The Development of Interactive Virtual Reality System to Distract Burns Patients Away From Their Pain During Clinical Interventions

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Project Protocol

1. Background

Burns patients often suffer excruciating pain during dressings change and physiotherapy, even when given strong analgesics. Opiates are used routinely in controlling the background pain associated with burn injury[1], but there are unpleasant side effects[2] and their efficacy in the context of procedural and anticipatory pain, such as during wound cleansing, dressing change and physiotherapy[3], has been described as limited[4]. The risks of poor pain relief are physical, psychological and social, and include greater sensitivity to infection, higher risk of PTSD and loss of confidence in the care team.[3]

Theories to explain the experience of pain, such as Gate Control Theory and neuromatrix theory,[5, 6] emphasize the role of psychological elements including perception, attention and anxiety. Non-pharmacological methods of pain relief, aimed at reducing these elements (such as mental imagery, hypnosis, video-watching, parental participation) have been demonstrated as potentially effective in tackling procedural pain, through their ability to distract[4].

Virtual Reality (VR) 'involves an artificial 3-dimensional environment that is experienced by a person through sensory stimuli (usually visual, aura, and often touch) delivered by a computer and in which one's actions partially determine what happens in the environment.'[7]. VR is an immersive experience for the user, and is postulated to act both directly and indirectly upon pain perception, through its effects on attention, emotion, concentration, and sensory involvement.[8] Compared with other forms of non-pharmacological distractive interventions, VR makes increased demands upon the users attention[9], and also reduces visual and auditory cues to pain before and during procedures[10], which could cause anxiety and anticipatory pain.

A number of studies and two systematic reviews (based on 9 and 17 studies respectively) [11, 7] have reported positive outcomes of VR interventions in a range of clinical applications, including pain management,[7] with the strongest evidence emerging its effectiveness in the relief of pain and associated anxiety in burns patients, both adults and children[7]. Compared with no distraction, reported pain scores were significantly lower when patients were engaged with the VR experience. Some studies also identified that greater immersion, for

example, using a headset, reduced perceived pain further, [12] and others have argued for specifically tailored VR environments for optimal pain relief. [13]

Given the growing evidence for its effectiveness in reducing burn pain during procedures, with very limited adverse effects, and the reducing costs of technology, IVR has considerable value in the management of clinical pain.[7] Reviews have concluded with suggestions for more work to enhance the evidence-base, with larger samples and rigorous methodological approaches[7]. The role which degree of immersion and tailored environments play in pain perception[12, 13] are further avenues of potentially fruitful research.

The research team has produced an innovative VR gaming environment, a highly interactive VR game controlled using eye and head movement. These will be compared to establish the characteristics of the VR environment that produce greater pain relief for burns patients. Medical Research Council funding has been obtained for this.

2. Pre-Project Preparatory Work

Two preparatory stages were conducted to inform the VR intervention and the design of the clinical feasibility trial with community and student samples. Sheffield Hallam University Research Ethics Committee approved these two separate stages (298-PHE and 328-PHE respectively).

2.1 A workshop with team members and a community sample of burn survivors

A workshop with a community sample of previous burn survivors and research team members helped to inform the development of the VR game and environment. Through discussion and a range of interactive activities, workshop participants (4 team members and 2 burn survivors) considered gaming environments, images and words, to determine which might prove useful or otherwise. Outcomes from this workshop helped the team to create four scenarios for VR interventions, including two more active and two more passive environments. Discussions identified a number of features to include or exclude (e.g. relaxing or engaging music vs. discordant or sudden noises; cold scenes or those indicating warmth, but not anything suggesting heat; bright colours, rather than those indicative of the hospital environment). These outcomes directly influenced the development of four VR environments

The workshop participants have also been invited to play a role in later stages of this project, acting as 'experts' in the experience of burns and burn care in an advisory role to the research team. They have been instrumental in developing the design of the current study, and may form part of a steering group for future work (more detail below).

2.2 A pre-clinical trial of the intervention with University students

The aim of the student trial was to ascertain the impact of the four active VR environments created by the team on the experience of pain (prolonged contact with a cold plate) as well as participants' experiences in using the technology. From this student trial we were able to identify and select the two (one interactive, one passive) considered most effective, enjoyable and distracting to take forward to the clinical trial.

3. Aims

The aims and objectives of the clinical feasibility trial are:

- to investigate the potential for VR to reduced perceived pain and anxiety during painful dressings changes in a small sample of burns patients;

- to measure the impact of the interventions on objective indicators of pain and distress during dressing changes within the small sample

- to assess pain medication use during virtual reality interventions

- to compare the above effects and experiences across two conditions within each participant: an active version of a virtual reality intervention, and a 'control' condition of no intervention;

- to assess the perceived usability, acceptability, engagement with and enjoyment of the virtual reality intervention to the patients

- to consider the apparent feasibility of the virtual reality intervention within a Burns Unit inpatient setting during painful dressing changes

4. Design

This is an exploratory feasibility study with a small clinical sample of burns patients and staff caring for them, in a single burns unit setting, employing mixed methods and a repeated measures design to achieve the aims set out above.

5. Ethical approvals and permissions

The study has been discussed at length with senior members of the nursing and clinical psychology teams on the burns unit, and input from these staff has informed the design of the study. Prior to commencing the study, the research team will also lead an information session for other staff members and provide written information about the study.

Ethical approvals are being sought from HRA with R&D approval and registration from Sheffield Hallam University and Sheffield Teaching Hospitals NHS Trust.

6. Patient and User Involvement

Burn survivor input was vital in informing the development of the VR intervention in the preparatory workshop, and exploring usability / acceptability of the intervention is a core aim of the clinical trial. Workshop participants have kindly agreed to act as 'experts' in the future stages of this project, will sit on a Steering Panel, and be reimbursed for their time.

In addition, the Patient and Public Involvement (PPI) Panel for Therapeutic and Palliative Care were extremely positive about the study. Their suggestions included reducing the number of variables from the original three it was originally planned to measure (pain, anxiety and distress), to reduce participant burden, and because it may be difficult for patients to distinguish between anxiety and distress. This suggestion was taken on board, and the participants are now asked to measure their pain and anxiety only, as the most important variables for this small study. Other variables are likely to be included in a future more extensive trial. The panel also suggested that the team consider recruitment in case of attrition, in order to maintain the minimum number of 10.

7. Participants and Recruitment

7.1 Target sample

The target sample for the clinical feasibility trial are adult burn patients (18+), who are English-speakers, and therefore able to consent for themselves to participate in the research. In order to avoid unnecessary psychological or physical distress, we will exclude those with active PTSD or psychotic symptoms, or high levels of distress as judged by Burns Unit clinicians, where the use of VR might be contraindicated. People with mild-moderate or well controlled mental health problems will not be excluded from the study. In addition, those with head and neck burns will be excluded as they would be unable to wear the VR equipment during dressing changes. The participants will be inpatients who are receiving regular dressing changes during the study period.

We aim to recruit 10 participants. In the case of attrition during the course of the study, additional participants will be recruited to replace any who withdraw during their involvement in the study, in order to achieve the target number at completion

7.2 Sampling strategy

Recruitment will be based on purposive opportunity sampling.

People who meet the criteria and are receiving in-patient care during the period of the study will be considered for suitability by the clinical team caring for them, including nurses, medical staff and clinical psychologist e.g. during a Multi-Disciplinary Meeting. In addition, information about inclusion / exclusion criteria will be explained in the information sheet, enabling people who have been approached to self-identify as ineligible if necessary.

If considered suitable for the research the patient will be approached by a member of clinical staff, such as a nurse, or a member of the research team who has a clinical role (e.g. OF, who is a clinical psychologist) and introduced to the study. No pressure will be placed upon these individuals to either express an interest or participate. They will be reassured verbally at this stage that deciding the study is not for them will have no consequences whatever for their future treatment. Patients interested in participating or simply in hearing more, will be provided with formal information (see detail below). The non-clinical research team will not have direct contact with any participant or knowledge of their personal details until they have requested information about the study.

7.3 Informed consent and participant rights

Having expressed an interest in hearing more about the study, potential participants will be provided with full, printed information about the study to read and consider in their own time. The information sheet will suggest they take time to think about the study and discuss it with loved ones if appropriate. It will also encourage the reader to ask questions and seek clarification from the person (clinician) who supplied the information or another member of the research team, whose contact details will be provided, including telephone numbers and email addresses.

The information sheet will provide a brief background and rationale for the project in lay terms, and explain why the person has been considered eligible for the study. It will provide detail about what participation involves, how to find out more and how to consent. The information will include a statement that participation is not obligatory and reassurance that refusal to participate will not affect care. The information sheet will explain that, having decided to participate, the person will be free to change their mind before, during or immediately after the study (prior to data analysis), without giving a reason. Advice will be provided regarding how to withdraw their consent or aspects of their data, where possible. Details regarding confidentiality, anonymity, data access, storage and retention also will be provided. It will be suggested that the person retain the Information sheet for future reference and in order to make contact with the research team.

It is likely that in deciding whether to participate, candidates will be shown a short video which shows a VR system being used and given the opportunity to see and try out the VR equipment. This will be actively encouraged to avoid unnecessary anxiety or problems on the day of the intervention. Opportunities for exposure to and practice with the equipment will be made available to all potential participants either on the day of receiving the Information sheet or as soon as possible afterwards, as well as after consent, if they wish. IP (the games designer from the research team) will attend the Burns Unit to facilitate this exposure and practice. It is intended that potential participants should spend at least 5 minutes in the headset to familiarise themselves with the sensations and experience at this stage, in order to decide if they are likely to feel comfortable with in during the intervention.

If the person, having read the Information Sheet, tried out the equipment, considered and discussed the study with team members and loved ones, wishes to go ahead, they will be asked to sign a consent form. This will be done in the presence of a clinician on the research team, ahead of the intervention being implemented. On the day of the intervention, a number of things will be verbally reiterated: the study aim, what will happen during the procedure, and the participant's rights. They will be given an opportunity to change their mind at this point and either withdraw from the study or postpone the intervention to a later date.

8. Staff Feedback on Feasibility and Potential

Staff members who have been directly involved in the care of patients participating in the study will be invited to a short post-study focus group, to share their impressions of the intervention, its impact, usability and acceptability. An Information sheet about the aims of the focus group will be provided and consent taken on arrival.

9. Methods

9.1 Materials and their use

Materials will include the VR headset and gaming environments, a booklet of questionnaires for the participants to complete, a monitor to measure heart rate, a brief interview schedule, a focus group schedule and digital recording equipment.

VR Headset / Gaming environments: IP will bring the VR headset for information-giving purposes and during dressing changes, and provide instructions to participants on how to use it and how to operate within the virtual environment to maximise their effectiveness and involvement within the environment during dressing changes. An active (participatory) gaming environment has been developed for participants to trial,

Questionnaire Booklet: Participants will be given a questionnaire booklet at the beginning of the intervention by the researcher, who will go through the booklet to explain the different sections. It will comprise 2 visual analogue scales - in the form of 'emotion thermometers' - of pain and anxiety. These will provide numerical values from 0 - 100, in which 0 is no pain / anxiety, and 100 represents the greatest levels imaginable of each. Participants will be asked to use these scales to rate their perceptions of their pain and anxiety a total of 4 times: on each of 3 dressing change days, and one after the intervention. Two of the dressing changes will involve the VR intervention as described below, and one will be without VR.

On three dressing change days participants will be asked to complete the two 0-100 ratings 4 times - before their dressing change and three afterwards: immediately after the dressing change and then after 2 and 4 hours. They will also be asked to complete the scales once on a non-dressing day after the study, to allow us to assess the impact beyond dressing days of

the VR intervention. The researcher will add in the dates and times for each participant in their booklet. These outcomes have been selected as especially important to the study, but we have opted to measure them simply and easily to minimise participant burden. The booklet will also contain boxes and prompts for participants to add free text responses about the experiences we are monitoring, should they wish.

Pulse Rate Monitor: During two dressing changes under study (the active VR experience and no intervention) patients will be attached to a pulse oximeter on finger or toe to monitor their pulse rate, which may be indicative of pain or distress. The limb will be selected to avoid interfering with the dressing procedure, e.g. if the burn is to an arm, the pulse oximeter will be applied to the patient's opposite side calf. IP (from the research team) will observe changes in PR and take a printed tracing of these readings throughout the dressing change.

Patients will not be asked during dressing changes to make any comment about their experience, so that they can concentrate on the VR environments and to avoid adding to patient burden on the non-intervention condition.

