

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study title: Mission Reconnect: Promoting resilience and re-integration of post-deployment veterans and their families

Agency responsible for the project: Collinge and Associates, Kittery, Maine

Study sponsor: National Institute of Mental Health

Consent version date: March 1, 2010

Principal Investigator: William Collinge, PhD, MPH
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Main Study

You are being asked to participate in a research study to evaluate the usefulness of an educational program designed to promote well-being and supportive relationships between veterans recently returned from military service and their family members or friends. In order to decide whether you want to be part of this study, you should understand enough about the activities and responsibilities involved, and any risks and benefits of participation, so that you can make an informed choice. This is known as “informed consent.” Please take your time to make your decision. This entire document applies to both the veteran and the support partner.

Definition: For purposes of this project a “veteran” is anyone who has served in OIF/OEF, regardless of their current military status now.

Why is this study being conducted?

Military deployment creates stresses and challenges of adjustment for both the veteran and the people in his or her life back home. When veterans return home after deployment, it takes time to make the transition back to civilian life and to overcome the effects of the stresses that may have accumulated during their deployment. During this time of readjustment, veterans may benefit from stress management practices as well as from supportive relationships with the people they trust and are comfortable with. Likewise, family members or friends may benefit from stress management and being in a supportive relationship with the veteran.

Many friends and family members of recently returned veterans wonder how they can provide support that is helpful. Studies in people who have been through stressful experiences have shown that simple techniques of mental relaxation or meditation, massage and touch can reduce stress and improve well-being. Research has also shown that people with no prior training or experience can learn and apply certain basic skills of massage and touch that readily bring relaxation and stress reduction. Using these skills may be a positive and rewarding experience for givers and receivers.

The National Institute of Mental Health has decided to sponsor the production of an educational program for home use on stress reduction for veterans and their partners by Collinge and Associates. The materials will consist of a DVD program, audio CDs, and an illustrated manual. The goal of the study is to produce materials that will be of value to

recently returned veterans and their chosen relationship partners, be they family or friends. We need to evaluate these materials in a scientific study to determine their helpfulness for users.

How many people will take part in the study, and who is being recruited?

Forty recently returned veterans plus their chosen partners (the veteran plus a family member or friend is referred to as a “pair”) will participate in this study at three different sites. The partner may be any family member or friend who the vet chooses and who consents to participate.

Who is eligible to participate?

Participants will enroll in pairs consisting of the veteran and a partner chosen by the veteran (relative or friend). Veterans must:

- a) Be post-deployment military personnel who have served in OIF/OEF.
- b) Be able to read, write, and speak English
- c) Agree to participate in data collection, orientation meeting, and focus group, as well as to participate in home use of the instruction.
- d) Be physically able to attend the full duration of the meetings.
- e) Complete a brief screening interview by phone with the Investigator.

Relationship partners must:

- a) Be chosen by the veteran to be the partner in this project.
- b) Be able to read, write, and speak English or Spanish.
- c) Agree to participate in data collection, attend the orientation meeting, focus group, and participate in home use of the instruction.
- d) Be physically able to attend the full duration of the meetings.
- e) Complete a brief screening interview by phone with the Investigator.

What is involved in being in the study?

1. You will be interviewed by phone to determine if you are eligible to participate in the study. There are two steps to this: First, a Project Manager will go over this Consent Form with you by phone, and will go over the eligibility criteria. If the Project Manager determines that you meet the criteria, next you will have a brief screening interview by phone with the Investigator (Dr. Collinge). This will be to determine whether there are any reasons why you should not participate. The Investigator will make the final decision on whether you will be in the study or not.
2. If accepted into the study you will complete a brief survey about your health and well-being that takes about 20 minutes to complete. You will be asked to complete this same survey once a month for the next three months of the study. The surveys may be completed on paper and returned by mail, or on a project website. This will be a secure website and no personal identifying information will be provided, only a username and password selected by you. If you use this method we will recommend that you complete the surveys at a private computer in a private place to help protect your confidentiality. The survey will include brief questionnaires in which you give ratings for the following:
 - a) The helpfulness of the materials used in the program,
 - b) The helpfulness of the program as a whole,

- c) Your attitudes toward using the techniques taught in the program,
 - d) Your frequency of use of the practices taught,
 - e) Your ratings of stress and depressed feelings,
 - f) Your quality of life,
 - g) Compassion for yourself, and
 - h) Compassion for others.
3. After being accepted into the study you will complete the first survey. This will be followed by a four week waiting period.
 4. Four weeks after the first survey, you will complete the second survey, which will be the same as the first one. After completing the second survey you will have the following activities:
 5. Attend an orientation meeting with other participants. This meeting is expected to last about 2 hours. At this meeting you will:
 - (a) Meet other participants in the project in your area.
 - (b) Watch the DVD and view the manual of instructions in simple touch and massage techniques for stress reduction and relaxation, and discuss any questions afterward.
 - (c) Listen to the CDs of guided exercises for relaxation and self-support and discuss any questions.
 - (d) Receive instructions for use of these materials at home, both alone and with your partner.
 - (e) Receive instructions for completing a weekly report card on your use of the materials.
 - (f) Receive your copy of the materials to take home and begin using.
 6. Partners will be encouraged to review the film or manual, or at least parts of them, frequently. Partners will be asked to offer at least three sessions per week to the veteran for 8 weeks, in which they use the techniques shown in the film. They will be encouraged to practice as often as they and the veteran wish, and may do so for more or less time.
 7. Partners and veterans will be asked to listen to the CDs of their choice at least once per week, and as often as they would like, and practice the techniques as often as they would like.
 8. Both the veteran and the partner will fill out and mail an activity report card each week. These will be 5x8 inch cards (one card for each person) with an envelope that will be stamped and pre-addressed for mailing back. The cards will be used to report on frequency of use of the materials, and on the effects of one of the massage sessions on the veteran's relaxation and stress levels. Alternatively, you may fill out the report card on the project website.
 9. You will receive a phone call every two weeks from your Project Manager to check in about how you are doing and if you are having any questions or problems with the project.
 10. Half way through the 8 weeks (week 8 of the entire project) you will fill out and mail in another copy of the survey form.
 11. At the end of the 8 weeks of using the program (week 12 of the entire project) you will complete and mail in the final survey form.
 12. After the final survey form, you will be asked to attend a follow-up focus group meeting (90 minutes) to share your views, opinions and recommendations about the

project and the materials.

Procedures that are considered experimental and are being tested in this study:

All activities being done in this study are being done for the purposes of this research.

1. Participants will be taught techniques that are commonly used for stress reduction and relaxation in people with a wide variety of health conditions. We want to see if these practices will help people living with the stress of military deployment.
2. The massage techniques will be done fully clothed, can be done sitting in a chair, and are limited to the head, neck, shoulders, back, feet and hands. These will be techniques often used for stress reduction, relaxation and comfort.
3. We will teach some techniques of very light touch, such as simple laying on of hands and other forms of gentle touch that people find relaxing and comforting.
4. We will teach some techniques of mental contemplation (sometimes referred to as “mindfulness”, “meditation,” and “mental relaxation exercises”) for reducing stress and for creating feelings of compassion for oneself and for others.

How long will I be in the study?

Thirteen to fourteen weeks (including the final focus group meeting).

What are the risks of the study?

Psychological discomfort is possible due to the following reasons:

1. Completing surveys that ask you to think about your feelings, stress levels, and well being.
2. Partners may have concerns about their performance in using the touch and massage techniques.
3. Veterans may have unrealistic expectations of the partner.
4. There may be disparity between partner and veteran as to desired frequency and duration of massage (beyond the weekly reporting session).

The above risks are considered unlikely to occur due to preparation of subjects, and would probably be minor if they occur.

Physical discomfort in participants due to use of the massage techniques is unlikely to occur, and would probably be of minor seriousness. Either the partner or the veteran could stop the process at any time if uncomfortable.

