Title of Study: Impact of a behavioral telehealth program (Lucid Lane) on the quality of recovery for patients undergoing total joint replacement surgery	
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Are you participating in any other research studies? _____ yes _____no

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

We invite you to take part in a research study because you are about to undergo total joint surgery. Patients are often prescribed opioid painkillers (for example, medications with hydrocodone such as Vicodin) during and after surgery to help manage pain. However, these pain killers are usually strong and people who use them are at risk of becoming dependent on them. This study will look at how patients can safely reduce the need to be on those medications with behavioral health support from Lucid Lane, Inc., the company funding and supporting this study.

Lucid Lane, Inc. is comprehensive telehealth company that offers a perioperative opioid tapering program utilizing daily behavioral health support (HIPAA-compliant sessions of Cognitive Behavioral Therapy (CBT), mindfulness, 1:1 psychotherapy, group therapy, and 2-way texting and chat, which are all direct interactions with Lucid Lane Licensed Therapists). The mission of Lucid Lane is to empower people with pain and substance use to live a better & healthier life.

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.

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

What is this research about and why is this research being done?

The study will include around 103 patients who are scheduled for orthopedic total joint surgery, just like you.

The purpose of this study is to understand how Lucid Lane's daily behavioral health support program helps patients manage their pain and improve their well-being before and after surgery. This will be done by comparing it to the typical program that is available for people who undergo total joint

surgery. You will be randomly placed either into Lucid Lane's program or the standard program available at the VA.

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

If you decide to participate, you will be randomly assigned to either the Lucid Lane program, which will involve working with a mental health therapist from Lucid Lane, or to the standard program, which will involve the standard of care treatment that you would normally receive including a Surgery Preparedness class. Individuals from both these groups will be asked to respond to surveys about their care and well-being. You will have a fifty percent chance of being assigned to either Lucid Lane program or the standard program.

The research will last for a different amount of time for each participant.

- If you are randomly placed into the Lucid Lane program, the research will begin 4 weeks before your surgery, continue 4 weeks after your surgery, and then you will have a 6 month follow-up.
- If you are randomly placed into the standard program, the research will begin a few days before your surgery, continue 4 weeks after your surgery, and then you will have a 6 month follow-up.

Here are the things you will asked to do during the time you are in the research study:

- You will be asked to do almost the same things regardless of which program you are randomly placed into:
    - If you are placed into the Lucid Lane program, you will be asked to work with a licensed mental health therapist who is also Lucid Lane certified for 1 hour every week, as scheduled, for 4 weeks before your surgery, and then for 4 weeks after your surgery. The mental health therapist will be personalized to your needs and dedicated to you. If you would like to, you can also communicate with the mental health therapist daily as needed, but it is not a required part of this study. You can also join weekly group sessions with other patients, but it is not a required part of this study. During this time, you will be asked to also respond to surveys about your pain, general health, emotional well-being, and satisfaction with the program. For the 6 month follow-up, you will be asked to respond to similar surveys.
    - If you are placed into the standard program, you will be asked to attend the VA's surgery preparedness course prior to your surgery, and then the standard program after your surgery for 4 weeks. During this time, you will be asked to also respond to surveys about your pain, general health, emotional well-being, and satisfaction with the program. For the 6 month follow-up, you will be asked to respond to similar surveys.

What are my responsibilities if I take part in this research?

Regardless of which group you are in, your commitment is 1 hour a week, as scheduled. For patients who are in the Lucid Lane group, patients can communicate with licensed mental health therapists daily as needed, but you do not have to. You can also join weekly group sessions, but you do not have to. You will submit a weekly survey that asks you about your well-being and health. Questions will include asking about how anxious or sad you may be feeling, how much pain you're in, how much you can move around and do your regular routine, and any symptoms you may have. You will also be asked questions on your thoughts about being in the Lucid Lane program or the standard VA program.

What are the possible risks or discomforts?

Lucid Lane uses psychotherapy and behavioral tools that can reduce pain, anxiety, and improve mood. There are potential risks for any type of psychotherapy. Therapy is often about making changes or about looking at yourself differently. This can make some people uncomfortable. As people first start thinking about their own feelings and emotions, they may initially feel worse as the therapy progresses. In rare cases, psychotherapy may even trigger some people to have thoughts about wanting to hurt themselves or end their lives. When this happens, licensed mental health therapists are trained to help you understand and cope with these feelings safely and can change the therapy to be more supportive until you are feeling stronger. It is always important that you tell your mental health therapist if you are having any frightening or dangerous thoughts or feelings, or if you are considering harming yourself or someone else.

We conduct our therapy remotely, which means therapy is not conducted in-person, using telehealth software that has been approved by the Health Insurance Portability and Accountability Act (or HIPAA). What this means is that we conduct therapy sessions following the rules set by telehealth laws protecting your privacy as a patient and participant. However, there are potential risks to your privacy that exist with any telehealth visits.

Will I benefit from the study?

This study may help you learn therapy techniques that can reduce pain. Some of the therapies we use have also been shown to reduce reliance on opioid pain medications, which can be helpful considering the major side effects of opioids. Therapy can also improve mood and reduce feelings of depression and anxiety. We cannot promise any benefits to you or others from your taking part in this research.

What are my alternatives to being in this study?

Your alternative to participating in this research study is to not participate.

Will I get paid?

Participants will receive $10.50 for participation at each major time point (30 days, 90 days, 180 days). For participation in at least 80% of the study, participants will receive an additional $10.50. In total, participants who meet these milestones can expect to receive up to $42.

You may need to provide your social security number to receive payment.

