Informed Consent/Authorization for Participation in Research

TITLE: A Phase II randomized controlled trial to determine the efficacy of an auGmented reAlity gaMe in pediatrIc caNcer patients who are Opioid Tolerant users undergoing surgery to reduce post-operative opioid use (GAMING-OT Study)

PROTOCOL NO.: 2022-0529

SPONSOR: National Institute of Drug Abuse

INVESTIGATOR: Juan Cata, MD
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United States

STUDY-RELATED PHONE NUMBER(s): 713-582-6452
713-792-2121 (24 Hours)

_____ _____
Participant's Name Medical Record Number

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

If you are reading and signing this form as a parent or legal guardian on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you may receive opioid medication after surgery as part of your standard-of-care cancer treatment and you took opioids for pain relief for 30 days or more before surgery.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn if playing an augmented reality game called SpellBound can reduce pain and the need for opioids in young patients following surgery. SpellBound is a scavenger hunt-style game using augmented reality. Augmented reality lets you view the real world through a device's camera and application ("app") but adds virtual or digital characters and items. The effect playing SpellBound has on pain level and pain medication use has not been evaluated in children with cancer taking opioid medications prior to surgery and followed after surgery and is investigational in this study.

How long will the research last and what will I need to do?

You are expected to be in this research study until 90 days after surgery.

You will be asked to play SpellBound on an iPad every day that you are in the hospital. Before surgery, during the time you are in the hospital after surgery, when you leave the hospital, and 30, 60, and 90 days after surgery you will be asked about your pain level and pain medications you have taken, your experience with the SpellBound game, and your overall quality of life. During the time you are on study, information about your health, pain levels, and use of pain medications will also be collected from your medical record.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

While you interact and play Spellbound with the iPad, there is a rare (less than 1% chance) risk of falls, dizziness, and/or nausea.

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, possible benefits include less pain after surgery, which could lower your need for pain medication. Future patients may benefit from what is learned. There may be no benefits for you in this study.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of taking part in this study, you may choose to have standard of care surgery without using the SpellBound game after.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 713-582-6452, 713-792-2121 (24 Hours).

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 34 people at MD Anderson will be enrolled in this research study. About 68 people will be enrolled in the entire study at all locations.

What happens if I agree to be in this research?

Before any research procedures are done, you will sign this consent form.

Pre-Surgery Questionnaire
If you agree to take part in this study, you will be asked to complete a questionnaire about your quality of life, which should take about 5 minutes to complete.

Study Groups
After you complete the questionnaire, you will receive a hospital-owned iPad with the SpellBound game installed. You will watch an introductory video by the game characters that introduces the game's story and quest and teaches you how to play. You or your parent/guardian can also set and change the language to English or Spanish at any time.

You may play the game whenever you want after surgery, but it is recommended you play at least 2 times a day. After you download the game, your parent/guardian and the study team will place stickers all over your room. You will use the iPad and game to "activate" the stickers and complete the tasks at each sticker. You will win points and characters for completing the tasks. The tasks will change every day based on your previous successes and challenges.

You will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one group is better, the same, or worse than the other.

- If you are in **Group 1**, you will play SpellBound using the iPad's standard camera, which will show you your hospital room and the decal/stickers s as they appear in the real world.
- If you are in **Group 2**, you will play SpellBound using augmented reality. Augmented reality lets you view the real world through a device's camera and application ("app") but adds virtual or digital characters and items.

You will have an equal chance (50/50) of being assigned to either group. The study team will know which group you are in, but you, your parent/guardian and your primary care team will not.

The iPad should not be used to play the SpellBound game without adult supervision. The study team can help answer any other questions you have about the game. You will not be able to use the iPad for any purpose other than playing the SpellBound game.

Post-Surgery Inpatient Visits

Every day that you are in the hospital after surgery, you will continue to play the SpellBound game on your iPad either with or without augmented reality, depending on which group you are in. Additionally:

- You and/or your parent/guardian will complete questionnaires about your quality of life and how you are feeling. These questionnaires take about 10 minutes to complete.
- The study team will check your medical record to track if you are prescribed opioids/pain medication and how many times you use the pain medication given to you after surgery. You and/or your parent/guardian will be asked how much pain you are feeling as well.
- The study app will also measure the distance you travel (either walking or in a wheelchair) based on the stickers activated.

You will return the iPad to the study team when you are ready to go home and leave the hospital. You will not have access to the iPad and SpellBound game after you leave the hospital. If the iPad is lost or broken during the study, you should report it to the study team. Broken or lost iPads will be replaced within 48 hours of the incident. You will not be responsible for the cost of the lost or broken iPad.

Data Collection

For both groups, information will also be collected from your medical record during the study. This may include demographic information (age, gender, race, date of birth, and so on) and information about your medical history (underlying medical conditions, date of surgery, pain levels, or use of pain medications or other drugs you are taking, for example).

Discharge Questionnaires

On the day that you leave the hospital (are discharged), you will complete questionnaires about your overall experience with the SpellBound game and your quality of life. Depending on your age, your guardian/caregiver may complete the questionnaire for you. These questionnaires will take about 10 minutes to complete.

After Surgery Follow-Up

After you leave the hospital, the study team will call you 3 times about 30, 60, and 90 days after your surgery and ask about how you are feeling, your pain levels, use of pain medications (opioids), and your overall quality of life in questionnaires similar to the ones you completed when you were in the hospital. The call should take about 10-15 minutes. Information about your use of pain medications may also be collected from your pharmacy records.

Your participation in this study will be over after the 90-day phone call.

If you cannot be reached, your medical record may be reviewed instead to collect other information needed, but the study team will not be able to complete the questionnaires.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

You should discuss the risks of **questionnaires** with the study chair. The known risks are listed in this form, but they will vary from person to person. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns after completing the questionnaire(s), you are encouraged to contact your doctor or the study chair. If you experience significant distress caused by any of the questions in the questionnaire, the study chair, child-life specialist, and/or a psychologist will discuss your concerns with you, if needed.

While you **interact and play the game with the iPad**, there is a rare (less than 1% chance) risk of falls, dizziness, and/or nausea.

In addition to these risks, this research may hurt you in ways that are unknown.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you for taking part in this study. You and/or your insurance provider will be responsible for the cost of standard of care surgery and opioid medications you receive.

Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Study data will be collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at MD Anderson. REDCap is a secure, web-based application with controlled access designed to support data capture for research studies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, National Institute of Drug Abuse, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that is collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. If you are removed from the study early, the study staff will tell you why.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form)

If you suffer a study-related injury, you may contact the Chair of the study, Dr. Juan Cata, at 713-582-6452 or 713-792-2121 (24 hours) with any questions you may have. By signing this consent form, you are not giving up any of your legal rights.

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is routinely available.

By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the National Institute of Drug Abuse.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - The National Institute of Drug Abuse, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants and it may be re-disclosed.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____

SIGNATURE OF PARENT/GUARDIAN DA

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:
____Other parent is deceased, unknown, incompetent, or not reasonably available.
____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.
_X__The IRB has determined that the signature of both parents is NOT required.

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.
____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.
____ 3.) Other:_____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR