Dear Madam, Dear Sir,

During your treatment in the Burn Unit/the Intensive Care Unit/the Emergency room, procedures for wound care and/or other care procedures are regularly necessary. Such procedures can cause pain/discomfort and/or fear, for which you receive medication if necessary. Virtual Reality (VR) – three-dimensional images combined with sound through headphones – offers an alternative for this medication and leads to an important reduction of pain and discomfort. The beneficial effect of virtual reality has been proven in several small studies. However, it is less clear what part of the admitted patients is open to this treatment and successfully undergoes VR. The goal of this study is to get to know this group of virtual reality candidates, to get an idea of how large this group is and to see if we can predict which patients are good candidates. The intent of this project – with the support of the Flemish Government – is to offer virtual reality to every patient admitted in the Burn Unit (BWC)/Intensive Care Unit who needed medication and/or experienced pain or fear during previous wound treatment. During this project of one and a half years, we will evaluate all patients admitted to the Burn Unit. Upon request of their attending team, we can also evaluate outpatients with burns, patients in the pediatric intensive care unit and patients from the emergency room for the use of VR during a painful procedure. By collecting basic data related to your accident, your injuries, your medical situation and also about your characteristics, we want to establish a reliable profile of the candidates that are eligible for virtual therapy. This will allow us in future to recognize good candidates for VR from the start and to establish how much VR material and personnel is required to help all potential candidates. In summary, the main goal is to offer the best possible care in future in an even more efficient way.

We invite you to participate in this clinical study. If you participate in this clinical study, you need to know the following:

 This clinical study starts after evaluation by one ethics committee. 

Your participation is voluntary and remains free of any coercion. Your participation requires a signed informed consent. Even if you have signed this form, you can inform the doctor/investigator that you want to withdraw your consent. The decision whether or not to (continue) to participate will in no way have a negative effect on the quality of your care nor on the relation with the attending doctor(s).

 The data collected within the context of the study in which you are taking part, will be treated confidentially. Your anonymity is guaranteed when the results are published. 

We will not charge you for specific treatments, visits/consultations, examinations for the purpose of this study.

 An insurance has been taken out in case you should suffer any damage in connection with your participation in this study. 

If you would like to receive more information, you can always contact the doctor/investigator or a member of his/her team.

Description of the study protocol

If you would like to participate in this study, we will ask you to fill out some questionnaires about your characteristics. Answering these questionnaires will take about 20 minutes. This is not a comparative study; we will offer VR to each patient for whom VR is an option. Nevertheless, we will make an estimate of the effect of VR support on pain, fear and the need for medication during wound care procedures in comparison to ‘classical’ procedures where medication was necessary and the patient experienced pain and/or fear. During weekends and on Mondays we cannot offer the VR technology for quality and logistic reasons. Comparisons between procedures with and without VR will provide insights though in the benefit of VR with regard to comfort and the need for medication. Heart frequency and respiratory frequency during the procedures will also be recorded. Patient satisfaction with the VR technology and side effects that might occur will also be documented. For some patients we will also compare the effect on the results obtained by physiotherapy when mobilizing a joint with and without VR. We will collect no blood or tissue samples as part of this study. We might contact you after six months to ask you to fill out a brief questionnaire concerning you wellbeing at that time. If you do not want to participate in this, you can of course just let us know. We hope to examine 300 – 400 patients during this project. Data collection will start after you have given consent to participate and ends upon your discharge from the unit. Risks and inconveniences The use of VR during wound care procedures is a validated and proven therapy, used by trained personnel with equipment especially designed for this purpose. You should experience no inconvenience, unless maybe – but this is rather rare – some nausea. Withdrawing consent Your participation in this study is voluntary. You have the right to withdraw your consent at any time and without giving a reason. If you withdraw your participation in this study, the study treatment will end. At that time, we will ask you whether we can proceed collecting new data. We will use the data already collected at that moment for analysis.

Confidentiality

Your participation in the study means that you agree that the medical doctor/investigator collects data about you and to the study sponsor to use these data for research purposes and in connection with scientific and medical publications. Your data will be processed in accordance with the European General Data Protection Regulation (GDPR) and with the Belgian legislation on the protection of natural persons with regard to the processing of personal data. KU Leuven/UZ Leuven shall act as data controller for your data. Your data will be encoded and only researchers involved in the analyses will have access to the encoded data. This means that your identity will be replaced by an identification code in the study. The medical doctor/investigator and his/her team will therefore be the only ones to be able to establish a link between the data transmitted and your medical records. After completion of the study, your data will be used for scientific publication, strictly safeguarding the anonymity of the patients who participated. The encoded study data may be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organizations working in collaboration with the sponsor. They may also be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent. As explained above, the transmitted data are encoded. Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities. The sponsor will use the data collected within the context of the study in which you are taking part, but would also like to be able to use them in connection with other research concerning the same disease as yours. Any use of your data outside the context described in this document is only possible with the approval of the ethics committee. Under strict conditions, direct access to the medical file may be granted to the authorized staff of the sponsor or his representative(s), to regulatory authorities or other people legally competent to check that the investigation is conducted correctly. Access is only granted to check the quality of the collected data and thus not systematically. Direct access to the medical file by third parties will only be granted in the presence and under the responsibility of the researcher (or one of his collaborators). All people who may have access to the medical file are subject to professional secrecy. You are entitled to ask the investigator what data are collected about you and what is their use in connection with the study. You have the right to inspect your personal data and correct them if they are incorrect. At your request, the Data Protection Officer can provide more information on the protection of your personal data (contact DPO-UZ Leuven, Herestraat 49, 3000 Leuven, e-mail gdpr.research@uzleuven.be). When you consent to participate in this study, your treating specialist will be informed. A description of the clinical study will be available on the website https://www.isrctn.com/. This website contains information on the study and a summary of the results, but will not contain any information that would allow identification of the participant.

If you have a complaint concerning the processing of your data, you can contact the Belgian supervisory authority who ensures that privacy is respected when personal data are processed: Data Protection Authority (DPA) Drukpersstraat 35, 1000 Brussels Phone +32 2 274 48 00 e-mail: contact@apd-gba.be www.dataprotectionauthority.be

Insurance

In accordance with the Belgian law relating to experiments on human persons dated May 7, 2004 the study sponsor even faultless is accountable for any damage the participants or, in the event of death, his/her dependants experience, directly or indirectly related to the study. The sponsor has taken an insurance that covers this liability. If you suffer from damage as a consequence of your participation in this study, the damage will hence be compensated for in accordance with the Belgian law relating to experiments on human persons of May 7, 2004.

The data for the insurance are: Vanbreda Risk & Benefits NV, Plantin en Moretuslei 297, 2140 Antwerpen (polis number 299.053.700).

KU Leuven/UZ Leuven is the sponsor of the study.

Ethics commitees

The study has been approved by the Ethics Committee Research UZ/KU Leuven, which acts as central committee for this project. The study is performed according to the guidelines for Good Clinical Practice (ICH/GCP) and the most recent version of the Declaration of Helsinki, deployed for the protection of participants in human clinical studies. In no way, approval by the ethical committee should be regarded as a stimulus to participate in this study. Contact If you wish to receive more information or if you object to this study, you can report this to the treating nurse or physician. You can also contact the secretarial office of the Division Intensive Care Medicine, where you can be referred to one of the researchers.

In case of complaints, you can contact the Mediation Service of the University Hospital. We hope we can count on your cooperation and thank you in advance.

Prof. Dr. Michael Casaer , Prof. Dr. Greet Van den Berghe Dr. Renata Haghedooren

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