The timed readings will also be taken to assess how aspects of the VR experience might be impacting on pain and distress, e.g. if the game includes a particularly involving or novel aspect at minute 2:30 and PR also dips around and after this time, it might be considered that the VR experience impacted on these changes. These data will be supplemented by qualitative responses as described below.

Brief Interview Schedule / Digital Recording Equipment: After each VR intervention dressing change, and once the patient is comfortable and ready for a short interview, they will be asked a few questions about their experience of pain and the gaming environment, such as 'How was your pain during the dressing change while you were in the VR environment?' 'How did you feel generally during the experience?' 'How helpful did you find the VR during the dressing change?' etc. These short interviews (max 10 minutes) will be recorded on a password protected digital recorder.

After both interventions, most likely on a non-dressing change day, another short interview (max 10 minutes) will be conducted to enable the participant to make comparisons between the different VR experiences and general comments about their effectiveness, usability and impact compared with no VR. Questions may include 'Which VR experience did you prefer and why?' 'From your experience how does a dressing change under VR compare with one with no VR experience?' etc.

Staff Focus Group Schedule / Digital Recording Equipment: Staff who attend the focus group will be asked questions from a short schedule, and invited to share and discuss their thoughts, experiences and opinions with one another. Questions would focus on their sense of the patient experience, as well as their own, and may include: 'How did the

dressing changes you were involved with when patients had VR in pace differ, if at all, from other dressing changes?' (prompts may include apparent pain / ability to communicate with the patient / anxiety and distress for the patient / need to give pain relief before, during, after); 'what do you think the patients' experience was of the dressing change under VR?' 'What have the difficulties or complications been when using this technology?' 'On balance, do you feel this sort of intervention is beneficial; if so / if not, why?' etc. The focus group would be recorded on a password protected digital recorder. It is anticipated to be of around 30-40 mins duration, and will be conducted immediately after participants' work shift, within a quiet, private workplace environment.

10. Procedure and Data Collection

Each participant will undertake three monitored dressing changes, ideally during a period of between 1 and 2 weeks, to be arranged between the participant, team members and staff. These will not include the very first dressing change experienced by the patient following admission, to avoid undue distress and to allow time for appropriate information to be given and arrangements made; thus it is possible that study participation may commence for an individual patient from around 3 days after admission. This is likely to vary considerably, and patients who have already been on the Unit for several days or longer at the start of the study can be included at any stage of their stay on the Unit. It is possible that some of the participants may have procedures under general anaesthetic during their time on the study, such as dressing changes under GA or the application of skin grafts. Since it is difficult to accurately map the timing of these interventions, the likelihood of these will not affect initial inclusion or ongoing involvement in the study, but they will be noted and considered in case they may have impacted in some way upon the variables and experiences being measured. For example, it is possible that dressing changes following a skin graft may be experienced as less painful than those beforehand.

The participant will be asked to begin using their questionnaire booklet from the day of the first monitored dressing change and continue doing so until the day after their third monitored dressing change.

Of the two identified dressing changes, one will occur under normal circumstances with no VR intervention, and one will take place with an active VR experience. The order will be altered for different participants to minimise order effects.

Prior to the VR dressings - at least one hour before if on the day or, if this is not possible, the day before - the participant will be reminded by IP how to use the VR and offered a 5 minute exposure to the game they have selected, to familiarise themselves with this and avoid unnecessary distractions and confusion during the dressing change itself.

IP will be present during all three dressing changes to record PR and, in the case of the VR conditions, to provide pre-dressing instruction in the VR equipment and to conduct the short post-dressing interview. He will also remind the participant each time about their questionnaire booklet, fill in the dates and times for completion of the booklet, and answer any questions the participant may have. During the dressing, IP will remain with the patient but in a position to avoid hampering the dressing process. The patient will remain in the VR environment for the whole duration of the dressing change, as long as they are comfortable and happy to do so.

One day after the final dressing change either IP or a clinical member of the research team will attend to conduct the final short interview and collect the questionnaire booklet, plus information from clinicians regarding the participant's medication use for the duration of the study. They will thank the participant for their involvement and offer them a summary of the findings when ready, taking contact details as required for this purpose.

The staff focus group will take place once all patient data collection is complete. Staff will also be offered a summary of findings from patient data in due course.

