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# The Effect of Audiovisual Distraction on Pain Perception During Reduction of Distal Radial Fractures: A Dual Center Randomized Controlled Trial

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☐ ABSTRACT—Background: Adequate pain management is a challenge in the Emergency Department (ED). This study explores whether audiovisual distraction (AVD) has a positive effect on pain perception. Objective: We aimed to compare the influence of AVD on reported pain, anxiety and satisfaction using a commercial AVD device as an adjunct to standard care in patients undergoing distal radial fracture reduction in the ED. Methods: This randomized controlled, dual-center study, conducted in the ED of 2 Level-1 trauma centers, included a total of 36 adult patients with a distal radial fracture requiring reduction in the ED. Patients were randomly assigned to either standard of care or the use of AVD in addition to standard of care. The primary outcome was reported pain after fracture reduction using a standardized verbal Numerical Rating Scale (v-NRS). Results: No significant differences were found between groups in pain (difference: 0.8; 95% CI, -1.2 to 2.8), anxiety (difference: 0.6; 95% CI, -1.6 to 2.8) or satisfaction (difference: 0.1; 95% CI, -0.7 to 1.0). However, the majority (>80%) of the patients, nurses and physicians stated they would recommend the use of AVD for future procedure. Conclusion: This study was unable to demonstrate the added value of using audiovisual immersion as a distraction tool to standard care, in terms of lowering perceived pain and / or anxiety in adults undergoing a wrist fracture reduction in the ED.

Nevertheless, patients and healthcare providers appeared to be satisfied and would recommend the use of the AVD device. © 2025 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/)

☐ Keywords—audiovisual distraction; pain; anxiety; fracture; virtual reality

#### Introduction

Adequate and safe relief of acute pain during painful procedures remains a major global challenge in Emergency Care (1). More than half of all patients presenting to the Emergency Department (ED) report experiencing pain (2). To date, peri-procedural pain management for the treatment of acute pain in the ED setting remains suboptimal (3).

One of the oldest non-pharmacological methods known to be effective and safe to mitigate pain is mental distraction (4,5). With the rise of high-tech video glasses and virtual reality (VR), distraction techniques have re-gained increasing attention as an adjunct for use in healthcare. Specifically, research has shown VR to be

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promising in the field of pain management. This includes wound care of burns in children, cystoscopy, and various surgical and dental procedures (6–9). Moreover, audiovisual distraction (AVD) has been shown to have potential to decrease sedative dosages needed in pain management (10).

How AVD works to reduce pain is only partially known. The gate control theory postulates pain perception to be modulated by interaction among different neurons. AVD or other stimuli might lead to the closure of certain neural gateways, thus reducing pain perception (11). Virtual reality (VR) appears to be more effective than traditional methods due to its immersive properties (12). It demands engagement from a patient's visual, auditory and, in some cases, also physical actions.

Distal radius fractures are the most common upper extremity fractures presented in the ED (13). When displaced, they can be repositioned manually and/or with the help of finger-trap traction. Reduction of the fracture is known to be a painful procedure, frequently performed in the ED (14). Placing an inter-osseous hematoma block in the fracture gap using lidocaine is a frequently used technique to obtain analgesia for this type of fracture reduction and is considered to be a safe and effective method (15). The analgesic effect of the hematoma block depends on the technique of injection and the amount of lidocaine used (16).

Our aim was to investigate whether the additional application of a commercial portable multimedia device with audiovisual glasses (HappyMed®) would be effective in reducing pain in adults with a displaced wrist fracture in need for manual reduction in the ED. We hypothesized that the addition of this AVD device to the standard of care (SOC) would result in lower pain scores, less anxiety and higher patient satisfaction. Additionally, our objective was to explore the feasibility of implementing a new innovative tool in a busy ED by evaluating the satisfaction and feedback from the emergency physicians and nurses.

# Methods

## 57 Study Design

A randomized controlled trial was conducted in 2
Dutch academic level-1 trauma centers to compare SOC
with SOC augmented with AVD. The annual ED census
of [blinded for review] was 4996 and [blinded for review] was 3281. The study was conducted in accordance
with the CONSORT guidelines (17). The protocol was approved by the Institutional Review Board of the relevant
study sites. (blinded for review). All included patients provided written informed consent.

#### **Participants**

Eligible patients were adults presenting to the ED with a displaced distal radial fracture requiring manual reduction, after assessment of radiographic imaging, and who presented within 24 hours after the sustained injury. Exclusion criteria were visual or auditory impairment, multiple traumatic injuries, illiterate, non-Dutch speaking, a known history of anxiety disorder, intoxication, chronic opioid use, lidocaine allergy, or an indication for acute surgical intervention. Study participants were patients who met the eligibility criteria and were both willing and able to give informed consent.

Recruitment 79

Patients underwent initial assessment and management by an ED triage nurse. Pain management was implemented according to the standard hospital protocols. Board-certified emergency physicians, who would also perform the hematoma block and reduction, approached the patients and provided verbal and written information about the study. If the patient was interested, additional questions were answered. Patients were fully assessed against the inclusion and exclusion criteria before written consent was obtained for those willing and able to participate.

# Study Procedure and Data Collection

Participants in both groups (SOC and SOC + AVD) received instructions on how to grade their pain, level of anxiety and satisfaction using the v-NRS; an 11-point scale ranging from 0 to 10 which is validated for measuring acute pain in the ED (18). With 0 indicating "no pain," "no anxiety" or "not satisfied at all with the total procedure" and 10 indicating "the worst pain possible," "severe anxiety" or "completely satisfied with the total procedure."

Pain perception and anxiety were measured right before the start of the procedure (before the administration of the hematoma block) and immediately after (when the plaster cast had been applied). When in cast (e.g., after reduction), patients were asked to score the maximum level of pain and anxiety they had experienced during the administration of the hematoma block and the fracture reduction. Just before discharge, patients were asked to score their overall satisfaction with the procedure. The patients in the intervention group (SOC+AVD) were asked to rate the quality of the audio and visual effects and the distraction on an 11-point scale and whether they would use the AVD device again under similar circumstances.

Data were collected on a standardized case report form 114 by the treating physician and included various patient 115

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characteristics and questions; these can be found in supplement A and B.

The informed consent and the case report forms were stored in an opaque envelope and the data was entered in a dedicated, password protected, SSL-encrypted database (Castor®, Ciwit BV, Amsterdam, The Netherlands) by the investigators.

#### Interventions 123

The standard operation procedure was instructed to all Emergency Physicians involved at the study sites. This was included in a package with study information in addition to consent forms in a concealed study envelope. Participants in both groups received similar care with regard to analgesic block and reduction method. All participants received the same information on the procedural steps (first, hematoma block; second, 10 min finger traction; third, manual reduction; and lastly, a plaster cast). A hematoma block was performed by injecting lidocaine into the fracture hematoma. A standard dosage of 20 mL of lidocaine 1% for adult patients with a body weight >50 kilograms was advised. Specific dosages of lidocaine were prescribed for patients weighing <50 kilograms. For increased distribution and analgesic effect, it was advised to inject 10 mL into the hematoma directly after successful withdrawal of blood in the syringe. Subsequently 10 mL was divided between the lateral and medial surface of the fractured radius. Hereafter, a finger trap traction device was applied and used for providing continuous fracture traction for a period of 10 minutes. Patients were asked to report their pain to ascertain the analgesic effect of the hematoma block before reducing the fracture. In the case that patients reported a pain score (v-NRS) >6, additional analgesia was offered. Consequently, the fracture was reduced manually, and a plaster cast was applied. Finally, a radiographic image in 2 dimensions was performed to check the fracture angles after reduction.

In addition to the SOC, a portable multimedia device was used in patients assigned to the intervention group. This device, referred to as the 'HappyMed®', consists of a pair of video glasses with headphones which is connected to a controller with a touchscreen. The headset is adjustable and shields the patient off completely from their surroundings. The high-quality video and audio are intended to give the patient a 'real' cinematic experience. In contrast to VR, HappyMed® video glasses show only 2-dimensional content. This is to ensure patients do not move their head/body as this may cause unintentional additional pain or problems with the procedure.

Prior to administration of the hematoma block, the AVD device was given to the patient and a movie of choice was started. Figure 1 shows a picture of the set-up in the intervention group. Five minutes after the initiation of the



Figure 1. Demonstration of audio-visual Set-up.

movie, the hematoma block was given. The AVD device 168 was first removed after immobilizing the wrist with a plas-

## Randomization, Allocation Concealment, and Blinding

Randomization with a 1:1 ratio to either intervention 172 (SOC+AVD) or control group (SOC) was done via a 173 secure web-based randomization system (Castor®). The 174 treating emergency physician accessing the randomiza- 175 tion website did not know the allocation for an individual 176 patient until recruitment was confirmed. Blinding was not 177 possible for this study due to the nature of the interven- 178 tion.

# Primary Outcome

The primary outcome of this study was the maxi- 181 mum pain experienced during placement of the hematoma 182 block and the manual fracture reduction.

# Secondary Outcomes

Our secondary outcomes included patient anxiety and 185 satisfaction scores, adverse events, analgesic medication 186 used, success rate of the manual fracture reduction and 187

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satisfaction of nurses and emergency physicians on the use of the AVD device.

### Sample Size

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The main objective of this study was to assess if there is a clinically significant difference in maximum pain intensity scores during a painful procedure with and without audiovisual immersive technology. Using the criteria of a balanced sensitivity and specificity, the best cut-off points determined by Farrar et al. (19) for pain intensity are > or =2 difference on a 0-10 numeric rating scale. Assuming a standard deviation of 2, and using a 2 tailed 2 sample t test, with a type 1 error rate of 0.05, a sample size of 17 participants per group provides sufficient power (80%) to detect a between group difference of 2 or more points on the v-NRS.

## Statistical Analyses

The data were analyzed using an intention-to-treat analysis. Baseline characteristics were presented using descriptive statistics. Continuous data were expressed as means with standard deviations and categorical data as numbers and percentages. Normality of the data distribution was analyzed by visually inspecting the histograms. For the primary and secondary outcomes, according to data distribution, a 2-sided Student's t-test or Mann Whitney U test was used. The mean difference between the 2 groups was presented together with 95% confidence intervals (CI). The secondary outcomes of anxiety and patient satisfaction scores were also examined for normality and tested using either the students t-test or the Mann-Whitney U test. The differences between the groups were displayed as mean difference with 95% CI or interquartile range (IQR).

#### Results

#### Recruitment and Flow Through Trial 221

Figure 2 outlines the flow of participants in our study. Recruitment took place from June 2019 to February 2021. Ten patients were excluded: 5 did not speak Dutch, 3 patients suffered from a multi-trauma and 2 patients opted out as they preferred to be able to see the procedure. Thirty-seven patients entered the study after providing informed consent and were randomly assigned: 18 to the control and 19 to the intervention group. Two patients could not participate: 1 because of a malfunctioning AVD device and another due to an error of the randomization software. When the AVD device malfunctioned for a second time, we changed this patient from intervention to control group. Hereby leaving 17 patients in the interven- 234 tion group and 19 in the control group.

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#### Baseline Characteristics

Baseline characteristics are shown in Table 1. The pa- 237 tients ranged in age from 21 to 86 years with a mean of 238 56 years. There were no significant differences in groups 239 for age, sex, fracture type, baseline pain and baseline anxi-240 ety. However, the control group reported a higher baseline 241 pain (6.2 vs 5.5 p = 0.36) and lower anxiety score (3.7 vs 242 4.9 p = 0.20) compared with the intervention group. This 243 was not considered statistically significant. Administra- 244 tion of pre-hospital pain medication was comparable in 245 both groups. Although the recommended dosage of lido- 246 caine was prescribed in the standard operating procedure, 247 the doses administered varied from 8 mL to 20 mL. No 248 significant difference was found in dosage between the 249 groups. Fentanyl was given intravenously in 2 patients 250 in the control group and in 1 patient in the intervention 251 group.

