Virtual reality and coping with procedural pain in patients with burn trauma

SUMMARY RESEARCH REPORT

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Virtual reality and procedural pain management in patients with burn trauma (reg. no. TL03000090) is co-financed with state support from the Czech Technology Agency within the Eta Programme.

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1. Home

The use of virtual reality (VR) in healthcare has its roots in the US around 2000, when researchers created one of the first therapeutic VR applications. This application successfully reduced the perceived pain, anxiety, and general discomfort of changing bandages in two American teenagers with burn trauma. The name of this app is *SnowWorld* and it has become known worldwide for those interested in virtual reality, not just in healthcare. This app has since started to spread to other countries as well, where you have VR goggles on while changing bandages, and you can see snowmen in them and roll around with them. The cool theme was not chosen by chance, as it has beneficial effects specifically for those who have been exposed to high temperatures and developed a painful burn, for example. Other VR apps with a related theme include an ice cream factory or a flyover over a snowy canyon.

Burn trauma is caused by a sufficiently prolonged, direct or indirect exposure of the human body to above-threshold thermal energy (or perhaps a chemical). Severity is given in up to four grades. However, trauma or injury is not only about physical pain, but it is equally important to address psychological injury, which can manifest itself in increased anxiety, even leading to post-traumatic stress syndrome or depression.

There are now many studies on reducing pain and anxiety in burn trauma patients during dressing changes. Most have taken place in the U.S., and we know of only four (two in the Netherlands and two in the UK) that took place in Europe. This places our study on Czech patients in the top ten European studies, although some features of our study are unique in the world, in particular the involvement of the eye camera and the system of positioning the patient without loss of the game experience.

We named the VR app *Cold River*, because the patient finds himself on a boat on a river, calmly floating through the landscape at the turn of winter and spring. With the headset on, he hears not only the sound of the water, but also the chirping of birds. On the banks there are rocks with mysterious symbols, hot air balloons float overhead and sometimes coloured crystals appear. Thanks to the built-in eye camera, the patient interacts with his virtual surroundings using only his eyesight, and the app rewards him with points for his curiosity. This is a completely revolutionary approach when compared to existing apps. Until now, VR reality and movement in it was only controlled by manipulating the controllers, which required a lot of movement that would significantly hinder wound care. Additionally, before each use, the VR helmet was sterilized in an effort to prevent possible transmission of infection. In addition, sterilizing the controllers as well would increase the time associated using VR technology. The revolutionary feature of this technology is also the eye camera installed in the glasses, which reacts only to eye movements and thus allows the patient to interact freely with his digital environment without restrictions. It also engages his attention much more effectively, which

so he has less capacity for pain perception when changing bandages. Patients could also stop at the ports and play a mini-game (e.g., feeding animals or throwing snowballs at snowmen) at their convenience. This allowed users to view the landscape in 360° and even observe a floatation vest on their virtual body to increase their sense of safety.

Cold River, unlike the now outdated VR apps that came into use 20 years ago, incorporates a globally unique solution that uses an eye camera to interact in a digital environment and deepen distraction so that healthcare professionals can seamlessly attend to changing dressings even on the hands if the patient has burns. Another unique *Cold River* solution is positioning the patient without the patient significantly feeling it in the virtual environment. In addition, the entire interdisciplinary team of experts are responsible for a whole host of other details that the user may not even notice, yet they are the ones that cause a more effective distraction. I would like to thank the entire team involved in the creation, development and use of *Cold River* for burn trauma patients at KV Hospital.

However, the patients of the Burn Medicine Clinic of the Faculty of Medicine of the Charles University Hospital had the opportunity to try this interactive application and decided to participate in this study on the basis of their informed consent. The order of their consent was decisive. Different in order, they formed the control group, while the judges formed the experimental group, in which the patients could try the described interactive VR application *Cold River*. In fact, one of the research topics was to investigate to what extent the interactivity of the app can distract and contribute to the reduction of pain and anxiety in patients. Thus, although the control group also wore VR glasses, the patients only saw static images from the *Cold River* app in them.

Another important research topic was to assess how patients' experience of pain and anxiety during dressing changes is affected by whether or not they have VR glasses. This posed a significant challenge for the research team because the perception of pain is highly subjective. In the end, we opted for a design that also put each patient in control for themselves. Every patient in the study, odd and even, completed at least two sessions of dressing changes. However, the VR goggles were only ever worn for part of this change, either at the beginning of the session (removal of dressings) or towards the end of the session (wound cleaning and application of new dressings). At the same time, this logically separated the patients' experience with the VR goggles from the experience with part of the dressing change without VR goggles. Thus, patients rated these different experiences and it was possible to put together all patients' experiences of the dressing change part when they had VR glasses on the one hand and when they did not have them on the other hand.

The results obtained are more than promising and are in line with foreign research. Patients' experience with VR glasses showed that they experienced significantly less pain and anxiety. On the other hand, we were surprised that this reduction occurred not only in the experimental group but also in the control group. Nevertheless, it appears that interactive, highly immersive VR can immerse patients more effectively than passive viewing of static images in VR. This is because the underlying mechanism is detachment

attention. Since many patients had not yet had personal experience with VR glasses, they also showed a significant response even if they only saw static images in the VR glasses. However, with interactive highly immersive VR, the sense of presence is even more profound, so that instead of observing
changing bandages and looking at their burnt body, the patient has a very realistic feeling of being somewhere else in a cool, soothing environment. We encountered mostly positive reactions, expressing the view that they found the dressing change much more bearable, in addition to the reduction in pain and anxiety. Nevertheless, there were also isolated negative views, for example, some patients with a significantly anxious disposition did not feel comfortable not seeing the dressing change and thus not having more control over the situation.

However, our efforts are far from over with the analysis and publication of the results. The purpose of this project was not only to confirm that non-pharmacological interventions can be used effectively in the management of procedural pain, in addition to pain medication. The next important step for patients undergoing painful procedures is to try to give them relief from pain and anxiety beyond the scope of the ending project, i.e. in routine practice. This step is not as simple as it may seem at first glance and involves several levels. The first level is the technical background of the hospitals, including the necessary knowledge and skills of the health professionals who should be able to use virtual reality for this purpose. Next is the legal level, where a purely experimental method should become a standardised procedure. And finally, the last level is the agreement between the partners of this project (Charles University in Prague, University Hospital Královské Vinohrady, Palacký University in Olomouc and VRSPACE company) that the work and know-how they have put into the whole procedure can be capitalized in a unified procedure for the commercialization of *Cold River*. We are very happy that at least this last level could be successfully completed with the outstanding contribution of CUIP (Charles University Innovations Prague, a.s.), which helped us to create a framework through which the *Cold River* application can be offered to other interested parties.

1.1 Project objective

The main aim of the intended project was to reduce the experience of procedural pain (during dressing changes) in burn trauma patients through a developed and piloted virtual reality (VR) application. The first study on this topic was conducted in the USA on two paediatric patients (Hoffman et al, In addition to pharmacological pain therapies, there are a number of non-pharmacological options (e.g. listening to music, relaxation techniques, aromatherapy, watching TV) that are based on distraction from the sensation of pain. VR seems to be the most promising of these options and, in addition to distraction, it also reduces anxiety symptoms and increases patient cooperation (Scapin et al., 2018), while studies also agree on the beneficial role of immersion, i.e. the feeling of being immersed in VR (Triberti et al., 2014).

1.2 Current state of knowledge

Every year, according to the WHO, about 11 million people worldwide are seriously burned. The potential of virtual reality in treating symptoms, particularly in areas such as pain, anxiety, depression and fatigue, has gained considerable attention. Ioannou and others (Ioannou et al., 2020) summarized the findings from 14 studies and highlighted the overwhelming positive impact of VR on symptom relief. A notable exception was a study that measured anxiety levels before and after treatment of burn wounds using VR (van Twillert et al., 2007). This review also highlighted the benefits of VR in reducing pain, particularly in pediatric and adult burn patients. Only one study differed from all the others when the researchers concluded that VR did not have a statistically significant effect in reducing pain here (Kipping et al., 2012).

VR reduces pain primarily by distracting. As part of this distraction, our mental processes are massively involved in the VR experience, competing for the attention normally devoted to pain perception. Matsangidou and others (Matsangidou et al., 2017) have divided VR strategies for procedural pain treatment into two categories: basic (i.e., any activity in VR) and more advanced distraction through VR. The latter includes icy environments in particular, with studies suggesting that such snowy VR environments can provide a perception of "coldness" that can be associated with pain reduction, especially in burn victims. The Cold River application we used was developed based on the player/game/therapy model (Mader et al., 2012), which emphasizes the synergy between player, game, and therapeutic outcomes (Zielina et al., 2022).

1.3 Definition of current projects

In Europe, with a few exceptions (e.g. UK, Netherlands), the effect of VR in the treatment of burns has not yet been investigated. Almost none of the relevant studies include a control group and are not longitudinal. Moreover, there is usually no published information on the process of creating therapeutic games or even on pilot testing of published designs. Only a few studies using VR apply interactive virtual environments, and although the hypothesis that the degree of immersivity has an effect on the experience of pain when it is reduced through VR application is repeatedly found in relevant studies, this hypothesis has not yet been experimentally tested in burn trauma patients.

1.4 Description of the novelty of the project

The use of VR in pain reduction has been consistently confirmed since 2000. Although it is often hypothesized in the literature that the greatest effect occurs in those patients with

burn trauma, who are able to immerse themselves in VR the most (i.e., higher levels of immersivity are present), this hypothesis has never been satisfactorily tested experimentally. Thus, the novelty of the proposed research design lies in the experimental verification of the relationship between increasing levels of immersiveness (as measured by the IPQ = Igroup Presence Questionnaire) and decreasing pain (as measured by the NPRS = Numeric Pain Rating Scale) and anxiety (as measured by the BSPAS = Burns Specific Pain Anxiety Scale) in burn trauma patients. Other unique features of this project include the incorporation of an eye camera and a patient positioning system without loss of play experience.

1.5 Team

The project team is made up of representatives of four institutions. The project actually took place at the Královy Vinohrady University Hospital.

Robert Zajíček (FNKV) - Head of the Burns Clinic, in the project he was responsible for selecting suitable patients for the study and was also an expert guarantor of the medical perspective in pain management.

Daniel Doležal (FNKV) - a clinical psychologist with several years of experience in caring for patients with burn trauma, knows the hospital environment very well and contributed significantly to the coordination of data collection directly at the burn clinic. In addition, he was also an expert supervisor on the psychological perspective in pain management.

The technical solution for creating the VR application was provided by VR Space.

Zbyněk Pohořelský (VR space) - has successfully completed a number of projects for creating virtual reality applications in various fields, including healthcare. In this project he was responsible for the development, implementation and technical support of a VR application for pain management.

Other institutions involved were Charles University in Prague and Palacký University in Olomouc.

Alena Javůrková (UK) - clinical psychologist, head of the department of clinical psychology, expert in pain including neuropsychological perspective, has clinical and research experience. In the project she was an expert guarantor on (neuro)psychological perspective in pain management.

Jaroslava Raudenská (UK) - clinical psychologist, pain specialist, has clinical and research experience. In the project she was an expert guarantor on the psychological perspective in pain management.

Martin Zielina (Charles University) - Head of the Institute of Medical Ethics and Humanistic Foundations of Medicine, cyberpsychologist, in pre-test training in clinical psychology (i.e. clinical experience), experience in research projects involving experiments including their coordination and statistical processing of results. In the project he held the role of principal investigator.

Jan Šmahaj (UP Olomouc) - cyberpsychologist, KBT therapist, who uses virtual reality, has a lot of research experience including statistical data processing, and has access to a virtual reality lab at his workplace. In the project he was responsible for the alignment of virtual reality and its impact on the psyche of patients.

1.6 FN KV Project location

The Královské Vinohrady University Hospital (FNKV) is a highly specialized medical facility providing health care in almost the entire range of the medical spectrum for its catchment areas of Prague 3 and Prague 10, and in some fields also for patients from the whole of Prague, Eastern Bohemia and
in the case of burn patients from all over Bohemia.

The vision of the University Hospital is to continuously increase the quality of care provided and to increasingly specialize in selected fields, especially traumatology - treatment of severely injured patients, cardiology and cardiac surgery and, last but not least, care for severely burned patients. The hospital also includes a comprehensive cancer centre, which provides treatment (including the latest radiation therapy) for adult cancer patients. It seems that further specialisation within Prague's teaching hospitals and other top medical facilities is the way to ensure top-quality care for patients.

In addition to the increase in the quality of care, in the past few years the KV Hospital has been intensively devoted to improving the position and comfort of patients in the treatment process. KV FN strives to meet the individual needs of patients, to inform them sufficiently and openly about their condition and treatment options, and to provide them with dignity and necessary privacy.

1.6.1 History of the Burn Medicine Clinic of the KV Hospital

The founder of the Clinic of Burn Medicine was **prof. MUDr. František Burian (*17 September 1881, Prague, † 15 October 1965, Prague)**. He served as a surgeon in the First Balkan War and based on his experience as a war surgeon, he pushed for the establishment of a plastic surgery station at the Jedlička Institute in 1925, which became the Institute of Plastic Surgery. In 1939, he was the first country in the world to recognise plastic surgery as an independent medical discipline. Prof. Burian initiated the establishment of plastic surgery departments in Prague, Brno, Bratislava and Košice.

prof. MUDr. František Burian

(*17 September 1881, Prague, † 15 October 1965 Prague)

The Burn Centre was founded on the initiative of Professor František Burian in Legerova Street in Prague in 1953. The leading physician was MUDr. Mario Dobrkovský and it was registered as the Burns Department of the Clinic of Plastic Surgery.

After 1968 MUDr. Dobrkovský emigrated abroad and the Burns Department was headed by MUDr. Jarmila Doležalová. Together with her, MUDr. Marta Zadorožná, MUDr. Radko Vrabec and MUDr. Marie Čakrtová worked there. Later they were joined by MUDr. Radana Königová.

Jan Palach was admitted to the burn ward on 16 January 1969 at 14.45. The attending physician, MUDr. Marta Zadorožná, diagnosed him with 2nd and 3rd degree burns on 85% of his body surface. He was hospitalized there in the intensive care room, guarded by the secret police, and on 19 January 1969 at 3.30 p.m. he died from the consequences of his extensive injuries.

