Scandinavian Surgical Outcomes Research Group
www.ssorg.net

PRETREATMENT GROUP CONSULTATION FOR PATIENTS WITH COLORECTAL CANCER

An explorative study of the patients' experience of participating at a group consultation, together with other patients with newly diagnosed colon or rectal cancer.

Patientens upplevelse av att delta i gruppmottagning innan operation för tjock- och ändtarmscancer.

Project plan

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1.0 STUDY ORGANISATION

1.1 PLANNING GROUP

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1.2 PRINCIPAL INVESTIGATOR

Eva Haglind

1.3 STUDY SECRETARIAT

SSORG/Göteborg at Department of Surgery, Sahlgrenska University Hospital/Östra, Göteborg.

1.4 SCIENTIFIC FRAMEWORK

The study is organised and performed within the framework of Scandinavian Surgical Outcomes Research Group SSORG.

The Scandinavian Surgical Outcomes Research Group SSORG is a network of surgeon-scientists in hospitals in Sweden and Denmark collaborating since 2008 in the formulation of scientific questions or hypotheses, initiating and running trials or studies. The secretariat is situated in Göteborg. The websites are www.ssorg.net and https://surgery.gu.se/Forskargrupper/ssorg.

The research group has previous experience of carrying out studies based on specific and validated questionnaires combined with clinical data from medical records or national quality registries. The response rates of previous studies have generally been high, permitting solid analyses and interpretations of results.

1.5 ORGANISATION

The principal investigator will be responsible for the inclusion, the control of the external validity and the data collection.

There will be no publication during the inclusion part of the study, apart from presentation of the protocol and number of included patients,. All analyses, results and conclusions will be discussed in the planning group, as will any publication issues.

1.6 WRITING COMMITTEE

In agreement with the internationally accepted guidelines for authorship (International Committee of Medical Journal Editors), the members in the planning group who are active in planning, running, analysing and writing will be part of the writing committee together with researchers that fulfil the authorship criteria. The decision of authorship is taken by the principal investigator.

Publication of results will be in peer-reviewed scientific journals and at professional meetings.

2. PROTOCOL

2.1 BACKGROUND

Colorectal cancer accounts for almost 10% of all malignant tumours in Sweden, with approximately 6000 patients newly diagnosed yearly. Results in terms of survival and recurrence rates have improved over the last two decades, based on enhanced preoperative investigations, improved surgical techniques, neoadjuvant and adjuvant treatments and the implementation of multidisciplinary teams.

During 2017, a new form of outpatients consulting was introduced at the Department of Surgery, Sahlgrenska University Hospital/Östra. This is a group consulting with several patients and their partner/family member participating together with a surgeon and a research/specialist nurse. The intention with the group consulting is to inform about several practical procedures that the patients themselves must do, when going through the surgical procedure. Another aim is to create an opportunity where "any" question can be raised and discussed by patients and partners. Part of time is scheduled for information about ongoing studies/trials, including time for questions, and to recruit patients to studies.

To assemble a group of patients who have recently been diagnosed with colon or rectal cancer at the outpatient clinic has, to our knowledge, not previously been done in Sweden. Group consultations have previously been a part of the rehabilitation of cancer and other illnesses but for this specific group of patients it is as far as we know a novelty.

2.2 AIM OF THE STUDY

The aim of this study is to explore how patients with colon and rectal cancer experience their participation in a group consultation before start of their treatment.

A secondary end-point is to study reasons for non-participation in the group consultation decribed above, by asking non-participants to answer a short questionnaire.

2.3 THE HYPOTHESIS

Our hypotheses are:

- The group consultation increases the patients' participation in the treatment of their colon or rectal cancer.

- The patients attending the group consultation gain increased knowledge about colon and rectal cancer and the planned treatment.
- The patients' have a positive experience of the group consultation.
- The participating patients experience a feeling of at least partly being in control.
- The non-participants choose not to participate mostly due to practical reasons.

2.4 THE GROUP CONSULTATION

The standardized care pathway gives that the patients receive an appointment to the specialized surgical outpatient clinic when the preoperative investigations are complete. At that consultation they receive information regarding the diagnosis and the planned treatment by a consultant colorectal surgeon.

The notice of the appointment to the group consultation is sent to the patients together with the letter with the date and time of their ordinary specialist consultation at the surgical outpatient clinic. The attending nurse at the surgical outpatient clinic is supposed to remind the patients about the upcoming group consultation, later the same week. The group consultation is voluntary, free of charge and usually takes about an hour.

The information given at the group consultation mainly consists of three topics, which by experience have been less well covered in the standard routines. These are first and foremost about patient mobilization postoperatively through the patients' active participation within hours and days following surgery, the routines for disinfection of the skin prior to surgery and, if applicable, information about pause of tobacco use before and after surgery.

The surgeons and nurses who have participated in the group consultation report that the patients' experience seems to be positive. However this is not enough as evidence of improved quality of care, for the group consultation to be included as a permanent part of the standard care.

2.5 STUDY DESIGN

This is a cross sectional study with information from participants collected by questionnaires. The data from the questionnaires will be supplemented by clinical data collected from the Swedish Colorectal Cancer Registry and/or medical records.

2.5.1 Development of a validated questionnaire

To construct the questionnaires, we will conduct semi-structured interviews with patients who recently have been diagnosed with colon or rectal cancer. Part of the questionnaire will consist of questions validated and used in questionnaires within several other studies. These include questions on socioeconomics, standardized questionnaires on health related quality of life (The EuroQol's "EQ-5D-5L") and alcohol consumption (WHO's "AUDIT") as well as habits of physical activity (the "Saltin-Grimy" question) and satisfaction with the "standard care" so far. We aim at interviewing patients before and after their participation in the group consultation. Based on the themes condensed from the interviews, new questions will be constructed. An expert group will then be assembled to decide which questions will be used in the questionnaire. The new questionnaire will then be face-to-face validated by invited patients and a research nurse present, to guarantee that all questions are easily comprehensible.

2.5.2 Patients

All patients newly diagnosed but who have not started their treatment for colorectal cancer, will be eligible for inclusion. The patients who chose not to participate in the group consultation will be asked to participate in the study by answering a short questionnaire, in part including the same questions as above, but instead of questions about how they found the group information with a few question about reasons for not participating. With knowledge about what stops some patients from attending, it is possible at least in part to overcome such difficulties. Thus there will be two groups of patients:

A: patients participating in the group consultation

B: non-participants

2.5.3 Collected data

The questionnaires (A and B) contain questions regarding the following demographics:

1. sex
2. age
3. co-morbidity
4. marital status
5. education
6. financial situation
7. occupation
8. smoking habits
9. alcohol consumption
10. physical activity
11. home district and travelling time to Sahlgrenska University Hospital/Östra

The questionnaires also contain questions according to the primary aim:

1. The patient's opinion of the information obtained at the group consultation (A)
2. The patient's preferences for type of information about the cancer and the planned treatment (A and B)
3. Specific questions regarding the patient's experience of participating at the group consultation (A)
4. The patient's experience of receiving information about the studies who want to recruit patients (A)
5. Their experience of the information obtained at the standard visit to the outpatient clinic (A and B)
6. The patients' perceived participation in their own treatment (A and B)

Clinical information on tumour stage, type of surgery and additional treatment will be collected from the medical records and/or the Swedish Colorectal Cancer Registry (A and B).

After information about the study and after obtaining written consent, the patients will be given the questionnaire (A and B). They will also be given a pre-paid envelope and asked to return the filled-out questionnaire by mail before their operation. The patients

will send the questionnaire by mail to the study secretariat, thereby avoiding the shift in answers seen when the same personnel that will be evaluated receive the questionnaires.

2.5.4 Primary endpoint

The primary endpoint is:

- The patients' satisfaction with the group consultation

2.5.5 Secondary endpoints

- The patients' level of knowledge of colon and rectal cancer and the planned treatment
- The patients' experience of increased participation in their treatment

2.5.6 Inclusion criteria

All patients with newly diagnosed colorectal cancer at the included hospital, that have not started treatment, will be eligible for inclusion.

2.5.7 Exclusion criteria

Inability to give informed consent, or speaking and reading the Swedish language and thereby not able to complete the questionnaire.

2.5.8 External validity

Information about the patients not attending the group consultation will be collected with a reduced questionnaire including only questions about sex, age, co-morbidity, education, financial situation, smoking habits, alcohol consumption and physical activity and reasons for non-participation as described above. Clinical information regarding tumour stage, type of surgery and additional treatment will be collected from medical records and/or the Swedish Colorectal Cancer Registry.

2.5.9 Patient information and informed consent

All patients will be asked to participate after receiving oral and written information, specific for group A and B respectively and a possibility to ask questions about the study. Written consent will be obtained from each patient.

2.6 WORK SCHEDULE

Application to the Ethical Committee will be made in the fall of 2018. Two specific questionnaires, including the themes listed above, will be constructed during the fall of 2018. The study is planned to begin during the spring of 2019 and the inclusion will be completed 6-12 months later.

2.7 STATISTICAL METHODS

The aim of assessing the patient-reported experience of participation in a group consultation is explorative and hypothesis generating. To our knowledge, no studies have been made on the appreciation of group consultation at this stage in a health care process for the treatment of cancer, thus an explicit sample size cannot be calculated but we aim at including 100 patients attending the group consulting. We aim at including patient

during 20-25 weeks during 2019, both participants at the group consultation (group A) and patients who did not participate (group B).

Demographic characteristics on participants and non-participants will be summarized and described. The association between outcome variables such as experience and various background variables will be explored using regression as well as graphical methods.

2.8 DATA RETRIEVAL AND REGISTRATION

The clinical data as well as data from the questionnaires will be included in a database that will identify the patients with a specific study code. The database is placed on a server belonging to Gothenburg University with username and code for entry, and access restricted to the data manager and study principal investigator. The data administrator at SSORG will be responsible for the database.

The key code coupling the specific study code and the personal identification number for each participating patient will be kept on a server belonging to Sahlgrenska University Hospital, protected by username and code for entry, and access restricted to the data administrator and the study principal investigator.

The appropriate data for the intended analyses will be retrieved from the original database, without personal identification numbers, only containing the study specific code. After finalization of all analyses this dataset with derivatives (if any) and statistical analysis plan (if applicable) will be returned to the data administrator.

The study will be registered at ClinicalTrials.gov. A report to the data protection officer at Sahlgrenska University Hospital will be made.

2.9 ETHICAL CONSIDERATION

Ethical approval will be applied for in the fall of 2018.