#### Primary Outcome

No significant differences in pain during analgesic 254 injection or fracture reduction were found between the 255 control group and intervention group (Table 2). The mean 256 reported pain during injection was higher in the control 257 group: 5.3 (SD 2.4) vs 4.4 (SD 2.5), p = 0.31. The mean 258 reported pain for the fracture reduction was higher in the 259 intervention group (4.8; SD 3.0 vs 5.6; SD 3.0 p = 0.43) 260 (Figure 3).

### Secondary Outcomes

No significant difference between the groups was 263 found in reported anxiety or satisfaction scores. (Table 2 264 and Figure 4). Patients in the intervention group graded 265 the quality of the video with an average of 7.8 and the au- 266 dio with a 7.9 on a 10-point scale (1-10). The effect of the 267 distraction of the video glasses was given a 6.2 out of 10. 268 When asked if they would use the video glasses next time, 269 83% of the patients, 88% of the physicians and 94% of 270 the nurses answered with a 'yes'. One physician reported 271 that the AVD device negatively influenced the procedure, 272 without further specification, and another commented that 273 the intervention "took too much time". One patient re- 274 ported that "the volume of the audio was too low". There 275 were no adverse events reported.

### Discussion

The current RCT suggests that the application of an 278 AVD device, in addition to the SOC does not provide 279 JID: JEM

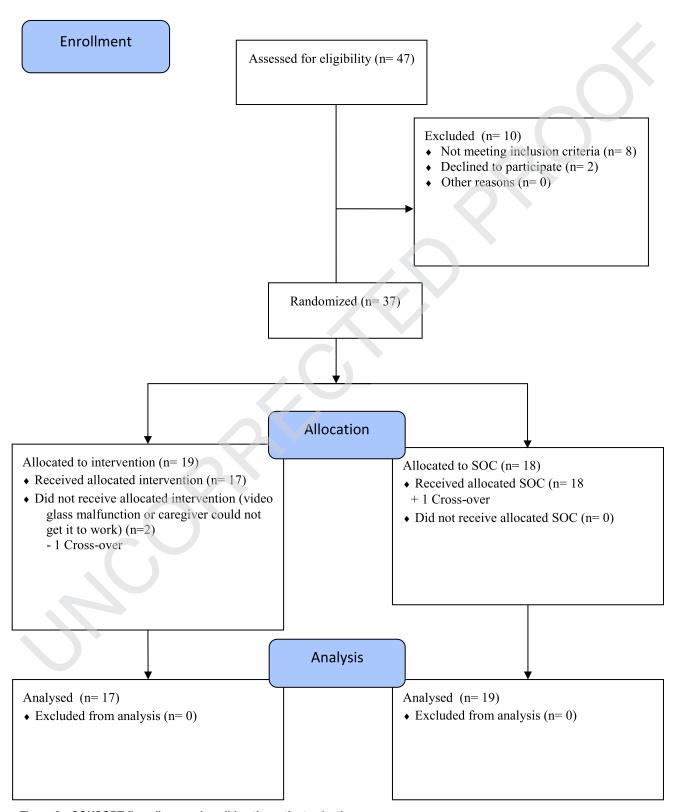


Figure 2. CONSORT flow diagram describing the patient selection process. SOC: standard of care; CONSORT: Consolidated Standards of Reporting Trials

Table 1. Baseline Characteristics.