MUDr. Radana Königová (*31.7.1930, Prague, † 20.9.2013, Prague), who gradually specialized in the treatment of burned patients, understood the necessity of centralized care for patients with extensive burns and at the workplace in Legerova Street for them established a special ward - an intensive care unit. In 1978-1990 she worked there as the head nurse. Under her leadership, the department flourished and in 1990 became an independent clinic. She headed the clinic as a professor until 1996.

MUDr. Radana Königová

(*31 July 1930, Prague, † 20 September 2013, Prague)

The originally quiet Legerova Street became unacceptable for the treatment of burned people with the construction of the main road and another location had to be found. The new building on the premises of the Královské Vinohrady University Hospital

The clinic moved in 1983. It was granted the status of a burn center in 1991. An intensive care unit for pediatric patients was established in 1994. The Burn Centre in Prague was the first unit in the so-called Eastern Bloc to apply Integra, a biological skin substitute, and is part of an integrated rescue system designed to eradicate the consequences of mass disasters, including radiation.
The centre provides comprehensive and continuous care for patients from 0 years of age with all types of burn trauma for the entire catchment area of the Czech Republic and provides long-term, often lifelong post-traumatic dispensation.
In the Czech Republic, the activities of burn centres are regulated by the Bulletin of the Ministry of Health of the Czech Republic, No. 6 of 2008 (Trauma Care in the Czech Republic). The centralisation of care for severe patients broadens and deepens the experience of the entire interdisciplinary team of specialists coordinated by a surgeon - an expert in burn medicine and reconstructive surgery. In addition to clinical work, the centre is responsible for undergraduate and postgraduate teaching.

1.6.2 Specialist outpatient clinics

The Burn Medicine Clinic has one outpatient clinic for adults and one for paediatric patients. The outpatient clinic is designed for continuous monitoring of patients with thermal injury.
The Burn Medicine Clinic consists of:

- ICU ward for adult patients (9 beds);
- ICU ward for paediatric patients (6 beds);
- Children's ward (15 beds);
- Standard ward (21 beds)

The clinic provides care for burn patients from the whole Bohemia. Accompaniment of mothers to burned children is solved individually, based on the health and psychological condition of the child, the decision of the head of the children's ward and the paediatrician. The main criterion is to ensure an optimal situation for the sick child. Information on the health status of patients is given by the attending physician at times agreed upon.

Operating theatre of the Burns Clinic of KV Hospital

Intensive Care Unit of the Intensive Care Unit of the

Post-Gyn Clinic of the Faculty of Medicine Source:

[History of the Clinic - 3rd Faculty of Medicine (cuni.cz)]

2. Burn trauma and wound dressing

Burn trauma is one of the most painful injuries, it can cause permanent damage to the skin and, in some cases, endanger the patient's life. The treatment of burns is not only traumatic for the patient, but also for the doctors and nursing staff, providing care for suffering patients, persons at risk of death whose injured skin heals with unsightly scars, represents a considerable burden, both physical and psychological (ŠIMEK, 2006). In the Czech Republic, 40,000 people seek medical help for burns, including 8,000 children. Persons over 15 years of age account for 80% of the total, of which 97% are treated on an outpatient basis and 3% require hospitalisation. The most common source of burns is hot liquid and steam 68%, followed by 16% from skin contact with a hot object, 14% from fire and flames and 2% from electricity (Popálky.cz). Proper first aid and immediate transport to a burn unit improves the prognosis. There are three specialised centres for the care of burn patients in the Czech Republic, a list of which is published in the Bulletin of the Ministry of Health of the Czech Republic No. 3 of 8 February 2016: the Burn Medicine Clinic of the Královské Vinohrady University Hospital in Prague, the Burn and Plastic Surgery Clinic of the University Hospital Brno and the Burn Medicine and Reconstructive Surgery Clinic of the University Hospital Ostrava. All patients who have suffered electric shock or radiation should be transported to these centres, adult patients with grade I burns > 50%, grade II burns > 20% and grade III burns > 5%. In addition, mainly patients with burns in the facial and respiratory areas, polymorbid and polytraumatised burns in a stable condition. In children under 2 years of age, the cut-off is grade I and II > 5% of the range, children aged 2-8 years > 10% of the grade II range.

2.1 Burns division

Burn trauma can be divided according to the type of agent causing the burn into thermal, electrical, chemical, radiation and frostbite burns, which also require care at a specialized facility. Thermal burns are caused by: 1. Radiant heat i.e. flames, 2. direct contact with a hot object, 3. hot liquid (scalding), 4. steam and hot gases. Flames cause burns on skin contact, inhalation trauma when inhaled (Wendsche & Veselý, 2015). The severity of electrocution or electric shock is determined by the magnitude of voltage, direction of current, duration of contact with the electric current, magnitude of resistance, mechanism, direction of passage, organs affected and comorbidities. Bone tissue imposes the greatest resistance, whereas the most severe damage occurs in skeletal muscle. Electrotrauma is accompanied by a relatively high number of amputations. Frostbite occurs mainly in the acral parts of the body, the reason being prolonged exposure to local cold. The freezing point for living tissues is -3°C. The body's protective mechanism for maintaining thermostability and for preserving the function of vital organs is the reduction of blood flow in the acres. From a pathophysiological point of view, vasoconstriction occurs in the organism and the peripheral parts of the body are not adequately supplied. It goes

mainly the fingers of the lower and upper limbs, ears, tip of the nose and chin. Frostbite is manifested mainly by grey-white colouration, followed by redness, blistering and in extreme cases tissue death. Peripheral nerves, muscles and bones are affected in the frostbitten area (Měšťák et al., 2015).
A burn, also called a chemical burn, is the result of skin contact with an acid or alkali. Gradually, the skin and possibly the subcutaneous tissue are damaged, and some chemical products are absorbed and cause systemic poisoning. Both lay and professional first aid is essential for chemical products causing local lesions. Professional first aid varies according to the chemical that causes the burn. First, the pH of the burned area is measured, thorough rinsing with sterile water or saline is performed, and debridement of the burned surface is performed. Next, the alkali can be neutralized with a 3% boric acid solution, while 4.2% sodium bicarbonate is used to neutralize the acid, all in the form of compresses applied every half hour to an hour. The alkalis cause coagulative necrosis, the acids coagulative dry necrosis. Radiation damage is rare. It occurs in war conflicts, but also iatrogenically, for example, during radiotherapy (Měšťák et al., 2015).

2.2 Extent and depth of burns

The extent of the burn is one of the most important factors. Initiation of anti-shock treatment and triage of patients depend on this factor. It is expressed as a percentage of the total body surface area (TBSA). The extent of the burn in an adult is, as a guide, assessed by the area of the palm of the hand including the fingers. This represents 1% of the total body surface area. For a more precise determination, the Lund-Browder table and the so-called rule of nine are used. The body surface is divided into units, the head and neck make up 9%, the upper limb also 9%, the lower limb 18%, the anterior side of the trunk 18% and the posterior side of the trunk the same - 18%, leaving 1% for the genital area. The basic division of the depth of skin cover is into superficial and deep. Professionally, a three-level classification is used in the Czech Republic. Grade I is characterised by erythema, local swelling and intact skin cover. Capillaries are dilated in the dermis. The area stops burning after the local signs of inflammation subside. In some patients, marked pigmentation persists for days to weeks. In stage II, superficial II.a and deep II.b are distinguished. A superficial second-degree burn is characterized by the formation of bullae and preservation of capillary return. In the bulla, the fluid content consists of lymph, plasma and a smaller or larger proportion of fibrin, without the admixture of red blood cells. A larger amount of fibrin may cause a deepening of the area. Grade IIb, or a deep second-degree burn, is already completely without capillary return. The epidermis and pars papillaris are destroyed throughout. The capillary network and ascending arterioles are affected. The free nerve endings in the epithelium and overlying cortex also undergo

disability and are therefore non-functional, only deep reading is preserved. The undersurface under the bullae is pale, whitish to yellowish. The sequelae can range from flat, smooth scars to hypertrophic and painful scarring. A grade III burn is characterised by full-thickness necrosis of the skin. It may involve subcutaneous fat, muscle fascia and rarely bone.
The underside is white, brown to black. Most often, this degree occurs in electrotrauma and with prolonged exposure to fire. The only possible solution is to remove the necrosis and cover the areas with a skin graft. The permanent consequence is always an irregular scar, which is influenced by the course of healing, the depth of necrotic tissue, possible infection in the wound and a number of other factors. Some sources add a grade IV for a burn that affects fascia, muscle, and bone.

2.3 Transferring wounds

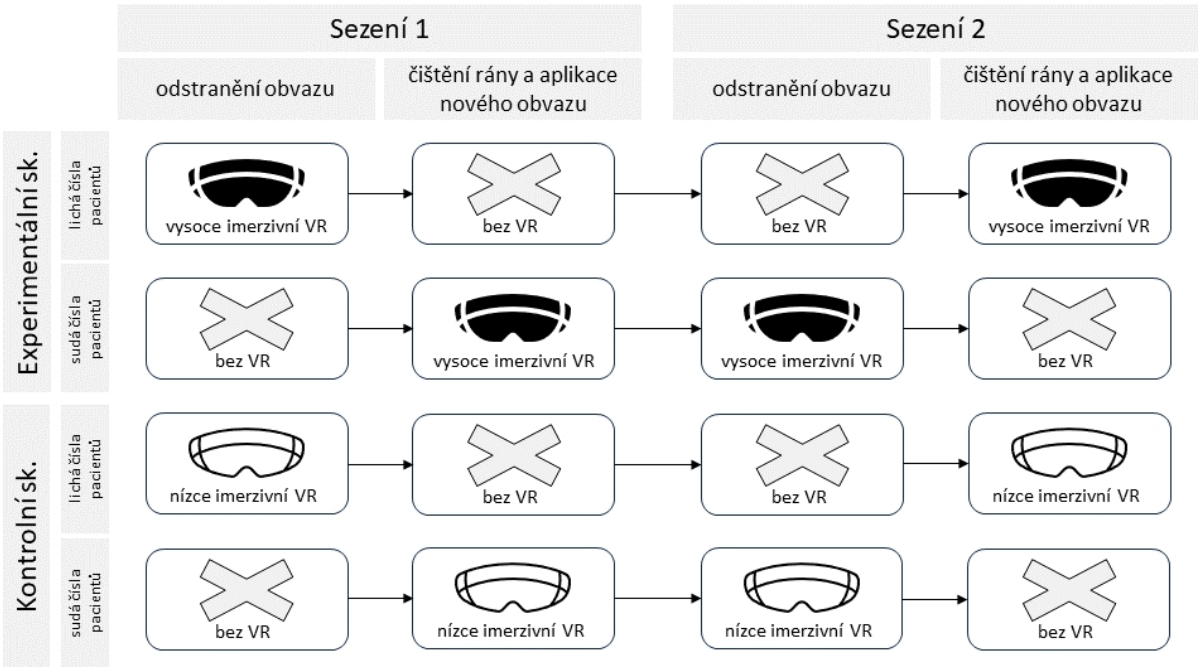
Dressing in burn trauma has one major distinction from other dressings in surgical disciplines and that is that the burned area must be approached in a strictly aseptic manner.
The staff at the treatment must be equipped with an apron, a cap and sterile gloves; under certain conditions a sterile emporium is also suitable. Indications for dressing burned areas include mainly dressing leakage and any suspicion of ongoing infection (pain, burning in the wound area, increased body temperature, odour from under the dressings, redness around the dressings). During dressing, the development of the depth of the burned areas is checked, exudates and loose necrosis are removed, and haematomas under the attached grafts are drained. It is essential to prevent both direct transmission of infection from the attending staff and from the air, and indirect transmission of infection from technical equipment and dressing material. The basic procedures during dressing are as follows: the top layer of the dressing is cut with dressing scissors, sterilely removed and discarded in an infectious waste bag; under no circumstances is it placed on the bed or on the floor. This is followed by the application of a sterile drape and removal of the inner layer of dressing (oily tulle and one layer of mule). It is essential to protect one limb from contamination from the other limb while removing the dressing from the limb.

3. Methods

3.1 Design studies

Only those patients who met the criteria were selected for the study (on the contrary, patients were not included in the study based on exclusive criteria - e.g. location of facial burns, acute psychotic illness, neurodegenerative diseases and other neurological diseases associated with the possibility of affecting cognitive function) and who also signed an informed consent form. The timing of the informed consent was used to establish the order of patient selection into the control (i.e., odd-numbered) or experimental (i.e., even-numbered) group. For both groups, an itemized list (i.e., checklist) was created that included all activities, including the responsible persons for each activity. Due to the varying severity of burns and the varying degree to which these unpleasant conditions are experienced (e.g., even minor burns to the face can be experienced much more severely than more extensive, higher grade burns to the leg), with some of the dressings taking place in the operating room, data collection did not begin until after the second dressing change in the dressing room. Ultimately, we were interested in individual differences in pain experience with and without VR not only for individual patients but also in aggregate, i.e., how the ratings of the VR and non-VR portions of the dressings differed in terms of the sensory aspect of pain (NPRS), the experience of pain distress (BSPAS), and the degree of immersiveness during VR deployment (IPQ). For patients, regardless of assignment to the control or experimental group, dressing with VR appeared the same. VR was deployed on one part and VR was deployed at a different site at the next exchange. Thus, part of the dressing was also always done without VR. The experimental group had a VR app (*Cold River*) in their VR goggles, which promoted a much more immersive feeling (e.g., realistic environment, ability to interact) than was the case for the control group (static images from the app). Thus, for each of these groups, VR was deployed either in the mode right from the beginning until after all bandages were removed (i.e., VR First) or in the mode after all bandages were removed through treatment and bandaging of all areas (i.e., VR Last). After this dressing was completed (regardless of whether it was VR First or VR Last mode), patients were instructed by healthcare professionals to complete different scales sequentially for the VR and non-VR portions. For better illustration, the overall study design is shown in the following figure (Fig. 1).

