My Surgical Success: A Randomized Controlled Pilot Study of a Pre-surgical Psychological Intervention

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1. PURPOSE OF THE STUDY

a. Brief Summary

The primary purpose of this study is to determine the feasibility of delivering a psychoeducational pain coping skills video to patients pre-operatively. We also aim to characterize the response to the video, in terms of participant satisfaction, perceived usefulness, and likelihood to use the skills learned. We will follow participants post-surgically to determine the impact of the video on post-surgical distress, pain, and use of pain medications. The proposed research will advance our understanding regarding the feasibility and effectiveness of remote psychoeducation interventions in terms of impact on post-surgical outcomes

b. Objectives

We hope to learn how a brief psychoeducational video intervention provided pre-operatively may affect pain, mood, and opioid use after surgery and throughout recovery. Completion of this study will ideally demonstrate good feasibility and acceptability of this video intervention—one that is viewed in one's own home. This study is our first step in broadening access to low-cost, efficiently delivered specialized pain psychology care. If successful, our study will tell us which patients are most receptive to this type of intervention, and thus will inform future studies. Additionally the proposed study will provide preliminary data for a future randomized controlled study to compare the effectiveness of the pain psychology video intervention to a general wellness video.

c. Rationale for Research in Humans

The aims of this study include examining psychological factors and examining the efficacy of a psychoeducational intervention on surgical patients. There are no adequate animal models to test the complex psychosocial dimensions that appear so important in the persistence of pain in people

2. STUDY PROCEDURES

a. Procedures

I. Recruitment:
Surgeons, anesthesiologists, and the pre-operative clinic will refer interested patients and veterans. Patients will receive a form at their normal pre-operative clinic appointment asking whether they'd like to receive more information about potential research studies, or will be asked

by their regular clinical provider or intake staff whether they are interested in speaking with the research team. Additionally, patients who inquire based on word of mouth knowledge, or based on approved advertisements will be screened. A member of the research team will then contact them via phone to discuss the study and perform initial screening. In-person screening can be an alternative to the phone screen, should individuals express interest to their provider on the day of their appointment and a researcher is available to speak with them at that time. Patients may also receive an email following their clinic appointment with a link to the HIPAA-compliant, secure REDCap study screening form.

II. Screening and consent:
Those indicating interest in participating will be contacted to describe the study and will be asked preliminary eligibility questions either at their clinic visit or later by phone or through an emailed link to the HIPAA-compliant, secure REDCap screening form. After confirming eligibility, we will obtain informed consent (HIPAA embedded for Stanford participants, and with additional HIPAA form for VA participants). Consent may be obtained over the phone if an in-person visit is not possible. Patients who are spoken with over the phone, will have a consent form mailed or faxed to them, or may schedule a visit to the lab if requested. The researcher will then go through the entire consent process over the phone with the patient. Eligibility and signatures will be verified upon receipt by the research team if the consent process was conducted over the phone. Alternatively, the research team may provide the patient with a link to a video that covers the content of the consent form, which can be viewed at the patient's convenience. If the patient opts to view the video, the research team has been trained to confirm understanding of the elements of consent with the participant (via phone, email, or other correspondence) before the research staff signs the consent form and verifies informed consent.

To reduce Stanford participant burden, participants will have the option to document their consent to participate via e-signature, utilizing REDCap- a secure, HIPAA compliant, online system that is 21 CFR Part 11 compliant. The research team member obtaining consent will then provide his/her e-signature documenting and verifying informed consent. The research team has been trained to not provide his/her e-signature on the document until speaking with and confirming the participant has understood all the elements of informed consent. If the participant's electronic signature occurs at a time when the person obtaining consent is out of the office, there might be a signature date difference between the e-signature dates of the participant and the person obtaining consent. E-consenting will not be performed with VA participants due to technical difficulties.

Alternatively, if the participant does not have access to the internet or wishes not to provide an e-signature then the participant may provide his/her signature on a hard copy document then fax or mail the consent form to the research team. The research team will not seek an original signature for consent forms received via fax or mail but will retain and sign the copy received. Consent forms that are mailed to the research team will likely have a different signature date as the research team will review and sign upon receipt. Consent may also be obtained in-person, if requested, by either scheduling a visit to our research offices or during the patient's clinic visit if the research team is available at the patient's clinic visit.

Those not wishing to participate will be asked for permission for the study team to collect de-identified data from their medical record or directly from them for the purposes of baseline comparisons between patients who enroll and those that do not. After enrolling, participants may

receive a thank you email from the study team.

III. Pre-surgical assessment and procedures:

To help ensure relatively equal numbers in both groups, an 8:2 of video group to printed information group randomization scheme may be used when group numbers are unbalanced and a 1:1 randomization scheme of video group to printed information group will be used when the group numbers are balanced. Participants assigned to the printed information group who have visual impairment and difficulty reading print material will be reassigned to the video group. All participants will be asked to provide demographic information, as well as fill out a variety of self-reported measures assessing mood, pain, cognitive and emotional responses to pain, catastrophizing, self-efficacy, and medications. These measures will be provided via a secure, HIPAA compliant, online system such as REDCap or Qualtrics. Alternatively, participants may receive those measures via regular mail, should they choose to do so. The survey may sometimes include questions monitoring depression and suicidal ideation. Should the surveys include such questions, responses will be monitored on a weekly basis for completeness and trigger questions such as depression and suicidal ideation. Patients exhibiting signs of depression or endorsing suicidality will be referred for counseling or immediate assessment as described in section 9a.

Prior to surgery, participants who have been randomized to the printed information group will receive patient handouts (either printed or a web link) about health and nutrition that are relevant for people recovering from surgery. Handouts may be selected from the VA "move" program that was designed by the VHA National Center for Health Promotion & Disease Prevention, from other Stanford handouts that are given to patients as standard of care, or from the National Comprehensive Cancer Network, depending on the specific participant sub-population. Participants randomized to the video group will be provided with a link via a secure, HIPAA compliant, online system such as REDCap, to a coping skills psychoeducational video. The video content includes instruction by Dr. Beth Darnall, a pain psychologist at the Stanford Pain Management Center, who teaches the viewer about the relationship between stress, pain, and catastrophizing and provides instruction and skills to reduce catastrophizing, decrease stress, and increase relaxation. Patients will be instructed to watch the video and participate in a post-video questionnaire to gain feedback on the video and to ensure the patient participated in watching and has understood the content of the video.

IV. Follow-up:

A. Post-video follow-up:

Participants may be contacted, after viewing the coping skills video, by Dr. Beth Darnall or the research staff to provide additional support and further instructions or clarification on the application or practice of skills described in the video. Participants are also encouraged in the video to reach out to the instructor, Dr. Beth Darnall, with any questions or for assistance.

B. Pre-surgery follow-up: Prior to or on the day of surgery, participants may also be contacted by phone to collect further baseline information.

C. Post-surgical follow-up:

Following surgery, all study participants will be followed as described below.

1) Additional assessments: Patients may also be asked to complete over the phone or online assessments (using a secure, HIPAA compliant, online survey system) of mood, pain, catastrophizing, skills use, medication use, and pain self-efficacy after surgery at 2,4,8,& 12 weeks post-surgery. Alternatively, participants may receive those measures via regular mail, should they choose to do so. Follow-up may be extended or modified, at the discretion of the investigator, beyond 3 months from the date of surgery to accommodate patient's scheduling and completion of the assessments. All questionnaires that may be used are attached in section 16.

2) Additional follow-up:
A study team member may also access the patient's medical record to obtain important study related information including surgical information, anesthetic information, medical history, medication use, physical exams, and pain-related information for the purpose of follow-up throughout the study.