11. Data Analysis

The dataset for the study will include:

Completed questionnaire booklets for all participants, comprising ratings of 2 variables on around 14-18 occasions (4 times for each dressing day plus once on another day);

PR data from each dressing change;

Medication use for the duration of the study;

Qualitative data about pain and anxiety from the questionnaire booklet;

Qualitative data from the short interviews about pain, distraction and the experience, usability and enjoyment of the VR environments;

Qualitative data from the focus group with staff about feasibility, impact and perceived effectiveness.

Quantitative data analysis: Quantitative data will be entered in excel, SPSS or similar. Descriptive statistics will be calculated for pain, anxiety, pulse rate, and medication use to demonstrate mean values and ranges for the sample, and graphical representations created, to enable visual comparisons between different conditions and different time points. The small sample size will to some extent limit quantitative analyses and the inferences we can draw; however these findings will be primarily illustrative and act as a basis for further larger scale study in the future.

Qualitative data analysis: Qualitative data saved as audio files, transcribed anonymously and stored in word documents or on a qualitative data package such as NVivo. Content analysis will be applied to the patient data from the booklet and interviews, and thematic analysis to the staff data from the focus group. This will involve a process of careful reading, coding and comparison in order to identify important patterns in the data, focused on answering the aims of the study. Themes will be generated based upon the analysis process, which will be discussed and refined within the research team.

12. Data Storage, Confidentiality and Anonymity

Data collected for the study will be treated with the utmost care, anonymised and coded, retained within the research team, and no one outside the team will have access.

On consenting, all participants will be assigned a code, and this code will be used to identify their data and related computer files. Personal information will be securely stored within password protected computer files and separately from anonymised coded data. A single file will be retained which links participant identities to their codes. All documents relating to the study will be kept by the PI at STH, within a study file in her password protected STH computer.

Files will be encrypted for any email transfer required (e.g. for purposes of analysis) between research team members. Hard copy data - questionnaire booklets and consent forms for example - will be kept in a locked STH cabinet during the study.

Interview and focus group recordings will be saved as audio files, identified only by code. The raw data files will then be immediately deleted from the digital recorder. Audio files will be used for transcription purposes, during which all identifiable data will be removed. Thus audio files will remain as full data and transcripts (used for analysis) will be anonymised. Both will be identified by participant code. In resulting reports, some qualitative data extracts will be reported verbatim; however personally identifiable details will be removed prior to analysis and dissemination, and the codes used to identify extracts, therefore others should not be able to identify individuals from reports

Quantitative data will be entered into SPSS or excel, coded using the participant codes, and analysed without reference to participant identity. When disseminated, no individually-based quantitative findings will be reported - findings will reflect the dataset as a whole - therefore it will be impossible to identify individuals from those findings.

In keeping with NHS and MRC policies, twelve months after the study has finished, files containing personally identifiable information will be deleted from STH and University files, and hard copy identifiable data will be confidentially destroyed. All anonymised, coded data will be retained for a period of 10 years in keeping with the MRC policy on data storage.

13. Outcomes, Benefits and Future Steps

Expected outcomes: It is expected that the study will provide detailed information from a small group of patients and staff about perceptions, experiences, usability and effectiveness of VR environments in painful dressing changes. These findings will be taken as illustrative, and will help us refine the intervention and design a definitive study, for local piloting and future national roll-out, if effectiveness is demonstrated.

Benefits for participants: It is anticipated that these participants will enjoy the experience of the two cutting-edge VR environments they test during the study, and appreciate the opportunity to help assess an intervention which could reduce pain and, thereby, enhance care for future burns patients. In addition, we would like to offer them feedback about the findings of the study, which they may find interesting.

It is hoped that testing out these interventions will significantly improve these participants' (and staff) experiences of burn care during their time in the study, and that these findings can support a larger scale study and, if shown to be acceptable, feasible and effective, future routinized availability and usage of VR on Burns Units in the UK.

Dissemination: We anticipate provide written summaries of findings to both participants and staff; we will also offer to visit the Unit to speak in person about the study, its findings, and to provide a VR experience to staff who are interested, as well as discussing our plans for future work. Beyond this, it is expected that the findings will be presented at relevant Game Design / Psychology / Burn Care conferences, and written up for publication in high quality peer-reviewed journals.

14. References

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