Characteristics	Control group $(n = 19)$	Intervention group $(n = 17)$
Age in years, mean (SD)	57.5 (18.0)	54.7 (20.2)
Sex, N (%)		
Male	3 (15.8)	5 (29.4)
Female	16 (84.2)	12 (70.6)
Fracture type, N (%)		
Dorsal	15 (78.9)	12 (70.6)
Volar	4 (21.1)	5 (29.4)
Baseline Pain-Score (SD)	6.2 (1.6)	5.5 (2.9)
Baseline Anxiety-Score (SD)	3.7 (2.6)	4.9 (2.7)
Pre-hospital medication, N (%)		
Acetaminophen 1000 mg	10 (52.6)	10 (58.8)
Diclofenac 50 mg	5 (26.3)	2 (11.8)
Ibuprofen 400 mg	0	1 (5.9)
Pre-procedural medication, N (%)		
Acetaminophen 1000 mg	6 (31.6)	1 (5.9)
Diclofenac 50 mg	3 (15.8)	1 (5.9)
Fentanyl 1 μg/kg	2 (10.5)	1 (5.9)
Piritramide 15 mg	0	1 (5.9)
Procedural medication		
Lidocaine 1% in mL, mean (SD) Additional	13.2 (4.7)	10.3 (4.4)
medication during procedure, N (%)		
Fentanyl 1 μg/kg	1 (5.3)	1 (5.9)
Piritramide 15 mg	1 (5.3)	0 `

SD: standard deviation.

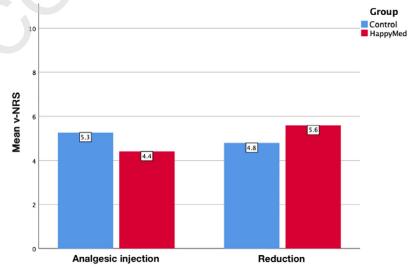


Figure 3. Pain scores. Mean v-NRS pain scores during analgesic injection and during fracture reduction. v-NRS: verbal numeric rating scale.

Table 2. Primary and Secondary Outcomes.

Variable	Control group $(n = 19)$	Intervention group $(n = 17)$	Difference (95% CI)	P
Maximum pain score (v-NRS) during:				
Analgesic injection	5.3 (2.4)	4.4 (2.5)	-0.9 (-2.5 to 0.8)	0.31
Fracture reduction	4.8 (3.0)	5.6 (3.0)	0.8 (-1.2 to 2.8)	0.43
Anxiety score	3.5 (3.0)	4.1 (3.4)	0.6 (-1.6 to 2.8)	0.59
Satisfaction score				
Patient	8.6 (1.3)	8.7 (1.3)	0.1 (-0.7 to 1.0)	0.77
Physician	8.1 (0.7)	7.4 (1.4)	-0.7 (-1.5 to 0.1)	0.07
Nurse	8.2 (1.0)	8.0 (1.4)	-0.2 (-1.1 to 0.7)	0.65
Would recommend HappyMed®				
Patient	-	83% (14/17)		
Physician	-	88% (14/16)		
Nurse	-	94% (16/17)		
Score HappyMed®				
Quality of video	-	7.8		
Quality of audio	-	7.9		
Distraction	-	6.2		
Fracture reduction successful after first attempt	73% (11/15)	86% (12/14)		
Adverse events	0	0		

CI = confidence interval; v-NRS = verbal numerical rating scale; SD = standard deviation.

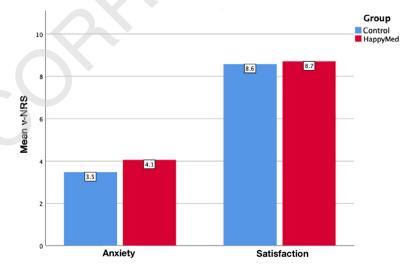


Figure 4. Anxiety and satisfaction scores. Mean anxiety and satisfaction v-NRS scores in patients receiving SOC with or without audiovisual distraction using the HappyMed device. v-NRS: verbal numeric rating scale.

