ISRCTN18012197 https://doi.org/10.1186/ISRCTN18012197

Restorative virtual environments for rehabilitation: Is it feasible to use interactive technology to enhance recumbent cycling on the intensive care unit?

Submission date
02/05/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
08/11/2017

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
A critical illness is a life-threatening condition. Whilst many patients recover from critical illness with few negative consequences, some develop a condition called “Intensive Care Acquired Weakness (ICU-AW)”, a condition where they suffer profound muscle wasting resulting in severe incapacitating weakness. As part of their therapy to aid recovery and rehabilitation, these patients are encouraged to perform in-bed cycling. Unlike the majority of exercise equipment found in commercial gyms and at home, the in-bed cycle device provides the patients with no form of performance feedback or distraction from the discomfort many experience as consequence of exertion. VeloVR is a new interactive game which has been designed to provide patients with feedback during their in-bed cycle sessions. The aim of this study is to find out whether it is feasible and safe to use VeloVR in stable patients, diagnosed with ICU-AW on the ICU.

Who can participate?
Adult ICU patients who are medically stable and have been diagnosed with ICU-AW.

What does the study involve?
All participants are asked to use the MotoMed device (in-bed cycling device) for four sessions, each lasting up to 20 minutes. Each session takes place in the patients' bedspace. The sessions usually take place over consecutive days, but there may be longer periods between sessions if other treatment or rest days are required. The first and last sessions use the standard MotoMed device, without any virtual reality. The second sessions uses distraction-based virtual reality game and the third session uses competition-based virtual reality game with the MotoMed system. Immediately after each session, a researcher asks questions to the participant, lasting approximately 30 minutes. Following this, participants receive usual follow up with their ICU rehabilitation team.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating.

Where is the study run from?
Queen Elizabeth Hospital Birmingham (UK)

When is study starting and how long is it expected to run for?
February 2016 to February 2018

Who is funding the study?
Ministry of Defence (UK)

Who is the main contact?
Dr Charlotte Small
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
33185

Study information

Scientific Title
Restorative Virtual Environments for Rehabilitation: Feasibility of the use of interactive technology-enhanced recumbent cycling to aid (VeloVR) mobilisation on the Intensive Care Unit

Acronym
REVERE Move

Study objectives
The aim of this study is to evaluate whether a new interactive game, VeloVR, designed to provide patients with feedback during their in-bed cycle sessions, is feasible and safe to use in stable patients, diagnosed with ICU-AW on the ICU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston REC, 06/12/2016, ref: 17/WM/0007

Study design
Non-randomised; Interventional; Design type: Treatment, Device, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Critical care, Primary sub-specialty: Critical Care; UKCRC code/ Disease: Musculoskeletal/ Other disorders of the musculoskeletal system and connective tissue

Interventions
VeloVR is a novel interactive technology-based device developed using commercial off the shelf (COTS) interface devices combined with custom designed gaming software. The MotoMed ergometer will be set to “Active” for each intervention. The duration of each intervention will be a maximum of 20 minutes. Patients will follow the standard QEHB recumbent ergometry protocol. The setting for the VeloVR game is Virtual Wembury, a virtual reality-based simulation of a natural environment, developed by the Human Interface Technologies Team at the University of Birmingham. This is based on the South West coastal path around Wembury Bay. The system has been adapted for use by patients in the ICU, with selection of appropriate interface systems and consideration of bed space and working environment ergonomics for staff. A cadence tracking system (Garmin) will track the MotoMed pedal movement. This data is entered, via custom-built midware, into the VeloVR game. The game will be displayed by a monitor mounted between the patient and the MotoMed, at patient eye level allowing a comfortable viewing distance. The game has two modes: 1. Distraction mode – patients pedal along the coastal path of Virtual Wembury. Speed along the path is determined by cadence speed. 2. Competition mode – patients pedal and compete against a cycling avatar, attempting to move faster than them along the coastal path. The avatar speed and progress is that achieved by the patient during their previous session. Thus, they are aiming to perform better than during the previous session. As the gear is increased, as per the protocol, the change in effort will be represented within the VeloVR game by either an increase in speed or increase in gradient. Patients will be asked to compete a questionnaire at the end of each session. Data on length of stay and in hospital death will be collected until the patient is discharged from hospital.

