"SMOP"

SOCIAL MEDIA ON PRESCRIPTION?

A randomized trial investigating if a health platform could improve patient outcomes

Social media på recept

Project plan

1.0 STUDY ORGANISATION

1.1 PLANNING GROUP AND STEERING COMMITTEE

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1.2 PRINCIPAL INVESTIGATORS

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1.3 DEPUTY PRINCIPAL INVESTIGATOR

Tomas Lindroth (Informatics)

1.4 STUDY SECRETARIAT

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

1.5 SCIENTIFIC FRAMEWORK

The study is organised and performed within the framework of Scandinavian Surgical Outcomes Research Group SSORG in collaboration with the research group LINA at University West, Trollhättan, Sweden, specialized in informatics and work-integrated learning.

The Scandinavian Surgical Outcomes Research Group SSORG is a network of surgeon-scientists in hospitals in Sweden, Denmark and Norway. This network collaborates since 2008 in the formulation of scientific questions or hypotheses, writing of protocols and in all parts of running trials. The first secretariat is situated in Göteborg. The website is www.ssorg.net.

LINA (Learning In and For the New Working Life) is a research environment at University West, engaging about 50 scientists from various fields, whereof Informatics

and Education are the dominant ones. LINA's purpose is to initiate, conduct and disseminate research on learning and knowledge related to the work. It involves, for example how information systems could generate new knowledge and insights in a profession.

1.6 ORGANISATION

In each participating hospital a local investigator will be responsible for the inclusion, the control of the external validity, the data collection and participate in the steering committee.

There will be no publication, apart from presentation of the protocol and number of inclusions, during the inclusion part of the trial. The steering committee decides if an interim analysis should be made. The PI and deputy PI will decide regarding any analyses of results prior to full inclusion.

All analyses, results and conclusions will be discussed in the steering committee, as will any publication issues.

1.7 WRITING COMMITTEE

In agreement with the internationally accepted guidelines for authorship ("the Vancouver criteria") the members in the planning group who are active in planning, running, analysis and writing will be part of the writing committee together with researchers that fulfil the Vancouver criteria. The decision of authorship is taken by the two PI.

Publication of results is planned to be in international "peer review" scientific journal.

2. PROTOCOL

2.1 BACKGROUND

Colorectal cancer accounts for almost 10% of all malignant tumour cases in Sweden, with approximately 6000 patients newly diagnosed yearly. Recent years have shown improved survival and recurrence rates, both due to enhanced preoperative investigations, surgical technique, adjuvant treatments and the implementation of multidisciplinary teams (1). However, there is still room for improvement, after surgery complications occur in up to 40% of all patients (2). In the long-term QoL can be affected, both due to morbidity from complications, but also due to the diagnosis itself.

It is known that many patients have functional problems after surgery, such as urinary and sexual problems (3-5). For rectal tumours above 5-6 cm it is possible to establish bowel continuity with a low anastomosis of the bowel and the remaining rectum, however, this increases the risk for anastomotic dehiscence (6). To reduce the consequences of leakage a protective stoma is recommended (7). The stoma is however associated with a substantial morbidity of its own, shown by our group as well as other studies (8-10), and a negative effect on QoL (11).

In other situations, a permanent colostomy may be necessary after surgery for colorectal cancer or anal cancer. A usual (20-70%) complication after this type of stoma is

parastomal herniation (12), i.e. that the hole in the abdominal wall is too large, through which intraabdominal structures protrude.

Quality of life is of importance to study. Patients with colorectal cancer has not been as well evaluated regarding QoL as many other patient group, such as patients with breast cancer(13). There are indications that QoL may affect survival due to indications that QoL may affect long-term outcome(14, 15).

Questionnaires used to study QoL can be divided into "generic" instruments, mainly used to compare different diseases and use normative data from the general population.

One of the most common is SF-36, an American instrument that has been translated and validated in many different languages including Swedish(16, 17). It contains 36 items into eight domains, and there is normative data from many different countries. Other generic instruments are from EuroQol that has five items and a visual analogue scale on percieved quality of life (18-20). This is also an instrument frequently used for cost effectiveness using calculations of Quality Adjusted Life Years "QALYs"(21).

Another type of questionnaire is more disease specific, addressing specific problems associated with a disease. The European Organisation of Research and Treatment of Cancer has developed several disease specific questionnaires, one is the Quality of life Questionnaire - Core 30 (EORTC C30), validated for patients with many types of cancer (22). For colorectal cancer there is a disease specific questionnaire with focus on symptoms, EORTC CR29.

In addition to these two types of questionnaires there are questionnaires developed using a process of in-depth interviews, content validation in expert groups and face-to-face validation. One type of questionnaire is the type developed by professor Steineck (23-25).

Even still, all these questionnaires are based on communication between the patient and the institution health care, often scientists, but representing health care. It has been been indicated that patients answer differently if the questionnaires are handed out by the treating clinician(26) and studies have shown that men seem to be less prone to answer questionnaires, rendering the risk of bias(27-29).

