Cover Letter

Title: Effectiveness of a Patient Centered Mobile Engagement Tool after Total Joint Arthroplasty

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RUSH

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Title of Study: Effectiveness of a Patient Centered Mobile Engagement Tool after Total Joint Arthroplasty

Sponsor: Department of Orthopedics

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions. The study doctor or staff will try their best to answer them. Once the study has been explained and all your questions have been answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before the study commences, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are over the age of 18 and will undergo total hip arthroplasty (THA) or total knee arthroplasty (TKA). This study investigates the potential benefits of a smartphone based postoperative text-messaging program that sends instructional messages and videos to you during the first six weeks after your surgery to potentially enhance your recovery from surgery.

What is the purpose of this study?

The purpose of this study is to investigate a postoperative text messaging program that delivers automated messages to your smart phone that are diagnosis and treatment specific at the most critical time points of your care. The messages are short and succinct

and are packaged with professional grade instruction videos for your home exercises. We have designed the content to be instructive and delivered to you at the appropriate time. The instructional videos will demonstrate the proper home exercises to come and offer other recovery tips. We are interested in the relationship between this type of electronic postoperative communication and success after surgery, specifically in regards to your knee range of motion and satisfaction. We will also be looking at how this affects the number of phone calls and emails to the surgeon's office.

How many study subjects are expected to take part in the study?

One hundred and fifty patients scheduled to undergo a total knee arthroplasty or total hip arthroplasty will be recruited and randomized to utilize the sophisticated mobile postoperative text-messaging program (treatment group) or standard paper instructions (control group).

What will you be asked to do?

If you agree to be in this study, we will obtain your cell phone number and enroll you in the postoperative text-messaging program. You will then begin to receive anywhere between one to four text messages per day with relevant information based on your specific surgery. The content of the messages will vary depending on the stage of your recovery. Initially, the messages will be about recovering from anesthesia and immediate postoperative care and then will transition to home exercises and ways to maximize your outcome after surgery. The messages will be "one way messages", meaning that the information is delivered to you but you will not be able to respond to the messages. We will evaluate your range of motion at your postoperative visits for the first 6 weeks after surgery. Additionally, any information told to you by your doctor should always override the information delivered in these messages. You will be asked to complete a short survey at the end of the study to provide feedback on this type of electronic program. It is anticipated that your participation in the study will not require additional time and energy but will require the possession of a smartphone that is able to receive SMS messages that include links to Internet instructional videos. Standard text messaging rates apply. Your cell phone number will not be distributed to any additional third parties.

How long will you be in the study?

The duration of your participation in the study will last until your 6th week postoperative visit. You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed in the study, your disease becomes worse, you are unable to take the treatment as directed, or the study is canceled.

What are the possible risks of the study?

The text-messaging program is standardized and a large cohort of patients who have had the same surgery as you will also be participating in the study. Each patient recovers from surgery in a unique patient-specific manner. Therefore, there may be a time when you receive a message that is not perfectly applicable to your recovery. This is potentially a risk of participating in this study. However, we do not expect this type of communication

error to negatively affect your recovery if it should occur. We do not anticipate any risks to you participating in this study other than those encountered in day-to-day life.

Are there any anticipated pregnancy risks?
There are no additional risks to pregnant women participating in this study.

Are there benefits to taking part in the study?
There is no direct benefit to you for their participation in this study. You may find that the text messages are a more convenient way to receive information related to your surgery or you may not. The study aims to determine if participation in this type of postoperative electronic communication enhances our ability to deliver meaningful information to patients after surgery and improve patient outcomes.

What other options are there?
The alternative to participation in this study is not to participate. Patients who decline to participate will proceed in the standard fashion. Your surgical care will not be jeopardized in any way and you will still receive the customary postoperative instructions. You will return to the office for postoperative follow-up per the rehab protocol for the specific procedure performed.

What about confidentiality of your information?
Throughout the text-messaging program you will not receive any messages that include your protected healthcare information. The messages will be individualized based on the type of surgery you completed but will not include your name or any other identifying information. Your cellular telephone number will not be shared with any other third party providers unless you give permission for this use.

Records of participation in this research study will be maintained and kept confidential as required by law. Only information necessary for the study will be collected. Study files will be kept with access limited to research staff. All data files will be kept on a password-protected computer. Your identity will not be revealed on any report, publication, or at scientific meetings.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

In order to conduct the study, the study doctor, will use and share personal health information about you with professional colleagues. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research. This will not be shared with any third parties.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

Standard text messaging and data costs will be the financial responsibility of the patient. In addition, all costs that are part of your usual medical care, such as the total joint arthroplasty, will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study. Preoperative and postoperative office visits will be billed to your insurance, as they are routine office visits.

Will you be compensated or paid?

You will not be offered compensation for your participation in this study. Your participation in this research study may contribute to the development of commercial products from which the sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit. In addition, you are entering into a Nondisclosure Agreement for the purpose of preventing the unauthorized disclosure of Confidential Information as included in this study. You agree to enter into a confidential relationship with respect to the disclosure of certain proprietary and confidential information as included in this type of electronic communication.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries, which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact your surgeon's office (with the number they have provided). If you have questions about the text messaging content please contact **orthofollowup@RushOrtho.com**. Please ask any questions you have now. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

Please also note that Drs. Campbell and Louie (the investigators on this study) have a financial interest, are inventors of the text messaging system and are Co-Founders of StreaMD Corporation. StreaMD owns the technology (the text messaging system) used in this study. The financial value of this investment might be affected by the results of this study. This means that Drs. Campbell and Louie could gain or lose money depending on the results of this study.

SIGNATURE BY THE SUBJECT

Name of Subject	Signature of Subject	Date of Signature

CELL PHONE #

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature