

PROVIDER CONSENT

(Control Group)

Study Title: Optimizing Acute Post-Operative Dental Pain Management Using New Health Information Technology

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This is a research study intended to optimize the management of your patients' postoperative dental pain using the FollowApp.Care text messaging system that periodically assesses pain in the first seven days following their dental procedures and allows you to securely communicate with them regarding their pain experience.

Members of the study team will explain this study to you. Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a dental provider at either UCSF Dental Center or Willamette Dental Group.

IRB NUMBER: 18-25477 IRB APPROVAL DATE: 12/27/2019 ity of California IRB EXPIRATION DATE: 05/06/2020

Why is this study being done?

The purpose of this study is to optimize the quality of dental pain monitoring and management by implementing mobile phone technology to monitor patients' pain during the critical acute post-operative phase. We believe that by actively tracking these symptoms using mobile phones, we will promptly identify the patients with sub-optimal pain experiences and offer providers an opportunity to intervene (e.g. modify analgesic prescriptions), thereby eliminating needless suffering, reducing the occurrence and/or severity of post-op complications, and enhancing the overall care experience. Our ultimate goal is to achieve the quadruple aim: improve patient experience, improve patient outcomes, improve physician experience and reduce per capita costs.

This research is funded by the Agency for Healthcare Research and Quality (AHRQ). The study researchers have no conflicts of interest to disclose.

How many people will take part in this study?

Up to 116 providers across all study sites will be participating in this study.

What will happen if I take part in this research study?

If you agree to take part in this study, the following procedures will occur:

- You have been randomized to the Control Group
- You will be invited to participate in a 1-hour training session where you will be provided with details of the study protocol, including the specified eligible CDT codes, reminders of current evidence-based analgesic prescription recommendations and patient education brochures/FAQs.
- You and your delegates (and/or the study team staff at UCSF) will invite patients to participate in the study and hand out the information sheet. Those patients interested in participating will be asked to register their mobile phone number on FollowApp.Care (a mobile phone text messaging system). The first text message will contain a link to the information sheet regarding consent. Clicking the link to advance the survey will serve as implied consent.
- All clinical care procedures will continue as normal and patients will be provided with routine post-op instructions and follow-up care.
- On Day 7, your patients will be invited to respond to a questionnaire asking about their postoperative pain experience.

How long will I be in the study?

This study is expected to last for a period of 12 months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

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What side effects or risks can I expect from being in the study?

The study was designed to ensure that participants are exposed to minimal risks/discomforts. The study team will maintain strict privacy and data confidentiality. For more information about risks and side effects, please ask one of the researchers.

Are there benefits to taking part in the study?

The information that you provide may help improve our understanding of the utility of text messaging systems for optimizing the quality of post-op pain management. It will allow the developers to improve the system and adapt it to better fit the needs of dental professionals. You will also have the added benefit of being able to chat with your patients using the secure messaging feature of FollowApp.Care, thereby allowing you to make recommendations on how to handle their pain at a much earlier timeframe and at more regular intervals in order to prevent unnecessary suffering.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still practice at your institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Agency for Healthcare Research and Quality
- Representatives of the University of California

Will I be paid for taking part in this study?

You will not be paid for taking part in this study

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can practice at your institution as you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact Elsbeth Kalenderian, DDS, MPH, PhD at 415-502-6504 or at Elsbeth.Kalenderian@ucsf.edu



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If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

| If you wish to participate in this study, you should sign below. | |
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| | |
| Date | Participant's Signature for Consent |
| Date | Person Obtaining Consent |