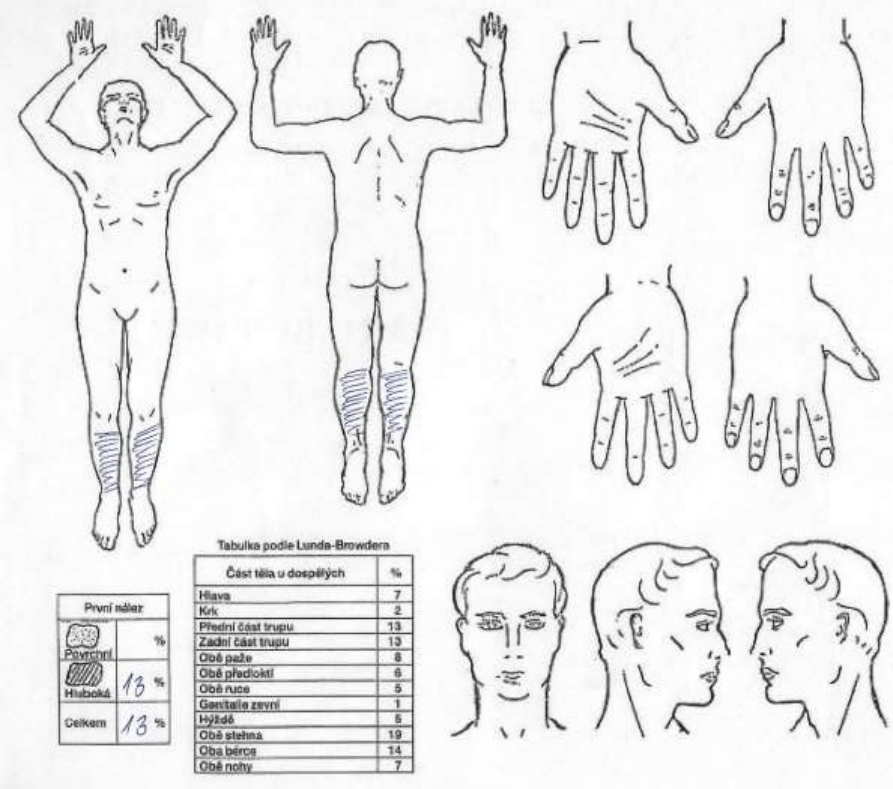
Fig. 1 - Design study



3.2 Scales used

Given the aim of the project, which was to assess whether VR goggles could be beneficial for patients suffering from procedural pain during dressing changes, we needed to use appropriate scales for the part of the dressing when patients had VR goggles as well as for the part of the dressing when they did not. In the case of pain assessment, we took into account what the healthcare professionals were already used to. Thus, for the subjective **measure of pain**, we chose an eleven-point *Numeric Pain Rating Scale* (NPRS) with a description of the extremes, where 0 was marked "Not at all" on one side and "The worst I can imagine" on the other side. In addition, the location was also recorded for each patient with an indication of the percentage degree of burn (Fig. 2).

Fig. 2 - Location and degree of burns



The BSPAS (Burn Specific Pain Anxiety Scale) is another scale that we used in parts of the dressing with and without the VR helmet. This nine-item scale is aimed at measuring the subjective **level of anxiety** in burn patients. For each item, there is always a Likert scale from 0 to 10 indicating the extremes, with 0 indicating "Not at all" on one side and "The worst I can imagine" on the other side.

In contrast to the part without VR helmet, we additionally measured the level of **nausea in** the part with VR helmet by means of a Likert scale from 0 to 10 with extremes marked on one side with "Not at all" and on the other side with "The worst I can imagine". In addition, for this section, we also measured subjective sense of presence through the *Igroup Presence Questionnaire* (IPQ), which has fourteen items that first measure general perceived *presence* and the remaining items measure three components: *spatial* presence, involvement, and realism. For each item, there is a seven-point Likert scale

with the extremes marked with respect to the wording of the item (see Annex 1 for more details).

3.3 Check-list

The study was conducted in patients who signed informed and voluntary consent. In an effort to reduce the burden on health care workers who not only went about their work (changing dressings on patients), but also collected data for this study in a standardized manner.

Before the live data collection, it was necessary to create a VR application and pilot test it including all required records. Another complication was the need to anonymise patients' personal data from researchers who were not involved in patient care. After discussions, it was finally found to be best if patients were classified according to the order of signing informed consent. Thus, it was only possible to supply the health professionals with blank item lists (i.e., checklists) with a label that could have four variations:

a) 1KA, i.e., the odd order corresponds to the control group and the letter A to the VR first condition, i.e., the VR helmet is put on when the dressings are removed (see Appendix 1).

b) 2EA, i.e., the even order corresponds to the experimental group and the letter A to the VR first condition, i.e., the VR helmet is put on when the bandages are removed.

c) 3KZ, i.e., the odd order corresponds to the control group and the letter Z to the VR last condition, i.e., the VR helmet is put on while cleaning the wound and applying new dressings.

d) 4EZ, i.e., the even order corresponds to the experimental group and the letter Z to the VR last condition, i.e., the VR helmet is put on while cleaning the wounds and applying new dressings.

The data was collected by the health workers, so not only was it necessary to create a pilot section where they were taught this, but we also held two workshops for this purpose. The final form of the checklist reflected not only piloting but also further discussion in an effort to make it as easy as possible for the health workers to collect data without keeping them busy at the expense of caring for patients who could leave the study at any time.

4. Project schedule

The main aim of the project was to reduce negative experiences (pain, anxiety, etc.) in patients with burn trauma during dressing changes in the dressing room through a suitable and piloted virtual reality application.

The schedule of this project consisted of three successive phases, i.e. **pilot validation** (1 May 2020 - 1 May 2021), **data collection** (1 June 2021 - 1 June 2023) and **publication of project results** (1 July 2023 - 31 December 2023). For a better idea, we will present the project by each of the years addressed, including the outputs achieved in them. In addition to the promised outputs, we managed to produce more than 20 beyond. Most of them were dissemination of the project results, including main events in CT or at prestigious scientific international forums, but also the project website or technology transfer.

4.1 First year (2020)

Two deliverables were planned for 2020, namely TL03000090-V3 (Workshop 1 to pilot test a virtual reality pain reduction application) and TL03000090-V8 (Software - Virtual Reality Application Pilot).

In the timetable for this project, we were in the pilot validation phase in 2020, which involved 1) creating a virtual reality application and 2) setting up a suitable organization for the sensitive implementation of this application in patients.

The development of the app involved interdisciplinary collaboration between all members of the participating organisations. In order to use this technically demanding application, two suitable devices were purchased through a public tender, for which only one supplier applied. Following a detailed review of the equipment procured under a small-scale public supply contract entitled "Computer set for pain relief through virtual reality" supplied by Quick & Quality IT s.r.o. (represented by Mr. M. Bryx) to the 2nd Faculty of Medicine of Charles University (represented by Dr. Zielina) and to the Faculty of Medicine of Charles University (represented by Ing. Samkova), two VR helmets with accessories were replaced after agreement with the supplier to meet all the specified technical specifications (i.e. Eye tracking technology for eye movement sensing, SteamVR tracking). All parties agreed to increase the price by CZK 13,000.00 without VAT (price with VAT CZK 15,730.00) for 1 piece. Also due to the
due to the lack of the required graphics cards, it was agreed that they would be delivered as soon as they were available on the market.

In order to set up an appropriate organisation of this application for patients, a procedure called Check-list was compiled, commented and verified and completed at the point of transferring patients. Prior to this, we obtained the approval of the ethics committee (Appendix 2), which also considered the informed consent on the basis of which patients will voluntarily enter into this project (patients can also withdraw from this collaboration at any time without giving reasons).

PROJECT OUTPUTS (2020):

The project had two deliverables planned for 2020, one of which (i.e. TL03000090-V3) was achieved in this year and the other (i.e. TL03000090-V8) was ongoing.

(TL03000090-V3) - Workshop 1 - pilot testing of a virtual reality pain reduction application

The workshop was held on 19 December 2020 at the KV Hospital. This workshop included an introduction of the project (Fig. 3), the participants involved and also answering key questions about the whole organization of the involvement of virtual reality in the transfer of patients (Fig. 4). The medical staff also experienced virtual reality (Fig. 5) including its inclusion in the dressing of burn trauma patients, i.e. the Check-list was presented.

Fig. 3 - Presentation the workshop

Fig.4 - Answering questions at

Fig. 5 - Medical staff trying out virtual reality

(TL03000090-V8) - Virtual Reality Application Pilot

As part of the achievement of the previous deliverable (i.e. TL03000090-V3), a pilot version of the virtual reality application was presented at the workshop. By the end of 2020, we had obtained four signed informed consents from patients to participate in the pilot testing of this app. Achieving this outcome was delayed by technical issues on the computer suite equipment. In addition to the aforementioned replacement of the VR helmet with the required eye tracking, only one graphics card was delivered in 2020, which was unstable and undergoing a challenging warranty claim.

4.2 Second year (2021)

Three deliverables have been planned for 2021, namely TL03000090-V1 (Software - Virtual Reality Pain Reduction Application), TL03000090-V4 (Workshop 2 - Validation of a Virtual Reality Pain Reduction Application) and TL03000090-V9 (Software - Control Group Application - Snowy Landscape). The completion of last year's deliverable TL03000090-V8 (Software - Virtual Reality Application Pilot) was also successful, and was followed up by deliverables from this year which were also completed.

In addition, other outputs (i.e. the project website, presentation of the project and results to Czech and international audiences, a popularization interview about the project) were also successfully implemented.

We were in the data collection phase of this project schedule in 2021.

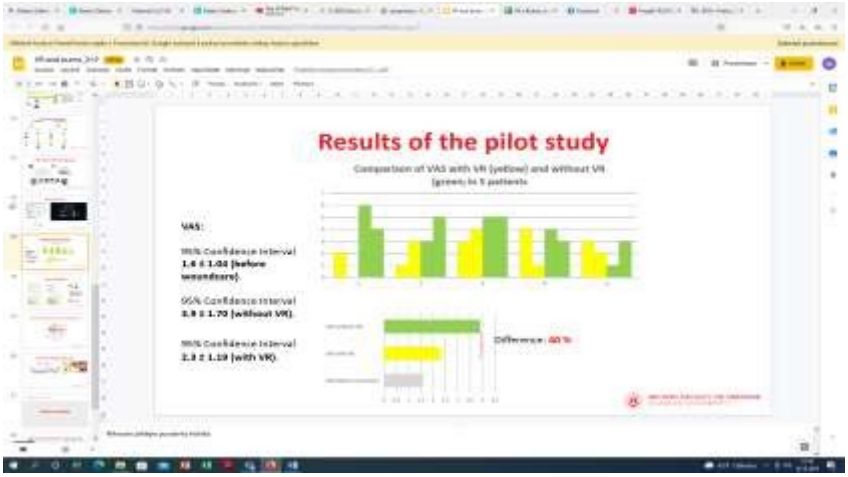
PROJECT OUTPUTS (2021):

The project had three deliverables planned for 2021, all of which have been completed (i.e. TL03000090-V1, TL03000090-V4 and TL03000090-V9) including the completion of the previous year's deliverable (i.e. TL03000090-V8).

(TL03000090-V8) - Virtual Reality Application Pilot

The pilot validation of the VR application was finally performed on five patients in two separate dressings in which they wore the VR helmet in different parts of the dressing. The results of the pilot validation confirmed that VR reduced the pain experienced by the patients by approximately 40% (see Fig. 6).

Fig. 6 - results from pilot testing on 5 patients



These results were published in a public lecture at Virtual Reality: Biological Research & Application 2021 on September 22, 2021.

At the same time, this pilot testing brought a number of comments and observations not only from patients themselves, but also from health professionals and other project participants. These comments led to an appropriate modification of the final version of the VR application (i.e. TL03000090-V1) as well as to a modification of the informed consent (Annex 3), which was accepted by the Ethics Committee of the KV Hospital (Annex 4). In relation to the above, data collection was also rationalised through appropriate modification of the collection sheets (check-lists).

(TL03000090-V1) - Pain reduction application in virtual reality

The results from the pilot phase were discussed with the project participants and the resulting VR application was enriched with a number of changes, e.g. For a greater sense of security, the rails were added to the boat, for better modulation of emotions, coloured objects were added, to increase motivation, the player's efforts in the virtual environment are rewarded more spectacularly, to reduce frustration, the difficulty of the mini-games was reduced, the possibility of stopping the game and changing the patient's position with the application centred on the player's original view, logs were programmed for statistical data processing, recording the course of playing the application.

A total of 16 patients were enrolled in the study in 2021, of which 3 patients were excluded (mainly due to problems with eye camera calibration in the VR helmet due to eye surgery or significant sensory defects).

(TL03000090-V4) - Workshop 2 - Validation of a virtual reality pain reduction application

Healthcare professionals were introduced to the final version of the VR application as well as the final procedure of data collection through the completion of checklists at a workshop held at the KV Hospital on 25 May 2021.

Fig. 7 - Presentation of the results from the pilot validation

Fig. 8 - Presentation of the results from the pilot validation

Fig 9. - Presentation of the final version of the VR application in the FN KV

(TL03000090-V9) - Control group application - snowy landscape

This output was implemented directly into the VR application (i.e. TL03000090-V1) to facilitate the administration of the VR application by healthcare professionals.

Fig. 10 - Input screen for control group selection

Selected patients are assigned to the control group after applying exclusion (e.g., epilepsy) and inclusion criteria (e.g., burned area on the body greater than 0.5%). Based on the ranking, every odd-numbered patient is kept in the control group (i.e., right arrow in Fig. 10), while every even-numbered patient is
in the experimental group (i.e., left arrow in Fig. 10).

While the experimental group has a fully interactive VR application in the VR helmet (i.e. TL03000090- V1), the control group has only "printscreens" of the winter landscape from that application in the VR helmet.

Other outputs:

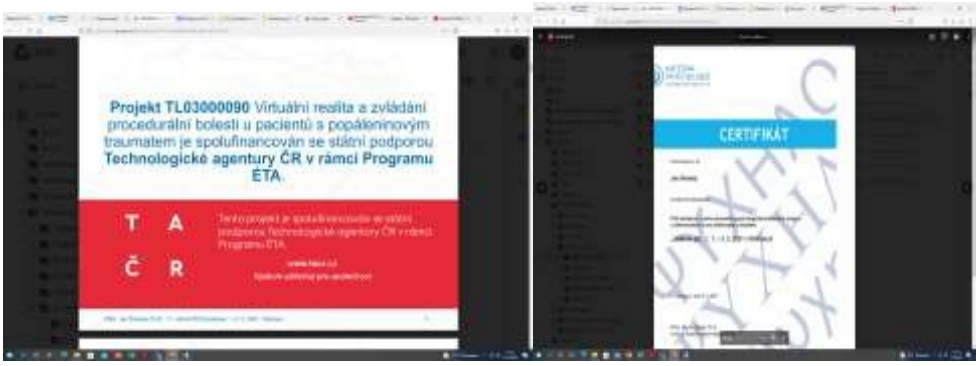
- **Web project**

In 2021, a website was launched in both CZ and EN versions informing about this project (www.vrburns.eu).