sufficient distraction to significantly reduce pain and anxiety in patients undergoing reduction of a distal radial fracture in the ED. These findings contradict earlier reported studies in literature, in which the authors showed a pain and anxiety reducing effect when using audiovi-

sual immersion using VR to complement standard care 285 (20,21). 286

One of the reasons may be that these studies used VR, 287 which has more immersive qualities compared with the 288 HappyMed® AVD device. According to Sinha et al., the 289

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greater the immersion the greater the analgesic effect will be. (22) The score for overall distraction in our study was rated with an average of 6. This sits in contrast to the 8+ score which was given for the quality of the video and audio of HappyMed®. It might be that the HappyMed® headset is satisfactory for watching a movie but is not sufficient in providing enough distraction during painful procedures. We know from other studies that have used VR, that the time spent thinking about pain during medical procedures is significantly less compared to watching television as distraction. (23,24) However, a recent investigation published in 2023, compared 2-dimensional (2D) audio-video experiences with 3-dimensional (3D) virtual reality in adult emergency department patients requiring a minor procedure. (25) Distraction by viewing a 3D virtual world in a head-mounted VR display did not result in lower average levels of procedural pain and anxiety than that by 2D viewing on a screen, despite a higher sense of telepresence. Another important reason for the differing results may be that the aforementioned VR studies were conducted in predominantly pediatric or young adolescent patients. Again, this sits in contrast to our predominantly adult female population with a mean age of 56. Children are well known to be more susceptible to immersive and distractive techniques when compared to adults. (26) For example, Olesen et al. demonstrated that children exhibit distinct brain activation patterns in response to distraction tasks, suggesting they are inherently more susceptible to such interventions. (25) Similarly, Birnie et al. provided evidence from a systematic review that distraction significantly reduces procedural pain and distress in pediatric patients, of finding that aligns earlier work by McCaul and Malott on the overall effectiveness of distraction in modulating pain perception. (5,26) However, these benefits observed in children may not directly translate to older adults, given the differences in cognitive processing, attention and pain perception between age groups. Although not statistically significant, we found that physicians rated satisfaction higher in the control group. This was also reflected in some of the reported comments provided by physicians. Some noted the additional intervention was too time-consuming. This is an important point. The ED can be a busy place where time and personnel are scarce at times. There may be threshold for implementing new devices if they appear to take too much time to set up. According Birrenbach et al VR seems to be effective and implementable in the ED. They enrolled fifty-two patients mostly with pain in extremities (n = 15, 28.8%) and abdomen (n = 12, 23.1%). It's important to note that this was a convenience sample. As such, it is unclear if VR was, for example, also implemented during a busy ED shift. About 1 third of patients in this study presented with trauma-associated pain (n = 16, 30.8%). When compared to our study, all patients presented with

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traumatic pain, requiring a painful procedure. The duration of pain in their study was subacute (> 24 h) (n =32, 61.5%) in most patients. In our study all patients presented with acute pain (<24 hrs). These differences may 347 be other indicators as to why we found different results.

In the study of Birrenbach et al. the authors con- 349 cluded they found a significant reduction in pain (NRS 350 median pre-VR simulation 4.5 (IQR 3-7) vs. median 351 post-VR simulation 3 (IQR 2–5), p < 0.001). It is debatable whether a reduction from 4.5 to 3 (a difference 353 of 1.5) is a clinically relevant reduction in pain. In our 354 study we considered  $\geq$  2-point difference on the NRS 355 scale to be clinically significant; this was based on a 356 validation study examining the changes in acute pain mea- 357 surement scales that are most strongly associated with a 358 patient-determined indicator of clinical importance. (19) 359 Clinically significant pain reduction is an important factor 360 to consider for future studies.

Despite the lack of a statistically significant reduction 362 in pain or anxiety, patients appeared to derive enjoyment 363 and comfort from watching a movie during the procedure. 364 For instance, 1 patient specifically requested to continue 365 watching for a longer period, and another wished to wear 366 the video glasses again for a second reduction attempt, 367 even though it was not part of the study. These experiences 368 suggest that the device offered a positive overall patientexperience, which could explain why patients, nurses and 370 physicians all recommended the use of the intervention.