It is a fact that modern information and communication technology, e.g. social networking sites, facilitates exciting opportunities for sharing information and for discussions. Patients want to use modern technique to facilitate efficient communication with their care provider. Furthermore, patients use the internet to find information about their health condition and to participate in communities where patients discuss with each other. It is easy to understand that these technical possibilities may offer some major opportunities for developing health care, and it may even be regarded as a potential veritable social revolution within health care (30). In a survey from 2013, roughly every fourth US adult reported that they had received information or support from others with the same health condition (31). There are different types of potential support that social interaction could provide, e.g. emotional support ("being there", listening, empathizing) or informational support (providing guidance and advice), even though there is a need for more evidence regarding benefits for the patients (32). One of the largest peer-to-peer forums for patients is "patients like me" attracting more than 400 000 of patients and ranging over more than 2500 health conditions, it has been reported that patients

have identified several benefits belonging to this community (33). The patients reported an increased understanding of their disease and their treatment options. The life after cancer includes both physical, emotional and social concerns, and it has been suggested that "Many people find that talking to other survivors, either one-on-one, in a support group or online, is very helpful" (34).

As pointed out above, peer-to-peer discussion may have the potential to support in different ways, e.g. emotional and informational. Potential gain includes better health outcome, e.g. quality of life but also how patients perceive and coop with their condition and situation. Therefore, as a complement to health outcome and quality of life questionnaires, instrument for measuring sense of coherence (35), questions about perceived illness, perceived recovery, health literacy and empowerment are also important to include. Finally, compliance to treatment will also be included.

In summary: The prognosis for patients with colorectal cancer has been improved in the last decades and it is important to focus on QoL after treatment. Survivors have to handle both physical, emotional and social problems and a health platform offering information, peer-to-peer discussion and the possibility to ask questions to care providers, could be a valuable support.

2.4 AIM OF THE STUDY

The overall aim with this study is to get a deeper understanding of the potential benefits with a health platform for patients diagnosed with colorectal cancer.

2.5 THE HYPOTHESIS

Our main hypotheses are that patients who are active on a health platform will:

- Have an improved self-efficacy for coping as measured by CBI-B?
- Be more well-informed and knowledgeable

2.6 THE HEALTH PLATFORM AND MENTORS

The research project will be using an existing health platform specially designed for post-cancer-treatment: www.eftercancern.se. This platform is developed in a research project between Gothenburg University and Sahlgrenska University hospital. The primary aim with this portal is to provide patients with up-to-date knowledge and to support increased quality of life by facilitating patients' self-care. This platform also allows patients to address questions to care givers. The platform will also support peer-to-peer discussion between patients (ongoing development).

Approximately 50 patients previously treated for colorectal cancer at Sahlgrenska University Hospital are recruited using previous patient cohorts from Sahlgrenska University Hospital/Östra using knowledge within the personnel from the outpatient clinic, the cancer rehabilitation unit at Jubileumskliniken Sahlgrenska University Hospital/Sahlgrenska, facebook advertisement and contact with Mag-och tarmförbundet (tillägg 180523). These patients will act as mentors active on the platform, and are invited to discuss their perception about the disease, treatment and symptoms. These mentors will have had their diagnosis at different time points, both 1, 2 and 5 years after their diagnosis, and they will be asked to participate at least once a week at the platform.

All participants in the study will be offered confidentiality and an alias when entering the study and will use that to create the account. However, as this is a research project they will be informed that their clinical data will be extracted from their patient charts and the Swedish Colorectal Cancer Registry. The alias will in a separate file be connected with their personal identification number.

2.7 STUDY DESIGN

2.7.1 Type of study / execution

This is a prospective randomized parallel group design. Consecutive patients will be recruited from participating hospitals and randomized to either "prescribed participation" or just receiving information about the platform but with no prescription. All patients are also receiving standard care.

After treatment all patients will receive information about the platform and the aim with the platform. A short demonstration of the platform will also be provided. The platform will contain general information on "Life after cancer treatment". It will be a forum to discuss with fellow-patients, both experienced and newly treated and it is also possible to address questions to health professionals.

After the demonstration an information about the study will be given and patients will be asked to participate. If accepted a consent form will be presented and signed by the patients. All patients will be given an alias – a username, to be used at the platform which gives the patients confidentiality. However, as this is a research project they will be informed that their clinical data will be extracted from their patient charts. The alias will in a separate file be connected with their personal identification number.

The patients randomized to intervention (prescribed participation) will be offered to contact a research nurse or researcher if they have any practical questions regarding the use of the platform.

All patients will be asked to answer a questionnaire at baseline, 3, 6 and 12 months after surgery. Patients will be answering the questionnaires electronically on the platform or in a paper version sent by ordinary mail.

2.7.2 Patients

All patients diagnosed or treated for colorectal cancer within the last year will be eligible for inclusion. An inclusion criteria is that the patient must be able to use the health platform, i.e. access to internet and digital equipment (computer, tablet or smart-phone).