- **Presentation of the project and results**

a) The Department of Psychology of Palacký University in Olomouc organized on February 1-2, 2021 the PhD existence: a Czech-Slovak psychology conference (not only) about and for PhD students with the theme "Going further...", where Dr. Šmahaj presented this project and the developed VR application (see Fig. 11).

Fig. 11 - Presentation and certificate from the PhD existence conference



The output of this conference is a collection of abstracts with ISBN and a separate proceedings.

b) On 22 September 2021, the Institute of Physiology of the Czech Academy of Sciences hosted an event titled Virtual Reality: Biological Research & Application 2021, where Dr. Zielina presented this project and the results from the pilot validation.

Fig. 12 - Introductory slide presentation and speaker Dr. Zielina

- **Popularization interview about the project**

An interview with Dr. Zielina about this project was published in the magazine Tema on 9 April 2021. The text also mentions the funding of TA ČR.

Fig 13. - Interview about the project with Dr. Zielina

4.3 Third year (2022)

No output has been planned for 2022. Only the continuation of data collection. In total, we collected data from 42 patients in 2022, with follow-up (e.g. early discharge, problems with calibration of HTC glasses) 5 patients had to be excluded. We were able to fulfill the deliverable **TL03000090-V6** (article in JSC) planned for 2023. We also realized nine other deliverables beyond the project, mainly dissemination of project outputs and technology transfer (i.e. presentation of results at the 12th Congress of the European Pain Federation, a requested lecture at the Department of Philosophy of the Faculty of Arts of the OU, the 22nd Annual Conference of Burn Medicine, the 39th Annual Conference of the Faculty of Medicine of the OU, the 39th Annual Conference of the OU, the 39th Annual Conference of the OU. Psychological Days, requested lecture at the Summer School of Philosophy of the UHK, Biological Research & Application, TRIMEDJOB, popularization podcast on BlueGhost and transfer of technology by Contract No. 036/2022). We are also continuously updating information about this project on the project website (https://vrburns.eu/cs/uvod/). Visitor access from 11/11/2022 to 12/21/2022, when monitoring was started, reached 115 visits and 231 views.

We were in the data collection phase of this project schedule in 2022.

PROJECT OUTPUTS ACHIEVED IN 2022:

Although no outputs were planned for 2022, we managed to meet the output TL03000090-V6 (article in JSC).

(TL03000090-V6) - article in JSC - Zielina, M., Šmahaj, J., Raudenská, J., Javůrková, A. (2022). Using and creating therapeutic games in virtual reality and the player/game/therapy model. *Czechoslovak Psychology* 66(3), 332-348.

Other outputs:

APRIL 2022

- Dr. Raudenská and Dr. Javůrková presented the results of the project at the international **12th Congress of the European Pain Federation** EFIC (27-30 April 2022, Dublin, Ireland).

Fig. 14 - Poster from the 12th Congress of the European Pain Federation EFIC

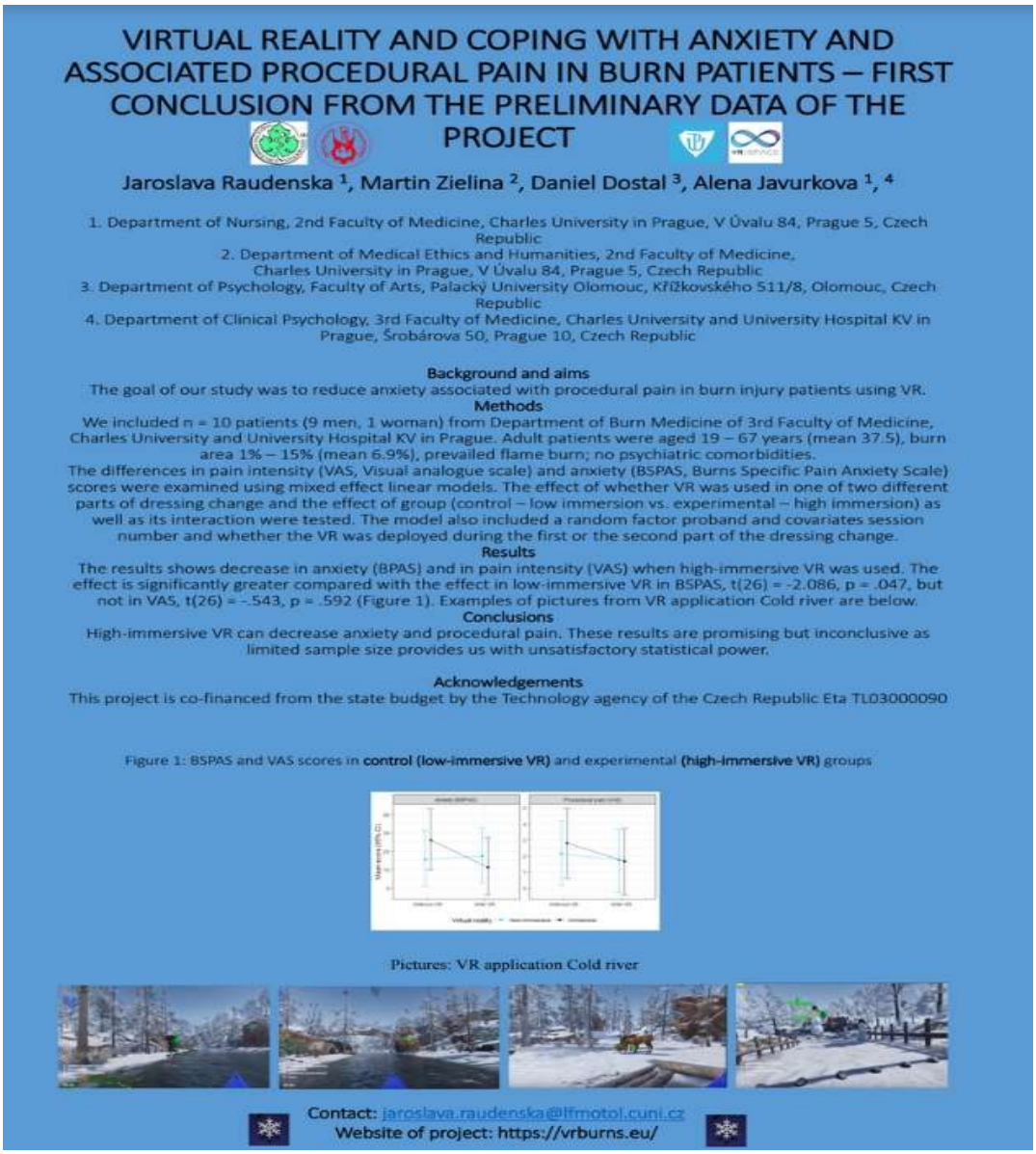


Fig. 15 - Dr. Raudenská presents at the 12th Congress of the European Pain Federation EFIC

MAY 2022

- Dr. Zielina gave a **requested lecture at the Department of Philosophy of the Faculty of Arts of the OU** on 6 May, in which he also presented the results of the project so far.
- Dr. Doležal presented the project at the **22nd Annual Conference of Burn Medicine** in Ostrava on 19 May.

Fig. 16 - Presentation of Dr. Doležal from the 22nd Annual Conference of Burn Medicine in Ostrava

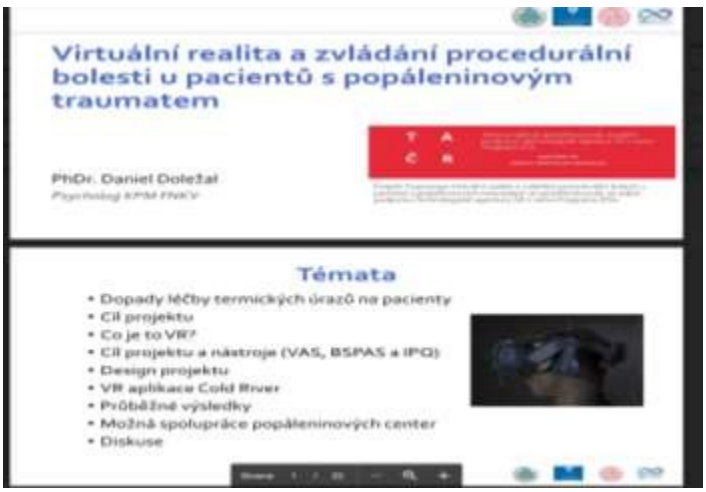


Fig. 17 - Cold River demonstration at the 22nd Annual Burn Medicine Conference in Ostrava

Fig. 18 - Cold River demonstration at the 22nd Annual Burn Medicine Conference in Ostrava

SEPTEMBER 2022

- Dr. Šmahaj presented the results of the project at the **39th Annual Meeting of the National Academy of Sciences. Psychological Days** on 14th - 16th September in Olomouc.
- Dr. Zielina gave a **requested lecture at the Summer School of Philosophy of the Jagiellonian University** on 25 September, in which he also presented the results of the project so far.

NOVEMBER 2022

- Dr. Zielina presented the results of the project with a practical demonstration of the VR application Cold River with the help of Ing. Pohořelský at the **Biological Research & Application** at the Institute of Physiology of the CAS on 10.11.

Fig. 19 - Dr. Zielina presents the results of the project at the Biological Research & Application at the Institute of Physiology of the CAS

Fig. 20 - Dr. Zielina watching a practical demonstration of Cold River at the Biological Research & Application at the Institute of Physiology of the CAS

- In November also doc. Zajíček arranged a demonstration of the VR application Cold River at the **TRIMEDJOB** fair, which took place at the 3rd Faculty of Medicine, Charles University in Prague on 22 November (more information at https://job.trimed.cz/).

Fig. 21 - Cold River presentation at TRIMEDJOB

Fig. 22 - Cold River presentation at TRIMEDJOB

DECEMBER 2022

- Dr. Zielina gave a popular interview about the project on the **Blueghost** podcast.
- Furthermore, in December, on 6 December, the **Contract No. 036/2022** was published - ensuring factual and legal negotiations on behalf of the Faculty of Physical Education of the UP for the purpose of successful application of the technology "Cold river - VR application to reduce pain and anxiety in procedural pain in the form of **technology transfer**. This contract was published by Palacký University in Olomouc with the contractual party Charles University Innovations Prague a.s. representing other legal entities involved in the creation and development of the VR application (more information here https://smlouvy.gov.cz/smlouva/22620473).

4.4 Fourth year (2023)

Two deliverables have been planned for 2023, i.e. **TL03000090-V5** (Research Summary Report) and **TL03000090-V7** (JSC Article). In addition, we also implemented 17 deliverables beyond the scope of the project consisting mainly of dissemination of project outputs including coverage in the main CT Events and prestigious international forums. We also continuously update information about this project on the project website (https://vrburns.eu/cs/uvod/). Visitor access last year was 1,220 visits, an increase of 819% on the previous year.

In the schedule of this project, we are in the phase of data collection and publication of project results. Particularly with regard to the delays in data collection, which cannot be fully planned in principle due to the fact that it is not possible to plan the numbers of hospitalised burn trauma patients who will meet the inclusion criteria and at the same time cannot be subjected to the exclusion criteria while agreeing to participate in the study. Further loss of usable data occurred during data cleaning (e.g., premature
discharged patients, technical failures or human factor failures). Despite the time margin, our data collection ended only on 09/2023. This also delayed the subsequent analysis of the results we want to publish, which would fulfill the output TL03000090-V7 (JSC - article). In view of this delay, we have requested TA CR to extend the achievement of this deliverable by 180 days. As a result, this request was acknowledged (PRZ202300692).

PROJECT OUTPUTS ACHIEVED IN 2023:

two outputs, i.e. **TL03000090-V5** (Research Summary Report) and **TL03000090-V7** (JSC - Article).

TL03000090-V5 (Research Summary Report)

This report summarizes our research from the preliminary stages in which we created a VR application (*Cold River*) and pilot tested it on selected patients who agreed to be included in the pilot phase. Subsequently, this report discusses the actual data collection and evaluation. We have posted this report on the project website and you are reading it now.

(TL03000090-V7) - article in JSC - Martin Zielina, Daniel Dostál, Jaroslava Raudenská, Jan Šmahaj, Robert Zajíček, Daniel Doležal, Alena Javůrková (2024). Comparing the Effects of High vs. Low Immersion Virtual Reality Interventions on Pain, Anxiety, and Presence during Burn Dressing Changes.

This article has been re-registered with OSF (https://osf.io/gmv79).

Other outputs:

JUNE 2023

- On June 11, 2023 a popularization article about this project was published in the Metro
- On June 17, 2023, Dr. Raudenská presented a lecture on Virtual Reality, Procedural Pain and Anxiety in Burn Trauma at the Roma Pain Days 2023 congress.

Fig. 23 - Dr. Raudenská presents at the Roma Pain Days 2023 congress

JULY 2023

After the publication of the **press release** on TA CR on 4 July, a popularization article about the project was published:

- In the daily BussinessInfo.cz on 4.7;
- In the July 4 issue of the Medical Journal;
- On 4.7. in Komora+;
- On 5.7. in HealthyNews;
- On 11.7. in MMspectrum;
- On 11.7. in Science and research;
- On 16 July, an interview with Dr. Raudenska and Dr. Javůrková about the project in Hospitalin;

SEPTEMBER 2023

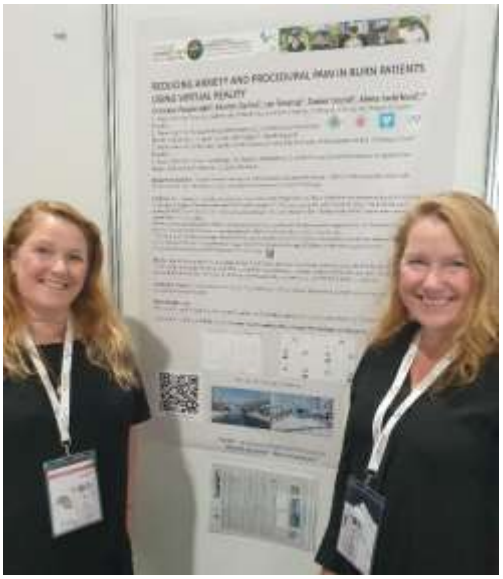
- On 27 September, a workshop was held at the KV Hospital, which was intended primarily for health professionals. Dr. Raudenská, Dr. Javůrková, Dr. Doležal, Dr. Šmahaj and Dr. Zielina presented the project and its results.

Fig. 24 - Invitation to a workshop on the project and its results at the KV Hospital (27 September 2023)

Fig. 25 - Workshop on the project and its results at the KV Hospital (27.9. 2023)

- Dr. Raudenská and Dr. Javůrková participated in the EFIC congress, which took place in Budapest from 20th to 23rd September and presented the results of our project.

Fig. 26 - Dr. Javůrková and Dr. Raudenská at the EFIC Congress



- Presentation of the project outputs at the 9th 100th European Burn Congress and 23rd Annual Conference of the Society of Burn Medicine in Košice, which took place on 21. and
  22.9. under the guarantee of doc. Zajíček.
- On 26 September, a popularization article about the project was published in CzechCrunch;

- **OCTOBER 2023**
- On 20 October, Dr. Raudenská and Dr. Javůrková presented the results of the project at the Congress of the Czech Society for the Study and Treatment of Pain CLS JEP in Ostrava.
- On 20 October, a popularization article about the project was published in the UPJournal.
- On 25.10. a report about the project was broadcasted in the main events of CT.

NOVEMBER 2023

- On 5.11. a report about the project was broadcasted in CT Věda 24.

5. Project results

5.1 PGT Model

So far, there is little mention in the literature about how to create therapeutic games in an appropriate way. One honourable exception is Mader and others (Mader et al., 2012) who present The Player/Game/Therapy Model. In this model, the authors draw attention to different aspects of creating a therapeutic game in VR. Very often, these aspects are so different that there is usually no one on the work team focused on developing a therapeutic game who can encompass them all at once. So in this case it is an interdisciplinary collaboration.

Psychologists and health professionals can contribute knowledge of the 'player', which in the therapeutic play setting is considered to be the patient suffering from the health problem that the therapeutic play should be aimed at. The 'game' itself, especially in technical terms, is much better understood by the game developers who program the application. And last but not least, the 'therapy' is understood by health professionals or psychotherapists who should have the most experience in treating the health problems that this intended application is aimed at.

Mader and others (Mader et al., 2012) also highlight the need to assess the intersections of the different aspects described to avoid undesirable effects. The aforementioned authors themselves applied this approach to the creation of an app called *The Bird Village* (*le village aux oiseaux*) with a therapeutic focus on patients suffering from Alzheimer's dementia. We also used this model to create an app to distract burn patients from the procedural pain that occurs with their regular dressings.

The player/play/therapy model attempts to overcome the problems associated with communicating important information related to the creation of therapeutic play. It overcomes this barrier of the limited knowledge of the individual members of this interdisciplinary team with guiding questions that gradually exhaust the different aspects of the model. For a better idea, we will present in an abbreviated form the questions and their answers for each aspect in the creation of an app for distraction from pain in burn patients. The answers to the questions below were obtained from the literature, from medical professionals and psychologists, or from game developers.

5.1.1 Player/Patient

1. **What is their gender?** (women and men);
2. **What is their age range?** (18-65 years);
3. **What are the inclusion criteria?** (thermal injury and its therapy, TBSA = total body surface area is 0.5 to 60%);
4. **What are the exclusive criteria?** (burns on the head, face, neck, sensorimotor disability, mental disability);
5. **What are the specific conditions of the patients?** (if necessary, administration of analgesics before and during dressing, positioning of patients on the dressing bed);
6. **Considering the age and specific conditions of the patients, what knowledge and abilities of these patients can be counted on?** (e.g. not all patients can speak Czech well, limited movement to allow smooth dressing changes).

In general, then, this aspect is focused on the detailed description of the player as a patient. In addition to general information on gender, age and personal preferences, this aspect should also target the specific characteristics of these patients (e.g., what are their daily needs, what kind of environments they are usually in) and their ability to play (e.g., how long they can stay with the game). This information is important to increase the playability and enjoyability of the game for players (Mader et al., 2016).

5.1.2 Game

1. **System input: How should the player interact with the game?** (use of eye tracking technology in virtual reality, where the player moves and interacts with elements in the environment based only on their gaze and by staying long enough on the interactive elements);
2. **System output: How should the game represent information to the player?** (Through a VR helmet with a built-in eye camera, the player is shown a relaxing landscape with a watercourse in late winter/early spring with experiential elements tailored to the players floating in a boat);

3. **Objectives: does the game provide attractive objectives?** (The player can choose a variety of options in this environment. The player is given the freedom to explore various interactive elements such as feeding animals, can explore the landscape by choosing to sail faster or stop at ports and play mini games such as snowball fights);
4. **Feedback: what means are used to communicate with the player in the game?** (Instructions to start and stop the application are placed in the virtual environment and communicated simultaneously by the attending staff, the player is rewarded for his activity in the game with points that unlock further options for this environment when advancing to the next level);
5. **Score: What should the score mean for the player in the game** (the score should encourage the player to be more active and at the same time serve to immerse him/her more in the game itself, and thus also to get away from painful dressings);
6. **Difficulty: what difficulty level is selected?** (It is impossible to be unsuccessful in this game, which could have a negative effect on the player. The difficulty is adaptive depending on the discovery of new environmental options, for which the player is rewarded with points, further unlocking more environmental options);
7. **Variability: does the game offer enough variability?** (The game's variability adapts to the player in such a way that it does not frustrate him on the one hand, and on the other hand the game keeps offering him new possibilities);
8. **Usability: what are the minimum skills and knowledge required to play the game?** (Playing this game does not place high demands on the player and depending on their performance the player can unlock additional options, although it does offer interesting content for those who choose to just sail the boat);
9. **Expected positive side effects: what can the game provide to the player that is not part of the treatment itself?** (The game offers a variety of fun elements that serve to immerse the player in the gameplay and distract from the pain associated with changing bandages, while also making this painful procedure more enjoyable for the player, which involves additional treatment);
10. **Expected negative side effects: can the game negatively affect the player?** (Cybersickness, which are manifestations of nausea occurring in the past, is sporadically reported in the literature
    mostly in conjunction with inadequate hardware performance or inappropriate application content. In addition, the player has the option to quit the game at any time and a nausea query will follow each time the game is played).

In general, this aspect focuses on game genre, platform, device and gameplay. Nevertheless, it is important that all these technical elements of the game itself are in line with other aspects (i.e. player and therapy).

5.1.3 Therapies

1. **What is the expected short-term effect of the treatment?** (pain relief at the sensory, cognitive and emotional levels);
2. **What is the expected long-term effect of the treatment?** (faster wound healing);
3. **Are there any parameters that have been scientifically validated for their effectiveness (e.g., long-lasting effects)?** (Most studies agree on the positive effect of VR in alleviating pain in dressing changes in burn patients, e.g., (Chan et al., 2018; Das et al., 2005; Hoffman et al., 2008; van Twillert et al., 2007);
4. **What immediately precedes therapy?** (measurement of pain via VAS and administration of analgesics if necessary);
5. **What is monitored during treatment?** (pain level, which can also negatively affect the patient's cooperation with the health personnel).

The focus of therapy in this model should include, in particular, treatment goals (not only short-term but also long-term), therapeutic protocol (e.g., incidence, frequency, duration), context (e.g., treatment site), and efficacy (e.g., scientific evidence that the therapy is effective).

5.2 Cold River

We capitalized on the PGT model to create a direct VR therapeutic game*, Cold River,* for burn trauma patients. Nevertheless, it should be noted that the PGT model was a useful and inspiring resource for us rather than an infallible guide. Moreover, this is not even the ambition of the PGT model, whose focus is on highlighting different aspects of therapeutic play-making, including the intersection of these.

Fig. 27 - Cold River

Considering the player aspect, burn trauma patients play this game while changing dressings on the dressing bed. In the game, the player is seated in a boat and, upon closer examination, can see his or her

a life jacket as well as boat gliders to give a feeling of greater safety for sailing. The VR helmet includes an eye camera that allows players to interact with the virtual environment without moving significantly (e.g., engaging their hands with motion controls), which could inappropriately affect the ongoing bandage exchange. Experienced clinicians select appropriate patients based on exclusionary (e.g., epilepsy) and inclusionary criteria (e.g., TBSA > 0.5%).

Fig. 28 - Cold River

With respect to the game aspect, Cold River (Figures 27 and 28) takes place in a natural landscape at the border between winter and spring around a river, where the player sits in a boat and is visually and point rewarded while viewing interesting elements in the game. At the same time, the player can choose to play mini-games in several ports (e.g. feeding the game) or continue the voyage. With respect to the therapy aspect, the basic game mechanism is a distraction including a changing virtual environment as well as adequate sound accompaniment (e.g., changing sound when passing through a spacious cave). The virtual environment is cold and predominantly coloured (Wang et al., 2018), or a snowy environment based on previous hypnotherapy practice used with patients with the possibility of inducing local anaesthesia (Wain & Amen, 1986).

5.3 Quantitative part

Our hypotheses for examining adult burn patients were as follows:

H1: Patients experience lower levels of pain and anxiety when using VR compared to the non-VR condition.

H2: Pain and anxiety reduction occurs regardless of whether high or low immersivity VR is used.

H3: VR with high immersivity is more effective in reducing pain and anxiety levels than VR with low immersivity.

Beyond the stated hypotheses, we compare subjective ratings of presence, immersion, and interactivity in groups of VR patients with high or low immersivity.

Linear mixed-effects models were used for pain (as measured by the NPRS) and anxiety (as determined by the BSPAS). Due to the repeated measures design, each patient provided 4 data points (two during each session). To account for this, a random effect of *patient was* included in the models with 67 different levels. The models also included regressors for *VR* (present or absent), *group* (high immersion-experimental vs. low immersion-control), and the interaction of these effects. In addition, there were regressors for *session phase* (either dressing removal or wound cleaning and new dressing application) and *session number* (first or second), again including an interaction.

A similar model was used to describe differences in IPQ scores between the control and experimental groups. The only change in this case was the non-inclusion of the *VR* regressor, as each session provided only one data point, due to the fact that VR was only ever used in one half of the sessions.

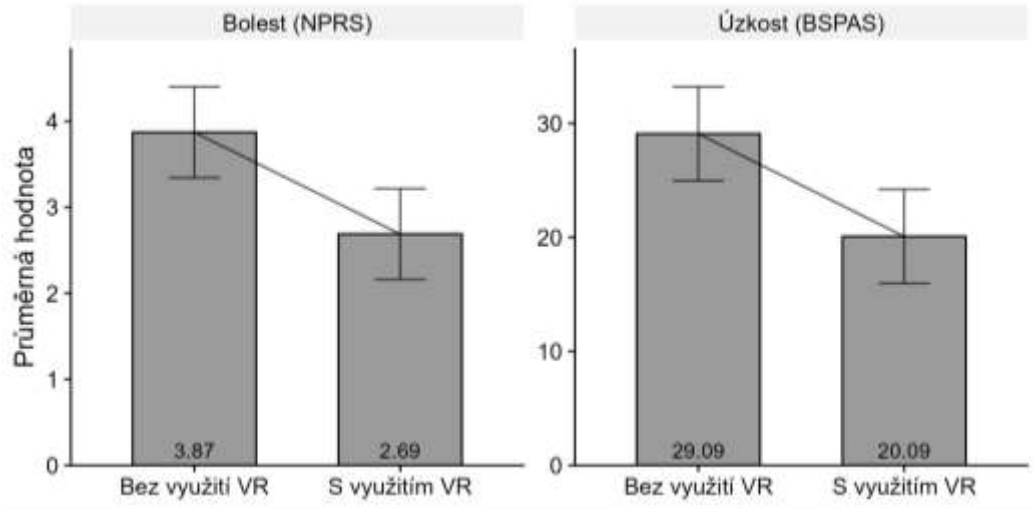
The effect size was measured using $_{\delta T}$ (Hedges, 2007). This index is defined as the difference in group means divided by the square root of the sum of the residual variance and the variance of the random factor and can be interpreted as a generalization of Cohen's d.

5.3.1 Patients experience lower levels of pain and anxiety when using VR compared to the non-VR condition

Models describing both pain (NPRS) and anxiety (BSPAS) showed normal convergence. Standardized residuals did not exceed ±3 standard deviations. The residuals showed only moderate skewness, with both NPRS (.37) and BSPA (.65) results.

The hypothesis of the effect of VR on pain and anxiety (H1) was tested without distinguishing between high immersion interactive VR and low immersion passive VR. Results indicated that the use of VR resulted in a 1.18 point decrease in NPRS scores, $t(198) = 4.88$, $p < .001$, $_{\delta T} = .46$, and a 9.00 point decrease in BSPAS scores, $t(198) = 5.15$, $p < .001$, $_{\delta T} = .45$, compared to the no VR condition (see Figure 3). The results support hypothesis H1.

Fig. 29 - Pain and anxiety levels during image exchange with and without VR



Note: Error bars represent 95% confidence intervals.

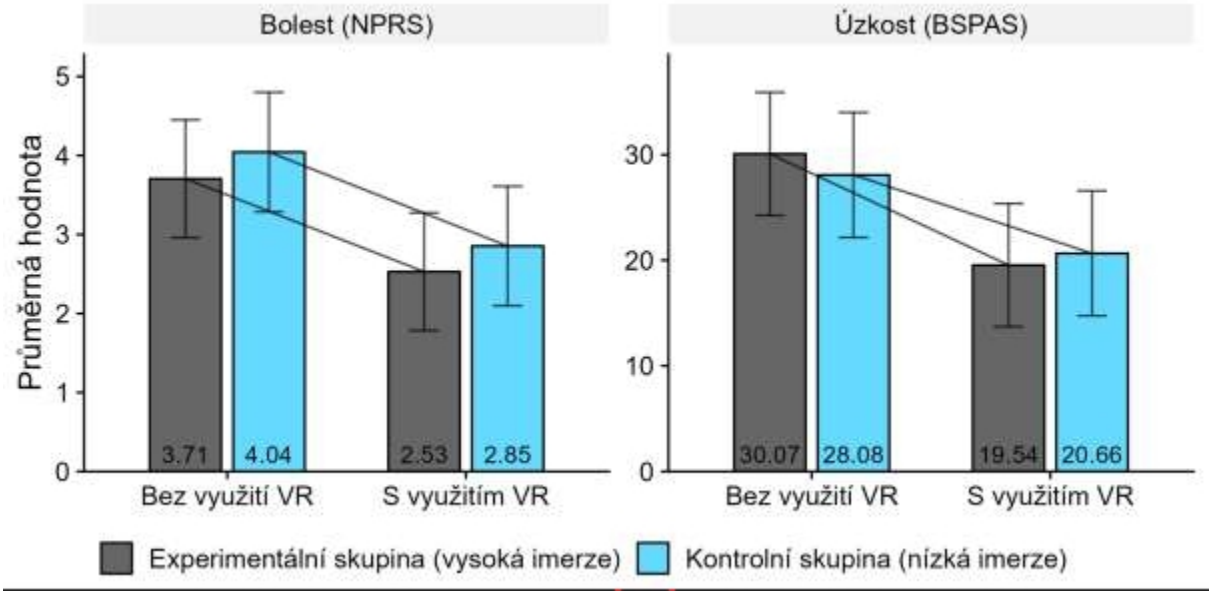
5.3.2 Pain and anxiety reduction occurs regardless of whether high or low immersion VR is used

When examining the effect of VR immersivity, we observed significant improvements in both groups of patients with high and low immersive VR, confirming hypothesis H2. In the case of pain relief, the high immersive VR variant resulted in a 1.17 point decrease in the NPRS scale, $t(197) = 3.45$, $p < .001$, $_{\delta T} = .45$. Conversely, the low-immersivity environment caused a 1.18 point decrease, $t(197) = 3.43$, $p < .001$, $_{\delta T} = .46$. In the area of anxiety reduction, the high-immersion group showed a significant decrease of 10.52 points on the BSPAS scale, $t(197) = 4.29$, $p < .001$, $_{\delta T} = .53$. The high immersivity group showed a significant decrease of 0.5 points. For the low immersivity group, there was a decrease of 7.42 points, $t(197) = 2.98$, $p = .003$, $_{\delta T} = 0.37$.