For more information about risks, ask Dr. Collinge (phone 207-423-0640).

Research Related Injury

No research-related injuries are expected from participation in this project. If you suffer a physical injury as a result of your participation in this study, you will not be reimbursed for medical expenses to treat the injury. No funds have been set aside for payments or other forms of compensation (such as for lost wages, lost time, or discomfort). However, you do not give up any of your legal rights by signing this consent form.

What are the benefits of my participation?

There may be no direct benefit to you for participating in this study.

Compensation:

1. You will receive a copy of the film (DVD) and manual and two CDs with guided mental exercises. You will be able to keep all materials given to you after the study is over.
2. Each participant will be paid up to \$310 for completing all parts of the project, as follows: you will be paid \$25 each (four times for both the veteran and the partner) for completing the survey, you will be paid \$20 each (8 times for both the veteran and the partner) for returning each weekly report card, and you will be paid \$50 for the focus group meeting. Checks will be mailed monthly for the activities that have been completed. You will not be paid for activities you do not complete.
- 3.

What other options are there?

As this is not a treatment study, the alternative to participating in this study is to not participate.

New Findings

All new findings discovered during the course of this research study that may reasonably influence your decision to continue to participate in this study will be provided to you by the study investigator (Dr. Collinge) as such information becomes available.

Voluntary Participation/Withdrawal:

Your participation in this study is voluntary. You may choose not to take part or may leave the study at any time. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled. You may stop your participation at any time.

The investigator (Dr. Collinge) may end your participation in this study for any of the following reasons:

1. If you are unable participate in any of the required activities;
2. If the study is cancelled by the National Institute of Mental Health, the New England Institutional Review Board, DHHS or by the Office of Human Research Protections (OHRP);
3. For administrative reasons.

Who will see the personal information provided?

1. The information on your application form will be seen only by the Investigators (Dr. William Collinge and Dr. Janet Kahn), and the study staff.
2. The surveys and report cards you complete will be identified by your subject identification number (ID#) and will not have your name on them. You will return these forms by mail to the investigator.
3. Your responses on the questionnaires and report cards will be entered into a computer program by a research assistant, and will be analyzed by the project's statistician (Dr. Kenneth Fletcher).

4. No information about your identity will be included in any publications about the project.
5. No information about your participation or your responses to surveys will be released to anyone outside the study.
6. Members of the New England Institutional Review Board, or personnel of the National Institute of Mental Health, or the federal Office of Human Research Protections, may also inspect the study records and see parts of the information you provide for this study and, therefore, may see your name and other personally identifiable information about you. The information collected is the property of Collinge and Associates, and you will not be able to get it back.

What about confidentiality?

You will be asked to respect confidentiality of personal information or feelings other participants may disclose during the project. Your records will be kept safely in the offices of Collinge and Associates. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality, as your personal information may be disclosed if required by law. If you choose to use the option of completing surveys online, the website is secure for research and no identifying information about you will be collected online. Your IP address will not be collected. We will recommend you use a private computer in a private place to protect your confidentiality.

What are the costs?

There is no cost to you for participating in this study.

Who do you call if you have questions or problems?

For questions about the study contact Dr. Collinge at (207) 423-0640.

For questions about your rights as a research participant, contact the New England Institutional Review Board (which is a group of people who review the research to protect your rights) at (800) 232-9570.

VOLUNTEER'S STATEMENT

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. William Collinge if I have any more questions about taking part in this study. Collinge and Associates is being paid by the National Institutes of Health for my participation in this study.

I understand that my participation in this research project is voluntary. I know that I may withdraw from the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions about my rights as a research subject in this study I may contact:

New England Institutional Review Board
Telephone: 1-800-232-9570

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records.

Study Participant 1 (signature)

Date

Print Participant's Name

Study Participant 2 (signature)

Date

Print Participant's Name

Signature of person who explained this study
with the subject

Date via the telephone