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Keywords: Malignant colorectal polyp; Shared decision-making; Patient Decision Aids; pT1 colorectal cancer; completion resections; patient involvement

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Abstract:

Introduction: Management of unexpected malignant colorectal polyps removed endoscopically can be challenging due to the risk of tumour residue and lymphatic spread. International studies have shown that of those choosing surgical management instead of watchful waiting there are between 54-82% of bowel resections without evidence of tumour residue or lymphatic spread. As surgical management entails risks of complications and watchful waiting management entails risks of residue or recurrence, a clinical dilemma arises when choosing a management strategy. Shared decision-making is a concept that can be used in preference-sensitive decision-making to facilitate patient involvement and empowerment to facilitate active patient participation in the decision-making process. Methods and analysis: This study protocol describes our clinical multi-institutional, non-randomized, interventional Phase II study at Danish surgical departments planned to commence in the last quarter of 2023. The aim of this study is to examine whether shared decision-making and using a patient decision aid in consultations affects patients’ choice of management comparing with historical data. The secondary aim is to investigate patients’ experiences, perceived involvement, satisfaction, decision conflict and other outcomes using questionnaire feedback directly from the patients. Ethics and dissemination: There are no conflicts of interest for principal or local investigators in any of the study sites. All results will be published at Danish and international meetings, and in English language scientific peer-reviewed journals. In accordance with Danish law this non-biological study does not require submission for review by the Danish Health Research Ethics Committee (DHREC), however, before commencing inclusion of patients the DHREC will be asked to review the study for formal purposes. This study is registered at clinicaltrials.gov trial number: NCT05776381.

Strengths of this study are:
* This is a multi-institutional study
* Retrieval of patient data via the personal registration number (CPR) assigned to all Danish citizens at birth or immigration making follow-up more precise
* Using National Databases which use personal registration numbers
* No incentives provided to local investigators or participants for enrolment

Limitations of this study are:
* This is a non-randomized trial.

1. Introduction

Screening for bowel cancer has been implemented in several countries, leading to an increased number of patients being diagnosed with cancer at a very early stage. Often the cancer is only a small invasive focus in a polyp, macroscopically judged as benign and therefore removed endoscopically. In most cases, the patient will be cured by the endoscopic treatment alone. However, some subgroups of patients have an increased risk of residual tumour either locally or with lymphatic invasion, and it must be decided whether to proceed with a segmental bowel resection (so-called “completion resection”) or to keep the patient under close observation (“watchful waiting”). Choosing the right treatment once pathological examination identifies a small cancer constitutes a dilemma and a preference-sensitive clinical decision that needs to be made.

1.1 Background

The most recent annual reports from the Danish Bowel Cancer Database (DCCG) have provided detailed information on patients from the calendar years 2016-18 with local (endoscopic) excision of malignant colorectal polyps with or without subsequent completion resections [1-3]. During the three years, 1685 patients had a local excision, of whom 45% proceeded to a formal completion resection. In only 5% of cases, the reason for not proceeding to bowel resection was that the “patient chose not to go on with
surgery”. Of the resected specimens, with full pathology reports, 54% were without tumour or lymph node metastasis [3].

National and international recommendations are in place to support clinical decision-making based on histopathological risk factors such as tumour size and grade, lymphatic invasion, etc. [4, 5]. In larger published series, roughly 75% of the completion resection bowel specimens are without residual cancer [6]. Moreover, it should be noted that even in the presence of risk factors, 5-year disease free survival is 70-80%, and overall survival is > 95%, in non-resected patients [6]. Hence, it seems that many patients are overtreated [7]. Moreover, surgery is not without risk as bowel resections entail a 15-20% complication rate, 4% anastomotic leakage rate and a considerable cost [8]. Therefore, it would be desirable to avoid as many unnecessary operations as possible, as long as the decision is consistent with the patient’s preferences.

A Danish national cohort study of propensity-matched patients from 2001 to 2011 showed that “watchful waiting” was not inferior to completion resection after endoscopic removal of a malignant colorectal polyp [9]. Of 629 patients, 61% were managed by watchful waiting rather than completion resection and there was no significant difference in disease free survival, overall survival and rates of local recurrence or metastases. No residual tumour or lymph node metastases were found in 82% of the resected specimens (268 patients). Furthermore, only 10% of patients with a resection margin less than 1 mm after polypectomy eventually had residual disease [9].

This problem of potential overtreatment may cause thousands of patients worldwide to undergo surgery each year that potentially could be avoided. Further research should be conducted to improve risk assessment and the evidence base of patient counselling; however, it is also of utmost importance that patients are involved in clinical decision-making. They should be adequately informed and their personal values and preferences should be taken into consideration in a structured and timely manner. Shared decision-making (SDM) may be used to achieve this.

Shared Decision-Making (SDM) is about helping patients faced with difficult choices and eliciting their preferences, not only diagnosing or treating disease. SDM is a concept based on the principle that the healthcare professional communicates medical knowledge to the patient, and that patients’ perspectives, preferences and medical options are included in the clinical conversation and decision-making. It is a collaborative process allowing patients and healthcare professionals to establish a partnership and together, through dialogue, identify how to best support and make the shared decision and which treatment is the best match to the patient’s perspectives and preferences. Shared decision-making thus helps patients to more actively participate in treatment decisions.