5.3.3 VR with high immersivity is more effective in reducing pain and anxiety levels than VR with low immersivity

Interestingly, comparison of the effects between the high and low immersion VR groups showed only negligible differences. The difference was not significant for NPRS, $t(197) = 0.03$, $p = .979$, nor for BSPAS, $t(197) = 0.89$, $p = .375$ (see Figure 30 for details). These results are inconsistent with hypothesis H3.

Fig. 30 - Comparison of pain and anxiety during dressing changes with VR with high and low attendance rates

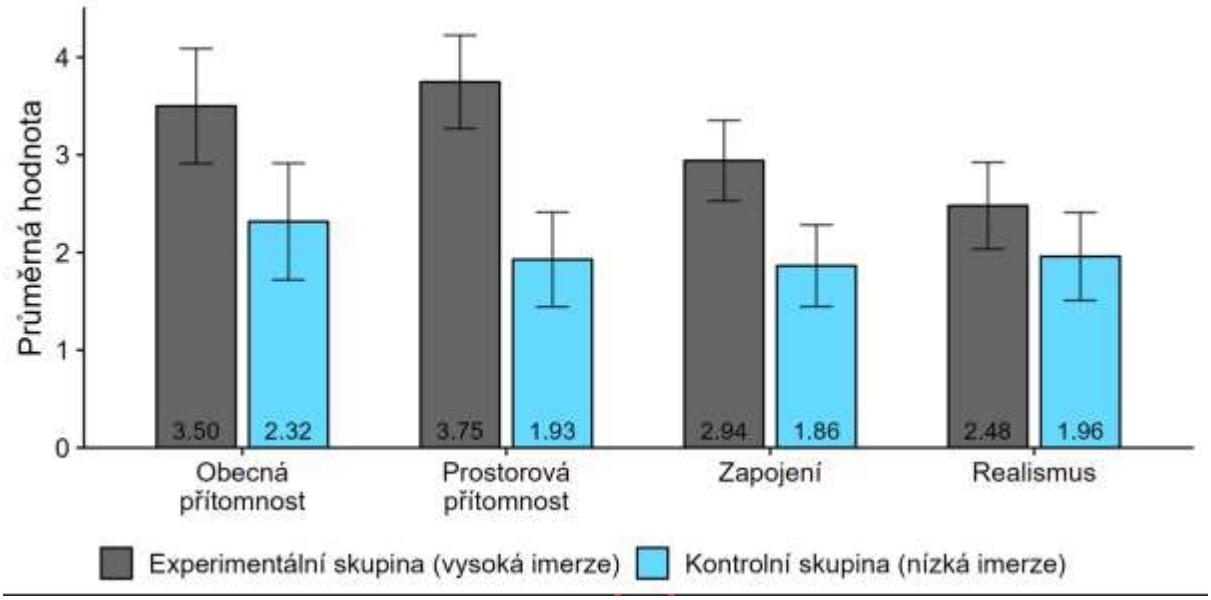


Note: Error bars represent 95% confidence intervals.

Estimated marginal averages are given. Results are averaged by session number and session part. Error bars show 95% confidence intervals.

While no difference was evident in the effectiveness of high- and low-immersion VR in relieving pain and anxiety, clear differences emerged in terms of the sense of presence felt by patients. Across all four indicators of presence, those exposed to high-immersion VR consistently reported better experiences. The most significant improvement was in the area of spatial presence, where a $_{\delta T}$ of 1.22, $t(64) = 5.34$, $p < .001$ was observed. There was also improvement in the area of spatial presence. This was followed by the engagement domain with $_{\delta T}$ = 0.83, $t(64) = 3.66$, $p < .001$, and the general presence domain showing $_{\delta T}$ = 0.58, $t(64) = 2.82$, $p = .006$. However, the difference in the realism domain, although present, was not statistically significant, registering $_{\delta T}$ = .36, $t(64) = 1.64$, $p = .105$ (see Figure 31 for details).

Fig. 31 - Differences in perception of presence: groups with high and low VR immersiveness



5.4 Qualitative part

The key actors who were present at most of the dressing exchanges and thus had the largest share of the data collection were interviewed consecutively. In the last section, we present an overview of the predominant responses of patients who took the opportunity to comment on their VR helmet experience.

5.4.1 Attending physician

The doctor said that some patients were uncomfortable with the winter landscape because they were cold due to the lack of epidermis. In this context, she suggested that it would be more appropriate to sensationally increase the temperature and rather emphasize the spring season. She also stated that some patients were upset when they were assigned to a control group that did not allow them to experience a fully interactive virtual environment. The doctor reported that the most annoying thing for health professionals was the sometimes lengthy calibration of the VR goggles. In fact, this calibration also eliminated patients with burns on their hands because they were unable to assist with this calibration (fine motor skills are required to turn the knob). Men were more likely to like it. On the other hand, there are fewer women burned in general.

Some patients experienced nausea, which may have been triggered by the water or the boat on which the patients were floating in the virtual environment. The boat may have been rocking, which the doctor said could also lead to feelings of nausea. Another obstacle was the nurse's broken ankle. No data was collected during her recovery. It also depended on how many patients there were at the time, some of whom were also sometimes foreigners who were not appropriate respondents for this study. They also excluded patients,

who wore distance glasses, had upper-limb disabilities, or suffered from epilepsy. Of the patients contacted, only two refused. However, most wanted to try it because they were bored on the ward. At one time, patients could have various work activities, which they also asked for themselves.

In the beginning, VR made it difficult for them to transfer, but gradually it got better (when they did it every day). The doctor also appreciates that they did not have to talk to the patients so much, because sometimes health workers do not have the mood, time and energy to talk to patients. VR was also a good tool for this. Patients also tolerated these transfers with VR better and some even looked forward to the next transfer with VR. On the other hand, the doctor did not think that VR had an effect on healing, but the patients had more fun with VR. The doctor concludes by saying that VR had an effect on the progress of the dressing but not on the healing of the areas themselves. She also welcomes the splitting of the study design into two parts, where patients could see their dressed wounds. The doctor even believes that if patients could not see their wounds in this way, they would not have flocked to this study so readily. The most painful part is taking off the dressings and cleaning the areas. Overall, the doctor is positive about the involvement of VR: "It's useful, it comes in handy. Especially for the children. The patients liked the snowmen the most."

5.4.2 Nursing nurse

The charge nurse notes that she switched to the outpatient clinic in June 2023, but always ran to the dressing room when someone needed to be dressed for a study. She further states that it was not always possible to follow everything from A to Z with regard to dressings as she had to respond to the current conditions. However, it was an interesting and new experience for the attending nurse with regard to burns. But she immediately stated that especially in the beginning it was difficult to get familiar with the documentation, to fill it out correctly, and to generally watch for the correct procedure and not to mess it up. According to the attending nurse, it is something else to show it and then follow it exactly in a time crunch. She admits that it was stressful in the beginning, but over time they got used to it.

Another stressful aspect was learning how to use the VR app. It wasn't too complicated, but being aware with the transfers that you have to turn VR on first, then calibrate, and then turn the timers on and off. Calibration was sometimes purgatory and sometimes they had to give up (the attending nurse set a maximum of 30 minutes for calibration because then the patients started sweating, they were nervous about being at fault; it was stressful for the attending nurse because she was exhausted from both calibration and reassuring the patient, and even when it was successful, she and the patient were already exhausted).

Although the work on the ward was separate (one of the nurses was in charge of the practical part, another was in charge of documentation and the doctor was in charge of patient selection), their coordination was sometimes very difficult. Especially when more patients were being bought in.

The nurse assesses patients as cooperating seamlessly. Although they were receiving analgesics, the

dressings were painful and challenging for the patients. It was the VR, according to the nurse, that made the patients mentally

entertained them and made them feel less pain. The attending nurse after her experience would recommend VR for large and extensive dressings. Also for her as a medical staff, VR had the advantage of not having to talk so much and focus more on the dressing itself. According to the attending nurse, it was a psychological and verbal relief. The attending nurse reports that she had more time to focus on herself as well. The attending nurse recalls five patients who strictly said no to VR during the project with the justification that they did not see any point in it or that it made them feel sick. There was an awkward situation at times when there were patients in the room, some of whom were in the experimental group and others in the control group. Sometimes it was hilarious. However, in the event of patient protests, the nurse handled the situation and told the patients truthfully that they had received what they had been assigned in their charts. Patients also varied in that some wanted to relive the VR experience even though they had completed all of the dressings in the study, while others were happy for the VR experience to end after the second dressing.

The nurse felt that VR was not appropriate for the elderly, for people in anxious states who had an increased need to control the situation, including the dressing procedure. When asked if VR should be for only part of the dressing or all of it, the nurse thought it should be patient by patient. Indeed, there were those who wanted to see the dressing, but there were also those who could do without such a view. According to the attending nurse, dressings also vary in terms of painfulness and it is impossible to predict in advance how a patient will react to his or her burned areas during a dressing. This could often be recognised non-verbally. Even when they were wearing VR. It might only be for a second, but then they were back to playing. Or maybe they even said, "Already. Only when it was necessary for the patient to lie on his stomach, it was not possible to use VR. So they always tried to put the patient in a semi-sitting position.

The biggest problems occurred at the beginning, when they were learning to navigate the study design in all aspects, to allocate time correctly, to learn how to handle patients. This is where it became very important to get everything organized. The attending nurse also highlights the great support in the workplace and always had everything she needed at the time. Nevertheless, there were many more patients with no VR than with VR. There were in fact a number of exclusive criteria, such as various psychiatric diagnoses, eye defects, fingers tied in such a way that the patient was unable to perform fine motor calibration, epilepsy or a language barrier.

The attending nurse does not remember experiencing any overtly negative reaction. According to the attending nurse, one could say that there was a part of her that took it positively, but also a part that took it negatively. A certain group of patients were disappointed that they only had static pictures. On the other hand, the young patients who had the experimental application took it as fun. However, there were also neutral patients as well as those who did not want to comment.

5.4.3 Patients

After each dressing change, patients completed a series of questionnaires and also had the opportunity to comment on the study. As each patient enrolled in the study underwent this dressing change twice, this opportunity was

Repeated. Not every patient took advantage of this option. Nevertheless, the majority of patients expressed themselves, and overall their reactions were positive. There were also a number of neutral ones and some comments were rather negative.

In the case of positive reactions, patients particularly praised the distraction of VR (e.g., "The feeling was beautiful for me because I saw a beautiful winter landscape and I didn't think about the dressing at all" or "When I was wearing the helmet, I didn't even notice that they were doing something to me"). The distraction made the dressing more bearable for many and relieved them of their fears (e.g. "Virtual reality made me completely forget about the real world and I didn't have to focus on my injury, I didn't have to look at the injury and I was much less worried" or "I enjoyed virtual reality it was a diversion and a great way to relax - fun").

There were also a number of neutral responses in which patients stated that they were not very interested in VR ("Unfortunately, I was not very interested in VR. I was already in a milder stage of healing"). In addition to the healing process, whether they were in the experimental group, where they could experience a highly immersive virtual environment, or in the control group, where they only saw static images that did not meet the expectations of some patients' VR pages (e.g. "They kept repeating images. I could look at the images in the surgery and it would come out the same" or "Virtuality must have a plot, a swing, a power. It must not be just rotating images - without sound"). Some expectations could not be met by the existing VR app (e.g. "I would have liked more images or programs i with other seasons. Accompanied by relaxing music").

Finally, the negative reactions were mostly related to the physical characteristics of VR (e.g. "The helmet is heavy and hard to put on" or "The virtual reality goggles fogged up"). Another group consisted of highly anxious patients who themselves admit that they need to be in control of the dressing change, which is what VR distracts them from (e.g., "When I was wearing the goggles, I was more scared and unsure of what was going to happen to me. When they took them off I was calmer when I saw the cleaning" or "It was fine at the beginning but during the treatment the VR made me upset, I couldn't communicate well and prepare for the pain and how much more there was. I am a person who finds it hard to relax and I like to keep things under control. I think it's great for kids and other personality types"). There was also the occasional complaint of nausea ("I became very nauseous during VR, sweating and spinning my 'world' slightly. After taking off the VR goggles I felt fine and everything was going fine. I didn't experience much pain during the VR. If I didn't feel sick, it is a good means of relaxing the patient") or for loss of contact with caregivers (e.g. "Maybe (for me) there was a lack of contact with the caregiver (headphones drown out communication)").

6. Conclusion

In retrospect, it seems incredible that a project that faced complications from the very beginning could be implemented. It would not have been possible if the vast majority of the people involved in this project had not turned out to be visionaries. The project itself was preceded by a VR demonstration at the burn clinic, which was attended by many health professionals from the ranks of doctors, nurses and psychologists. If they did not agree with the benefits of the project for their patients, then it would not have been possible to seek funding at all.

The project preparation itself was accompanied by bureaucratic delays and partial distrust in the efforts to introduce VR into the hospital environment. At the beginning of the implementation, we were faced with a shortage of graphics cards, which at the time were being used en masse for cryptocurrency mining. Moreover, after delays, the implementation of the purchase of this scarce commodity was to be delivered before the Christmas holidays. Little did we know at the time that we were facing a COVID-19 pandemic that would mean company-wide restrictions that would significantly affect our data collection.

