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Article:

Phelan, I., Furniss, P., Fehily, O. et al. (2019) A mixed-methods investigation into the acceptability, usability and perceived effectiveness of active and passive virtual reality scenarios in managing pain under experimental conditions. *Journal of Burn Care and Research*, 40 (1). pp. 85-90. ISSN: 1559-047X

<https://doi.org/10.1093/jbcr/iry052>

This is a pre-copyedited, author-produced version of an article accepted for publication in *Journal of Burn Care and Research* following peer review. The version of record Phelan et al, A mixed-methods investigation into the acceptability, usability and perceived effectiveness of active and passive virtual reality scenarios in managing pain under experimental conditions (2018) is available online at: <https://doi.org/10.1093/jbcr/iry052>

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1 Title:

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

5

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37 Conflicts of Interest and Funding Statement

38 The research was supported by a British Medical Research Council Confidence in Concept
39 Grant [reference omitted here for anonymity; to be added later].The authors declare no other
40 conflicts of interest.

41

43 **Abstract**

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

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

62

63 **Introduction**

64 Burns patients often suffer excruciating pain during dressings change and physiotherapy,
65 even with strong analgesia¹. They are a unique group because the acute pain of treatment is
66 superimposed on the chronic background pain associated with tissue damage². Opiates are
67 used routinely for the background pain of burn injury³, but there are unpleasant side effects⁴
68 and their efficacy for procedural and anticipatory pain, such as during wound cleansing,
69 dressing change and physiotherapy⁵, has been described as limited⁶. The risks of poor pain
70 relief are physical, psychological, social and clinical. They include greater sensitivity to
71 infection, acute stress symptoms in hospital⁷, higher risk of Post-Traumatic Stress Disorder
72 (PTSD), concerns about impact on appearance⁸, and even suicide post-discharge^{9,10}, loss of
73 confidence in the care team⁵, and lower compliance with rehabilitation activities¹¹.

74 Theoretical perspectives on pain, such as Gate Control Theory and neuromatrix theory^{12, 13},
75 emphasize the role of psychological elements including perception, attention and anxiety.
76 Non-pharmacological methods of pain relief, aimed at reducing these elements (such as
77 mental imagery, hypnosis, video-watching, parental participation), have been demonstrated
78 as potentially effective through their ability to distract⁶. Virtual Reality (VR) involves an
79 artificial three-dimensional environment that is experienced by a person through sensory
80 stimuli (usually visual, auditory, and often touch) delivered by a computer and in which one's
81 actions partially determine what happens in the environment¹⁴. VR is postulated to act both
82 directly and indirectly upon pain perception, through its effects on attention, emotion,
83 concentration, and sensory involvement¹⁵. Compared with other forms of non-
84 pharmacological distractive interventions, VR makes increased demands upon the user's
85 attention¹⁶, and reduces visual and auditory cues to pain linked to anxiety and anticipatory
86 pain before and during procedures¹⁷.

87 Interest in the clinical applications of VR technology has inspired studies to explore its
88 feasibility and effectiveness in pain relief, including burn pain¹⁸. Studies have reported
89 significant reduction in both adult and child subjective procedural pain scores for VR with
90 pharmacological analgesia compared with analgesia alone^{19,20}. Qualitative findings from staff
91 and parents suggested greater relaxation and cooperation and less evidence of pain and
92 anxiety with VR, and, although immersed, patients continued to communicate well²⁰. Malloy
93 and Milling¹⁸ noted that early findings were often based on uncontrolled designs or case
94 material studies; however these outcomes are supported in three recent systematic reviews
95 (based on 9, 11 and 17 studies respectively)^{21,18,14}, which have included more recent,
96 carefully controlled studies^{22,23}. Reviews have concluded that the strongest evidence for the
97 effectiveness of VR was in the relief of pain and associated anxiety in adult and paediatric
98 burns patients^{18,14}. The downsides to VR are few: costs are falling¹⁸ and new technologies,
99 such as water-friendly VR headsets (for water-bath based wound care⁵), are becoming more
100 accessible²². Some older patients are resistant to VR, and people with pre-existing nausea or
101 a history of motion sickness tend to be excluded from research²⁴. This suggests that the VR
102 technology has its limitations and is not universally welcome or applicable; however among
103 those willing and able to use it, evidence suggests that side effects, such as nausea,
104 attributable to the VR rather than the pharmacological intervention, are rare^{22,25}.

105 Given the growing evidence for its effectiveness in reducing procedural pain, limited adverse
106 effects, reducing costs and increasing clinical applicability, immersive VR has considerable
107 value in burn pain management¹⁴. Favourable evidence is impeded by small sample sizes, but
108 is amassing and becoming more compelling², although there is scope for more work to
109 enhance the evidence-base, with larger samples and rigorous methodological approaches¹⁴.
110 Reviewers have recommended its introduction to burn care and rehabilitation²⁶, but more
111 work is required to explore the impact of varied VR environments, in different patient groups

112 and with different individuals, to ascertain the variables which moderate effectiveness¹⁸. It
113 has been suggested that VR environments may need tailoring for maximum effect²⁷. This
114 may involve designing a scenario to meet specific patient group needs, such as a ‘cold’
115 scenario for burns patients, and in children, offering a range of scenarios to suit all ages²⁰.

116 Hoffman and colleagues^{1,22} note that the degree of immersion offered by VR - the reported
117 sense of ‘presence’ - is related to the degree of VR pain reduction, a finding supported
118 elsewhere^{18,28}. A recent study compared an immersive, active VR scenario via headset with a
119 passive pain distraction experience via bedside video and found that, although pain fell in
120 both groups, those in the experimental VR group reported a significantly greater fall²⁴.

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

124 To add to the growing body of evidence, the roles played by degree of immersion and
125 tailored VR environments are fruitful areas for exploration. This study aimed to develop user-
126 informed scenarios based on either active (where the user is actively involved in the VR
127 environment) and passive VR (where the user is only watching) and compare them in
128 experimental conditions, exploring user experience, acceptability, and effectiveness in
129 distracting participants and reducing pain. The benefits of investigating VR scenarios in
130 experimental pain is that it allows greater variable control than clinical pain: each participant
131 can be administered the same pain stimulus and intervention, whereas in the clinical
132 environment, patients are likely to differ in types and levels of pain, and medical needs may
133 affect how the intervention is delivered¹⁸. Findings have shown that experimental pain ratings
134 with VR were significantly lower than with no VR²⁸⁻³⁰. However because experimental pain
135 is relatively mild, of short duration, escapable, and has no health implications, it is unclear to
136 what extent these effects can be generalised to clinical studies¹⁸, so experimental findings

137 should also be tested in the clinical arena. The study was supported by a Medical Research
138 Council Confidence in Concept grant.

139 **Aim**

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

143 - what is the impact on objective and self-rated measures of pain of each VR scenario?

144 - how do participants perceive and experience each different VR scenario?

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

148 **Methods**

149 Participants

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

157 Materials

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

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

180 VR equipment: An Oculus Rift CV1 headset and PC were used. Experimental pain was
181 administered via a cold pressor test using an iced water tank, with water circulated to

182 maintain a temperature of 4° C, and monitored using a thermometer. This temperature
183 provides an uncomfortable experience without causing tissue damage.

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

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

194 Procedure

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

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

203 Scenarios were ordered differently for each participant, in case habituation effects influenced
204 pain ratings. The non-dominant hand was placed in iced water 30 seconds into the VR

205 scenario. The scenario ran until complete (approx. 5 minutes) or the participant requested to
206 stop. Tolerance timings were recorded for comparison with the baseline, following which
207 booklet and interview data were gathered. The next trial started when participants' hands
208 returned to pre-test temperature. The four trials and interview lasted around one hour in total.

209 Analysis

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

218 Results

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

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

222 TABLE 1 HERE

223 The four scenarios were clearly differentiated by rank, with Basket the most popular.
224 Qualitative comments indicated that, although participants enjoyed the professional
225 appearance of the two passive scenarios, which were already in the public domain, their lack
226 of personal involvement limited impact on pain and distraction. These latter elements were

227 better in the two active scenarios developed by the team, but shortcomings in the appearance
228 sometimes jarred and reduced their effectiveness.

229 Pain Threshold

230 Pain threshold was the point in seconds from the start of the VR scenario at which pain was
231 reported. There was a statistically significant difference in threshold times depending upon
232 the VR scenario that a participant was exposed to, $\chi^2(4) = 15.80$, $p=0.003$. Significant
233 differences in threshold for pain were found between Baseline (median 26 secs) and three VR
234 scenarios: Flocker (median 55 secs, $Z = -2.94$, $p=0.003$), Blindness (median 33 secs, $Z = -$
235 3.18 , $p=0.001$) and Basket (median 59 secs, $Z = -2.81$, $p=0.005$). No other significant
236 threshold differences were found.