Patient decision aids (PtDA) are tools used in SDM to illustrate and inform patients about the choice and different options in a standardized way, to empower and invite the patient to participate in the decision-making process, considering their personal values [10]. These tools can be handouts, pamphlets or links to online information. The PtDA can be used before, during or after the consultation. The use of such tools is relevant when there are several options and when the options have benefits and risks that are valued differently by patients, in other words, when making a preference-sensitive decision. [11] Stacey et al. evaluated the use of PtDAs in a Cochrane review from 2017 [10]. The conclusion was that PtDAs enabled patients to become active, informed participants. Moreover, PtDAs have been shown to increase patient knowledge, reduce decisional conflict and thereby help patients make decisions that align with their personal preferences [10]. An ‘effective’ patient decision aid requires evidence that the PtDA improves the quality of the SDM process and the decision itself [12, 13].

Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences [10]. PtDAs were also shown to reduce the number of people choosing major elective invasive surgery in favour of more conservative options [10, 14]. Of the 18 studies included in the review focusing on the choice of major elective surgery, only five were studies on cancer patients: two
studies on prostate cancer and three studies on breast cancer. Two of these five studies showed statistically significant reductions in surgical rates [10].

Tailoring interventions to match the individual patient and clinical situation as precisely as possible is a hallmark of modern surgery. With an increased focus on the patient’s right to self-determination as well as long-term outcomes, it is self-evident that information on the individual patient’s expectations and preferences should be discussed. This is particularly true in clinical dilemmas like the present one, in which all options include a trade-off between pros and cons, and the evidence base is incomplete. This calls for a new and more structured consultation design. Incorporating PtDAs and SDM in patient counselling may empower the patient to actively make the best preference-sensitive decision, leading to better decisions as perceived by the patient, and potentially fewer unnecessary surgeries. SDM has not previously been studied in the management of malignant colorectal polyps and few studies exist on the impact of overtreatment.

The primary aim of this study is to investigate whether the use of an in-consult PtDA, when counselling and sharing decisions with patients with an unexpected malignant polyp, leads to improved decision-making and a change in the number of patients undergoing completion resections. Secondary aims are to investigate the effect of the use of an in-consult PtDA and the shared decision-making approach on Patient Reported Outcome Measures, Patient Reported Experience Measures, and on the change in long-term outcomes compared to historical data” or to keep the patient under close observation (“watchful waiting”). Choosing the right treatment once pathological examination identifies a small cancer constitutes a dilemma and a preference-sensitive clinical decision that needs to be made.

2. Materials and Methods

2.1 Study design and setting

The study is a clinical multi-institutional, non-randomized, interventional Phase II study. Three to five colorectal surgery departments in Danish hospitals will be invited to participate in the study (list of study sites will be available on clinicaltrials.gov once the study has been submitted). The eligibility criteria for study centres are surgical departments in Denmark offering completion resection surgery. Departments will be included based on their previously reported resection rates [2] to obtain a reliable estimate of the true effect.

2.2 Participants

Eligible patients for inclusion are over 18 years of age, with a histopathologically verified malignant colorectal polyp removed endoscopically, and in whom a CT-scan (and MRI if the malignant polyp was situated in the rectum) shows N0, M0 disease. Patients with known residual tumour left in situ after local resection, >N0 or >M0 are excluded. Patients are also excluded if they are unable to provide informed consent or are deemed inoperable due to comorbidity.

The surgical consultants participating in the study are certified colorectal surgeons with a high level of experience in colorectal cancer surgery and in cancer consultations.

2.2.1 Patient and Public Involvement

Patients were asked to evaluate the prototypes of the Decision Helper in a prior not yet published study, leading to this larger multi-centre study. The patients and public were not involved in the design of this study. The patients were not involved in the development of the research questions or outcome measures. Neither will they be asked to assess the burden of the intervention and time required to participate in the study. The patients in this study will first become involved in the study when asked whether they wish to participate. The participants will be asked whether they would like to receive a copy of the results of the project. At least one patient will be part of the data management committee.
2.3 Recruitment

Three to five surgical departments in Danish hospitals will be invited to participate in recruiting patients. One or more local investigators will be responsible for recruitment at each surgical department. The standard procedure for all patients with a verified colorectal cancer diagnosis in Denmark is discussion of management at multidisciplinary team meetings. Eligible patients for the project will be therefore be identified at these meetings by the local investigator or other study delegates. As the patients are identified prior to the consultation, recruitment will be invited upon arrival at the department before the consultation can take place.

All eligible patients will be asked, prior to the start of the consultation with the surgical consultant, to participate in the study. The consultation nurse or surgical consultant will provide the patient with oral and written information concerning the project and informed consent will be ensured before the consultation starts. Once informed consent has been given the consultation can start and the in-consult patient decision aid (PtDA) can be used in the consultation to facilitate shared decision-making. Participants may withdraw from the study for any reason at any time.

There are no financial incentives provided to local investigators or participants for enrolment.

2.4 Intervention

The intervention comprises the surgeon actively using SDM and the tailored in-consult PtDA with the patient in the consultation concerning the management of an unexpected malignant colorectal polyp.

All participating departments will receive an introduction to shared decision-making and the PtDA. The PtDA used in this study was developed in a previous study in accordance with IPDAS criteria [13], using current Danish national guidelines as the evidence informing the PtDA [4], and using the generic patient decision aid template developed and clinically tested by the Centre for Shared Decision Making, Vejle Hospital, Denmark [15, 16]. The tailored PtDA is presently being investigated in a field test study to substantiate whether there is a change in level of patient involvement in the decision-making process in consultations including the in-consult PtDA versus those without. This study has been reviewed by the National Committee on Health Research Ethics (reference number 20222000-09), is funded by the University of Southern Denmark and Lillebaelt University Hospital and the results will be published in peer-review journals in Q4, 2023.