Will I have to pay anything?

There will be no costs to you for any of the treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

Do I have to be in this study?

Participation in research is completely voluntary. You can decide to participate or not to participate. A decision not to participate will not result in any penalty or loss of benefits that you may be entitled.

Can I change my mind later and stop being in this study?

You can choose whether or not you want to be in the study, and you can withdraw your consent and stop participating at any time. Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled. That means you can leave the research at any time it will not be held against you.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Here are some possible reasons for removing you from the study:

- If you experience any adverse event(s) that the clinical team considers to be too risky to continue with the study. Some examples of adverse event(s) include:
  - requires inpatient hospitalization or prolongation of existing hospitalization
  - results in persistent or significant disability/incapacity
  - is a congenital anomaly/birth defect; or
  - requires medical or surgical intervention to prevent permanent impairment or damage.
- If you repeatedly miss scheduled sessions with your mental health therapist. In this case, the clinical coordinator will decide whether to continue the program for you, if the clinical protocol needs to be changed for you, or if you should transition or move to a different mental health therapist or program at Lucid Lane.
- If you and your health coach do not agree to clinical recommendations, the treatment will be discontinued and considered against advice. You could be removed from the study, and no further clinical action will be taken.

Who is funding this study?

This research is being funded by Lucid Lane, Inc.

Will my information be protected from the public?

We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Identifiers might be removed from identifiable private information, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

How will my health information be used in the study?
Any information that you provide to us in connection to this research study and that can identify you will stay confidential. We will use all efforts to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. For example, we will use a special number, which will be connected to your name, to represent your research records. However, we cannot promise complete secrecy. The project's research records may be examined and reviewed by the departments at the VA Palo Alto who are responsible for making sure all research conducted at the VA Palo Alto are meeting federal guidelines and keeping patients safe. Also, absolute confidentiality cannot be guaranteed in the event that we discover abuse, neglect, or a reportable disease, as we are required by law to let the appropriate authorities know about this and research documents are not protected from subpoena.

Any information that you provide as a part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

We will store the information we collect from you on a private computer server for at least 3 years. This will be password-protected, and data will be encrypted. Only people who are a part of the direct research team will have immediate access to this information. The reason we keep the information is so we can publish the results of this research and share what we learned with others. We want to assure you that when we publish and share the results, we will keep your name and other identifying information confidential.

The sponsor, monitors, auditors, the IRB, 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.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

What Personal Health Information Will Be Used or Shared?
The following health information, linked to you by your *name, SSN, and date of birth,* will be used for this research:

- Medical history and physical examination information
- Progress notes
- Operative reports, only limited to the type of total joint procedure being done
- Survey/Questionnaire responses
- Mental health (not psychotherapy) notes
- Psychological test results
- Drug abuse Information
- Alcoholism or alcohol use information
- Billing records
- Other: your opioid painkiller usage, dose, and refill information

Who May Use or Share Your Health Information?

By signing this document, you allow the following individuals and entities to obtain, use and share your health information for this research study:

- The Principal Investigator, Dr. Kyle Harrison, and members of the VA research team.
- Departments within the VA Health Care System responsible for the oversight, administration, or conduct of research.
- The Stanford University Administrative Panel on Human Subjects in Medical Research and other Stanford University Officials responsible for the oversight, administration, or conduct of research.

Who May Receive and Use Your Health Information?

The investigators may share your health information with the following individuals as part of this research study.

- Lucid Lane, Inc. (study sponsor)

- The Palo Alto Veterans Institute for Research (PAVIR), who administers the funding for this project, and any agents or outside entities hired by PAVIR to assist them in carrying out their responsibilities
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Other outside individuals or entities hired by the VA Palo Alto Health Care System to do certain work in support of the VA Health Care System

We will protect your health information as required by all laws, however health information shared with others may no longer be protected by Federal laws or regulations and might be shared by the parties above.

Do I have to sign this form?

No. Signing this form is voluntary. The VA may not condition treatment, payment, enrollment or eligibility for benefits based on signing this form. If you decide not to sign the form, you will not be able to take part in this study.

If I sign now, can I decide later not to continue in the study?

Yes. You are free to take back your permission and stop being in the study. The investigators will not collect any more information about you after you take back your permission, but they can continue to use your information that was collected before you took back your permission.

Your request to take back your permission must be done in writing. Either give your written request to the investigator or send it by mail to: Dr. Kyle Harrison, 3801 Miranda Avenue, Mail Code: 112A, Palo Alto, CA 94304

Does My Permission for the use my Personal Health Information Expire?

Yes. Your information cannot be used forever. Your permission related to the use and sharing of your identifiable health information expires 6 years

after the research study is completed. However, your deidentified health information can continue being used for research purposes.

HIPAA regulations require you to give separate written permission (signature) for the use of your protected health information.

_____ _____

Signature of Participant Date

What happens if I think I've been hurt by being in this study?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence. You should contact the Principal Investigator if you feel you have been hurt by being a part of this study.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Dr. Kyle Harrison at (650) 493-5000 x65638. You should also contact him at any time if you feel you have been hurt by being a part of this study.

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Will this study be registered with ClinicalTrials.gov?

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.

What are my rights if I take part in this study?

You have the right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

_____ _____

Signature of Participant Date

_____

Print Name of Participant

Person Obtaining Consent:

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent

HIPAA regulations require the participant to give separate written permission (signature) for the use of their protected health information.

Person Obtaining Consent HIPAA Authorization confirmation:

☐ Confirm the participant signed the VA HIPAA Authorization section of this consent form