NCT NumberNCT06564532

Evaluative Conditioning and Relationship Satisfaction

Consent form, updated July 19, 2024

PHONE INTERVIEW/ORAL CONSENT
STUDY TITLE: *Evaluating the Efficacy of a Marital Enhancement Application*
Principal Investigator: CDR Shawna Grover

Hello/Hi, my name is _____, and I am employed at Florida State University, Department of Psychology. I'm working on a research study being conducted at Naval Medical Center Portsmouth (NMCP) and outlying clinics, in collaboration with NMCP Department of Nursing Research and Mental Health. Do you have a few minutes to discuss the study? This will take less than 10 minutes of your time and requires that you respond to some basic personal questions to identify if you meet criteria to participate in the study. You may choose to have the information e-mailed to you if this is an inconvenient time.

- If yes, continue below or send this form by e-mail.
- If no, but the potential subject is interested in participating, determine a better time to call back to discuss the study.
- If no, thank them for their time and record name of subject below.

Yes: Subject is willing to listen to study information and answer questions.

Yes: Subject is willing to participate but desires e-mailed information.
E-mail address: _____
(Oral consent not read to subject)

Date e-mailed: _____
(DDMMMYYYY)
PI/AI initials: _____ _____
(DDMMMYYYY)

No: Subject is interested but doesn't have time to listen.
Call back on date: _____
(DDMMMYYYY)

No: Thank them for their time.

Printed Name of Subject:

_____

The purpose of this study is to evaluate a new computer program that may improve

marital sentiments in military service members and their spouse. We estimate that approximately 500 active duty members and their spouse (500 couples) for a total of 1000 participants may take part in this research study over a period of two years and are inviting you to take part because you responded to one of our solicitations, you are an active duty member or spouse, you are legally married, and you are 18-89 years of age.

If you agree to be in this study, we would ask you to do the following things:

(1) Complete an initial intake session that will occur in two parts and take approximately one hour total. The first half of this session will be a 30-minute online MS Teams session with your spouse. During this initial MS Teams meeting, we go over the particulars of the study and your rights as a participant, take several screenshots of you and your partner that will be used for study purposes and subsequently destroyed, and engage in a private discussion with your partner aimed at resolving a marital problem of your choosing. This discussion will be recorded, used for the purposes of the study, and subsequently destroyed. The second half of the intake session will involve each of you independently completing some questionnaires online. Some of the questions ask about sensitive/personal information (sex life, marital problems). Although we hope you complete all questions, you can skip any questions you do not feel comfortable answering.
(2) Complete a computerized procedure online at home every three days for six weeks. The procedure should take around 5 minutes each time it is completed.
(3) Complete follow-up survey questionnaires online at home four times: once two weeks after the initial intake, once two weeks after that, once two weeks after that, and once more two weeks after that. The first three sets of questionnaires will take about 10 minutes to complete. The fourth and final set of questionnaires will take about 30 minutes to complete and require another marital discussion via MS Teams that will be recorded. The entire study participation will cover a period of six weeks.

Naval Medical Center Portsmouth (NMCP) will make every effort to keep the information collected from you private. However, any time information is collected for a study there is a small risk of a breach of confidentiality. Your research data will be confidential and identified by a unique study number. All measures allowed by law to protect your confidentiality will be taken by research staff.

If you choose to take part in this study, there is also a risk of:

This study involves no more than minimal risks. Some of the questions are personal in that they ask about your relationship, problems with your relationship, and other personal problems. There is a chance that some of the questions may make you feel uncomfortable. You may refuse to answer any of the questions, skip any questions you don't want to answer, take a break or stop participation at any time. These activities may

cause discomfort. If you do experience any discomfort, we encourage you to talk to us about it. If you continue to experience distress after that, we will assist you in setting up an appointment with a professional with expertise in dealing with your particular experience of distress.

You may or may not benefit from participating in this study. The possible benefits of the study are that you will have a greater appreciation of your feelings about yourself, your partner, and your marriage. Further, the findings of this study may inform and improve existing interventions designed to improve and sustain marital quality.

This study is being sponsored by the Department of Defense (DoD) through the Military Operational Medicine Research Program.

You will receive payment for each of the assessments/procedures you complete. Each of you can earn up to $140. You will receive $60 as a couple for your intake session. This $60 includes the MS Teams session and the online survey. You will receive an additional $5 for each of the 12 5-minute computerized procedure that each person completes. You will receive an additional $10 for each of the 10-minute assessments that take place every two weeks for the first six weeks of the project. Finally, you will receive an additional $40 as a couple for your final online survey. Further, as an additional incentive to complete all aspects of the study, if you and your spouse complete every aspect of the study, you will be entered into a lottery to receive one of five $1000 cash prizes. If you and your spouse combined complete all but one aspects of the study, you will be entered into a lottery to receive one of five $750 cash prizes. If the two of you combined complete all but two aspects of the study, you will be entered into a lottery to receive one of five $500 cash prizes. If the two of you combined complete all but three aspects of the study, you will be entered into a lottery to receive one of five $250 cash prizes.

Do you have any questions? You may ask me now, or if you have a question later, you are encouraged to contact me at _____. You may also contact CDR Shawna Grover, the Principal Investigator, at 757-953-0605 about your questions with this study. You may also contact the Institutional Review Board which approved this study about any problems or concerns at Naval Medical Center Portsmouth (NMCP) Clinical Investigation Department, 757-953-5939.

- If yes, respond to questions/provide additional information.
- If no questions, confirm participation.
- If subject does not want to participate, document and record name of subject below.

After hearing this information, do you agree to participate in this study verbally or desire information by e-mail? Your participation is voluntary. You can decide not to participate or to withdraw at any time, for whatever reason and you will not be penalized in any way

if you do not want to participate.

Yes, verbally: Document oral consent below and continue with study questions.

Yes, by e-mail: Inform subject that they will receive the oral consent/study information with questions and return instructions.
E-mail address: _____
Date e-mailed: _____
(DDMMMYYYY)
PI/AI initials: _____ _____
(DDMMMYYYY)

No: Thank them for their time.

Printed Name of Subject:

_____

(Not read to subject) If subject agrees to participate, this consent serves as documentation that the required elements of informed consent have been presented orally to the participant by using the telephone consent script.

Printed Name of Subject:

_____

Investigator Obtaining Consent:

I have read this form to the subject. The nature and purpose of the study was given and questions from the subject were solicited and answered to the subject's satisfaction. The subject has provided oral consent to participate in this study prior to participation.

_____
Printed Name of Investigator

_____ _____
Signature of Administering Investigator Date (DDMMMYYYY)

I witnessed the consent. The nature and purpose of the study was given and questions from the subject were solicited and answered to the subject's satisfaction.

_____
Printed Name of Witness

_____ _____
Signature of Witness Date (DDMMMYYYY)