Before commencing recruitment, the surgical consultants will have received a 3-hour introduction to shared decision-making from the principal investigator. The introduction will entail classroom teaching defining and explaining shared decision-making and PtDAs based on the evidence in the current literature, such as the latest Cochrane review on decision aids [10]. They will also be taught how to transition the theory to clinical practice based on the “Three talk model”, as an example of how to achieve shared decision-making [17, 18]. The tailored patient decision aid will then be introduced to the surgeons, who will be asked to actively practice using it in a simulation setting [19]. This will give them an opportunity to experience and reflect on how the PtDA can be used in a clinical setting, both with the individual patient, and integrating into the clinical pathway, prior to the first encounter with a real patient.

The estimated duration of the study is 4 years, comprising a one-year period for inclusion of patients and a 3-year follow up period for collection of long-term outcomes regarding residual disease and survival. The inclusion period is expected to begin in Q4, 2023.

2.5 Data collection and methods

2.5.1 Outcomes and data collection methods
The primary outcome is the change in proportion of completion resections in management of malignant colorectal polyps in the PtDA exposed cohort (number of patients undergoing a completion resection out of the total number of patients with an unexpected malignant polyp included in the study) compared to the historical data retrieved from the Danish Colorectal Cancer Database, the National Pathology database and the National Patient Register, as shown in Table 1.

The historical data will be retrieved from February 2018 to the end of 2022 as the current national guidelines were implemented at the start of 2018 and we are expecting the study to commence in ultimo 2023.

Secondary outcomes are:

- The change in the proportion of completion resections without residual tumour and/or lymph node metastases in the PtDA cohort (number of patients with a completion resection without residual tumour or lymph node metastases divided by the total number of patients with an unexpected malignant polyp included in the study phase) when compared with historical data.

- The differences in distribution of patient characteristics associated with choosing major elective surgery versus conservative management, 30- and 90-day postoperative morbidity and mortality, and recurrence and overall survival in the 3-year follow up period.

Further details concerning the outcome measures and collection methods are described in Table 1.
Table 1. Details concerning data collection outcome measure, unit and collection methods

<table>
<thead>
<tr>
<th>Data collection outcome Measure</th>
<th>Data collection Outcome Unit</th>
<th>Data collection method – study anno 2023-2024</th>
<th>Data collection method – historical data anno 2018-2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
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<tr>
<td>Completion resection</td>
<td>Proportion (number of patients undergoing a completion resection out of the total number of patients with an unexpected malignant polyp included in the study)</td>
<td>Danish Colorectal Cancer Group database</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resection without tumor or lymph node metastases</td>
<td>Proportion (number of patients with a completion resection without residual tumour or lymph node metastases divided by the total number of patients with an unexpected malignant polyp included in the study phase)</td>
<td>National Pathology Database</td>
<td>National Pathology Database</td>
</tr>
<tr>
<td>Patient Reported Experience Measures and Patient Reported Outcome Measure</td>
<td>See Table 2</td>
<td>Questionnaires</td>
<td>N/A</td>
</tr>
<tr>
<td>31 30- and 90-day morbidity and mortality</td>
<td>Proportion</td>
<td>Danish Colorectal Cancer Group database</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&amp; National Patient Register</td>
<td>&amp; National Patient Register</td>
</tr>
<tr>
<td>34 Recurrence and overall survival 3 years</td>
<td>Proportion</td>
<td>National Patient Register</td>
<td>National Patient Register</td>
</tr>
</tbody>
</table>

- Other secondary outcomes are Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs). PREMs measure the patient’s experiences throughout a treatment process, such as how well information was explained to them or perceived level of involvement in the clinical encounter [20]. PROMs measure the patient’s perspective of symptoms and health related quality of life in different stages of treatment in order to identify changes [20]. These measures are collected through the questionnaires described in detail in Table 2, including distribution, measures and scoring of each measure.
<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Distribution</th>
<th>Measures</th>
<th>No. Items</th>
<th>Item Range</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared Decision Making Questionnaire 9 (SDMQ-9)</td>
<td>At baseline after encounter</td>
<td>A patient-reported experience measure of the perceived level of involvement in decision-making in the clinical encounter</td>
<td>9</td>
<td>6 point Likert scale with extremes (Completely Disagree= 1 to Completely Agree= 6)</td>
<td>Raw total sum of 45. Transformed score: summed score, multiplied with 20/9. Range from 0 = lowest possible level of SDM to 100 = highest level of SDM</td>
</tr>
<tr>
<td>Shared Decision Making Process-4 (SDMP-4)</td>
<td>At baseline after encounter</td>
<td>A short patient-reported measure of the amount of SDM that occurs around a medical decision (Questions regarding: Options, pros, cons and preferences)</td>
<td>4</td>
<td>Q 1 &amp; 2: 4 point Likert scale (Not at all= 0 to A lot= 1) Q 3 &amp; 4: (Yes= 1 point, No= 0 points)</td>
<td>Total sum 0-4, with higher scores indicating more shared decision making</td>
</tr>
<tr>
<td>CollaboRATE [23]</td>
<td>At baseline after encounter</td>
<td>A patient-reported measure of patient experienced involvement in the decision-making process (regarding provider communication)</td>
<td>3</td>
<td>10 point Likert scale with Top score approach: extremes (Not at all= 0 points to Very much =9 points)</td>
<td>Reported as the percentage with the top score (27 points) versus anything less.</td>
</tr>
<tr>
<td>Decisional Conflict Scale (DCS) [24, 25]</td>
<td>At baseline after encounter</td>
<td>A patient-reported perceived measure of 5 dimensions of decision making (uncertainty, informed, values clarity, support, effective decision).</td>
<td>16</td>
<td>5 point Likert scale with extremes (Strongly agree= 0 points to Strongly disagree= 4 points)</td>
<td>Mean of sum Total score: summed score, divided by 16 and multiplied by 25. Ranges from 0 = no decisional conflict to 100 = extremely high decisional conflict.</td>
</tr>
<tr>
<td>Decision Regret Scale (DRS) [26]</td>
<td>3 months after clinical encounter</td>
<td>A patient-reported experienced measure of distress or remorse after a medical decision</td>
<td>5</td>
<td>5 point Likert scale with extremes (Strongly agree= 1 point to strongly disagree= 5 points)</td>
<td>Mean sum Total converted score: Mean sum of the 5 items, however, reversing items 2 and 4 as they are phrased in a negative direction. Then subtracting the mean sum by 1 and multiplying by 25. Ranging from 0 = no regret to 100 = high regret</td>
</tr>
</tbody>
</table>
Quality of Life

