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Original Article

Assessing the impact of mixed reality-assisted informed consent: A study protocol

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ABSTRACT

Background: Informed consent is a crucial aspect of modern medicine, but it can be challenging due to the complexity of the information involved. Mixed reality (MR) has emerged as a promising technology to improve communication. However, there is a lack of comprehensive research on the impact of MR on medical informed consent. The proposed research protocol provides a solid foundation for conducting future investigations and developing MR-based protocols that can enhance patients' understanding and engagement in the decision-making process.

Methods: This study will employ a randomized controlled trial design. Two arms will be defined: MR-assisted informed consent (MRaIC) as the experimental arm and conventional informed consent (CIC) as the control arm consent, with 52 patients in each group. The protocol includes the use of questionnaires to analyze the anxiety levels and the awareness of the procedure that the patient is going to perform to study the impact of MRaIC versus CIC before medical procedures.

Results: The study will evaluate the impact of MR on patients' information comprehension, engagement during the process of obtaining informed consent, emotional reactions, and consent decisions. Ethical concerns will be addressed.

Conclusion: This study protocol provides a comprehensive approach to investigate the impact of MR on medical informed consent. The findings may contribute to a better understanding of the effects of MR on information comprehension, engagement during the process of obtaining informed consent, psychological experience, consent decisions, and ethical considerations. The integration of MR technology has the potential to enhance surgical communication practices and improve the informed consent process.

Keywords: Informed consent, Mixed reality, Patient engagement, Surgical interventions, Surgical outcomes

INTRODUCTION

Informed consent is a fundamental ethical and legal requirement in medical practice to ensure that patients have a comprehensive understanding of the risks, benefits, and alternatives associated with a particular surgical or medical procedure. However, traditional methods of delivering information to patients may be limited in their effectiveness.[6,16] Despite all efforts, a comprehensive and satisfactory understanding can be difficult to achieve due to either (1) the use of medical jargon by physicians in communications with patients, (2) the low literacy levels of patients that make it challenging for them to comprehend medical information, or (3) the psychological status of the patient. It has been shown that a lack of understanding or a misunderstanding of surgical procedures can increase preoperative anxiety and undermine the mutual trust between patients and physicians, potentially favoring medicolegal issues.[3,5,10,21,24]

Mixed reality (MR) belongs, alongside augmented reality (AR) and virtual reality (VR), to the extended realities group and involves a fusion of real-world and virtual elements. In AR, there exists an overlap but still a separation between physical and digital elements, which can only be visualized. Conversely, in VR, the user is entirely immersed in a virtual space with exclusively digital elements. MR represents an advancement from AR and is distinguished by active interaction with the digital objects displayed within the real world, offering new possibilities to address the challenges in conventional communication techniques improving the informed consent process.[11] The interaction with digital objects displayed in the real world is the key characteristic that differentiates MR from AR and VR. In AR, digital objects are displayed in the real world without any opportunity for direct engagement, while in VR, the digital environment is completely disconnected from the real world. Therefore, MR offers the unique opportunity to actively interact with a digital component beyond simple visualization aids, which engages patients and their family members and/or caregivers. In addition, the uses of MR while providing details about the purposes, risks, and benefits of surgical procedures can improve patients' understanding and decrease preoperative anxiety in patients.

This study protocol aims to investigate the impact of MR on patient understanding and experiences during communications involving surgical/medical management for their condition, with the goal of improving surgical outcomes and patient experiences.

Objectives

The main objectives of this study protocol are as follows:

1. To evaluate the effectiveness of MR tools in enhancing patient comprehension during the informed consent process
2. To assess patient satisfaction and engagement when using MR-assisted informed consent (MRaIC) using psychological tests and anxiety questionnaires.

MATERIALS AND METHODS

Study design

This study will employ a randomized controlled trial design. This could be done using a computer-based random number generator to ensure that the process is truly random. The allocation could be done in a 1:1 ratio, meaning an equal number of patients (n = 52) would be assigned to each group. The sample size of 52 participants for each arm was determined based on assumptions of a normal distribution, with guidance from a planned statistical analysis. Patients scheduled for surgical interventions will be randomly assigned to either the MR group or the control group. The MR group will receive the informed consent using MR technology, while the control group will receive the standard informed consent process without MR.

The first anxiety self-evaluation questionnaire [Supplement 1] should be answered before obtaining consent, both MRaIC and conventional informed consent (CIC). After completion of this first questionnaire, consent is taken for the two groups (MRaIC and CIC). Finally, a second questionnaire investigates the level of understanding of the patient about the diagnosis and the therapeutic strategy, which will be answered after consent [Supplement 1]. The anxiety levels pre- and post-consent will be calculated, and the changes in the anxiety levels will be compared between the two groups (MRaIC and CIC). A final consent satisfaction questionnaire is taken, which will be used to compare the differences between patients in the two groups (MRaIC and CIC) [Supplement 1].

Study participants

The study will include adult patients (aged 18 years and above) scheduled for elective surgical interventions or medical procedures. Patients with severe visual or cognitive impairments will be excluded. Patients who consent to participate in this study will be asked to sign a formal agreement and will be randomly allocated to one of the two groups (MRaIC and CIC).

MRa-IC

Dicom files (magnetic resonance imaging and computed tomography scans) of radiological imaging performed by the patient will be uploaded to a cloud manager VSI software powered by ApoQlar. The dataset will be anonymized, and a pseudonym will be automatically assigned to each patient. 3D holographic rendering will be produced. Microsoft HoloLens 2 will be used to share with the patient and family members holograms of radiological images. The hologram can be visualized independently or after superimposition on the affected anatomical part of the patient. With the assistance of the medical staff, patients can easily interact

with the hologram, including scrolling through the image dataset, zooming in and out of the 3D holographic rendering, and moving around the 3D rendering. Video and audio files acquired during the informed consent process will be archived as part of the clinical files of the patient.

Data collection

Questionnaires will be collected to capture a comprehensive understanding of the impact of MR on surgical/medical informed consent. All data, including patients' radiological images and visual and audio recordings of meetings, will be anonymized. Radiological images will be collected and stored in the Microsoft VSI clouded database. Data uploaded in the cloud will be automatically deleted after 30 days. Questionnaires and video-audio recordings of the informed consent will be stored as part of the clinical files. A Data Processing Agreement is signed by Health Sciences North and ApoQlar GmbH. Ethical Committee approval obtained by Health Sciences North, Canada Project Number: *21-042.*

Statistical analysis

Descriptive statistics will be used to summarize patient characteristics and outcomes. Qualitative data from interviews will be analyzed thematically to identify key themes and patterns.

To compare the MR and control group, non-parametric methods will be applied to ordinal data, such as Likert scale data involving the determination of the ranking for patient understanding, engagement, and satisfaction. The Statistical Package for the Social Sciences software or R-package will be used for statistical analysis. $P < 0.05$ will be considered statistically significant.

Ethical considerations

Health Sciences North has obtained Ethical Committee approval, Canada Project Number: 21–42. This study will adhere to ethical guidelines and obtain relevant institutional review board approvals in case of a multi-center study. Informed consent will be obtained from all participants prior to their inclusion in the study. Confidentiality and privacy of participant data will be ensured throughout the research process.

RESULTS

Expected outcomes

We anticipate that the use of MR in the informed consent process will lead to improved patient understanding and engagement, reducing preoperative anxiety by promoting patient engagement and strengthening the relationship between patients and medical professionals. By providing a visual and interactive representation of the entire surgical procedure and relevant anatomy, patients may have a clearer understanding of the risks, benefits, and alternatives involved in the procedure. This can contribute to more informed decision-making, potentially enhancing patient satisfaction. Beyond improved patient satisfaction, heavy documentation performed in this study can avoid illicit conduct by doctors, patients, lawyers, and insurance companies, which could lead to a reduction in insurance costs. However, evaluating the impact of this study on insurance costs will require a longer follow-up of 5–10 years. Finally, a potential drawback of the use of MR could involve patients who do not want detailed information about the surgical procedure or are afraid of either the realistic visualization of the procedure or the representation of their condition. Since this differs in each patient, the impact of MR technology can be highly varied.

DISCUSSION

The findings from this study may contribute to the growing body of literature on the use of MR in healthcare.[13] If the results demonstrate positive effects on patient understanding, engagement, and satisfaction, it will support the integration of MR technology into the informed consent process for surgical or medical procedures. However, it is important to acknowledge potential challenges, such as technical limitations, accessibility issues, and patient preferences, which may impact the implementation of MR in clinical settings.

One of the potential benefits of using MR in the informed consent process is the ability to provide patients with a more immersive and interactive experience.[15] By visualizing the surgical or medical procedure, patients may have a better understanding of the steps involved, the anatomical structures affected, and the potential risks and benefits of the procedure.[14] This enhanced understanding can also lead to more informed decision-making.

Engagement is another crucial aspect of the informed consent process. Unlike traditional methods of presenting information, such as written documents or verbal explanations, which may not fully engage patients or capture their attention, MR technology has the potential to create a more engaging and memorable experience by allowing patients to interact with the virtual environment actively.[20] This interactivity can facilitate discussions between patients and healthcare providers, enabling them to address questions or concerns more effectively [Figure 1]. Furthermore, patient satisfaction plays a key role in healthcare outcomes and patient experiences. If the use of MR technology improves patient understanding and engagement, it may also contribute to higher levels of patient satisfaction [Video 1]. Patients who feel more informed and involved in the decision-making process are likely to have increased

confidence in their healthcare providers and the proposed interventions.[2,4,8,9,18-20] This, in turn, can lead to improved patient experiences and potentially better surgical outcomes.