After study completion, participants may continue to be contacted at 6 month intervals for up to 10 years to assess mood, pain, cognitive and emotional responses to pain, current medical status, and medications, unless the patient prefers not to be contacted at these additional time points or has requested to no longer be contacted by the research team.

Participants may also be mailed a thank you and/or newsletter with updates on this study and other studies in our lab; This is a standard newsletter template used throughout the lab to update participants on study progress, website and contact information, and general information on the lab and personnel. The newsletter content will vary depending upon date and will be modified accordingly at each date.

b. Procedure Risks

Risk is minimal. All members of the study team receive extensive training on appropriate research conduct and data security

c. Use of Deception in the Study

NA. No deception will be used in this study.

d. Use of Audio and Video Recordings

NA

e. Alternative Procedures or Courses of Treatment

Standard of care is not being withheld. The alternative is to not participate

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study

Not relevant. No treatments are being withheld due to participation in the study

g. Study Endpoint(s)

The study will end when all participants have completed research procedures.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

The proposed study aims to investigate response to a 2 hour psychoeducation video that is treatment for pain catastrophizing. Pain catastrophizing is foremost among the psychological factors that worsen pain and contribute to pain chronicity. Pain catastrophizing is defined as persistent negative cognitive and emotional responses to actual or anticipated pain [1]. In part, pain catastrophizing contributes to a cycle of futility in the medical treatment realm because it undermines behavioral and medical treatments [2-9].

Across chronic pain conditions, pain catastrophizing has been associated with an array of negative phenomena including greater pain intensity [10-15], affective distress [6], muscle and joint tenderness [11], muscular tension at rest [16], pain-related disability [11, 12, 14, 17-19], poor response to various pain treatments [6, 16, 20] including surgery [14, 21], and to greater use [21] and misuse of opioids [22].

Pain catastrophizing is also harmful in the context of acute pain and even for individuals who are pain-free because pain catastrophizing is associated with increased risk for developing chronic pain. In combination, data from multiple studies show that pain catastrophizing is detrimental, and that early treatment for pain catastrophizing may serve as chronic pain prophylaxis.

Standard PC treatment involves multiple sessions of cognitive behavioral therapy that pose substantial burden to patients in terms of cost, travel, and time. Often, these burdens stand as barriers to care, thus leaving pain catastrophizing untreated. To provide efficient, low-cost treatment, we developed at Stanford a single-session, 2-hour class that solely treats PC ('From Catastrophizing to Recovery'; FCR). We conducted an uncontrolled prospective pilot study to test the FCR class intervention in 76 patients with chronic pain in the Stanford Pain Management Center [23]. The Pain Catastrophizing Scale was administered at class baseline and post-class at 2 weeks and 4 weeks. Feasibility was demonstrated, and anonymous post-class surveys indicated excellent ratings for participant satisfaction with the class, usefulness of the information presented, ease of understanding the material presented, and likelihood to use the skills and information learned. Participants had significantly reduced PC at both post- class time points ($p<.0001$) and large effect sizes were found (2 week Cohen's $d = 0.85$ and 4 week $d = 1.15$). Thus, our preliminary data suggest that the in-person class format of FCR is acceptable and effective treatment for PC [23]. In the proposed study we aim to determine the feasibility and utility of the video format of FCR.

b. Findings from Past Animal Experiments

NA

4. RADIOISOTOPES OR RADIATION MACHINES

a. Standard of Care (SOC) Procedures

Identify Week/Month of Study	Name of Exam	Identify if SOC or Research
NA	NA	NA

b. Radioisotopes

i. Radionuclide(s) and chemical form(s)

NA

ii. Total number of times the radioisotope and activity will be administered (mCi) and the route of administration for a typical study participant

NA

iii. If not FDA approved: dosimetry information and source documents (package insert, Medical Internal Radiation Dose [MIRD] calculation, and peer reviewed literature)