(EORTC QLQ-C30) [27]

At baseline after encounter & 3 months & 6 months after clinical encounter

A patient-reported outcome measure of health-related quality of life with three subscales:
functional scales/items, symptom scale and global health status.

Incorporated are nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social); three symptom scales (fatigue, pain and nausea and vomiting); and a global health and quality of life scale. Six additional single items, which are categorized as functional items: five single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, sleep disturbance, appetite loss, constipation and diarrhoea) and perceived financial impact of the disease.

Scores can be calculated for each scale/item or as a mean sum for each subscale:

**Functional scales score:** (sum subtracting 1, divided by range) multiplied by 100. Range in score from 0-100, where a high score indicates high level of functioning.

**Global health status score:** (sum subtracting 1, divided by range) multiplied by 100. Range in score from 0-100, where a high score represents high QOL.

**Symptom scales/items score:** (sum subtracting 1, divided by range) multiplied by 100. Range in score from 0-100, where a high score represents a high level of symptomology or problems.

Other secondary outcomes are significant predictors for treatment choices, recurrence, survival and morbidity. Predictors will be sought in patient demographic, morbidity, tumour and surgery-related variables. These variables and collection methods are presented in Table 3.

Demographic data on participating surgical consultant will also be collected. The consultants will be asked to fill out a background data form consisting of the following questions: years of experience as colorectal surgeon (number in years), participated in the SDM training (yes/no), gender (male/female), age group (20-30, 30-40, 40-50, 50-60, 60-70).
Table 3. Patient, tumour and surgery-related variables and method of collection

<table>
<thead>
<tr>
<th>Variable category</th>
<th>Variables</th>
<th>Collection methods for study and historical data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-related</td>
<td>Sex, age, diagnosis, height, weight, Tumour location, stage and TNM category, Tobacco and alcohol use, ASA score, performance status, Charlson Comorbidity Index (CCI) score</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td>Socioeconomic and demographic data</td>
<td>Statistics Denmark</td>
<td></td>
</tr>
<tr>
<td>Disease-related</td>
<td>Screening status, polyp histology, localization of polyp, reason for choice of conservative management as registered in the database, Histopathological risk-factors according to national guidelines</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Pathology Database</td>
</tr>
<tr>
<td>Surgery-related</td>
<td>Operative approach, procedure, reason for surgical completion resection</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Pathology Database</td>
</tr>
<tr>
<td>Outcome of completion resection according to national guidelines</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.5.2 Adherence

Patient and surgical consultant adherence to the study protocol will be sought by explaining the importance of the study when recruiting.

In order to monitor care provider adherence to the use of the PtDA in the actual consultation, the surgeon and the patient will be asked to fill out a questionnaire after the consultation describing to what degree the PtDA was used during this particular consultation.

2.5.3 Databases

The data collection outcome sources listed in Tables 1 and 3 are described in further detail below:

- The DCCG database is a high-quality national database hosted by RKKP (Regional Clinical Quality Control Program) holding clinical, demographic and histopathological data on patients with a first-time diagnosis of colorectal cancer in Denmark with >95% completeness [28]. Prospective registration in the database is compulsory for Danish surgeons and pathologists.
- The Danish National Pathology Database contains detailed nationwide records of all pathology specimens analysed since 1997 and a database with a high quality and high level of completeness of almost 100% [29].
- The Danish National Patient Registry contains information on all inpatients admitted to somatic hospital departments since 1977. Since 1995 persons admitted to psychiatric departments, outpatients and contacts in the emergency department have also been recorded. International Classification of Diseases (ICD) codes, procedure codes, examination codes and surgical procedures are among the data that have been registered since 1995. [30]
• Statistics Denmark is the central authority on national statistics. All socioeconomic and demographic data can be found in this database.
• The common key to all these databases is the personal registration number (CPR) assigned to all Danish citizens at birth or immigration.

2.5.4 Questionnaires

At the end of the consultation, the patient will be asked to complete the outcome questionnaires and at different points during the study, which are described in detail in Table 2.

The PREMS and PROMs will be retrieved by electronic questionnaire feedback. The REDCap platform (copyright Vanderbilt, Nashville, Tennessee, U.S., version 12.0.19) will be used [31] to build a study database from which the electronic questionnaires are sent automatically to e-Boks with the correct intervals.

e-Boks is a personal digital mailbox for secure mail used in Denmark by public and private senders, including the health authorities. All Danish citizens have this digital mailbox unless they have actively declined electronic mail and asked for ordinary mail. The system is used in several countries and has over 21 million users globally [32].

License to use the questionnaires before start of the study will be sought where necessary.

2.5.5 Retention

Participants may withdraw from the study for any reason at any time. To promote retention patients will be asked for consent to use their email address and telephone number for the follow-up period; in this way we will be able to remind them to complete the study questionnaires.