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Limitations 372

There were some differences between the 2 groups, including baseline pain and anxiety scores as well as dosing 374 of analgesic and anesthetic medications. Although these 375 differences were not statistically significant, we cannot 376 rule out their influence on the study outcomes. Addition- 377 ally, due to the limited sample size, it is possible that 378 procedural complexity varied between the groups. Nu- 379 ances in the technique of performing the hematoma block 380 or the reduction procedure, may have led to unmeasured 381 differences.

We encountered issues with the recruitment of sub- 383 jects. Although wrist fracture reduction is a common 384 presentation in the ED, the presentations were very low 385 in the initial research location. Our study sites are level 386 1 trauma centers and mostly receive multi-trauma pa- 387 tients. Wrist fractures are more frequently seen in level 388 2 or 3 trauma centers in the Netherlands. Further delay 389 was caused by the outbreak of the COVID-19 pandemic, 390 in this timeframe all clinical research was temporarily 391 ceased; this caused significant delay in recruitment.

Our study design aimed to replicate a real-world clin- 393 ical scenario where the audiovisual distraction is fully 394 implemented. Participants were free to choose from over 395

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100 movie titles on the HappyMed<sup>TM</sup> device. We believe that they are likely to be more engaged and distracted 398 by a movie they find appealing, compared to 1 that does not capture their interest. While this patient-centered approach enhances the experience, it may introduce vari-400 ability in the level of distraction. Blinding the physician was not possible and thus could lead to observer bias. 402 Although blinding using an 'off' headset for the control 403 group was considered, we were concerned that it might alter patient behavior and inadvertently increase their fo-405 cus on pain. To mitigate selection bias, randomization and 406 allocation were concealed through a computer program after assessment of eligibility and inclusion. 408

#### Conclusion

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This study did not find a clinically significant differ-410 ence in pain or anxiety in patients using an AVD device 411 during distal radial fracture reduction in the ED. While objective measures of pain and anxiety did not differ significantly between groups, satisfaction was equally high and willingness to use the device in future procedures in the intervention group was also high. Due to our study 416 limitations, we cannot draw any definite conclusions. Fur-417 ther investigations are warranted to explore the potential benefits and negative side-effects of AVD, especially in 419 pediatric and elderly patients, in the emergency depart-420 ment setting. We recommend future research to focus on 421 clinically relevant differences in pain. Lastly, it is impor-422 tant to consider that an innovative tool needs to be intuitive and easy to implement and maintain in the ED setting.

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#### **Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

# Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jemermed. 2025.03.015.

## CRediT authorship contribution statement

Hilmar H. Heijmans: Writing - review & editing, 438 Writing – original draft, Project administration, Inves- 439 tigation, Formal analysis, Data curation. Maybritt I. 440 **Kuypers:** Writing – review & editing, Writing – origi- 441 nal draft, Supervision, Methodology, Conceptualization. 442 Milan L. Ridderikhof: Writing - review & editing, 443 Supervision. Kaoutar Azijli: Investigation. Susan VAN 444 **Dieren:** Methodology, Formal analysis. **Marlies P. Schi-** 445 jven: Supervision, Software, Conceptualization. 446

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# **Article Summary**

# 1. Why is this topic important?

Pain management in the Emergency Department remains suboptimal. This study explores a new innovative method to reduce pain during medical procedures.

# 2. What does this study attempt to show?

This study attempts to show that audiovisual distraction with the help of video glasses for patients with a wrist fracture can be an effective and feasible non-pharmacological pain treatment.

# 3. What are the key findings?

No statistically significant differences were found in pain, anxiety and satisfaction scores between both groups. However the method seems safe and feasible.

# 4. How is patient care impacted?

We tested audiovisual distraction during wrist fracture reduction to improve patient experience. However this study has not found a difference in patient reported outcomes. Thus, patient care has not (yet) been impacted.