Study Title: Positive Affect as a Source of Resilience for Adults in Chronic Pain
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WEILL CORNELL MEDICINE

Oral Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title:	Positive Affect as a Source of Resilience for Adults in Chronic Pain
Research Project #:	20-04021881
Principal Investigators:	Cary Reid, MD, PhD (Weill Cornell Medicine) Anthony D. Ong, PhD (Cornell University)
Subject Name or number:	

INSTITUTIONS: **Weill Cornell Medicine**
Cornell University

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you were identified as someone that is over 50 years of age or older and has fibromyalgia.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.
(b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others;
(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research study is being funded by National Institutes of Health. The National Institutes of Health is providing a research grant/funds for this study. Dr. Anthony Ong and Dr. Cary Reid are the primary investigators on this study.

The study will take place mostly from a location of your choosing over the internet. The initial visit will be an in-person visit at Weill Cornell Medicine/NewYork-Presbyterian or can be by phone or by video conference from a location of your choosing. Some portions of the study may take place at Weill Cornell Medicine/NewYork-Presbyterian where the investigators are members of the medical staff. Weill Cornell Medicine/NewYork-Presbyterian is neither a sponsor nor an investigator for this study.

WHY IS THE STUDY BEING DONE?

This research study aims to evaluate the feasibility and acceptability of a 6 to 8-week intervention focused on improving pain-related outcomes and increase psychological resources to cope with stress.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 150 subjects will take part in this study worldwide; all subjects will be recruited through Weill Cornell Medicine.

WHAT IS INVOLVED IN THE STUDY?

You will be "randomized" into one of two study groups: an intervention or an attentional control group.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers will choose what group you will be in. You will have an equal chance of being placed in any group.

You will be assigned to one of two groups; the study plan for each group is described below:

Group 1 – Intervention: Active intervention participants participate in a 6 to 8 week online course focused on improving pain-related outcomes and increase psychological resources to cope with stress . As part of the intervention, participants will learn and practice skills, including gratitude, savoring, and mindfulness. You will be asked to login to the website daily for 6 to 8 weeks to report your emotions and also receive some basic instruction, and these will not take longer than 90 minutes per week.

Group 2 – Attention Control: Participants in the attention control group will login to the website to complete daily emotion check-ins for 6 to 8 weeks. We predict that these daily check-ins will take about 5 minutes to complete each day.

Both Groups: All participants will complete online questionnaires at three time points; at the start of the study, immediately following the 6 to 8 weeks of intervention or attention control, and 1-month after your last daily survey on the website. These questionnaires take about 60-75 minutes to complete and may be done by phone/videoconference. Additionally, at the time of these assessments, all participants will be asked to complete one week of 5-10-minute surveys (21 total surveys at the three time points).

All participants will also complete a 15-minute survey over video conference or phone call asking for your feedback on the Bright Outcome website. With your permission, the feedback survey will be recorded (audio or video) for the purposes of evaluation and collection of data. The recording will be destroyed upon study completion. You may still participate in this study if you do not agree to be recorded.

With your permission, you will be sent automated text message reminders for upcoming assessments and/or questionnaires, through a secure, WCM-approved service. You may still participate in this study if you do not agree to receive text messages.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for 4 months. You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

We do not expect any serious consequences from suddenly withdrawing from this study. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medicine, NewYork-Presbyterian , your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

For trials of interventions, there may be risks. Some of the questions might be sensitive because we ask about chronic pain, coping, anxiety, stressful events related to chronic pain, or reflecting upon experienced negative emotions. At any point, you may skip questions you do not wish to answer or exit the questionnaires. You may also decide to stop participation at any time. At any time, you can also ask to speak to the Principal Investigator, Dr. Cary Reid, about any discomfort or questions that arise during the study. Additionally, there is a risk of loss of confidentiality when participating in this study. The research team will take every possible precaution to minimize this risk, including coding data and not linking the data collected with any personal identifiers. Study data will be kept in safe locations, both virtually (e.g., private servers and password protected files) and physically (e.g., in locked filing cabinets and offices at WCM).

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. We hope the information from this study will benefit other people now or in the future by revealing best practices in conducting a cost-effective online intervention to increase feasibility, retention, efficacy, and adherence to ongoing or future pain treatments.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medial record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medicine and NewYork-Presbyterian
- Cornell University
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medicine and NewYork-Presbyterian by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. Master lists linking participants with their interview and questionnaire data will be stored in locked file cabinets and/or as password protected documents on a secure server. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

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 website will include a summary of the results. You can search this Web site at any time.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCM researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medicine (WCM) and/or NewYork-Presbyterian (NYP) researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCM and/or NYP researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCM and/or NYP researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCM and/or NYP.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from their research that is considered protected health information (e.g. diagnoses).

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor the WCM Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with researchers at Cornell University.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCM and/or NYP researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Officer
1300 York Avenue, Box 303
New York, NY 10065
If you have questions about this, call: (212) 746-1179 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCM and/or NYP researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, you will have access to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medicine (WCM) and/or NewYork-Presbyterian (NYP) policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

WHAT ARE THE COSTS?

There are no costs to you in this study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

We are obligated to inform you about WCM's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCM or NewYork Presbyterian. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will receive compensation for participating in this study. Participants will be compensated up to $142 for completing the study over 4 months. Participants will receive $25 for each of the three study questionnaires, up to $42 ($2 per survey) for the daily 5-10-minute surveys following the study questionnaires, and $25 for the feedback survey. Activities completed during the 6-8 weeks of interaction with BrightOutcome will not be compensated.

This will be disbursed to you in the form of a ClinCard. You will receive compensation in three installments: $25 after completing the first study questionnaire, $50 after completing the second study visit ($25 each for questionnaire and feedback survey), and up to $67 at the end of the study ($25 for completing the third study questionnaire and up to $42 for the daily surveys). For the first two installments, the funds will be available to you within 5 business days after you complete the study questionnaires. For the third installment, the funds will be available to you within 5 business days after you complete the final daily survey. The ClinCard can be used as a credit or debit card. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medicine /NewYork-Presbyterian, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Cary Reid at 212-746-1378 or email him at mcr2004@med.cornell.edu. If you are calling on a Saturday or Sunday, or on a weekday before 9am or after 5pm, call the Center on Aging at 212-746-7000 and ask to be connected to the physician on call. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCM IRB Office. Direct your questions to:

Institutional Review Board at:

Address: 1300 York Avenue
Box 89
New York, New York 10065

Telephone: (646) 962-8200
Email: irb@med.cornell.edu

Consent for Research Study

Project Title: Positive Affect as a Source of Resilience for Adults in Chronic Pain (LARKSPUR Study)

Principal Investigator: Cary Reid, MD, PhD; Anthony Ong, PhD

SUBJECT'S STATEMENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I have given consent, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Reid, Dr. Ong, and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____ _____

Name of Subject Date

RECORDING CONSENT (Optional)

I voluntarily agree to be audio or videotaped during my assessment phone calls and/or video conferences.

_____ _____

Name of Subject Date

TEXT MESSAGE CONSENT (Optional)

I voluntarily agree to receive text message reminders for upcoming study activity from a secure, WCM-approved service.

_____ _____

Name of Subject Date

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____ _____

Signature of person obtaining the consent (Principal Investigator or Co-investigator) Print Name of Person Date