The patient will receive a reminder to complete the follow-up questionnaire 2 weeks later if the questionnaire has not been completed, and a telephone call 3 weeks after the first questionnaire was sent, if the questionnaire is still not completed.

In the case of non-retention, outcome data recorded are analysed according to intention-to-treat principle, however, missing data will be described for transparency.

2.5.6 Data management

All paper forms related to the study will be kept in locked cabinets. The data will be stored on the secure online servers of the Region of Southern Denmark at REDCap, which prevents unauthorized access to participant data. Single data entry will be entered by the primary investigator and the data will be stored for 5 years after the end of the study.

Information about potential and enrolled patients will be collected by the local investigators and entered in the aforementioned secure database in REDCap. The local investigators will have login permission to enter data regarding their own department only. Access to the study database will be restricted to the investigators involved in the study and data management, and the Region of Southern Denmark who own the database. The principal investigator is responsible for the storage and use of data.

2.6 Sample size

The trial is based on Simon’s two-stage mini-max design [33]. According to the DCCCG database, approx. 45% of all patients with a small polyp cancer are currently treated with a completion bowel resection. The hypothesis is that the use of SDM principles and a PtDA will reduce the number of completion resections by 30% (to 0.7x45% = 32%; absolute risk reduction (ARR) of 13%). In other words, the target is to increase the percentage of non-resected patients from 55% to 68%; With a significance level of 5% and power of 80%, the trial must initially include 51 patients in stage 1 of Simon’s two-stage design. If 27 or
fewer of these patients end up being treated conservatively (i.e., without resection), the trial will be
terminated owing to insufficient effect. However, if more than 27 patients are treated conservatively, the
study will move on to stage two and include a further 36 patients. The total number of included patients will
amount to 87, and if more than 56 of these are treated conservatively, we will conclude that the PtDA
intervention is sufficiently promising to warrant a phase III trial. To account for a dropout rate of 20%, a total
of 110 patients will be included. Data from stage 1 will be analysed using interim analyses and if the trial
continues to stage 2, data will be further analysed using inference analyses.

The yearly numbers of registered unexpected malignant colorectal polyps have been
identified in the DCCG database for each department in Denmark. The departments participating will be
selected based on this patient flow and their number of cases per year. With an estimated accrual rate of 70%
the participating departments will be able to recruit the estimated number of patients within approximately
12 months.

2.7 Statistical analysis

Descriptive statistics will be used to describe the study population and surgical consultant
demographics (mean, SD, range and frequencies). For binary outcomes analyses, Chi2 test or Fisher’s Exact
test will be employed as appropriate, and for ordinal outcomes analyses Mann-Whitney U test will be used.
Analyses on the total sample population will take into account the adaptive nature of the sampling while
considering both the planned and actual sample size [34]. A p-value of <0.05 will be considered statistically
significant. Statistical analysis will be performed using Stata version 17/BE (StataCorp, College Station, TX,
USA.).

30- and 90-day postoperative morbidity and mortality and 3-year recurrence and overall
survival will be analysed using Cox regression models using time since SDM-consultation as time scale.
Results from regression analysis will be presented as odds ratios (OR) with 95% confidence intervals (CI).
Time-to-event-analyses will be displayed, if possible, using Kaplan-Meier survival curves. In the case of
fewer than 10 events per group, Cox regression cannot be used, and the mortality and recurrence rates will
be shown.

2.8 Missing, monitoring and auditing data

The number of missing items will be described for each variable for transparency.

There will be a data monitoring committee independent of the study steering group
comprising of at least 2 independent researchers and at least one patient. The committee will review the
accumulating data every 6 months to determine whether the trial needs to be modified or discontinued. It
will report the outcome to the steering committee. The trial has also been designed with interim analysis and
stopping guidelines according to Simon’s two-stage design [33] as described above.

3. Ethics

Participants will receive both written and oral information and will be requested to sign an
informed consent before inclusion in the study, which will be scanned and stored in the electronic database.

In accordance with Danish law a non-biological study does not require submission for review
by the Danish Health Research Ethics Committee (DHREC). However, before commencing the study the
DHREC will be asked to review the study for formal purposes. The National Health Research Ethics
Committee require that participants have at least 24-hour deliberation time, if possible, before signing an
informed consent form before inclusion in the study. The participants will therefore receive an invitation to be
part of the study concerning the use of SDM in the consultation setting. However, the participants cannot
receive detailed information about the study as these patients are not informed of their cancer diagnosis before
attending the clinic. The consultation nurse or surgical consultant will recruit the patient using oral and written
information on the project and informed consent will be ensured before the consultation is started. After the
consultation the patients will receive a detailed description of the study. The study will follow the ethical
standards of the Declaration of Helsinki.

The permission to store study data according to the Danish rules on protection of personal data
will be approved by the Danish Data Protection Agency before inclusion of patients, and all data will be
deleted 5 years after end of study.

There are no conflicts of interest for principal or local investigators in any of the study sites.

The Danish Patient Compensation offers the opportunity to seek formal compensation if the
patients should suffer any harm due to the study.

4. Dissemination

All results will be published at Danish and international meetings, and in English language
scientific peer-reviewed journals. The recommendations for the conduct, reporting, editing, and publication
of scholarly work in medical journals as described by the International Committee of Medical Journal
Editors will be followed. Professional writers will not be used.

5. Discussion

The potential for overtreatment of thousands of patients each year despite compliance with
national guidelines calls for improvement of standard consultation practice. Patients must be empowered
and invited to participate in the decision-making process, taking their personal values into consideration,
making sure that they understand the pros and cons of each choice, and supporting them in making an
informed preference-sensitive decision. The shared decision-making concept can assist us in achieving this.

