keyword: Intensive Care, Virtual Reality

Outcome measures

Primary outcome

Difference in handgrip strength by handheld dynamometer at 4 weeks

Secondary outcome

Difference in handgrip strength by handheld dynamometer at 12 weeks

Difference in upper limb function by Stroke Upper Limb Capacity Scale, MRC score and range of motion at 4 and 12 weeks

Difference in balance and mobility using the Morton Mobility Index at 4 and 12 weeks

Observational and interview data on support needs

Study description

Background summary

Patients admitted to the Intensive Care Unit (ICU) due to critical illness may experience new or increased physical, mental, cognitive or social problems. Research from the MCL showed that patients with inadequate physical recovery after one year also have lower handgrip strength at discharge from the ICU and after three months. In addition, a recent study indicated that hand function after ICU admission is lower than in a healthy control group. Early mobilisation focussing on regain of function is therefore essential in ICU patients. Previously, the MCL and 8D Games developed a Virtual Reality exergame that is safe and feasible to use as an addition to standard care mobilisation in the ICU ward. Although the primary goal of the VR-exergame is to provide personalised and fun options in rehabilitation, it may also have additional

benefits when it comes to recovery after critical illness. In addition, the VR-exergame may be a feasible option for performing rehabilitation exercises after hospital discharge.

Study objective

Primary:

To investigate the effect of a 4-week VR-exergame intervention on handgrip strength in patients staying in the ICU for 48 hours or longer compared to standard rehabilitation practices.

Secondary:

To investigate the longer term effect of a 4-week VR-exergame intervention on handgrip strength in patients staying in the ICU for 48 hours or longer compared to standard rehabilitation practices.

To investigate the effect of a 4-week VR-exergame intervention on hand and arm functionality in patients staying in the ICU for 48 hours or longer compared to standard rehabilitation practices.

To investigate the effect of a 4-week VR-exergame intervention on balance and mobility in patients staying in the ICU for 48 hours or longer compared to standard rehabilitation practices.

To identify support needs of patients staying in the ICU for 48 hours or longer related to the use of a VR-exergame in hospital and in the home situation.

Study design

Multicentre mixed-methods randomised controlled trial.

Intervention

4-week VR-exergame intervention.

Study burden and risks

VR-based exercises have been used previously in various patient groups, including ICU-patients, and are a safe addition to standard healthcare.

Participation with this training is voluntary and an addition to the standard care physical rehabilitation protocol. Patients can stop the exercise at any moment in time, without having to provide an explanation. The exercise activity will be guided and supervised by a trained researcher. Participation in the study measurements and semi-structured interview will require mental effort, but can be conducted in the patients* current living situation to limit burden. Overall, the expected extent of the burden and risks associated with using this healthcare innovation are limited.

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

- Length of stay ICU ≥ 48 hours
- Lives in catchment area of one of the Frisian hospitals
- Understands the Dutch language
- Intact motor skills of at least one upper extremity

Exclusion criteria

- Active delirium (CAM-ICU ≥ 1)
- Severe cognitive dysfunction
- Internal cardiac defibrillator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-01-2024
Enrollment:	108
Type:	Actual

Ethics review

Approved WMO	
Date:	18-12-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL85317.099.23