However, we also had many bright moments in the project. For me personally, the defining moment that the *Cold River* VR app being developed would work was when the lead clinician assigned to the project tried the app for the first time. This doctor was silent for a long time and I tried to overcome this silence by explaining and maybe even convincing her of the usefulness of this application. The doctor did not respond for a long time, but then in a firm voice she uttered, "Don't disturb, I'm watching the deer."

If there was one thing that really pleasantly surprised me, it was the deployment of the paramedics in the project. I was very concerned at the beginning of the project about the standardisation of data collection, which you can get a better idea of by looking at Annex 1 (check-list) below. Add to this the not entirely user-friendly calibration of the VR helmet, and the not always appropriately cooperative patients who were experiencing pain and distress. It would be untrue if I claimed that there were no errors or technical problems. What is remarkable, however, is that with consideration of all the influences that went into this uneasy data collection, those errors were minimal and all were properly and promptly reported, so there were no further complications.

For me, the most important impact of the whole project is the willingness of healthcare professionals to use VR in their future work. In addition, without standardised data collection, I expect that the benefits for patients (reduced perceived pain and anxiety) as well as for healthcare professionals (being able to give full attention to the dressing, not being forced to interact with the patient and knowing that the patient is provided with the best possible comfort for dressing changes) could be further enhanced. At the same time, the results of this project also served to confirm the possibility of non-pharmacological pain reduction in the Czech Republic, although it still appears that a combination of pharmacological and non-pharmacological pain reduction is the most appropriate.

We have contributed to the global discussion by mapping the relationship between immersivity and pain reduction with our results from the project. This is because the underlying mechanism is distraction through immersion (immersion) in a virtual environment. The quality of processing of this environment as well as the degree of interactivity has a significant impact on immersivity. However, it appears that VR is still a novelty that most patients had not experienced firsthand before enrolling in this study. This may also explain our results that there was a reduction in pain and anxiety even in patients in the control group that did not have fully interactive and immersive virtual reality. However, when comparing these groups in terms of perceived immersiveness or presence (i.e., the feeling of being present or acting in a place, even
if the site is physically located elsewhere), the differences are clearly visible.

This situation can be compared to nations that have not yet experienced, for example, television. This lack of experience often leads them to be so overwhelmed by the technology that they do not distinguish the content to the same extent as a member of a nation that grew up with a television set. Thus, even in the case of VR, one cannot be lulled by the simultaneous positive effect that can be conveyed, especially to people with no experience of VR, more by the technology itself than by the content.

This opens up further avenues of research, both in the use of VR applications for other types of pain and in other medical specialties or to investigate in more detail the mechanism of analgesic effects and the content of VR applications. At this point, I would like to sincerely thank the large number of people who have contributed to this project. Whether it was the collaborators in the project, the patients and many others, without whom this project would not have been possible to carry out in the breadth presented.

Prague, 31.12. 2023

Martin Zielina

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Attachments

Annex 1 - Check-list

Annex 2 - Consent of the Ethics Committee of the Faculty of Medicine (EK-VP/71/0/2020)

Annex 3 - Informed consent

Annex 4 - Extended consent of the Ethics Committee of the Faculty of Medicine (EK-VP/71/1/2020)

ANNEX 1
(check-list)

K

Session number: _____

_____ **Patient Code:** _____

_____ **Date:** _____

Version:

VR FIRST

(VR FIRST)

staff present

Doctor: _____

Nurse: _____

ATTENTION

1. Thick arrow (➡) and **bold text** indicate the space to be filled in.

2. The assignment is divided into **three parts**: *part I.* removal of bandages, *part II.* treatment and bandaging, *part III.* submission of tests
the patient.

3. The patient completes all the tests marked in the white box. E.g. *VAS - NMR* d

4. The patient completes the VAS - NMR before coming to the transfer room, the other tests (from page 3 onwards) are completed after the transfers.

I) *Before we get to the transfer room.*

- Submit VAS - NMR.

VAS - NMR

On this line, indicate how intense the pain related to the burn is at this time.

Not at all. *The worst, as you can imagine*

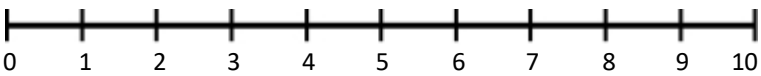
➡ - **If medication has been administered according to VAS - NMR:**
  - ◊ **write down the current time:** _____:_____
  - ◊ **medicine:** _____**dose:** ml_____g_____
- Wait 30 minutes.
- Transfer the patient to the dressing room.

PART I. - REMOVAL OF DRESSINGS

II) *After transport to the transfer room.*

VAS - NMR - Only in case of analgesic administration

On this line, mark how intense the pain is related to the burn.



Not at all. *The worst, as you can imagine*

➡ - **Write down the current time:** _____:_____

- Place the patient on the bed (lift the bed at least a little in the head).
- Turn on/wake up the computer.
- Wipe the lenses of the VR glasses with a tissue (to remove smudges on the lens).
- Disinfect the VR glasses (wipe the plastic parts - i.e. the headset, the plastic around the nose and the whole glasses - with a damp cloth).
- Put a sanitary pad in the VR goggles.
- Press the blue button on the VR control box (connects the VR glasses and the computer).
- Check the lights on the VR goggles (on the side) and the beacons (must be green).
- Put on VR goggles:
  - ◊ Enable the wheel at the back.
  - ◊ First put on the face.
  - ◊ Pull the harness over your head
  - ◊ Tighten with the wheel at the back.
  - ◊ Cover and adjust the headphones.
- **CALIBRATION of VR glasses (follow the pictures on the PC).**
- Launch the VR app - click on the "U" icon and then click "enable".
- Select **"Control group"**, press the right arrow.
- **Inform the patient about virtual reality (e**.g. *you will see pictures in virtual reality*).
- Press the "T" key (to start the timer).
- **Write down the current time:** _____:_____
- 1. Procedure:
  - ◊ Removing the bandages.
- (If the patient needs to change position - alert the patient to recalibrate - press the "R" key - **recalibrate**. After settling into the new position - press the "R" key again).
- Notify the patient that VR is ending.
- Press the "T" key (stop timer).
- Press the "K" key (end of application).
- Confirm VR termination ("Are you sure you want to terminate VR?") - press the arrow again - confirm "Yes/No".
- Take off the VR goggles:
  - ◊ Enable the wheel at the back.
  - ◊ Unplug the headset.
  - ◊ Take off the VR goggles.
  - ◊ Place loosely on the table.

PART II - TREATMENT AND DRESSING

- 2. Procedure:
  - ◊ Treat the surfaces.
  - ◊ Bandage the areas.
- **Write down the current time:** _____:_____
- **Tell the patient:** *At this point, you will record information related to what you felt when you were wearing the virtual reality helmet and then focus on what you felt when you were NOT wearing the virtual reality helmet.*
- Provide the patient with the tests from page 3-8 to complete.
- Complete page 9.

PART III - SUBMISSION OF TESTS TO THE PATIENT

TO BE COMPLETED BY THE PATIENT: TESTS 1

I N S T R U C T I O N : ***In this section, record information related to what you felt while wearing the virtual reality helmet (Nausea, VAS - NMR, BSPAS and IPQ).***

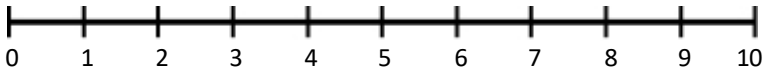
Nausea

Determine the extent to which the virtual reality helmet made you feel uncomfortably nauseous or dizzy (lightheaded).

Not at all. *The worst, as you can imagine*

VAS - NMR

On this line, indicate how intense the pain related to the burn was when you **were** wearing a helmet with a virtual reality.

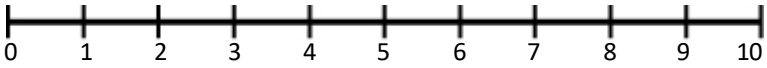


Not at all the worst *that the doc Introducing*

BSPAS

I N S T R U C T I O N : ***Record what you felt when you were wearing the virtual reality helmet.***

1. If I saw my burns, I would feel I wouldn't be so sure he'll heal.



Not at all. *Worst representative of the way*

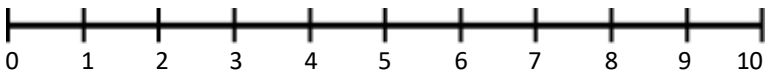
2. I thought about the pain pretty much all the time.

Not at all. *Worst representative of the way*

3. It was difficult for me to relax during the treatment (wound cleaning, dressings).

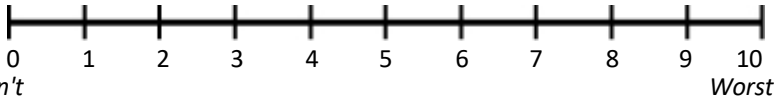
Not at all. *Worst representative of the way*

4. The pain made me feel nervous and anxious.



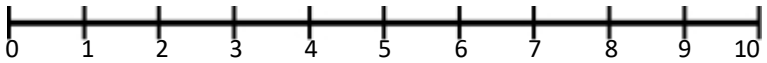
Not at all. *Worst representative of the way*

5. The pain was often so severe that I had to interrupt everything I was doing did - *(what did you feel when you* ***was*** *wearing a virtual reality helmet).*



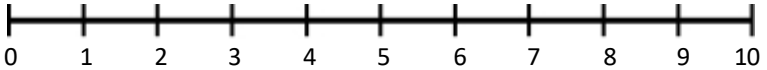
didn't *Worst Representative of manner*

6. When the treatment started (e.g. wound cleaning, dressings), I felt my muscles tighten.



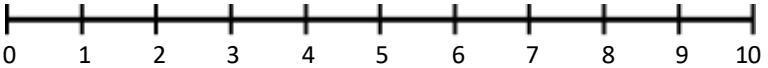
Not at all. *Worst representative of the way*

7. I was afraid of pain during and immediately after the treatment (e.g. wound cleaning, dressing).



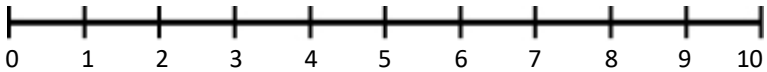
Not at all. *Worst representative of the way*

8. Every time I had to undergo a (medical) procedure, I was worried that it would hurt.



Not at all. *Worst representative of the way*

9. The pain was so intense that I was afraid I would lose control.



Not at all. *Worst representative of the way*

IPQ

INSTRUCTION: ***Record what you felt when you were wearing the virtual reality helmet. There is no right or wrong answer, we are only interested in your opinion.***

1. I felt like I was really in a computer-generated world.

Not at all. *Very*

2. In a way, I felt like I was surrounded by the virtual world.

At all *Completely*

I disagree *Agreed*

3. I felt like I was just looking at pictures.

Totally

disagreeTota

lly agree

4. I didn't f e e l like I was really in virtual space.

0 1 2 3 4 5 6

I didn't feel like I was really in it

I really had a feeling in it.

5. The feeling that I was really acting in a virtual world was stronger than the feeling that something was just
I control from the outside.

general

0 1 2 3 4 5 6

In

Comp letely

I disagree

Agreed

6. I really f e l t that I w a s in a virtual space.

0 1 2 3 4 5 6

At all

Compl etely

I disagree

Agreed

7. How were you aware of the real world while you were in the virtual world? (e.g. sounds, room temperature,

other
persons)?

0 1 2 3 4 5 6

Extremely

Mediu m

At all

aware(a)

aware(a)

not aware

8. I wasn't aware of the real surroundings.

0 1 2 3 4 5 6

At all

Compl

etely

I disagree

Agreed

9. I still paid attention to my real surroundings.

0 1 2 3 4 5 6

At all

Compl etely

I disagree

Agreed

10. The virtual world completely captivated me.

0 1 2 3 4 5 6

At all

Comp

letely

I disagree *Agreed*

11. How real did the virtual world feel to you?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Absolutely all *Not at*

realnot

real

12. How much was your experience of the virtual environment comparable with the experience of from the real world?

0 1 2 3 4 5 6

They weren't Comparable

Mediu m Comparable

Very Compare

13. How real did the virtual world feel to you?

0 1 2 3 4 5 6

About as real as able if he was a real world

Indistinguish fictional

14. The virtual world felt more realistic to me than the real world.

0 1 2 3 4 5 6

At all I disagree

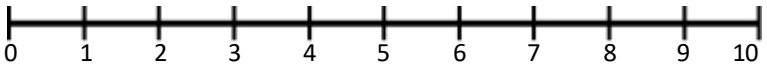
Comp letely Agreed

PART III - SUBMISSION OF TESTS TO THE PATIENT
TO BE COMPLETED BY THE PATIENT:
TESTS 2

I N S T R U C T I O N : ***We will now proceed with a second set of tests focusing on what you felt when you were NOT wearing a virtual reality helmet (VAS - NMR, BSPAS).***

VAS - NMR

On this line, indicate how intense the pain related to the burn was when y o u w e r e **NOT** wearing virtual goggles.

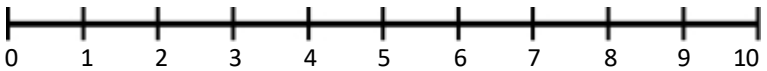


Not at all. *The worst, as you can imagine*

BSPAS

I N S T R U C T I O N : ***Record what you felt when you were NOT wearing a virtual reality helmet.***

1. If I saw my burns, I would feel I wouldn't be so sure he'll heal.



Not at all. *Worst representative of the way*

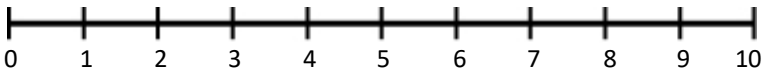
2. I thought about the pain pretty much all the time.