Our results will show whether a change in the proportion of completion resections occurs
when consultation management is exposed to the use of SDM and an in-consult PtDA, perhaps with more
patients opting for a more conservative approach. Our results will also give us important details concerning
patients’ experiences of shared decision-making in these consultations with a preference-sensitive choice that
needs to be made. This may help optimise SDM consultations in the future by helping us to understand how
SDM and the PtDA are perceived by the patient and in turn giving us the opportunity to tailor our
consultation approach or making changes to the PtDA. Finally, disclosing any demographic or
socioeconomic predictors for treatment choices may help us in developing better support for vulnerable and
deprived patients.

6. Conclusions

This clinical multi-institutional, non-randomized, interventional Phase II study will be the
first to examine whether the exposure to SDM and an in-consult PtDA in the management of an unexpected
malignant colorectal polyp can result in a change in the patients’ choice of completion resections and key
experience outcomes.

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Steffensen; Funding acquisition, Helene Würtz and Karina Steffensen; Investigation, Helene Würtz, Jan Lindebjerg and
Karina Steffensen; Methodology, Helene Würtz, Hans Rahr, Adrian Edwards and Karina Steffensen; Project
administration, Helene Würtz; Resources, Helene Würtz; Supervision, Hans Rahr and Adrian Edwards; Validation,
Adrian Edwards; Visualization, Helene Würtz and Karina Steffensen; Writing – original draft, Helene Würtz and Karina
References


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<td>24-Aug-2023</td>
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| Complete List of Authors: | Würtz, Helene; Vejle Hospital, Center for Shared Decision Making and Department of Surgery  
|                  | Rahr, Hans; University of Southern Denmark, Lindebjerg, Jan; Vejle Hospital, Pathology Department  
|                  | Edwards, Adrian; Cardiff University, Steffensen, Karina; University of Southern Denmark          |
| Primary Subject Heading: | Surgery                       |
| Secondary Subject Heading: | Gastroenterology and hepatology        |
| Keywords:       | Colorectal surgery < SURGERY, Clinical Decision-Making, Decision Making, Gastrointestinal tumours < GASTROENTEROLOGY, Patient Reported Outcome Measures, Patient-Centered Care |
The impact of an in-consult patient decision aid on treatment choices and outcomes of management for patients with an endoscopically resected malignant colorectal polyp. A study protocol for a non-randomized clinical Phase II study.

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Keywords: Malignant colorectal polyp; Shared decision-making; Patient Decision Aids; pT1 colorectal cancer; subsequent bowel resections; patient involvement
Abstract:

Introduction: Management of an endoscopically resected malignant colorectal polyps can be challenging due to the risk of residual tumour and lymphatic spread. International studies have shown, that of those choosing surgical management instead of surveillance strategy, there are between 54-82% of bowel resections without evidence of residual tumour or lymphatic spread. As surgical management entails risks of complications and surveillance strategy entails risks of residual tumour or recurrence, a clinical dilemma arises when choosing a management strategy. Shared decision-making is a concept that can be used in preference-sensitive decision-making to facilitate patient involvement and empowerment to facilitate active patient participation in the decision-making process. Methods and analysis: This study protocol describes our clinical multi-institutional, non-randomized, interventional Phase II study at Danish surgical departments planned to commence in the second quarter of 2024. The aim of this study is to examine whether shared decision-making and using a patient decision aid in consultations affect patients’ choice of management, comparing with retrospective data. The secondary aim is to investigate patients’ experiences, perceived involvement, satisfaction, decision conflict and other outcomes using questionnaire feedback directly from the patients. Ethics and dissemination: There are no conflicts of interest for principal or local investigators in any of the study sites. All results will be published at Danish and international meetings, and in English language scientific peer-reviewed journals. Our study underwent evaluation by the Regional Committees on Health Research Ethics for Southern Denmark (file number 20232000-47), concluding that formal approval was not required for this kind of research. This study is registered at clinicaltrials.gov trial number: NCT05776381.

Strengths of this study are:
* This is a multi-institutional study
* Retrieval of patient data via the personal registration number (CPR) assigned to all Danish citizens at birth or immigration making follow-up more precise
* Using National Databases which use personal registration numbers
* No incentives provided to local investigators or participants for enrolment

Limitations of this study are:
* This is a non-randomized trial.
1. Introduction

Screening for bowel cancer has been implemented in several countries, leading to an increased number of patients being diagnosed with cancer at a very early stage. Often the cancer is only a small invasive focus in a polyp, macroscopically judged as benign and therefore removed endoscopically. In most cases, the patient will be cured by the endoscopic treatment alone. However, some subgroups of patients have an increased risk of residual tumour either locally or with lymphatic invasion, and it must be decided whether to proceed with a subsequent bowel resection or to keep the patient under close observation with the surveillance strategy. Choosing the right treatment once pathological examination identifies a small cancer constitutes a dilemma and a preference-sensitive clinical decision that needs to be made.

1.1 Background

The most recent annual reports from the Danish Bowel Cancer Database (DCCG) have provided detailed information on patients from the calendar years 2016-18 with local (endoscopic) excision of malignant colorectal polyps with or without subsequent bowel resections [1-3]. During the three years, 1685 patients had a local excision, of whom 45% proceeded to subsequent bowel resection. In only 5% of cases, the reason for not proceeding to bowel resection was that the “patient chose not to go on with surgery”. Of the resected specimens, with full pathology reports, 54% were without tumour or lymph node metastasis [3].

National and international recommendations are in place to support clinical decision-making based on histopathological risk factors such as tumour size and grade, lymphatic invasion, etc. [4, 5]. In larger published series, roughly 75% of the subsequent bowel resection specimens are without residual cancer [6]. Moreover, it should be noted that even in the presence of risk factors, 5-year disease free survival is 70-80%, and overall survival is > 95%, in non-resected patients [6]. Hence, it seems that many patients are overtreated [7]. Moreover, surgery is not without risk as bowel resections entail a 15-20% complication rate, 4% anastomotic leakage rate and a considerable cost [8]. Therefore, it would be desirable to avoid as many unnecessary operations as possible, as long as the decision is consistent with the patient’s preferences.

A Danish national cohort study of propensity-matched patients from 2001 to 2011 showed that surveillance strategy was not inferior to subsequent bowel resection after endoscopic removal of a malignant colorectal polyp [9]. Of 629 patients, 61% were managed by surveillance strategy rather than subsequent bowel resection and there was no significant difference in disease free survival, overall survival and rates of local recurrence or metastases. No residual tumour or lymph node metastases were found in 82% of the resected specimens (268 patients). Furthermore, only 10% of patients with a resection margin less than 1 mm after polypectomy eventually had residual disease [9]. This problem of potential overtreatment may cause thousands of patients worldwide to undergo surgery each year that potentially could be avoided. Further research should be conducted to improve risk assessment and the evidence base of patient counselling; however, it is also of utmost importance that patients are involved in clinical decision-making. They should be adequately informed and their personal values and preferences should be taken into consideration in a structured and timely manner. Shared decision-making (SDM) may be used to achieve this.

Shared Decision-Making (SDM) is about helping patients faced with difficult choices and eliciting their preferences, not only diagnosing or treating disease. SDM is a concept based on the principle that the healthcare professional communicates medical knowledge to the patient, and that patients’ perspectives, preferences and medical options are included in the clinical conversation and decision-making. It is a collaborative process allowing patients and healthcare professionals to establish a partnership and together, through dialogue, identify how to best support and make the shared decision and which treatment
is the best match to the patient’s perspectives and preferences. Shared decision-making thus helps patients to more actively participate in treatment decisions.

Patient decision aids (PtDA) are tools used in SDM to illustrate and inform patients about the choice and different options in a standardized way, to empower and invite the patient to participate in the decision-making process, considering their personal values [10]. These tools can be handouts, pamphlets or links to online information. The PtDA can be used before, during or after the consultation. The use of such tools is relevant when there are several options and when the options have benefits and risks that are valued differently by patients, in other words, when making a preference-sensitive decision. [11] Stacey et al. evaluated the use of PtDAs in a Cochrane review from 2017 [10]. The conclusion was that PtDAs enabled patients to become active, informed participants. Moreover, PtDAs have been shown to increase patient knowledge, reduce decisional conflict and thereby help patients make decisions that align with their personal preferences [10]. An ‘effective’ patient decision aid requires evidence that the PtDA improves the quality of the SDM process and the decision itself [12, 13].

Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences [10]. PtDAs were also shown to reduce the number of people choosing major elective invasive surgery in favour of more conservative options [10, 14]. Of the 18 studies included in the review focusing on the choice of major elective surgery, only five were studies on cancer patients: two studies on prostate cancer and three studies on breast cancer. Two of these five studies showed statistically significant reductions in surgical rates [10].

Tailoring interventions to match the individual patient and clinical situation as precisely as possible is a hallmark of modern surgery. With an increased focus on the patient’s right to self-determination as well as long-term outcomes, it is self-evident that information on the individual patient’s expectations and preferences should be discussed. This is particularly true in clinical dilemmas like the present one, in which all options include a trade-off between pros and cons, and the evidence base is incomplete. This calls for a new and more structured consultation design. Incorporating PtDAs and SDM in patient counselling may empower the patient to actively make the best preference-sensitive decision, leading to better decisions as perceived by the patient, and potentially fewer unnecessary surgeries. The underlying hypothesis is that, patients who are involved in shared decision-making and informed impartially with the use of a patient decision aid, about the advantages and disadvantages of conservative versus surgical approaches for management of an (already) endoscopically removed colorectal polyp may, with the support of their surgeon, opt for a more conservative treatment pathway. One that also reflects their individual preferences. SDM has not previously been studied in the management of malignant colorectal polyps and few studies exist on the impact of overtreatment.

The primary aim of this study is to investigate whether the use of an in-consult PtDA, when counselling and sharing decisions with patients with an endoscopically resected malignant polyp, leads to improved decision-making and a change in the number of patients undergoing subsequent bowel resections. Secondary aims are to investigate the effect of the use of an in-consult PtDA and the shared decision-making approach on Patient Reported Outcome Measures, Patient Reported Experience Measures, and on the change in long-term outcomes compared to historical data.

2. Materials and Methods

2.1 Study design and setting

The study is a clinical multi-institutional, non-randomized, single-group, interventional Phase II study with retrospective data as comparator. Three to five colorectal surgery departments in Danish hospitals will be invited to participate in the study (list of study sites will be available on clinicaltrials.gov once the study has been submitted). The eligibility criteria for study centres are surgical departments in...
Denmark offering subsequent bowel resection surgery. Departments will be included based on their previously reported resection rates [2] to obtain a reliable estimate of the true effect. A table describing the study according to the World Health Organization Trial Registration Data Set has been added as Supplementary Material 1 and the SPIRIT guideline checklist has been added as Supplementary Material 2.

