ISRCTN23330756 https://doi.org/10.1186/ISRCTN23330756

Virtual restorative environment therapy for burns dressing changes

Submission date	Recruitment status	[_] Prospectively registered
25/02/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/02/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/11/2018	Injury, Occupational Diseases, Poisoning	[_] 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
15785

Study information

Scientific Title
Investigation of virtual restorative environment therapy to aid pain control during dry burns dressing changes

Study objectives
The burns unit at the Queen Elizabeth Hospital Birmingham admits nearly 300 patients a year, including wounded military patients. The pain of a severe burn injury is characterised by an unremitting background pain, coupled with severe exacerbations associated with essential procedures such as dressing changes, staple removal from grafts and physiotherapy. A recent audit showed that 23% of patients experience moderate or severe pain during dressing changes. This study will evaluate the use of an interactive computer game, based on a virtual restorative environment (VRE), as an adjunct to pain management during burns dressing changes.The system has been developed specifically for this patient group to allow usability for all but the most severely injured patients. The study will be a single blinded (data collector only) within-subject crossover trial where patients who are undergoing dry burn dressing changes will be receive non-interactive VRE distraction, interactive VRE distraction and a control condition using standard analgesia over three consecutive dressing changes. The order of conditions will be randomised. The primary outcome will be highest pain score (numerical rating scale) during the dressing change. Secondary outcomes will be average pain scores during dressing change, pain score one hour after dressing change, anxiety, rescue analgesia, usability, level of immersion and satisfaction. Data will also be collected on staff satisfaction with and usability of the system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/WM/0205

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Anaesthetics

Interventions

Virtual reality (active), Interactive game, based within Virtual Wembury, whereby the patient can control movement of a speedboat viewed on a high definition screen, listening to associated sounds via headphones. The speedboat will be controlled by a single-hand use hand controller. Points can be scored by collection objects and steering between buoys.

Virtual reality (passive), Viewing of a nature based virtual world based on Wembury Bay, South Devon coastal path. The VR system consists of a high definition TV screen and headphones to provide sounds of the VR environment. The image will be viewed as if through a window, the patient will not be able to change the field of view or navigate through the scene. There will be movement associated with the sea and foliage.

Intervention Type
Device

Primary outcome measure
Worst pain (numerical rating scale); Timepoint(s): During dressing change

Secondary outcome measures
1. Anxiety; Timepoint(s): During dressing change
2. Average pain; Timepoint(s): During dressing change
3. Nausea; Timepoint(s): During dressing change
4. Nursing satisfaction with VR system; Timepoint(s): During dressing change
5. Satisfaction with pain management; Timepoint(s): During dressing change
6. Satisfaction with VR distraction; Timepoint(s): During dressing change
7. Worst pain; Timepoint(s): One hour after dressing change

Overall study start date
06/01/2014

Completion date
06/04/2014

Eligibility

Key inclusion criteria
1. Patients with burns (any cause) admitted to the Queen Elizabeth Hospital Burns Unit
2. Those above requiring at least three dressing changes.
3. Those above requiring opioid based analgesia (eg oral morphine, codeine phosphate or tramadol)or inhaled nitrous oxide (entonox) for the dressing change (ie, patients who may potentially experience moderate or severe pain)
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: 25; UK Sample Size: 25

Key exclusion criteria
1. Inability to use the interactive distraction equipment eg blindness, severe bilateral hand injuries.
2. Requirement for general anaesthesia or sedation with ketamine or midazolam.
3. Poor cognitive state eg severe dementia, delirium or severe psychiatric illness.
4. Multi-drug resistant infection (due to potential equipment contamination, although low risk, this criteria is appropriate for the feasibility study)

Date of first enrolment
06/01/2014

Date of final enrolment
06/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Centre for Defence Medicine (UK) Grant Codes: 20110914DMSRSGVRPLP

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2017 results presented at Pain Science in Motion 2017: https://www.researchgate.net /publication /316990817_Virtual_Restorative_Environment_Therapy_as_an_adjunct_to_conventional_analgesia

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?
Protocol article	protocol	05/08/2015		Yes	No
HRA research summary			28/06/2023	No	No