

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study title: Couples and Cancer: Building Partner Efficacy in Caring
Agency responsible for the project: Collinge and Associates, Kittery Point, Maine
Principal Investigator: William Collinge, Ph.D., M.P.H.
Study sponsor: National Cancer Institute, National Institutes of Health
Consent version date: March 19, 2008

Project Activity: Randomized Controlled Study

This project has three parts – film production, film screening, and randomized controlled study. You may participate in only one of these three parts

(Note: Please request a Spanish or Chinese translation of this form if needed.)

You are being asked to participate in a research study to compare two activities of caregiving in cancer. We want to compare their usefulness in improving the well-being of people with cancer and their caregivers.

In order to decide whether you should agree to be part of this project, 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.

Why is this project being conducted?

The caregivers of people with cancer are vitally important sources of support. Many caregivers want to learn effective ways to provide comfort and support to their loved one. Studies have shown that simple techniques of massage and touch can reduce suffering and improve well-being in people with cancer. Research has also shown that caregivers with no prior training or experience can learn and apply certain basic skills of massage and touch that bring comfort to people with cancer. Using these skills may also make caregiving a more positive and rewarding experience for caregivers.

The National Cancer Institute has decided to sponsor the production of an educational film on this topic for caregivers by Collinge and Associates. The goal of the project is to produce a film that will be of value to the general population of people with cancer and their caregivers. We need to evaluate this film in a scientific study to determine its effects on people with cancer and their caregivers.

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

One hundred people with cancer plus their caregivers (a person with cancer and her/his caregiver is referred to as a “pair”) will participate in this study. The caregivers may be spouses, partners or family members who are in a caregiving role with the person with cancer. The pairs selected for the project will represent a diverse mixture of people from the general population of people with cancer and their caregivers.

What is involved in being in the study?

1. You will complete a brief survey about your health and well-being that takes about 20

minutes to complete. You will do this four times: upon entering the study, and at four, twelve and twenty weeks.

- a. For people with cancer only, each packet will include a small saliva sample kit. This is the size of a matchbook and contains small filter papers you will just moisten with your tongue and then mail back with the survey. This will allow the researchers to measure whether there are changes in stress hormones that are present in saliva during the project. The purpose is to see if the activities of the project affect stress levels in the recipient's body over time. With each survey you will be asked to moisten three of these papers per day over two consecutive days with your saliva.
2. After completing the first survey, each pair will be randomly assigned to one of two caregiving activities. You will have an equal chance of being assigned to either activity.
3. If you are assigned to the experimental group, you will have the following activities:
 - a. Attend an orientation meeting with other participants who speak your language. Translators will be present if needed. At this meeting you will:
 - Meet the project's massage therapy consultant and a research assistant who will be assigned to support you during the study.
 - Watch the film (in English, Spanish or Chinese) with the other participants and discuss it afterward.
 - Receive instructions for completing a weekly report card on your use of massage.
 - Receive your copy of the DVD and manual to take home and begin using.
 - If you do not have a DVD player you will be given one which you may keep when the study has ended.
 - b. Caregivers will be encouraged to review the film, or at least parts of it, frequently. They will be asked to give at least one massage per week (at least 20 minutes) to the person with cancer for 20 weeks, in which they use the techniques shown in the film. They will be encouraged to practice more than once per week, and may do so for more or less time.
 - c. Both the person with cancer and the caregiver will fill out and mail a report card each week concerning one of their practice sessions. These will be 5x8 inch cards (one card for each person) with an envelope that will be stamped and pre-addressed for mailing back.
 - d. A massage therapy consultant will make a home visit to you during the first two weeks, and if needed after that, to make sure you understand and follow the safety precautions that apply to you. A translator will be present if needed.
 - e. You will receive a phone call every two weeks from your research assistant to check in about how you are doing and if you are having any questions or problems with the project.
4. If you are assigned to the control group, you will have the following activities:
 - a. Attend an orientation meeting with other participants who speak your language. Translators will be present if needed. At this meeting you will:
 - Meet the project's research assistant who will be assigned to support you during the study.

- Receive instructions for a “quality time” activity to do together each week for at least 20 minutes, for four weeks (described below).
 - Receive instructions for completing a weekly report card on your use of the quality time activity.
- b. Quality time activity: This will be the caregiver reading aloud from literature that is pleasant and enjoyable to the person with cancer. The literature may be poetry, stories, spirituality, humor, non-fiction, etc., but not news or stressful topics. You will be asked to do this activity at least once per week (at least 20 minutes) for four weeks. You will be encouraged to do this more than once per week, and may do so for more or less time.
 - c. Both the person with cancer and the caregiver will fill out and mail a report card each week concerning one of their reading sessions. These will be 5x8 inch cards (one card for each person) with an envelope that will be stamped and pre-addressed for mailing back.
 - d. You will receive a phone call every two weeks from your research assistant to check in about how you are doing and if you are having any questions or problems with the project.
 - e. At the end of the four weeks you will join the experimental group and have the activities described in Section 3 above for the remaining 16 weeks of the study.

