A mixed-methods investigation into the acceptability, usability and perceived effectiveness of active and passive virtual reality scenarios in managing pain under experimental conditions

PHELAN, Ivan, FURNESS, Penny <http://orcid.org/0000-0003-4916-8800>, FEHILY, Orla, THOMPSON, Andrew, BABIKER, Nathan, LAMB, Martin and LINDLEY, Shirley

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A Mixed-Methods Investigation into the Acceptability, Usability and Perceived Effectiveness of Active and Passive Virtual Reality Scenarios in Managing Pain under Experimental Conditions.
Abstract

Burns patients often suffer excruciating pain during clinical procedures, even with analgesia. Virtual Reality as an adjunct to pharmacological therapy has proved promising in the management of burn pain. More evidence is needed regarding specific forms of Virtual Reality. This mixed-method study examined the impact of active and passive Virtual Reality scenarios in experimental conditions, gathering data relating to user experience, acceptability and effectiveness in managing pain. Four scenarios were developed or selected following a consultative workshop with burns survivors and clinicians. Each was trialled using a cold pressor test with 15 University students. Data were gathered regarding pain threshold and tolerance at baseline and during each exposure. Short interviews were conducted afterwards. The two active scenarios were ranked highest and significantly extended participants pain threshold and tolerance times compared to passive and baseline conditions. Passive scenarios offered little distraction and relief from pain. Active scenarios were perceived to be engaging, challenging, distracting and immersive. They reduced subjective awareness of pain, though suggestions were made for further improvements. Results suggested that active Virtual Reality was acceptable and enjoyable as a means of helping to control experimental pain. Following suggested improvements, scenarios should now be tested in the clinical environment.

Key words: Burn Pain, Anxiety, Wound care, Virtual Reality, Mixed Methods
Introduction

Burns patients often suffer excruciating pain during dressings change and physiotherapy, even with strong analgesia\(^1\). They are a unique group because the acute pain of treatment is superimposed on the chronic background pain associated with tissue damage\(^2\). Opiates are used routinely for the background pain of burn injury\(^3\), but there are unpleasant side effects\(^4\) and their efficacy for procedural and anticipatory pain, such as during wound cleansing, dressing change and physiotherapy\(^5\), has been described as limited\(^6\). The risks of poor pain relief are physical, psychological, social and clinical. They include greater sensitivity to infection, acute stress symptoms in hospital\(^7\), higher risk of Post-Traumatic Stress Disorder (PTSD), concerns about impact on appearance\(^8\), and even suicide post-discharge\(^9,10\), loss of confidence in the care team\(^5\), and lower compliance with rehabilitation activities\(^11\).

Theoretical perspectives on pain, such as Gate Control Theory and neuromatrix theory\(^12,13\), 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 through their ability to distract\(^6\). Virtual Reality (VR) involves an artificial three-dimensional environment that is experienced by a person through sensory stimuli (usually visual, auditory, and often touch) delivered by a computer and in which one’s actions partially determine what happens in the environment\(^14\). VR is postulated to act both directly and indirectly upon pain perception, through its effects on attention, emotion, concentration, and sensory involvement\(^15\). Compared with other forms of non-pharmacological distractive interventions, VR makes increased demands upon the user’s attention\(^16\), and reduces visual and auditory cues to pain linked to anxiety and anticipatory pain before and during procedures\(^17\).
Interest in the clinical applications of VR technology has inspired studies to explore its feasibility and effectiveness in pain relief, including burn pain\textsuperscript{18}. Studies have reported significant reduction in both adult and child subjective procedural pain scores for VR with pharmacological analgesia compared with analgesia alone\textsuperscript{19,20}. Qualitative findings from staff and parents suggested greater relaxation and cooperation and less evidence of pain and anxiety with VR, and, although immersed, patients continued to communicate well\textsuperscript{20}. Malloy and Milling\textsuperscript{18} noted that early findings were often based on uncontrolled designs or case material studies; however these outcomes are supported in three recent systematic reviews (based on 9, 11 and 17 studies respectively)\textsuperscript{21,18,14}, which have included more recent, carefully controlled studies\textsuperscript{22,23}. Reviews have concluded that the strongest evidence for the effectiveness of VR was in the relief of pain and associated anxiety in adult and paediatric burns patients\textsuperscript{18,14}. The downsides to VR are few: costs are falling\textsuperscript{18} and new technologies, such as water-friendly VR headsets (for water-bath based wound care\textsuperscript{5}), are becoming more accessible\textsuperscript{22}. Some older patients are resistant to VR, and people with pre-existing nausea or a history of motion sickness tend to be excluded from research\textsuperscript{24}. This suggests that the VR technology has its limitations and is not universally welcome or applicable; however among those willing and able to use it, evidence suggests that side effects, such as nausea, attributable to the VR rather than the pharmacological intervention, are rare\textsuperscript{22,25}.

