



Tom Baker Cancer Centre

**Department of Psychosocial Resources**

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**TITLE:** Getting Well Together: A pilot study of an online support and coping skills intervention for breast cancer patients with limited access to existing support programs

**SPONSOR:** Canadian Breast Cancer Foundation  
Tom Baker Cancer Centre

**INVESTIGATORS:** Dr. Michael Speca, Tom Baker Cancer Centre  
Jill Taylor-Brown (MSW), CancerCare Manitoba  
Dr. Linda Carlson, Tom Baker Cancer Centre  
Dr. Joanne Stephen, BC Cancer Agency  
Dr. Jill Turner, Cross Cancer Institute

You are being asked to participate in a research study. This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

**BACKGROUND**

You have been invited to participate in this study because having breast cancer can be distressing. Previous research has shown that although women want to participate in programs to help with their distress, access can be limited for a variety of reasons. Women with breast cancer have been accessing the Internet for information and to chat with others going through the same situation. The Internet has the potential to give quality support services to those with limited access to programs. This study tests the effectiveness of an Internet-based professionally led support group compared to a self-help coping skills workbook. This is the first study of its kind in this region of Canada, and is being sponsored by the Canadian Breast Cancer Foundation, Prairies and Northwest Territories Chapter.

## **WHAT IS THE PURPOSE OF THE STUDY?**

This is a pilot study. A pilot study tests how a study is designed and how well the study works for its participants. The purpose of this study is to compare the effectiveness of an Internet-based support group with self-guided coping skills training program to a self-guided coping skills workbook only. These programs will be assessed for how they affect emotional well-being and problems related to having breast cancer.

## **WHAT WOULD I HAVE TO DO?**

If you choose to participate in this study, you will be randomly assigned to **only one of the two groups**, like a flip of the coin:

- An Online Support and Skills Group. You will meet other participants with a trained counselor on the Internet, at regularly scheduled times for 1 and 1/2 hours each week for 12 weeks. You will receive access to an online coping skills workbook; completing the workbook, which takes between 20 minutes to 1 hour a week, **is optional**.
- A Self-help Program group. You will be mailed a coping skills workbook to be completed over 12 weeks. Participation time required is around 1 hour per week.

Please note that you will be randomly assigned to **only one of these two groups**, and we will decide using a computer program which group you are in – you won't be able to choose which one you prefer.

Regardless of which group you are assigned to, you will be asked to complete a series of questionnaires at the following times:

- before any of the programs begin
- after the programs are completed
- three months after program completion

All of the questionnaires will be completed in a secure Internet environment.

## **WHAT ARE THE RISKS?**

There are no identifiable risks associated with participating in this study.

## **ARE THERE ANY REPRODUCTIVE RISKS?**

There are no reproductive risks associated with this study.

## **WILL I BENEFIT IF I TAKE PART?**

If you agree to participate in this study there may or may not be a direct benefit to you. We have shown previously that participation these programs may help people cope with their illness, and we believe that you may receive some personal benefit regardless of which group you are assigned to. People often also appreciate the opportunity to contribute to scientific studies. The

information we get from this study may help us to determine the benefit of these programs in the future.

### **DO I HAVE TO PARTICIPATE?**

Participation in this study is completely voluntary and you may withdraw from the study at any time.

### **WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

You will not be paid for your participation in this study, nor will you have to pay any additional expenses. The programs are free of charge.

### **WILL MY RECORDS BE KEPT PRIVATE?**

Your records will be kept completely private. Only the investigators will have access to the information you provide. Your consent form will be separated from the questionnaire package and stored in a separate area. The data and consent forms will be kept in separate locked filing cabinet in the Department of Psychosocial Resources. Information will be kept for 7 years after publication and then destroyed confidentially. Any information that is published will not contain any personal reference to the participants.

The chat room for the online support group is a secured site whereby only persons involved in the study including participants, facilitators, and investigators will have access to view information posted there. However, participants should be aware that there are inherent privacy risks whenever the internet is accessed. Investigators in this study have taken reasonable and prudent steps to limit your risk such as restricting the number of people who have access to the information you provide and by eliminating identifying information from data records.

### **SIGNATURES**

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Michael Speca (403) 355-3216

If you have any questions concerning your rights as a possible participant in this research, please contact The Ethics Resource Officer, Internal Awards and Research Services, University of Calgary, at 220-3782.

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Participant's Name

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Signature and Date

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Investigator/Delegate's Name

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Signature and Date

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Witness' Name

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Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.