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

1. Participants will be taught techniques that are commonly used by nurses and massage therapists to provide comfort and relaxation to people with cancer.
2. The techniques will be limited to massaging the head, neck, shoulders, back, feet and hands. These will be techniques used primarily for stress reduction, relaxation and comfort.
3. We will avoid tumor sites, radiation sites, incisions, bone or spinal metastases, areas of communicable disease (e.g., herpes simplex), medical device sites (e.g. ostomy or chemotherapy port), and arms and legs. We will also teach about pressure restrictions and position restrictions.
4. We will teach some techniques of very light touch, such as simple laying on of hands and other forms of gentle touch that the people with cancer find comforting.
5. We will show participants how to position themselves for use of the techniques in a chair and on a sofa or bed, since most people will not have a massage table at home.

How long will I be in the study?

Twenty weeks.

What are the risks of the study?

Psychological distress is possible due to the following reasons:

1. Being disappointed at being assigned to the control group.
2. Completing surveys that ask you to think about your health, well-being, symptoms, and behavior.
3. Caregivers in the experimental group may have concerns about their performance.
4. Participants in the experimental group may have unrealistic expectations of the caregiver.

5. There may be disparity between caregiver and person with cancer as to desired frequency and duration of massage (beyond the weekly assigned session).
 6. Control subjects could experience distress over the contents of the reading material used during quality time.
 7. After the study is over and control subjects have received the film and manual, they could experience the same sources of distress as experimental subjects in terms of performance and expectations.
- The above risks are considered unlikely to occur due to preparation of subjects, and would probably be of minor seriousness.

Physical discomfort in subjects is possible for the following reason:

1. If a caregiver attempts to provide massage techniques that would be contraindicated due to the subject's physical condition; i.e., disregarding or being unaware of safety precautions and contraindications that were taught in the multimedia materials (during the study for experimental subjects or after the study for controls).

This risk is considered unlikely to occur, and would probably be of minor seriousness as the person with cancer could stop the process if uncomfortable.

For more information about risks, ask Dr. Collinge (phone 207-439-8049).

Research Related Injury

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 (for the control group, at the end of the study).
2. Each caregiver will be paid \$280 and each person with cancer \$360 for completing all parts of the data collection, as follows: you will be paid \$20 each (four times for both the person with cancer and the caregiver) for completing the survey, you will be paid \$10 each (20 times for both the person with cancer and the caregiver) for returning each weekly report card, and the person with cancer will be paid \$20 (four times) for each saliva kit. Checks will be mailed monthly for the data collection that has been completed. You will not be paid for tasks you do not complete.

What other options are there?

The alternative to participating in this study is not participating.

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.

Withdrawal/Removal:

Your participation in this study is voluntary. 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 without affecting your ongoing medical care.

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

1. If you develop a side effect or medical condition that may place you at risk of further complications by continuing your participation;
2. If you need a medicine or form of treatment that interferes with your ability to participate;
3. If you are unable participate in any of the required activities;
4. If the study is cancelled by the sponsor, the New England Institutional Review Board, DHHS or by the FDA;
5. For administrative reasons.

Who will see the personal information provided?

1. The information on the Personal Information Form and Medical Information Form will be seen only by the Investigator (Dr. William Collinge), the project consultants (Dr. Kahn and Ms. Walton), possibly a translator, and the massage therapy consultant and research assistant assigned to you.
2. The questionnaires and report cards you complete will be identified by your subject identification number (ID#) and will not have your name on them. Normally you will return these forms by mail to the investigator. However, because of language or literacy considerations, there may be some cases where a research assistant may need to assist a participant in completing questionnaires. In this case, that research assistant would be aware of your identity.
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.

In order to assure that your rights and safety are protected, members of the New England Institutional Review Board, Wellesley, MA; or personnel of the National Cancer Institute or the federal Office of Human Research Protections, may also 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 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. Also see “Who will see this information?” section above. Any publication of findings will not include any way of identifying you.

What are the costs?

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

What are my rights as a participant?

Taking part in this study is your choice. You may choose not to take part or may leave the study at any time. Leaving will not result in any penalty or loss of benefits to which you are entitled. However, if you leave the project early you will not be paid for any tasks not completed.

Who do I call if I have questions or problems?

For questions about the study or a research-related injury contact Dr. Collinge at (207) 439-8049.

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:

Alan M. Sugar, M.D., Chairman
New England Institutional Review Board
40 Washington Street, Suite 130
Wellesley, MA 02481
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 (signature)

Date

Print Participant's Name

Study Participant (signature)

Date

Print Participant's Name

Person who explained this study (signature)

Date