Not at all. *Worst representative of the way*

3. It was difficult for me to relax during the treatment (wound cleaning, dressings).

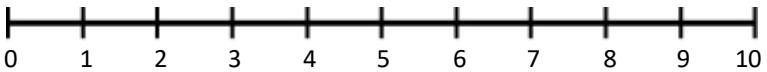
Not at all. *Worst representative of the way*

4. The pain made me feel nervous and anxious.



Not at all. *Worst representative of the way*

5. The pain was often so severe that I had to stop whatever I was doing - *(what you felt when you* ***I WASN'T*** *wearing a helmet with a virtual reality).*



Not at all *Worst*

Representat

ive of

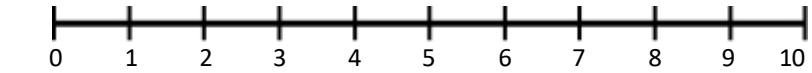
manne

6. When the treatment started (e.g. wound cleaning, dressings), I felt my muscles tighten.

Not at all. *Worst*

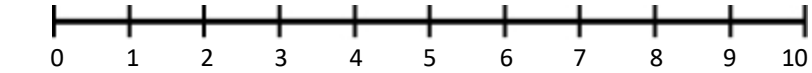
representative of the way

7. I was afraid of pain during and immediately after the treatment (e.g. wound cleaning, dressing).



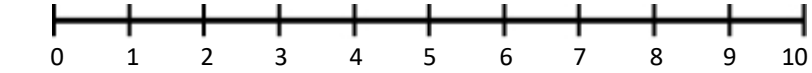
Not at all. *Worst representative of the way*

8. Every time I had to undergo a (medical) procedure, I was worried that it would hurt.



Not at all. *Worst representative of the way*

9. The pain was so intense that I was afraid I would lose control.



Not at all. *Worst representative of the way*

Thank you for completing

END OF PATIENT TESTING

CHECK THAT THE PATIENT HAS NOT SKIPPED ANY OF THE ABOVE ITEMS.

Confirming signature: _____

Supplementary medication during dressing:

medicine: _____**dose:** ml_____g_____

time: :

Do not turn off the computer. Space for notes:

ANNEX No 2
(EC FN KV)

ETICKÁ KOMISE
FAKULNÍ NEMOCNICE KRALOVSKÉ VINOHRADY

ROZHODNUTÍ
ETICKÉ KOMISE FAKULNÍ NEMOCNICE KRÁLOVSKÉ VINOHRADY

EK-VP/71/0/2020

NÁZEV PROJEKTU:

„Virtuální realita a zvládání procedurální bolesti u pacientů s popáleninovým traumatem"

Řešitelka ve FNKV: **PhDr. Alena Javůrková, Ph.D.**
Oddělení klinické psychologie

Výzkumný tým:
Mgr. et Mgr. Martin Zielina, Ph.D., 2LF UK
MUDr. Robert Zajíček, Ph.D., přednosta Kliniky popáleninové medicíny 3. LF UK a FNKV
PhDr. Alena Javůrková, Ph.D, vedoucí Oddělení klinické psychologie FNKV, 2. LF UK
PhDr. Doležal, psycholog ve zdravotnictví, Oddělení klinické psychologie FNKV
PhDr. Jaroslava Raudenská, Ph.D, klinická psycholožka, Oddělení klinické psychologie FNKV, 2. LF UK
Ing. Zbyněk Pohořelský, SPACE s.r.o.
PhDr. Jan Šmahaj, Ph.D., Univerzita Palackého v Olomouci

Etická komise na svém zasedání dne **2. prosince 2020** projednala návrh vědeckého projektu doloženého následujícími dokumenty:

1. Žádost
2. Anotace projektu
3. Informace pro pacienta a informovaný souhlas
4. Checklist_v0.8
5. CV navrhovatelky

Na základě hlasování EK vydává ☒ **Souhlasné stanovisko** ☐ Nesouhlasné stanovisko

Upozornění ke stanovisku EK FNKV:

- Hlavní řešitel ve FNKV je povinen ohlásit EK FNKV realizaci, zahájení a ukončení projektu a zaslat závěrečnou zprávu.
- V případě, že z projektu vzejde publikace, je hlavní řešitel povinen publikaci dedikovat FNKV.

Seznam členů etické komise

Jméno a příjmení	Muž/ Žena	Odbornost	Zaměstnanec zřizovatele EK* Ano	Ne	Funkce v EK	Přítomen Ano	Ne	Hlasoval Ano	Ne
prof. MUDr. Jan Pachl, CSc.	M	anesteziolog	☒	☐	předseda	☒	☐	☒	☐
MUDr. Martin Herold	M	kardiolog	☒	☐	místopředseda	☒	☐	☒	☐
MUDr. Milan Brychta	M	onkolog	☒	☐	člen	☒	☐	☒	☐
Jarmila Folprechtová	F	zástupce pacientů	☐	☒	člen	☒	☐	☒	☐
PhDr. Libuše Gavlasová	F	zdravotní sestra	☒	☐	člen	☐	☒	☐	☒
Dana Kovandová	F	tajemnice	☒	☐	člen	☒	☐	☒	☐
MUDr. Eva Krpenská	M	chirurg	☒	☐	člen	☒	☐	☒	☐
PharmDr. Lukáš Láznička	M	lékárník	☒	☐	člen	☒	☐	☒	☐
MUDr. Nikola Mejzlíková	F	internistka	☒	☐	člen	☐	☒	☐	☒
Luboš Olejár	M	zástupce pacientů	☐	☒	člen	☒	☐	☒	☐
MUDr. Leo Slavkovský	M	anesteziolog	☒	☐	člen	☒	☐	☒	☐

(pozn: *Zaměstnanec zřizovatele EK)

Etická komise prohlašuje, že byla ustavena a pracuje podle jednacího řádu v souladu se správnou klinickou praxí (GCP) a platnými právními předpisy: ☒Ano ☐Ne

2. 12. 2020
Datum

Prof. MUDr. Jan Pachl, CSc.
předseda EK FNKV

Podpis předsedy/místopředsedy EK

FAKULTNÍ NEMOCNICE KRÁLOVSKÉ VINOHRADY
Šrobárova 50/[illegible] 34 Praha 10
ETICKÁ KOMISE

ANNEX 3 (IS)

FAKULTNÍ NEMOCNICE KRÁLOVSKÉ VINOHRADY
ODDĚLENÍ KLINICKÉ PSYCHOLOGIE

ŠROBÁROVA 50, 100 34 PRAHA 10, TELEFON: 26716 1111, 26716 2932, IČO: 000 64 173

Informovaný souhlas pro pacienta s účastí na výzkumném projektu "Virtuální realita a zvládání procedurální bolesti u pacientů s popáleninovým traumatem"

Informace pro pacienta

Vážená paní, vážený pane,
dovolujeme si Vás požádat o zvážení Vaší účasti ve výzkumném projektu. Vzhledem k tomu, že jako svéprávný jedinec se podílíte významným způsobem na diagnostickém a léčebném postupu navrženém u Vaší osoby, máte právo se svobodně rozhodnout o dalším navrhovaném postupu a máte nezadatelné právo být před Vaším rozhodnutím o těchto postupech podrobně informován(a). Je velmi důležité, abyste si pečlivě pročetl(a) následující text a Váš případný souhlas s účastí v projektu zvážil(a). Pokud se rozhodnete do výzkumného projektu nevstoupit, budete nadále léčen(a) dosud běžně používanými postupy, které jsou běžné při hospitalizaci na Klinice popáleninové medicíny 3.LF UK a FNKV, přitom Vaše neúčast v projektu neovlivní dostupnost běžně dostupné léčby.

Stručný popis výzkumného projektu

Projekt "Virtuální realita a zvládání procedurální bolesti u pacientů s popáleninovým traumatem" je projektem, kde se bude sledovat, jak procedurální bolest v průběhu převazů může být ovlivněna nefarmakologickými prostředky. Běžná péče proběhne zcela standardním způsobem. Vědecká část projektu spočívá v aplikaci brýlí VR a v pečlivějším sledování v době převazů, než je obvyklé. V praxi to znamená, že Vám budou nasazeny na oči brýle s VR minimálně u 2-3 převazů, a také Vám budou administrovány dva dotazníky, zaměřené na úzkost, depresi (BSPAS) a imerzivitu (IQP) (schopnost ponoření se do virtuální reality) a opakovaně Vám bude měřena intenzita bolesti (VAS). Všechny proměnné, včetně odpovědi na jednotlivé položky bude ošetřující personál zaznamenávat do anonymizovaného Check listu. Jelikož se jedná o studii randomizovanou, budete na základě kódu hned na počátku zařazen/a buď do skupiny klinické, nebo do skupiny kontrolní. Kontrolní skupina bude mít v brýlích VR jen statický obraz VR, zatímco skupina klinická v nich bude mít interaktivní VR, jejíž průběh bude digitálně uchován pod anonymizovaným kódem. Nežádoucím účinkem VR může u některých senzitivnějších jedinců být nauzea (pocit na zvracení). Tato studie bude sloužit k potvrzení efektu VR na snížení procedurální bolesti při popáleninovém traumatu.

Zkušenosti získané v projektu bychom rádi vědecky vyhodnotili a publikovali. Proto Vás žádáme o souhlas se zařazením do tohoto projektu. Vaše osobní údaje nebudou nikde veřejně prezentovány mimo Kliniku popáleninové medicíny 3.LF UK a FNKV a Oddělení klinické psychologie FNKV. Při všech budoucích vědeckých prezentacích výsledků tohoto projektu budou samozřejmě veškeré informace plně anonymizovány, takže nikdo nepovolaný nemůže v souvislosti s registrem zjistit Vaše osobní data.

Pokud se rozhodnete kdykoliv ukončit účast ve výzkumném projektu, odmítnout ji nebo přerušit nebude to mít žádný vliv na poskytnutou péči. V případě jakýchkoli dotazů je možné se obrátit na PhDr. Alenu Javůrkovou, Ph.D., tel. 267162932, alena.javurkova@fnkv.cz

Informovaný souhlas

Prohlašuji, že mi byl náležitě objasněn důvod, předpokládaný prospěch, nežádoucí účinky, možná rizika a komplikace, které souvisejí s mou účastí v tomto výzkumném projektu. Prohlašuji, že jsem byl(a) poučen(a) o možnosti, abych nepřijal(a) účast ve výzkumném projektu, a o tom, že mi bude v této situaci poskytnuta současná standardní léčba nebo diagnostika včetně jejich alternativ. Byl(a) jsem poučen(a) o tom, že výzkumný projekt schválila Etická komise FNKV Praha, která bude nad průběhem projektu dohlížet. Měl(a) jsem možnost zeptat se na všechno, co mě ve vztahu k výzkumnému úkolu zajímá a obdržel(a) jsem vysvětlení, kterému jsem porozuměl(a). S mou účastí ve výzkumném projektu souhlasím. Byl(a) jsem poučen(a), že mohu kdykoliv účast ve výzkumném úkolu odvolat, a to i bez udání důvodu. Souhlasím s publikací výsledků výzkumného úkolu. Byl(a) jsem poučen(a), že při publikaci výsledků bude dodržena anonymita mých osobních údajů.

Informaci pacientovi poskytl: …… (jméno a podpis lékaře)
Dne ……

Informaci jsem plně porozuměl(a), měl(a) jsem možnost položit lékaři otázky a mé otázky mi byly srozumitelně k mé spokojenosti zodpovězeny. Dobrovolně souhlasím se svou účastí v projektu **" Virtuální realita a zvládání procedurální bolesti u pacientů s popáleninovým traumatem"**

Jméno a podpis pacienta:
……
Datum: ……

ANNEX No 4

(Extension EC FN KV)

ETICKÁ KOMISE
DCNICE KRALOVSKÉ VINOHRADY

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ctscxê xoanas r "svui xEuawarcxe4to+'s "f vi.*oxe^o*'

EK-VP/71/1/2020

„Virtuální realita a zvládání procedurální bolesti u pacientů s popáleninovým traumatem"

Řešitelka ve FNKV:
1 künivkt p-svRdiigé

Výzkumný tým:
Mgr. et Mgr. Martin Zielina, Ph.D., 2LF UK
MUDr. Robert Zajíček, Ph.D., přednosta Kliniky popáleninové medicíny 3. LF UK a FNKV
PhDr. Alena Javůrková, Ph.D, vedoucí Oddělení klinické psychologie FNKV, 2. LF UK
gg§ ' p$ys§ggug h's €¥M¥Ctvl, ¢¥dMb¥¥¥l k)t€si€bê €gol FMt¢¥'
Pbg¥'. 3aosbvs Rozihszd'1 Pls.D. kltnkks pstdiol Odt0i "s-i wedges "k4 lwy Jaäuglc F*"*+V. L* UK
) Polzz¥dek . Sf'ACE -r c
zazh. w Small nu... Liniwrdic ea" kaio - r'xx-

2. Informace pro pacienta a informovaný souhlas – dodatek 1

Na základě hlasování EK vydává ☒ Souhlasné stanovisko ☐ Nesouhlasné stanovisko.

Seznam členů etické komise

Jméno a příjmení	Muž/ Žena	Odbornost	Zaměstnanec zřizovatele EK* Ano	Ne	Funkce v EK	Přítomen Ano	Ne	Hlasoval Ano	Ne
prof. MUDr. Jan Pachl, CSc.	M	anesteziolog	☒	☐	předseda	☒	☐	☒	☐
MUDr. Martin Herold	M	kardiolog	☒	☐	místopředseda	☒	☐	☒	☐
MUDr. Milan Brychta	M	onkolog	☒	☐	člen	☒	☐	☒	☐
Jarmila Folprechtová	F	zástupce pacientů	☐	☒	člen	☒	☐	☒	☐
PhDr. Libuše Gavlasová	F	zdravotní sestra	☒	☐	člen	☐	☒	☐	☒
Dana Kovandová	F	tajemnice	☒	☐	člen	☒	☐	☒	☐
MUDr. Eva Kepenská	M	chirurg	☒	☐	člen	☒	☐	☒	☐
PharmDr. Lukáš Lázníčka	M	lékárník	☒	☐	člen	☒	☐	☒	☐
MUDr. Nikola Mejzlíková	F	internistka	☒	☐	člen	☐	☒	☐	☒
Luboš Olejár	M	zástupce pacientů	☐	☒	člen	☒	☐	☒	☐
MUDr. Leo Slavkovský	M	anesteziolog	☒	☐	člen	☐	☒	☐	☒

(pozn: *Zaměstnanec zřizovatele EK)

Etická komise prohlašuje, že byla ustavena a pracuje podle jednacího řádu v souladu se správnou klinickou praxí (GCP) a platnými právními předpisy: ☒Ano ☐Ne

23. 6. 2021
Datum

Prof. MUDr. Jan Pachl, CSc.
předseda EK FNKV

Podpis předsedy/místopředsedy EK

FAKULTNÍ NEMOCNICE
KRÁLOVSKÉ VINOHRADY
Šrobárova 50, 100 34 Praha 10
ETICKÁ KOMISE