



Outcomes and Quality of Life after Prophylactic Total Gastrectomy Information Sheet

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Purpose of the Research

The purpose of this study is to understand the complications and symptoms experienced by individuals who have had prophylactic total gastrectomy and their effects on a person's quality of life. Your participation in this study is voluntary. If you agree to participate, you may withdraw from the study at any time. Your medical care will not be affected if you withdraw from the study.

Procedure

If you decide to participate, you will be asked to do the following:

- A. Sign the enclosed study permission form to allow us to enroll you in the study
- B. Sign a Release of Information form to provide us with permission to obtain your hospital records pertaining to the surgery.
- C. Complete surveys that include information about yourself, clinical symptoms you may experience after the surgery and surveys about your daily living experiences. These questionnaires will be sent to you one time.
- D. We will also contact you by telephone to obtain a family history. We will ask you specific questions about your family history of cancer.

The study has three parts to it:

1. Learning more about the medical symptoms experienced by you after prophylactic gastrectomy. This involves two steps: signing the enclosed release form to allow us to obtain medical records from the surgery and hospital stay and completing a questionnaire that asks about the medical symptoms that you are experiencing.
2. Learning how any symptoms you are experiencing may affect your daily experiences (the quality of your life).
3. The information that is obtained from this study may allow us to develop evidence based information tools on prophylactic gastrectomy to both individuals considering the surgery and to their health care providers.

Risks:

There are no known risks associated with participation in this study.

Benefits:

This study may not directly benefit you. However, the information collected and analyzed in this study may provide individuals who are thinking about having prophylactic gastrectomy with evidence-based information on the complications after the surgery, clinical symptoms and any effects on their quality of life. The study will also provide information that will allow the investigators to create resources that may help in the counseling of individuals undergoing the surgery.

Confidentiality

Your confidentiality will be respected. 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 only. All information associated with this study will be kept behind locked doors or in secure computer files.

Any study related data, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data, that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information). Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the transfer of your information, to organizations located outside of Canada.

Your rights to privacy are legally protected 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 your study doctor or the UBC BCCA Research Ethics Board.