Given the growing evidence for its effectiveness in reducing procedural pain, limited adverse effects, reducing costs and increasing clinical applicability, immersive VR has considerable value in burn pain management\textsuperscript{14}. Favourable evidence is impeded by small sample sizes, but is amassing and becoming more compelling\textsuperscript{2}, although there is scope for more work to enhance the evidence-base, with larger samples and rigorous methodological approaches\textsuperscript{14}. Reviewers have recommended its introduction to burn care and rehabilitation\textsuperscript{26}, but more work is required to explore the impact of varied VR environments, in different patient groups.
and with different individuals, to ascertain the variables which moderate effectiveness. It has been suggested that VR environments may need tailoring for maximum effect. This may involve designing a scenario to meet specific patient group needs, such as a ‘cold’ scenario for burns patients, and in children, offering a range of scenarios to suit all ages.

Hoffman and colleagues note that the degree of immersion offered by VR - the reported sense of ‘presence’ - is related to the degree of VR pain reduction, a finding supported elsewhere. A recent study compared an immersive, active VR scenario via headset with a passive pain distraction experience via bedside video and found that, although pain fell in both groups, those in the experimental VR group reported a significantly greater fall.

However, as authors noted, it was not possible from this design to ascertain whether the difference was attributable to the three-dimensional vs two-dimensional experience, the active vs passive aspect, or the visual and audio variations between the two.

To add to the growing body of evidence, the roles played by degree of immersion and tailored VR environments are fruitful areas for exploration. This study aimed to develop user-informed scenarios based on either active (where the user is actively involved in the VR environment) and passive VR (where the user is only watching) and compare them in experimental conditions, exploring user experience, acceptability, and effectiveness in distracting participants and reducing pain. The benefits of investigating VR scenarios in experimental pain is that it allows greater variable control than clinical pain: each participant can be administered the same pain stimulus and intervention, whereas in the clinical environment, patients are likely to differ in types and levels of pain, and medical needs may affect how the intervention is delivered. Findings have shown that experimental pain ratings with VR were significantly lower than with no VR. However because experimental pain is relatively mild, of short duration, escapable, and has no health implications, it is unclear to what extent these effects can be generalised to clinical studies, so experimental findings...
should also be tested in the clinical arena. The study was supported by a Medical Research Council Confidence in Concept grant.

**Aim**

To explore the user experience, acceptability and analgesic impact of the two active and two passive VR scenarios in healthy adults under experimental pain conditions (a cold pressor test), answering the following research questions:

- what is the impact on objective and self-rated measures of pain of each VR scenario?
- how do participants perceive and experience each different VR scenario?

The ultimate aim was to select two scenarios for improvement and later trial in the clinical setting with burns patients. The University Research Ethics Committee (328-FUR) approved the study.

**Methods**

**Participants**

Participants (aged 18 or over; English speaking) were drawn from the local student population, with a target sample of 10-15 participants. Adverts with contact details were placed on Campus and on University web platforms. We excluded those with self-reported mental health diagnoses, migraines, nausea, pre-existing painful conditions, such as Fibromyalgia, sports or hand injuries, which were likely to exacerbate or interfere with the pain experience. Exclusions were explained in the information sheet, along with full details of the procedure and participant rights. Informed consent was obtained from 15 volunteers.