237 Pain Tolerance

238 Pain tolerance was the point at which the participant withdrew their hand from the cold water.
239 There was a statistically significant difference in tolerance times depending upon the VR
240 scenario that a participant was exposed to, $\chi^2(4) = 33.67$, $p<0.001$. Significant differences in
241 tolerance of pain were found between baseline (median 57 secs) and Henry (median 300 secs,
242 $Z = -2.93$, $p=0.003$), Flocker (median 300 secs, $Z = -2.85$, $p=0.004$) and Basket (median 300
243 secs, $Z = -2.93$, $p=0.003$). Tolerance of pain was found to be significantly different between
244 Blindness (median 194 secs) and Henry ($Z = -3.20$, $p=0.001$), Flocker ($Z = -3.23$, $p=0.001$)
245 and Basket ($Z = -3.17$, $p=0.002$), but other tolerance differences were not significant.
246 Blindness was the only scenario during which participants were unable to tolerate pain for the
247 full 5 minute test duration.

248 Maximum pain

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

253 Immersion and Enjoyment

254 Both immersion and enjoyment were rated out of 10. Significant differences in immersion
255 scores were found between VR scenarios, $\chi^2(3) = 18.02, p<0.001$. Immersions scores were
256 significantly higher in the Henry (median 8, $Z = -2.81, p=0.005$), Flocker (median 8, $Z = -$
257 $2.79, p=0.005$), and Basket (median 8, $Z = -3.19, p=0.001$) VR scenario compared to the
258 Blindness scenario (median 6). Significant differences in enjoyment scores were found
259 between VR scenarios, $\chi^2(3) = 14.31, p=0.003$. Enjoyment scores were significantly higher in
260 the Henry (median 8, $Z = -2.83, p=0.005$), Flocker (median 8, $Z = -2.70, p=0.007$), and
261 Basket (median 8, $Z = -2.90, p=0.004$) VR scenarios compared to the Blindness VR scenario
262 (median 5).

263 Comparisons between types of VR

264 Types of VR were active (Basket and Flocker scenarios), passive (Henry and Blindness
265 scenarios), and control (baseline test). There was found to be a significant difference between
266 the threshold scores depending upon the type of VR, $\chi^2(2) = 16.00, p<0.001$. Post hoc
267 analysis found that pain threshold scores were significantly lower in the control condition
268 (mean, 25 secs, $U=135.00, p=0.012$) and passive scenarios (mean 43.57 secs, $U=44.50,$
269 $p<0.001$) than the active VR scenarios (mean 69.05). There was no significant difference
270 between the control and passive threshold scores ($U=95.50, p=0.02$).

271 There was found to be a significant difference between the tolerance scores depending upon
272 the type of VR, $\chi^2(2) = 11.15$, $p=0.004$. Post hoc analysis found that tolerance scores were
273 significantly higher in the active VR scenario (mean 224.37 secs) compared to the control
274 (mean 122.33 secs, $U=105.00$, $p=0.002$). There was no significant difference found between
275 active and passive VR scenarios (passive mean 173.17, $U=311.50$, $p=0.03$) or control and
276 passive VR scenarios ($U=152.50$, $p=0.08$). There was found to be no significant difference in
277 maximum pain scores between any of the scenarios, $\chi^2(2) = 3.74$, $p=0.15$.

278 **Discussion**

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

285 This study goes some way towards meeting existing recommendations for research into VR¹⁸,
286 such as the suggestion to explore fun and presence as variables which contribute to the
287 effectiveness of VR. Our findings offer some insight into these aspects. Qualitative data
288 suggested that VR, especially where the person was actively involved and competing to gain
289 high scores, was fun. Active VR was ranked higher and gave a greater sense of presence and
290 immersion than passive alternatives. This study didn't compare VR with other interventions
291 for pain, such as hypnosis and CBT, but these are exceptional rather than standard in clinical
292 settings. While these other non-pharmacological distraction techniques are effective, there is
293 wide variability in their use and two thirds of European Burn Centres have reported
294 dissatisfaction with their current analgesia strategies³¹. A recent systematic review showed

295 that non-pharmacological interventions are rarely used in practice³². More could be done to
296 reduce procedural pain, and VR could play a vital role.