NA

c. Radiation Machines – Diagnostic Procedures

i. Examination description (well-established procedures)

NA

ii. Total number of times each procedure will be performed (typical study participant)

NA

iii. Setup and techniques to support dose modeling

NA

iv. FDA status of the machine and information on dose modeling (if procedure is not well-established)

NA

d. Radiation Machines – Therapeutic Procedures

i. Area treated, dose per fraction/number of fractions, performed as part of normal clinical management or due to research participation (well-established procedures)

NA

ii. FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions (if procedure is not well-established)

NA

5. DEVICES USED IN THE STUDY

a. Investigational Devices (Including Commercial Devices Used Off-Label)

Investigational Device 1	
Name:	NA

Description:	NA
Significant Risk? (Y/N)	NA
Rationale for Non-Significant Risk	NA
Investigational Device 2	
Name:	NA
Description:	NA
Significant Risk? (Y/N)	NA
Rationale for Non-Significant Risk	NA
Investigational Device 3	
Name:	NA
Description:	NA
Significant Risk? (Y/N)	NA
Rationale for Non-Significant Risk	NA

b. IDE-Exempt Devices

IND-Exempt Device 1	
Name:	NA
Description:	NA
IND-Exempt Device 2	
Name:	NA
Description:	NA
IND-Exempt Device 3	
Name:	NA
Description:	NA

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

a. Investigational Drugs, Biologics, Reagents, or Chemicals

Investigational Product 1	
Name:	NA
Dosage:	NA
Administration Route:	NA
Investigational Product 2	
Name:	NA
Dosage:	NA
Administration Route:	NA
Investigational Product 3	
Name:	NA
Dosage:	NA
Administration Route:	NA

b. Commercial Drugs, Biologics, Reagents, or Chemicals

Commercial Product 1

Name:	NA
Dosage:	NA
Administration Route	NA
New and different use? (Y/N)	NA
Commercial Product 2	
Name:	NA
Dosage:	NA
Administration Route	NA
New and different use? (Y/N)	NA
Commercial Product 3	
Name:	NA
Dosage:	NA
Administration Route	NA
New and different use? (Y/N)	NA

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

NA

8. PARTICIPANT POPULATION

a. Planned Enrollment

(i) In total, up to 315 participants may be enrolled.
(ii) 75 participants may be enrolled at the VA and 240 at Stanford.
(iii) Patients and veterans undergoing surgery will be recruited as we are studying a preoperative psychoeducational intervention.

b. Age, Gender, and Ethnic Background

Patients 18 years of age or older, of both genders, and all ethnic backgrounds will be recruited

c. Vulnerable Populations

NA

d. Rationale for Exclusion of Certain Populations

NA

e. Stanford Populations

We will not recruit specifically among laboratory personnel, employees, and/or students, however it is possible some may be enrolled in the study. They will undergo the same informed consent process as all other patients

f. Healthy Volunteers

NA

g. Recruitment Details

Participants will be identified from the pre-operative appointments at Stanford and at the VA hospital. They may be recruited via referrals from clinic personnel or when a member of the research team, when present at the clinic, approaches relevant patients either before or after their scheduled appointment. Patients may self-refer through responses to advertisements, or via the clinical trials website, which will be open to the general public, if the patient is scheduled to receive surgery at Stanford or the VA hospital. Recruitment will be open to all patients scheduled for an eligible surgical procedure. Patients willing to be spoken with regarding the research will be approached by a member of the research team during their appointment, or will be called by the research team to discuss the study further.