2.7.3 Questionnaires / variables

At baseline information about: sex, age, co-morbidity, education, financial situation, occupation, smoking, drinking and physical activity will be collected. Furthermore, important clinical variables as stage of tumour, clinical variables regarding the type of surgery, additional treatment, hospital stay and complications will be collected from the Swedish Colorectal Cancer Registry

The comprehensive questionnaire will be given to the patients at inclusion after 3 ,6 and 12 months and will include:

1. Questions regarding return to a normal life after treatment if possible, perception of empowerment and knowledge of disease.
2. Compliance
3. Sense of Coherence (36, 37) (comprehensibility, manageability, and meaningfulness)
4. Specific questions regarding the Health platform regarding usability and perceived health impact.

2.7.4 Primary endpoint

The primary endpoints are:

- Perception of empowerment measured by CBI-B
- Knowledge of disease

2.7.5 Secondary endpoints

- Compliance to treatment and health advices
- Quality of life
- The perceived health impact by the Health platform
- The usability of the Health platform usability

2.7.6 Inclusion criteria

All patients diagnosed or treated for colorectal cancer within the last year at the including hospitals will be possible to include in the study. Patients that find the forum through the internet can also be included, regardless of treating hospital

2.7.7 Exclusion criteria

Inability to give informed consent or speaking and reading the Swedish language. No possibility to use a health platform.

2.7.8 External validity

All patients treated at the including hospitals will be registered and non-participation and the reason for this will be registered. We will also describe all patients that find the website on their own and compare them to the general population.

2.7.9 Patient information and informed consent

All patients will be asked to participate after receiving written information and a possibility to ask questions. They can accept participation either in writing on the informed consent form or through accepting information (exactly the same information) on the internet platform.

The mentor patients will also be asked to participate using an informative letter and signing an informed consent.

Written consent is obtained from each patient (Appendix III and IV).

2.8 WORK PLAN

Application to the Ethical Committee will be made in the fall of 2016, and after approval the printing of the short questionnaire will take place. The study is planned to begin at including hospitals in the end of 2016.

2.8 STATISTICAL METHODS

The data will be analysed with classical tests for comparing two independent samples. For quantitative data the primary choice will be independent samples student´s t-test, but maybe replaced by a Mann-Whitney U´s test in case of significantly skewed distribution shape. For categorized data, classical chi-square test will be used.

In case of significant differences between the two samples in terms of important potential confounders, the simple two-sample tests above will be replaced with regression analyses, adjusting for covariates. A list with potential confounders will be provided in the analyses plan.

Based on previous data the estimated standard deviation for CBI (12-item) is 16. During one year the estimated number of colorectal cancer patients is 500. Thereby, we predict that it will be possible to recruit at least 200 patients to each group. This will give us 80% power to detect a difference of at least 4.5 units at the CBI-B scale, based on a two-sided independent samples t-test and 5% level of significance. In other words, this study is dimensioned for detecting also a small difference, in terms of effect size (a difference of 4.5 corresponds to a Cohen's effect size of 4.5/16=0.29.

2.9 DATA RETRIEVAL AND REGISTRATION

The data on clinical information from the SCRCR will be included in a database that will identify the patients with a specific study code. The key code to the specific study code and the personal identification number will be held at a server at Sahlgrenska University Hospital. It will be locked with a password and it will not be possible to obtain without the consent from the PI or deputy PI. The results database will be placed on a server belonging to Gothenburg University with username and code for entry. A data manager, employed by the SSORG unit will be responsible for the database. All patients will retrieve a username for participation at the platform and via the platform respond to questionnaires.

The questionnaire and forum database contain patient identity in order to create a questionnaire dispatching systems upon follow-up. This database is located on O.G.L.A. Observable Global Life Analytics AB's dedicated and secured servers physically located in Germany. These servers are dedicated to medical research studies in Sweden. In order to access the patient's identity, the authorized personnel must go through O.G.L.A.'s data manager, Mark Meurer, in order to obtain the list. Mark only has access via an SSH key from his secured workstation only.

Patients that are non-active at the platform will be sent paper questionnaires by ordinary mail or use the Sunet Server within Göteborgs Universitet, whatever they prefer. (Updated up to this point 180522) Prior any contact with patients regarding questionnaires there will be a process started by checking the National Population Registry to ascertain that the patient is still alive. After a telephone contact with the

patient a questionnaire is sent out if the patient consents to continue participation, together with a prepaid return envelope. Two weeks later a "thank you or reminder" card is sent and if the questionnaire has not been returned two weeks after that, a reminder telephone call is made. After that no further contact is made.

For the various analyses described, a copy of the original database is made, without personal identification numbers, only with the study specific code. The study will be registered at ClinicalTrials.gov. An application to "Personuppgiftsombudet" at Sahlgrenska University Hospital for the key code database will also be made.

2.10 HEALTH ECONOMY

A health economic analysis regarding in and outpatient contact could be performed using data from the questionnaires.

2.11 ETHICAL CONSIDERATION

Ethical approval will be sought in the fall of 2016.

3.0 FINANCING

Financing has been applied for to the Swedish Cancer Society and the Kampradstiftelsen. ALF will also cover some of the costs.

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