Beyond the benefits of MR use in obtaining informed consent, the challenges of using MR need to be acknowledged. These challenges may include (1) technical limitations, (2) financial constraints, (3) lack of trained personnel, (4) access limitations, and (5) patient receptiveness. Technical limitations can include specialized equipment and software. Second, financial constraints are a minor issue since the costs are exiguous and can be split, involving all the specialties of the hospital. In fact, the total cost could range from tens of thousands to hundreds of thousands of euros for each hospital.[22] However, it is important to note that as of 2023, MR technology is still relatively new, and the costs could change over time. Furthermore, the potential benefits of this technology, such as improving healthcare staff efficiency and enhancing patient outcomes, could offset the initial costs. Third, the lack of developers may slow down the improvement of technology, particularly the development of dedicated hardware to replace the actual commercial device. Fourth, limitations in the availability and access to high-speed Wi-Fi connection may increase disparities across geographical locations. Finally, patient preferences and acceptance of MR technology are other critical aspects to explore. While some patients may appreciate the immersive and interactive nature of MR, others may have concerns about the realism of the virtual environment or feel uncomfortable with the technology. Understanding patient preferences and addressing any potential hesitations is essential for the successful implementation and acceptance of MR in the informed consent process. The integration of MR technology into the informed consent process for surgical interventions holds great promise in improving patient understanding, engagement, and satisfaction. If the results of this study demonstrate positive outcomes, it would provide valuable evidence to support the use of MR as a tool to enhance the informed consent experience. By addressing the challenges and considering patient preferences, healthcare providers can leverage the benefits of MR technology while ensuring equitable access and personalized care for all patients.[12,23] The use of MR in the informed consent process highlights the medical condition while acknowledging the psychological status of the patient, leading to a holistic therapeutic approach. Beyond the benefits and challenges of MR technology, the implementation of MR in the informed consent process raises ethical considerations. While MR can enhance patient understanding and engagement, it is important to ensure that the information presented through MR technology is accurate and comprehensive. Healthcare providers must ensure that the virtual representations of surgical procedures and associated risks are realistic and aligned with current medical knowledge. In addition, clear guidelines and protocols should be established to address potential biases or misinterpretations that may arise from using MR technology in the informed consent process. Another aspect to consider is the impact of MR on healthcare providers. The integration of MR technology may require additional training and resources for healthcare professionals to use and communicate the information presented through MR effectively.[1,7] It is crucial to assess the perceptions and attitudes of healthcare providers toward MR and their ability to incorporate it into their workflow effectively. Collaboration between healthcare providers, technology experts, and researchers is essential to develop user-

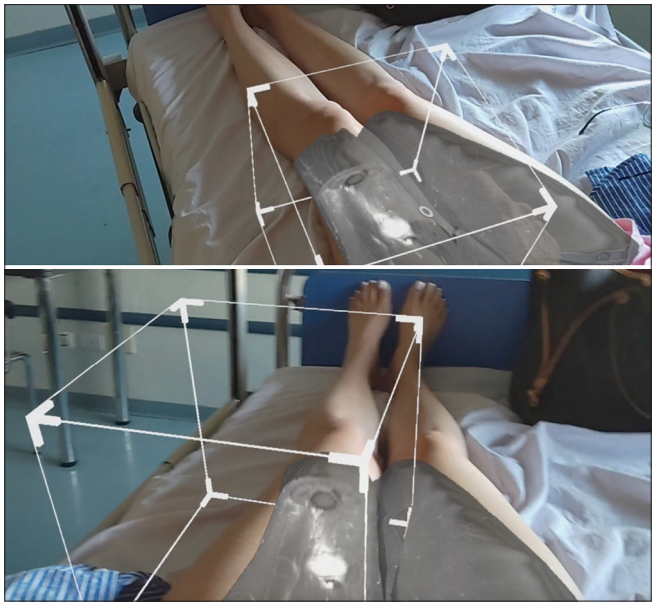

Figure 1: Mixed reality technology images showing the potential to create a more engaging and memorable experience by allowing patients to actively interact with the virtual environment, in this case, with preoperative magnetic resonance imaging.

Video 1: Within the realm of surgical preparation, the integration of mixed reality (MR) technology has revolutionized patient engagement and comprehension. This video encapsulates a pivotal moment as a patient utilizes MR technology to gain a comprehensive understanding of their upcoming surgical procedure. Through this immersive experience, informed consent transcends traditional boundaries, fostering heightened levels of patient satisfaction. Witness firsthand the transformative power of MR technology in shaping the future of surgical informed consent.

friendly MR applications that align with clinical practice and meet the needs of both patients and healthcare professionals.[17]

Future research should explore the long-term effects of using MR in the informed consent process. While this study focuses on immediate outcomes such as patient understanding, engagement, and satisfaction, it is necessary to assess the impact on patient outcomes and clinical decision-making over time. Longitudinal studies can provide insights into the durability of the effects of MR on informed consent and its potential impact on patient compliance, postoperative outcomes, and overall healthcare costs. In addition, the potential applications of MR in other areas of healthcare should be explored. Beyond surgical interventions, MR technology can be utilized in various medical scenarios, such as patient education, preoperative planning, and rehabilitation. Investigating the efficacy and acceptability of MR in different healthcare contexts can provide a more comprehensive understanding of its utility and benefits.

Study limitations

Hawthorne effect

The use of MR technology may introduce a Hawthorne effect, where participants may alter their behavior or responses due to the awareness of being observed or receiving a novel intervention. This effect could potentially influence the outcomes related to patient understanding, engagement, and satisfaction.

Learning curve

The learning curve associated with using MR technology for both patients and health-care providers may influence the findings of this study. Participants may require some time to become familiar with the MR application, potentially affecting the outcomes during the initial stages of the study. Adequate training and support should be provided to minimize the impact of the learning curve.

Follow-up period

The study protocol should determine the appropriate follow-up period to assess the long-term effects of using MR in the informed consent process. Depending on the nature of the surgical interventions, it may be necessary to extend the follow-up period beyond the immediate postoperative stage to capture potential changes in patient outcomes and experiences over time.

Resource constraints

The implementation of MR technology may require additional resources, including technological infrastructure, personnel, and financial investments. The study protocol should consider the potential limitations and challenges associated with resource availability, as this may impact the feasibility and scalability of integrating MR into the informed consent process.

CONCLUSION

The findings from this research may contribute to the advancement of knowledge in the field of healthcare technology and inform evidence-based decision-making regarding the integration of MR into surgical practice. Ultimately, the goal is to enhance patient understanding, engagement, and participation in the informed consent process, leading to improved patient outcomes and satisfaction in the surgical journey. By conducting this study, we can pave the way for the responsible and effective implementation of MR in obtaining clinical informed consent, thus fostering patient-centered, holistic care in the digital era.

Ethical approval

The research/study was approved by the Institutional Review Board at Health Sciences North/Horizon Santé-Nord, Sudbury, Ontario, number 21-042, dated 09/01/2023.

Declaration of patient consent

Patient's consent is not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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SUPPLEMENT 1

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Name_____Date_____S_____

Age_____ Gender (*Circle*) **M F** T_____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
I feel calm	1	2	3	4
I feel secure	1	2	3	4
I am tense	1	2	3	4
I feel strained	1	2	3	4
I feel at ease	1	2	3	4
I feel upset	1	2	3	4
I am presently worrying over possible misfortunes	1	2	3	4
I feel satisfied	1	2	3	4
I feel frightened	1	2	3	4
I feel comfortable	1	2	3	4
I feel self-confident	1	2	3	4
I feel nervous	1	2	3	4
I am jittery	1	2	3	4
I feel indecisive	1	2	3	4
I am relaxed	1	2	3	4
I feel happy	1	2	3	4
I am worried	1	2	3	4
I feel confused	1	2	3	4
I feel steady	1	2	3	4
I feel pleasant	1	2	3	4

CONSENT INSTRUMENT

1. List an expected discomfort of the surgery.
2. List an expected benefit of the surgery.
3. List an expected major and minor risk of the surgery.
4. List one consequence of not having your surgery soon.
5. List one alternative to the surgery.
6. Do you understand why you need the surgery?
7. Do you know enough about the surgery that you could basically explain to another person how it will occur?
8. Was the surgical procedure explained to you?
9. Did you understand the explanation of the surgery?
10. Were you informed of the risks of the surgery?
11. Were you informed of the benefits of the surgery?
12. Do you understand the risks of the surgery?
13. Do you understand the benefits of the surgery?
14. Were you informed of the rare possibility of a life-threatening complication from the surgery?
15. Did you know that you could refuse the surgery?
16. Were you given the opportunity to refuse the surgery? Ti è stata data l'opportunità di rifiutare l'intervento?
17. Were you informed about alternatives to the surgery? Sei stato informato sulle alternative all'intervento?
18. Were you informed about possible consequences of not having the surgery?
19. Are you able to locate where your disease is? Riesci a localizzare dove si trova la tua malattia?
20. Did you get all the information you need to make a good decision about the surgery?

PATIENT SATISFACTION

1. I am satisfied that I was adequately informed about the issues important to my decision.

2. The decision I made was the best decision possible for me personally.

3. I am satisfied that my decision was consistent with my personal values.

4. I expect to successfully carry out (or continue to carry out) the decision I made.

5. I am satisfied that this was my decision to make.

6. I am satisfied with my decision.