TITLE OF RESEARCH: Reducing Prescription Opioid Misuse: ROPEs Pilot Trial

NCT NUMBER: NCT03691948

DOCUMENT DATE: September 20, 2018

DATE UPLOADED: September 17, 2020

Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

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SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this research is to determine the feasibility of testing an online dental continuing education intervention targeting enhancing dentists' knowledge and implementation of risk mitigation strategies when prescribing opioid analgesics to their patients.

Once screened for eligibility, participants will complete an online pre-test questionnaire, be randomized to complete either the continuing dental education intervention or an attention control condition, and will complete an online post-test questionnaire. Participants will be contacted one-month later and will be asked to complete an online questionnaire. Completion of the pre-test, post-test, and one-month follow-up will take less than 15 minutes each. Completion of the intervention (or attention control condition) will take between 60 and 80 minutes. Total study duration is about 2 hours across two time-points.

Although not guaranteed, participation in this study may improve your knowledge regarding the risks associated with opioid prescribing, as well as tools to decrease those risks associated with prescribing opioids to your patients for acute pain management. The greatest risk of this study is the possible loss of confidentiality of your responses to questionnaire items. You do not have to participate in this study and may terminate your participation at any time.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

This is a randomized controlled pilot trial to establish methodological feasibility and determine whether a web-based, continuing dental education intervention regarding opioid prescribing risk mitigation strategies - consistent with American Dental Association guidelines - produces pre-to-post changes in knowledge, motivation, and behavioral skills pertaining to the use of risk mitigation strategies when prescribing opioids in dental practice.

Please read this consent form carefully and take your time making your decision. As you read this consent form, you may ask the investigator to explain any words or information that you do not clearly understand. You are being asked to participate in this study

because you are a practicing dentist or resident in a Dental College. The National Institutes of Health/National Institute on Drug Abuse sponsors the study. The investigator in charge of this study at MUSC is Jenna L. McCauley, PhD. Portions of Dr. McCauley and her research team's salaries will be paid by this grant. The study is being done at one site. Approximately 60 people will take part in this study.

B. PROCEDURES

The current study involves completion of a self-report pre-test, randomization to complete the dental intervention or attention control intervention, completion of a self-report post-test (immediately following intervention/control completion), and completion of 1-month self-report follow-up assessment.

If you agree to be in this study, the following will happen:

1. You will respond to the study email (ropesadmin@musc.edu) confirming that you meet eligibility criteria for participation.
2. You will then be emailed a web-link and log-in credentials unique to you and asked to follow the instructions to access the secure web-platform.
3. Following log-in to the site, you will complete a pre-test questionnaire.
4. After completing the pre-test questionnaire, you will be randomly assigned to complete either the continuing dental education intervention or the attention control condition.
5. You will then be directed to complete the post-test questionnaire. We ask that you complete the pre-test, intervention/control, and post-test in one sitting if possible, and in no more than 2 weeks if completed over multiple sittings.
6. You will be emailed approximately one-month later and asked to complete an online (REDCap) follow-up questionnaire.

C. DURATION

Participation in the study will take about 2 hours during your initial participation (online) and approximately 15 minutes during your second participation (online) over a period of approximately 1 month.

D. RISKS AND DISCOMFORTS

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. We will implement several previously successful procedures to keep data confidential. Participants will not use their names to log onto the website, nor

will they provide any other form of identifying information during their completion of the ROPEs intervention/control. Further, de-identified (log-in coded) data will be collected and stored via a secure server. For participants completing the ROPEs data platform assessments, primary data will be housed on a secure MUSC server using Secure Sockets Layer 128-bit encryption. Further, assessment (pre-intervention, post-intervention, one-month follow-up) data for this study will be stored electronically in de-identified manner using participant identification numbers (USERID). Only members of the study team will have access to the linkage document associating USERID with identifying and contact information. Identifying information will be used only for the purposes of participant reimbursement, linkage of assessment data from various time-points, and contact for follow-up. Participants' identifying information and linkage to data USERID will be stored on a secure MUSC server in a password protected file and will be destroyed at the conclusion of the study.

There is also a very low-probability risk that you may become offended by questions regarding your experiences and opinions around opioid prescribing. If this happens, you are free to terminate participation at any time or not respond to specific items on the questionnaires.

E. MEDICAL RECORDS

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

The potential benefit to you is that the continuing dental intervention you complete may prove to be more effective than the other study condition and result in knowledge gained regarding (a) standard prescribing practices of dentists statewide; (b) the safe and appropriate use, storage, and disposal of opioid analgesic medications; and (c) available opioid prescribing risk mitigation tools, although this cannot be guaranteed.

If you are in the group that receives the intervention and it is successful, you may benefit from participating in the study; however, this cannot be guaranteed.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 for completing the pre-test questionnaire, $50 for completing the post-test questionnaire, and $100 for completing the one-month follow-up questionnaire. If you do not complete the study, you will receive payment for the components that you completed prior to study withdrawal. Payment will be in the form of an Amazon gift code, emailed to the participant within 10 business days of completing the given assessment.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF STUDY RESULTS

All data will be analyzed and reported in an aggregate, de-identified manner. Key results will be posted in compliant manner on http://www.clinicaltrials.gov. Findings will also be disseminated via peer-reviewed publications, professional presentations, and to practice groups (upon request). Individual participants may request a report of aggregate findings from the PI directly by emailing ropesadmin@musc.edu to request a report of aggregate findings following the close of the study.

L. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

M. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

N. CLINICAL TRIALS.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.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Jenna McCauley at (843)***

792-3922. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.