**Materials**
VR Scenarios: Four scenarios were tested. Two were free-access passive scenarios and two were active scenarios, which were specially developed for the study. Selection and development of scenarios was informed by a prior consultative workshop with two burn survivors and team members, including a games designer, two clinical psychologists with expertise in burn care, an academic clinical psychologist with expertise in burn care, and an academic psychologist with prior experience as a burns nurse. The University Research Ethics Committee approved the workshop (PHE-298). Workshop discussions and activities focused on potential positive VR environments, images, moods and words, aspects to avoid, and generation of VR storyboards. For example, suggestions from the workshop included ‘entertainment’, ‘variety’, ‘immediacy’, ‘novelty’ and ‘laughter’, but also ‘relaxing’ scenarios, images related to ‘cold’ and ‘nature’, and sounds which ‘calm’ or with a ‘regular rhythm’ to avoid jarring. Similarly, images related to ‘heat’, ‘kettles’, ‘bright sun’ the colour ‘red’ and sounds which were ‘upsetting’, ‘jumpy’ ‘too loud’, ‘discordant’ or ‘arrhythmic’ were avoided.

The four scenarios used were named Henry, Flocker, Blindness and Basket. Henry was a pre-existing passive scenario based on the birthday celebrations of a hedgehog; Flocker was an active scenario developed by the games designer in which the character, controlled by the user, had the tasking of rounding up and herding sheep through obstacles; Blindness was a pre-existing passive scenario based on a person’s story of his visual disability; Basket was an energetic active scenario developed by the games designer, based on making basketball shots with varied feedback to engage the user. User control in active scenarios was achieved through head tracking and a simple remote device.

VR equipment: An Oculus Rift CV1 headset and PC were used. Experimental pain was administered via a cold pressor test using an iced water tank, with water circulated to
maintain a temperature of 4°C, and monitored using a thermometer. This temperature
provides an uncomfortable experience without causing tissue damage.

Data Collection Booklet: The booklet collected baseline information including demographic
and initial pain threshold and tolerance data, pain scores for VR experience using visual
analogue scales, and participants' ranking of the VR scenarios after all four exposures. The
booklet also contained boxes for participants to add free text comments about their
experience, if they wished. The booklet was given to the participant for the duration of their
involvement, but they were assisted with its completion by the researcher.

Interview Schedule: Short interviews after each scenario aimed to gather further qualitative
comments regarding the experience (enjoyment, difficulty, appearance of, immersion in and
problems with scenarios, plus suggestions for improvement) and perceived impact on pain
and written notes were taken of participant responses.

Procedure

Trials took place on University premises. On arrival, participants were able to try out a
standard VR scenario for comfort and orientation before consenting.

Participants pain threshold and pain tolerance were recorded by placing their hand in the iced
water for as long as possible. Threshold was the first point at which pain was reported and
tolerance was the duration before pain became unbearable and the participant removed their
hand from the water (total time minus threshold). Participants' non-dominant hand was used
as the dominant hand was required to control the VR. Participants were asked to rate their
maximum pain on a pain scale, providing a baseline (no VR) value.

Scenarios were ordered differently for each participant, in case habituation effects influenced
pain ratings. The non-dominant hand was placed in iced water 30 seconds into the VR
scenario. The scenario ran until complete (approx. 5 minutes) or the participant requested to
stop. Tolerance timings were recorded for comparison with the baseline, following which
booklet and interview data were gathered. The next trial started when participants' hands
returned to pre-test temperature. The four trials and interview lasted around one hour in total.

Analysis

To explore the differences between the VR scenarios a repeated-measures ANOVA or
Friedman's test was conducted if the data violated parametric assumptions, with significance
set at $p \leq 0.05$. A Kruskal-Wallis test was conducted to analyse the differences between the
types of VR (e.g. active, passive, and control), again with significance set at $p \leq 0.05$. Post-hoc
analysis was conducted with a Bonferroni correction made. All analysis was conducted using
IBM SPSS Statistics Version 24 for Windows (IBM United Kingdom Limited, Hampshire,
UK). Qualitative booklet and interview data were analysed for content, identifying common
patterns and terms in the data.

Results

Participants were 10 men and 5 women, ranging in age from 18 – 49 (mean 25).

Table 1 presents descriptive results for each the four scenarios, presented by rank, alongside a
summary of qualitative comments.

The four scenarios were clearly differentiated by rank, with Basket the most popular.

Qualitative comments indicated that, although participants enjoyed the professional
appearance of the two passive scenarios, which were already in the public domain, their lack
of personal involvement limited impact on pain and distraction. These latter elements were
better in the two active scenarios developed by the team, but shortcomings in the appearance
sometimes jarred and reduced their effectiveness.

Pain Threshold

Pain threshold was the point in seconds from the start of the VR scenario at which pain was
reported. There was a statistically significant difference in threshold times depending upon
the VR scenario that a participant was exposed to, $\chi^2(4) = 15.80$, $p=0.003$. Significant
differences in threshold for pain were found between Baseline (median 26 secs) and three VR
scenarios: Flocker (median 55 secs, $Z = -2.94$, $p=0.003$), Blindness (median 33 secs, $Z = -
3.18$, $p=0.001$) and Basket (median 59 secs, $Z = -2.81$, $p=0.005$). No other significant
threshold differences were found.

Pain Tolerance

Pain tolerance was the point at which the participant withdrew their hand from the cold water.
There was a statistically significant difference in tolerance times depending upon the VR
scenario that a participant was exposed to, $\chi^2(4) = 33.67$, $p<0.001$. Significant differences in
tolerance of pain were found between baseline (median 57 secs) and Henry (median 300 secs,
$Z = -2.93$, $p=0.003$), Flocker (median 300 secs, $Z = -2.85$, $p=0.004$) and Basket (median 300
secs, $Z = -2.93$, $p=0.003$). Tolerance of pain was found to be significantly different between
Blindness (median 194 secs) and Henry ($Z = -3.20$, $p=0.001$), Flocker ($Z = -3.23$, $p=0.001$)
and Basket ($Z = -3.17$, $p=0.002$), but other tolerance differences were not significant.
Blindness was the only scenario during which participants were unable to tolerate pain for the
full 5 minute test duration.

Maximum pain
Maximum pain was the score (from 0-100) given by participants to their worst pain after each scenario. Significant differences in maximum reported pain were found between VR scenarios ($F(2.36, 32.98) = 7.06$, $p=0.002$), but post hoc tests revealed these were only between Henry and Blindness (means 52.53 and 65.27 respectively, $p<0.001$).

Immersion and Enjoyment

Both immersion and enjoyment were rated out of 10. Significant differences in immersion scores were found between VR scenarios, $\chi^2(3) = 18.02$, $p<0.001$. Immersions scores were significantly higher in the Henry (median 8, $Z = -2.81$, $p=0.005$), Flocker (median 8, $Z = -2.79$, $p=0.005$), and Basket (median 8, $Z = -3.19$, $p=0.001$) VR scenario compared to the Blindness scenario (median 6). Significant differences in enjoyment scores were found between VR scenarios, $\chi^2(3) = 14.31$, $p=0.003$. Enjoyment scores were significantly higher in the Henry (median 8, $Z = -2.83$, $p=0.005$), Flocker (median 8, $Z = -2.70$, $p=0.007$), and Basket (median 8, $Z = -2.90$, $p=0.004$) VR scenarios compared to the Blindness VR scenario (median 5).

Comparisons between types of VR

Types of VR were active (Basket and Flocker scenarios), passive (Henry and Blindness scenarios), and control (baseline test). There was found to be a significant difference between the threshold scores depending upon the type of VR, $\chi^2(2) = 16.00$, $p<0.001$. Post hoc analysis found that pain threshold scores were significantly lower in the control condition (mean, 25 secs, $U=135.00$, $p=0.012$) and passive scenarios (mean 43.57 secs, $U=44.50$, $p<0.001$) than the active VR scenarios (mean 69.05). There was no significant difference between the control and passive threshold scores ($U=95.50$, $p=0.02$).
There was found to be a significant difference between the tolerance scores depending upon the type of VR, $\chi^2(2) = 11.15$, $p=0.004$. Post hoc analysis found that tolerance scores were significantly higher in the active VR scenario (mean 224.37 secs) compared to the control (mean 122.33 secs, $U=105.00$, $p=0.002$). There was no significant difference found between active and passive VR scenarios (passive mean 173.17, $U=311.50$, $p=0.03$) or control and passive VR scenarios ($U=152.50$, $p=0.08$). There was found to be no significant difference in maximum pain scores between any of the scenarios, $\chi^2(2) = 3.74$, $p=0.15$.

**Discussion**

Results suggested that, compared to baseline, participants' threshold for and tolerance of pain was best in the two active scenarios, Flocker and Basket. There were no significant differences between these two in maximum pain. Active scenarios significantly extended threshold time compared with both baseline and passive scenarios. Blindness emerged as least effective in controlling pain, and least enjoyable and immersive. Qualitative comments suggested that the content in Henry was perceived to be intended more for children.

This study goes some way towards meeting existing recommendations for research into VR\textsuperscript{18}, such as the suggestion to explore fun and presence as variables which contribute to the effectiveness of VR. Our findings offer some insight into these aspects. Qualitative data suggested that VR, especially where the person was actively involved and competing to gain high scores, was fun. Active VR was ranked higher and gave a greater sense of presence and immersion than passive alternatives. This study didn't compare VR with other interventions for pain, such as hypnosis and CBT, but these are exceptional rather than standard in clinical settings. While these other non-pharmacological distraction techniques are effective, there is wide variability in their use and two thirds of European Burn Centres have reported dissatisfaction with their current analgesia strategies\textsuperscript{31}. A recent systematic review showed
that non-pharmacological interventions are rarely used in practice. More could be done to reduce procedural pain, and VR could play a vital role.

Results demonstrated that active VR technology was positively received and evaluated under experimental pain conditions. However, the small sample may have contributed to the non-significant results between active and passive scenarios in tolerance and maximum pain. The feasibility of VR within a Burns Unit should now be tested, ideally with inpatients, whose pain may be most acute. Previous work has focused on an outpatient samples, with minor injuries or at a later stage of care. Clinical trials are also essential to assess the burden, costs and benefits of new treatments and to ensure support systems are in place to facilitate their integration into the care setting beyond the end of a research project. If VR proved as effective in managing perceived pain in clinical settings as was demonstrated under experimental conditions, it may have positive impact on opiate analgesia use, whose side effects include respiratory depression, constipation, sedation, nausea. VR could also be used to promote earlier mobilisation after burns by allowing patients and clinicians to focus on mobilisation and recovery of full movement, rather than on pain.

A strength of our study was user involvement. In developing and selecting scenarios, the potential for a targeted VR environment was discussed between a range of stakeholders, including clinicians and two previous burns patients. Inclusion of burns survivors in designing or conducting research was recommended in a recent report on priorities for burn rehabilitation research. Some VR studies report considering the applicability to their group of a particular intervention, and others used specifically designed software, but few report details of user involvement in the design or decision-making process. Existing evidence has little to say about the aspects which may prove either problematic or useful in VR for burns, so these discussions were novel in helping develop our scenarios. It went some way towards
the tailoring suggested by previous literature\textsuperscript{27}. Clinical testing will allow us to explore this aspect further.

These results have helped us make decisions regarding further development and selection of scenarios for the clinical trial. The two active scenarios are being developed and improved for use in the clinical setting. However, the experimental findings suggest that neither Blindness nor Henry is likely to prove suitable for the clinical setting. Blindness was ineffective in pain control, so it would be unethical to offer this as an intervention with patients. Henry was more effective but too brief for use in painful procedures such as dressing changes and participants saw it as more suited to children. Alternative forms of passive VR will be chosen for trial. Trials with larger clinical samples and using controlled approaches are recommended by reviewers in the area\textsuperscript{32}. However, our experience suggests that future trials would also be wise to consider mixed methods as inclusion of qualitative responses enables nuanced aspects of the experience to be monitored.

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