

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: 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.

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**Sponsor: Canadian Breast Cancer Foundation – Prairies/NWT Chapter
CancerCare Manitoba**

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your friends, family or (if applicable) your doctor or other health care provider before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

Purpose of Study

This research study is being conducted to study the effectiveness of an Internet-based support group with self-help coping skills workbook program to a program with a self-help coping skills workbook. These programs will be evaluated for how they affect emotional well-being and problems related to having breast cancer. Previous research has shown that although women want to participate in programs to help with the distress that they are feeling, 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.

A total of 120 participants will participate in this study.

Study Procedures

In this study, you will be “randomized” into one of 2 study groups described below. “Randomized” means that you are put into a group by chance, like flipping a coin. You will have an equal one in two chance of being placed in either group.

In the Online Support and Skills Group, the participant will attend an Internet support group, facilitated by two trained counselors, and will also have access to a self-help coping skills workbook to complete. In the Self-help Program Group, the participant will be mailed out a self-help coping skills workbook to complete. We will use a computer program to randomly place you into one of the two groups.

If you take part in this study, you will have the following procedures:

Depending on how you found out about this study, we may need to confirm your breast cancer diagnosis with your medical records or by talking to your doctor. The Research Assistant for the study will only use this information for confirming your diagnosis. You will fill out a series of questionnaires three times during this study. You will fill out these questionnaires on a secure Internet page before you start the group, after you finish the group and three months after you finish the group. These questionnaires will ask you about how you are feeling right now, how you are coping in your life, how having breast cancer is currently affecting your quality of life, and your experience of being in a support group (only for those randomly assigned to support group).

Online Support and Skills Group: We will assign you a user name and password, and then you will be able to access the Internet Support group page. This page will contain access to your support group, transcripts of previous sessions and a group chat forum. You will be mailed a NuCare coping skills workbook to be completed over 12 weeks. Completing the workbook takes about 1 hour a week. 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 be reminded to complete the questionnaires on this forum, by phone or email.

Week	Activity	Time required
1	Fill out Questionnaires Attend Internet Group Work on self-help workbook	.5 hours 1.5 hours 1 hour
2	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
3	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
4	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
5	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour

6	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
7	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
8	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
9	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
10	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
11	Attend Internet Group Work on self-help workbook	1.5 hours 1 hour
12	Attend Internet Group Work on self-help workbook Fill out Questionnaires	1.5 hours 1 hour .5 hours
48 (3 month follow-up)	Fill out Questionnaires	.5 hours
Total Time:		31.5 hours maximum

A Self-help Program group: We will mail out to you the Nucare self help coping skills workbook. It will contain 8 different units to be completed over 12 weeks. Participation time required is around 1 hour per week. You will be reminded to complete the questionnaires by email or telephone.

Week	Activity	Time required
1	Fill out Questionnaires Work on self-help workbook	.5 hours 1 hours
2	Work on self-help workbook	1 hour
3	Work on self-help workbook	1 hour
4	Work on self-help workbook	1 hour
5	Work on self-help workbook	1 hour
6	Work on self-help workbook	1 hour
7	Work on self-help workbook	1 hour
8	Work on self-help workbook	1 hour
9	Work on self-help workbook	1 hour
10	Work on self-help workbook	1 hour
11	Work on self-help workbook	1 hour
12	Work on self-help workbook Fill out Questionnaires	1 hour .5 hours
48 (3 month follow-up)	Fill out Questionnaires	.5 hours
Total Time:		23.5 hours maximum

Participation in the study will be for 12 weeks. You will be contacted 3 months after your participation in the group is finished to complete the last set of questionnaires.

The researcher may decide to take you off this study if funding is stopped.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first. There will be no severe consequences to your health if you withdraw from this study.

Aggregate results will be available to participants when the results are published.

Risks and Discomforts

There are no physical risks to this study. Nonphysical risks may include anxiety or sadness resulting from talking about your experience of cancer with other cancer survivors in an online support group.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope the information learned from this study will benefit other people with distress from breast cancer in the future.

Costs

All the procedures, which will be performed as part of this study, are provided at no cost to you.

Payment for participation

You will receive no payment or reimbursement for any expenses related to taking part in this study.

Confidentiality

Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. All study related documents will bear only your assigned study number.

Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba.

Your study number will be electronically submitted to a secure server in the United States in order to create a user name and password for your Internet account with this study. This account will not contain any patient identifiable information.

The University of Manitoba Health Research Ethics Board may review records related to the study for quality assurance purposes.

All records will be kept in a locked secure area at the Tom Baker Cancer Centre in

Calgary and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the Tom Baker Cancer Centre.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care. If the study staff feels that it is in your best interest to withdraw you from the study, they may remove you without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Medical Care for Injury Related to the Study

You are not waiving any of your legal rights by signing this consent form or releasing the investigator or the sponsor from their legal and professional responsibilities.

Questions

You are free to ask any questions that you may have about the study and your rights as a research participant. If any questions come up during or after the study or if you have any concerns, contact the study staff at CancerCare Manitoba, Jill Taylor-Brown MSW, RSW at 204-787-1325.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Jill Taylor-Brown or the study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board, for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant signature _____ **Date** _____
(day/month/year)

Participant printed name: _____

I, the undersigned, attest that the information in the Participant Information and Consent Form was accurately explained to and apparently understood by the participant or the participant's legally acceptable representative and that consent to participate in this study was freely given by the participant or the participant's legally acceptable representative.

Witness signature _____ **Date** _____
(day/month/year)

Witness printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____ **Date** _____
(day/month/year)

Signature: _____