Intervention Type
Other

Primary outcome(s)

Feasibility and acceptability outcomes:
1. Ability to recruit participants to the REVERE Move study is assessed by dividing the total number of participants by total screened
2. Participant completion of the REVERE Move protocol is measured by recording the duration in minutes at the end of each session
3. Usability of the VeloVR system by patient users is assessed using a modified system usability scale at the end of each session
4. Usability of the VeloVR by staff users is assessed using a modified system usability scale at the end of each session
5. Safety and adverse events associated with use of the VeloVR system is assessed through patient responses end of each session
6. Patient ability and willingness to complete measurement tools, including semi-structured interview is assessed through patient responses end of each session

Key secondary outcome(s))

1. Distance covered during each session (as measured by ergometer) in metres is measured using the MotoMed dashboard at the end of each session.
2. Duration of active cycling during each session is measured in minutes/seconds at the end of each session
3. Total duration of session is measured in minutes/seconds at the end of each session
4. Active:passive ratio during each session is measured using the MotoMed dashboard at the end of each session
5. Perceived dyspnoea during ergometry session is measured using the Borg Breathlessness scale (1-10) at the end of each session
6. Pain and anxiety experienced during ergometry session is measured using a visual analogue scale (VAS) at the end of each session
7. Perceived enjoyment during the MotoMed/VeloVR session is measured using the Likert scale at the end of each session
8. Perceived competitiveness of the VeloVR competition scenario is measured using the Likert scale at the end of each session
9. Mood after MotoMed/VeloVR session is measured using the Likert scale at the end of each session
10. Exercise self-efficacy after MotoMed/VeloVR session is measured using the Likert scale at the end of each session
11. Perceived exertion during ergometry session is measured using the Borg scale (1-10) at the end of each session
12. Side effects experienced during ergometry e.g. nausea is measured by the a semi-structured interview at the end of each session
13. Adverse events experienced during ergometry – e.g. dislodging of intravascular catheters is measured through clinical observation at the end of each session
14. Duration of mechanical ventilation is measured in days on discharge from ICU
15. Duration of tracheal intubation (until decannulation of trachea) is measured in days on discharge from ICU
16. Patient mobility is measured using the Manchester Mobility Score on ICU discharge
17. Severity of ICU-Acquired Weakness is measured using the MRC-Sum Score at ICU discharge
18. Functional performance is measured using the Barthel Score at ICU discharge
19. ICU and hospital lengths of stay is measured in days on discharge from ICU
20. In-hospital death rates are measured using the patient information communication system (PICS) at monthly intervals during the trial

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. Patient in ICU
2. Conscious and able to communicate
3. Aged over 18 years, any gender
4. RASS score -1 to +1
5. Diagnosed with ICU-AW as defined by the presence of 1, 2, 5, and either 3 or 4 from:
5.1. Weakness developing after the onset of critical illness
5.2. The weakness being generalized (involving both proximal and distal muscles), symmetrical, flaccid, and generally sparing the cranial nerves (e.g. facial grimace is intact)
5.3. Muscle power assessed by the Medical Research Council (MRC) sum score of 0.48 (or a mean score of 0.4 in all testable muscle groups) noted on 2 occasions separated by 24 hours
5.4. Dependence on mechanical ventilation
5.5. Causes of weakness other than ICUAW have been excluded

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. Severe visual loss
2. Active delirium or psychosis at screening from the Richmond Agitation and Sedation Score (RASS) and the Confusion Assessment Method for the ICU (CAM-ICU) score
3. Severe cognitive impairment or encephalopathy
4. Orthopaedic patients with contraindications to mobilise (e.g. pelvic / spinal fractures)
5. Poor prior level of mobility (< 10yds)
6. Neuromuscular disease (e.g. Motor Neurone Disease)
7. Expected withdrawal of treatment/palliative care in process
8. Patients with already established rehabilitation pathways (e.g. amputees)
9. Previous participation in this study

Date of first enrolment
03/04/2017

Date of final enrolment
03/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital Birmingham
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from drcharlottesmall@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No