ISRCTN63077147 https://doi.org/10.1186/ISRCTN63077147

Restorative virtual environments for rehabilitation

Submission date	Recruitment status	[ ] Prospectively registered
27/06/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/06/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/05/2020	Other	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16714

Study information

Scientific Title
REstorative Virtual Environments for REhabilitation: Does Virtual Nature Therapy enhance sleep on the Intensive Care Unit?

Acronym
REVERE 1

Study objectives
Interactive technology can be used to improve the patients perception of their environment. Engagement in this environment will lead to relaxation and improvement in sleep quality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - South Birmingham; 26/03/2014, ref: 14/WM/0058

Study design
Non-randomised; Interventional and Observational; Design type: Process of Care, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Critical care; Subtopic: Critical care; Disease: All Critical care

Interventions
Exposure to virtual nature therapy (VNT) will comprise:
1. Viewing the virtual reality scene (Virtual Wembury a virtual reality reconstruction of the South Devon coastal path) on a 32in computer screen.
2. Listening to the sounds using noise cancelling headphones (noise cancelling function can be switched off at the patients request)

Three conditions will be used in sequence
A. Static image. Patient unable to navigate or alter their position within Virtual Wembury but objects within Virtual Wembury will move; including sun setting, sea wave motion and animal movements.
B. Toggle view with 180 degree viewing motion. Patients will be able to toggle between

different viewpoints and look around from a static position
C. Interactive version of VNT, whereby patients can navigate Virtual Wembury.

Each condition represents increasing complexity of and potential engagement within VNT. Patients offered condition B or C will be able to revert to condition A by not using their hand controllers if they wish. The HIT team will record this activity and the results used to inform patient usage preferences.

The intervention will comprise up to two hours of access to VNT before they go to sleep. This will usually be following the 22:00 drug round prior to their sleep time, however if patients wish to go to sleep earlier they may receive the VNT any time after 20:00. Patients will not be woken up to receive VNT. Should patients fall asleep before receiving VNT and wake before 04:00, they will be offered VNT if they wish to try to go back to sleep. Timings of sleep and offering of VNT will be documented by the nurse caring for the patient

On study day 1 the patient will receive control conditions (no VNT), usual clinical care (night sedation prescription will be standardised, environmental conditions will be recorded).
On study day 2 the patient will be offered VNT A
On study day 3 the patient will offered VNT B
On study day 4 the patient will be offered VNT C
On study day 5 the patient will receive control conditions, usual clinical care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Richard Campbell Sleep questionnaire; Timepoint(s): Each night of study participation

Secondary outcome measures
Secondary outcomes (where overnight is 20:00 08:00):
1. Hours of sleep recorded by nursing staff.
2. Systolic blood pressures, pulse rate, respiratory rate recorded at hourly intervals overnight.
3. Arterial CO2 concentrations recorded at 2-4 hourly intervals (usual care) overnight, or End tidal CO2 concentrations if arterial line not in situ.
4. Presence of delirium, identified by a positive CAM-ICU or RASS score >2 or <-2
5. Pain scores overnight usual numerical rating scale 0-3.
6. Nausea, sickness and anti-emetic use
7. Qualitative patient feedback of factors affecting sleep and their perceptions of the VNT system.
8. Patient usage of VNT duration and type of activity, downloaded directly from embedded software within the VNT system.

Overall study start date
16/06/2014

Completion date
19/01/2015

Eligibility

Key inclusion criteria
1. Patient in intensive care unit
2. Conscious and able to communicate
3. Aged over 18 years
4. RASS score 1 to +1
5. Considered unlikely to be discharged from critical care for 5 days
Target Gender: Male & Female; Upper Age Limit 90 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30; Description: see IRAS R&D

Key exclusion criteria
1. Bilateral upper limb paralysis or limb loss preventing ability to use hand controller
2. Severe visual or hearing loss
3. Active delirium or psychosis at screening from RASS and CAMICU
scor
4. Severe cognitive impairment including dementia or hepatic encephalopathy
5. Active infection or colonisation with multidrug
resistant organism

Date of first enrolment
16/06/2014

Date of final enrolment
19/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Edgbaston
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Queen Elizabeth Hospital (UK)

Sponsor details
Centre for Clinical Haematology
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Sponsor type
University/education

ROR
https://ror.org/048emj907

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Defence Medical Services Surgeon General's Research Group; Grant Codes: 20110914_DMSRSG_REFR

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

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