



BC Cancer Agency

CARE & RESEARCH

An agency of the Provincial Health Services Authority

Participant Information & Consent Form

BC Cancer Agency Online Support and Discussion Groups

Principal Investigator:

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Fraser Valley Cancer Centre
Telephone 604-930-4055 ex. 4505

Co-Investigator:

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Regional Practice Leader
Vancouver Cancer Centre
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Sponsor

Funding for this study has been provided by the Public Health Agency of Canada

Emergency Contact Number: (24 hours/7 days a week)

For emergencies only: Call the centre nearest you and ask for Patient and Family Counseling Services

Vancouver Centre	604-877-6000
Fraser Valley Centre	604-930-4000

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contact”

Background

You are invited to participate in this research project because cancer brings many challenges. We are doing this study as part of our efforts to help those who may be experiencing cancer related distress.

If you are taking part in this study, you will join a professionally led support and discussion group that is delivered through the Internet.

Taking part in this project is voluntary. You can decide not to participate or to withdraw from this project at any time.

Purpose

This project is a demonstration study. Before proceeding to a full scale program, a demonstration study is often carried out first to test the design of a study and its acceptability to participants. The design of a study is how the program is implemented, how the data will be collected, whether the data can provide useful information and whether it will be practical to proceed to a larger program.

Who can Participate?

You **can** participate in this study if:

- You fully understand the project and give your informed consent to participate as demonstrated by signing this consent form
- You live in BC
- You are a BC Cancer Agency patient or a family member caring for a person diagnosed with cancer who has received treatment at the BC Cancer Agency
- You are familiar with computer usage and have access to the Internet in a private area where you will feel comfortable entering personal information
- You have the ability to read and write in English
- You can commit to the weekly time requirement
- You do not have a history of serious psychiatric disorder
- You see yourself as having at least moderate distress because of your cancer experience
- You are not in the advanced stage of a cancer diagnosis

You **cannot** participate if:

- Any of the points above do not apply to you.

Study Procedures

If you agree to take part in this study, you will be asked to fill out a series of questionnaires online. The forms will be completed at the following times:

1. Prior to enrollment into the online support group
2. At the end of the online support group (8 weeks from start)

You will be prompted by email and sent a link and password to access the forms. It is important that you complete each set of forms on time. Each time you complete the forms it will take approximately 30 minutes.

After you have completed the first set of forms you will be enrolled in the online support group. You will participate in a 1½ hour online group with a BC Cancer Agency counselor, once a week for 8 weeks.

You will be telephoned by the Research Coordinator and provided with instructions for logging onto the online group.

After the end of the study, you may also be contacted for a follow up interview.

If you have any questions about the research procedures, please feel free to contact the Principal Investigator, Dr. Joanne Stephen. Her telephone number is listed on the first page of this consent form.

Benefits

The potential benefits of the study include the investigators learning better how to conduct this type of study. Individual subjects may learn new coping skills and experience enhanced mood and well being and feeling supported by peers but we cannot be sure this will happen.

Risks

There are no known medical risks to participating in this study. It may be distressful to participate in the support groups. If you experience increased distress over the course of the study, you may request to speak with a counselor individually, and she will help you to identify an appropriate mental health professional in your area.

In the online support groups, there may be risks associated with the electronic transfer of information. As with any online interaction, it is possible that third parties could view the electronic information through interception or misdirection of network transmissions. In addition, information could be directly viewed on a participant's computer or from printed copies of the session transcripts. However, no personal information could be linked to potential viewings. The following measures will be taken to ensure that confidentiality in the online support groups is maintained:

- Your privacy on the online support groups will be protected through the utilization of security features that include the use of study ID numbers, first names only, file encryption and password protection.
- Questionnaire data will be stored offsite in the US. These data which leave Canada will be identified with a first name only. They will be stored in a secure site that supports other medical internet communication applications.
- Electronics transcripts of the online groups will be stored in a secure site in the US and within the BC Cancer Agency. This data will be associated with a first name only, and will not include identifying information.
- Participants will be made aware of the need for physical privacy during online sessions and the need to protect printed copies of session transcripts.

These measures safeguard the privacy of participants to the best of our ability. However, we cannot guarantee absolute privacy of electronic data, and the confidentiality risks involved in this study are the same as with other online exchanges.

Confidentiality

As a participant in this study your confidentiality will be respected. The following measures will be taken:

- No information that discloses your identity will be released or published without your specific consent.
- Your identity will not be used in any reports about the study.
- In records that leave this centre you will be identified by a study code number only. Your birth date will also be provided if requested by the sponsor or responsible regulatory agency.
- All identifying and medical treatment data will be stored within Canada.
- All information associated with this study will be kept behind locked doors, in a locked filing cabinet or in computer files secured by a password.

In the presence of the principal research investigator or her designate, research records and medical records identifying you may be inspected by Health Canada, the US Food and Drug Administration and UBC BCCA Research Ethics Board, for the purpose of monitoring the research. However, no records that identify you will be allowed to leave the centre. These organizations have policies of strict confidentiality and the individuals inspecting your records must sign a BC Cancer Agency confidentiality form (the form is not applicable to Health Canada or US Food and Drug Administration officials, who have the legal right to inspect health records and are bound to confidentiality by specific laws).

Reports concerning your progress and photocopies of certain portions of your medical record, identified by a study code number only, may also be sent to:

- UBC BCCA Research Ethics Board, the research ethics committee that oversees the ethical conduct of this study in your centre
- Health Canada

Your rights to privacy are protected and guaranteed by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator or the UBC BCCA Research Ethics Board.

Compensation

You will not be paid for participating in this study. As this is an at home intervention, there are no costs to you for participating, and no re-imbusement will be provided.

You do not waive any of your legal rights for compensation by signing this form.

Remuneration

The sponsors of this study may reimburse the BC Cancer Agency for all or part of the costs of conducting this study. However, the investigators conducting this study will not receive any personal payments for conducting this study. In addition, neither the BC Cancer Agency nor any of the investigators or staff conducting this study will receive any direct financial benefit from conducting this study.

Contact

If you have any questions about this project, you can ask the principal research investigator Dr. Joanne Stephen - Telephone (604) 930-4055 ex. 4505

If you have any concerns about your treatment or rights as a research subject you may contact the Research Subject Information Line at the UBC Office of Research Services at the University of British Columbia at (604)-822-8598.

Please keep this letter for your own records. Thank you for your time!



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Subject Consent

- I understand that participation in this study is entirely voluntary.
- I may choose not to participate in this study and I may withdraw from the study at anytime.
- I understand that I may ask questions about this study in the future.
- I understand that I may be contacted after the study.
- I consent to participate in the online support group research study.