297 Results demonstrated that active VR technology was positively received and evaluated under
298 experimental pain conditions. However, the small sample may have contributed to the non-
299 significant results between active and passive scenarios in tolerance and maximum pain. The
300 feasibility of VR within a Burns Unit should now be tested, ideally with inpatients, whose
301 pain may be most acute. Previous work has focused on an outpatient samples³³, with minor
302 injuries or at a later stage of care. Clinical trials are also essential to assess the burden, costs
303 and benefits of new treatments^{34, 35} and to ensure support systems are in place to facilitate
304 their integration into the care setting beyond the end of a research project³⁴. If VR proved as
305 effective in managing perceived pain in clinical settings as was demonstrated under
306 experimental conditions, it may have positive impact on opiate analgesia use, whose side
307 effects include respiratory depression, constipation, sedation, nausea³⁶⁻³⁸. VR could also be
308 used to promote earlier mobilisation after burns²⁶ by allowing patients and clinicians to focus
309 on mobilisation and recovery of full movement, rather than on pain.

310 A strength of our study was user involvement. In developing and selecting scenarios, the
311 potential for a targeted VR environment was discussed between a range of stakeholders,
312 including clinicians and two previous burns patients. Inclusion of burns survivors in
313 designing or conducting research was recommended in a recent report on priorities for burn
314 rehabilitation research²⁶. Some VR studies report considering the applicability to their group
315 of a particular intervention²⁰, and others used specifically designed software²², but few report
316 details of user involvement in the design or decision-making process. Existing evidence has
317 little to say about the aspects which may prove either problematic or useful in VR for burns,
318 so these discussions were novel in helping develop our scenarios. It went some way towards

319 the tailoring suggested by previous literature²⁷. Clinical testing will allow us to explore this
320 aspect further.

321 These results have helped us make decisions regarding further development and selection of
322 scenarios for the clinical trial. The two active scenarios are being developed and improved for
323 use in the clinical setting. However, the experimental findings suggest that neither Blindness
324 nor Henry is likely to prove suitable for the clinical setting. Blindness was ineffective in pain
325 control, so it would be unethical to offer this as an intervention with patients. Henry was
326 more effective but too brief for use in painful procedures such as dressing changes and
327 participants saw it as more suited to children. Alternative forms of passive VR will be chosen
328 for trial. Trials with larger clinical samples and using controlled approaches are
329 recommended by reviewers in the area³². However, our experience suggests that future trials
330 would also be wise to consider mixed methods as inclusion of qualitative responses enables
331 nuanced aspects of the experience to be monitored.

332

333 **Acknowledgements**

334 Authors would like to thank the workshop attendees and students who gave time to
335 participate and share their perceptions. The research was supported by a British Medical
336 Research Council Confidence in Concept Grant [reference omitted here for anonymity; to be
337 added later].

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433 Table 1: Ranks and qualitative comments for each scenario

Scenario name	Passive or active VR	Rankings: Median (range)	Summary of qualitative comments
Basket	active	1 (1-3)	<ul style="list-style-type: none"> • An active game, distracting, addictive, competitive, lots to do, different levels of difficulty and challenge • Got into it, good immersion • Pain noticeable but less. Frustrating if not good at game, or if challenge not enough, both of which increased pain experience. • Appearance could be made more realistic and improved, dark at times
Flocker	active	2 (1-4)	<ul style="list-style-type: none"> • Fun, interactive, motivating • Challenge was distracting but not too hard • Had to focus and concentrate, forgot about cold • Some elements of graphics (characters, scenery, text, speed of movement) and sound reduced positive impact, were frustrating - could be improved • Could increase difficulty and build in levels.
Henry	passive	3 (1-4)	<ul style="list-style-type: none"> • Nice story • Liked characters, images and quality of detail • Maybe more appropriate for kids • Pain, distraction and immersion were better when more was happening, worse when bored.
Blindness	passive	4 (3-4)	<ul style="list-style-type: none"> • Calmer and slower • Just watching • Not interesting enough, boring, depressing, passive, dull • Visual effects and appearance good • Had little positive impact on pain and immersion; very aware of cold and pain

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