If the patient indicates they do not wish to participate in the research study, they may be asked if it is ok for us to collect some anonymous information about them so that we know how they may differ from patients who choose to participate in the study. The anonymous data collection form (attached to section 13 with waiver of documentation for consent) will be filled out by the research staff and the research staff will first inform patients on the 8 elements of consent prior to asking for the anonymous data. The informational sheet script is attached to the anonymous data collection form.

h. Eligibility Criteria

i. Inclusion Criteria

1. Age 18+
2. Undergoing a scheduled surgery
3. English speaking
4. Ability and willingness to complete study procedures including online questionnaires, assessments, and the psychoeducational video.

ii. Exclusion Criteria

1. Any conditions causing inability to complete study procedures (e.g. education, cognitive ability, mental status, medical status) or lack of access to internet and phone that would prevent participation in study procedures - at the discretion of the investigator.
2. Known Pregnancy
3. Ongoing legal action related to pain or disability claim.

i. Screening Procedures

Patients will be identified through their response to a form given to them at a pre-operative visit requesting contact information if they are interested in hearing more about the study, or through

their clinic provider requesting permission for the research team to speak with them. Further phone screening or in-person screening at the pre-operative appointment will occur to determine initial eligibility. We are seeking a limited waiver of authorization for recruitment to obtain the names, contact information, date of surgery, and eligibility information of patients prior to obtaining informed consent. No qualifying laboratory values will be obtained. After screening for eligibility, informed consent will be obtained from eligible participants.

j. Participation in Multiple Protocols

Patients will be asked whether they are participating in any other research studies. Those participating in other studies that may interfere with the procedures of this study, or pose additional risk, will be excluded.

k. Payments to Participants

Participants will not receive payment for their participation

l. Costs to Participants

There will be no costs charged to the participant.

m. Planned Duration of the Study

We anticipate completing enrollment in 2 years. However data will continue to be collected and reported intermittently over years. We plan to continue to asses patients for pain, medication use, and medical status every 6 months up to 10 years.

(i) total time for screening will be approximately 1 hour
(ii) median time of active participation is roughly 90 days
(iii) analysis of participant data will take several months

9. RISKS

a. Potential Risks

i. Investigational devices

NA

ii. Investigational drugs

NA

iii. Commercially available drugs, biologics, reagents or chemicals

NA

iv. Procedures

NA

v. Radioisotopes/radiation-producing machines

NA

vi. Physical well-being

NA

vii. Psychological well-being

There are no known risks to completing the study questionnaires. There is a chance some patients may feel uncomfortable answering certain questions and they have the option to refuse to answer certain questions. We may administer the BDI or PROMIS Depression to participants and their responses may indicate suicidality and depression. Patients exhibiting signs of depression will be provided with a referral list of mental health providers. Patients endorsing suicidality by answering 2 or greater on the BDI suicidality question will be offered immediate assessment.

viii. Economic well-being

NA

ix. Social well-being

NA

x. Overall evaluation of risk

LOW

b. International Research Risk Procedures

NA

c. Procedures to Minimize Risk

Risks of discomfort due to the questionnaires will be minimized by allowing the participant to refuse to answer particular questions.

PHI will be kept in a secure location accessible only to study staff. Electronic data will be kept on a password protected and encrypted computer accessible only to study staff. All research personnel are trained in confidentiality and protection of PHI.

d. Study Conclusion

The experiment will terminate when all participants have completed participation. If an individual participant chooses to withdraw, or the researcher determines it is unsafe or scientifically invalid for him/her to continue, his/her participation will end. We do not anticipate the study will directly result in adverse effects to the participants but we have physicians on staff should a medical intervention become necessary in the event of an adverse event.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

NA

ii. Person(s) responsible for Data and Safety Monitoring

NA

iii. Frequency of DSMB meetings

NA

iv. Specific triggers or stopping rules

NA

v. DSMB Reporting

NA

vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Y

vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

Y

f. Risks to Special Populations

NA

10. BENEFITS

We cannot guarantee personal benefit to any participant. Participants in the observational study will receive no direct benefit for their participation. However, participants in the intervention arm may experience a reduction in pain catastrophizing, as a result of viewing the educational video. Coping skills learned from the video may aid recovery from surgery.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.