2.2 Participants

The current Danish guidelines recommend proceeding with formal bowel resection after endoscopic resection of a malignant polyp, if the following histopathological features are present in the polypectomy specimen: resection margin < 1 mm, deep submucosal invasion comparable to Kikuchi level ≥ 2, poor differentiation, lymphovascular invasion, or tumor budding density ≥ 2. Moreover, if one or more of these histopathological factors are missing from the pathology report, this is also considered a risk factor per se. If the clinical T category of the tumour as judged by preoperative imaging (cT) is > 1 then subsequent bowel resection is also recommended. If none of the above risk factors are present the recommendation is to follow the surveillance strategy with endoscopies and CT-scans. [15]

In this study, a malignant colorectal polyp is defined as an endoscopically resected colorectal polyp with subsequent histopathological demonstration of a focus of adenocarcinoma. Legally competent patients aged 18 or older with a malignant colorectal polyp are eligible for inclusion, provided that preoperative imaging with thoracoabdominal CT-scan (and MRI in case of a rectal polyp) shows N0, M0 disease. Patients with known residual tumour left in situ after local resection, or >cN0 or >cM0 are excluded. Patients are also excluded if they are unable to provide informed consent or are deemed inoperable due to comorbidity, i.e., if formal bowel resection is not an option.

The surgical consultants participating in the study are specialist gastrointestinal surgeons experienced in colorectal cancer surgery and cancer consultations.

2.2.1 Patient and Public Involvement

Patients were asked to evaluate the prototypes of the Decision Helper in a prior not yet published study, leading to this larger multi-centre study. The patients and public were not involved in the design of this study. The patients were not involved in the development of the research questions or outcome measures. Neither will they be asked to assess the burden of the intervention and time required to participate in the study. The patients in this study will first become involved in the study when asked whether they wish to participate. The participants will be asked whether they would like to receive a copy of the results of the project. At least one patient will be part of the data management committee.

2.3 Recruitment

Three to five surgical departments in Danish hospitals will be invited to participate in recruiting patients. One or more local investigators will be responsible for recruitment at each surgical department. The standard procedure for all patients with a verified colorectal cancer diagnosis in Denmark is discussion of management at multidisciplinary team meetings. Eligible patients for the project will be therefore be identified at these meetings by the local investigator or other study delegates. As the patients are identified prior to the consultation, recruitment will be invited upon arrival at the department before the consultation can take place.

All eligible patients will be asked, prior to the start of the consultation with the surgical consultant, to participate in the study. The consultation nurse or surgical consultant will provide the patient with oral and written information concerning the project and informed consent will be ensured before the consultation starts. Once informed consent has been given the consultation can start and the in-consult
patient decision aid (PtDA) can be used in the consultation to facilitate shared decision-making. Participants may withdraw from the study for any reason at any time.

There are no financial incentives provided to local investigators or participants for enrolment.

2.4 Intervention

The intervention comprises the surgeon actively using SDM and the tailored in-consult PtDA with the patient in the consultation concerning the management of an endoscopically resected malignant colorectal polyp.

All participating departments will receive an introduction to shared decision-making and the PtDA. The PtDA used in this study was developed in a previous study in accordance with IPDAS criteria [13], using current Danish national guidelines as the evidence informing the PtDA [4], and using the generic patient decision aid template developed and clinically tested by the Center for Shared Decision Making, Vejle Hospital, Denmark [16, 17]. The Patient Decision Aid (PtDA) underwent testing with prospective patients and clinicians before its use in the clinical setting. Usability, acceptability, and effectiveness in facilitating the decision-making process were assessed through an alpha-test involving 11 clinicians and 16 patients. This assessment included structured interviews guided by questionnaires inspired by the alpha-testing method introduced by Dawn Stacey [18]. Feedback, responses, and insights collected from participants were collated by the principal investigator and subsequently utilized to revise and refine the PtDA. The tailored PtDA is presently being investigated in a field test study to substantiate whether there is a change in level of patient involvement in the decision-making process in consultations including the in-consult PtDA versus those without. The PtDA has been added as Supplementary Material 3. This preceding PtDA development study was also reviewed by the Regional Committees on Health Research Ethics for Southern Denmark (reference number 20222000-09). The PtDA development study was funded by the University of Southern Denmark and Lillebaelt University Hospital and the results of this isolated PtDA development study will be published in peer-review journals in Q2, 2024.

Before commencing recruitment, the surgical consultants will have received a 3-hour introduction to shared decision-making from the principal investigator. The introduction will entail classroom teaching defining and explaining shared decision-making and PtDAs based on the evidence in the current literature, such as the latest Cochrane review on decision aids [10]. They will also be taught how to transition the theory to clinical practice based on the “Three talk model”, as an example of how to achieve shared decision-making [19, 20]. The tailored patient decision aid will then be introduced to the surgeons, who will be asked to actively practice using it in a simulation setting [21]. This will give them an opportunity to experience and reflect on how the PtDA can be used in a clinical setting, both with the individual patient, and integrating into the clinical pathway, prior to the first encounter with a real patient. The PtDA facilitates patient engagement in the decision-making process by aiding them in determining the most suitable management option based on individual circumstances. This is accomplished through the provision of a paper leaflet (the PtDA) containing summaries of potential advantages and disadvantages associated with each available option for management. The PtDA is designed to be universally applicable across instances of malignant colorectal polyps. The statistical data presented therein portrays the broader population trends, which the surgeon will subsequently customize to offer personalized information to each patient. The estimated duration of the study is 4 years, comprising a one-year period for inclusion of patients and a 3-year follow up period for collection of long-term outcomes regarding residual disease and survival. The inclusion period is expected to begin in Q2, 2024.

2.5 Data collection and methods

2.5.1 Outcomes and data collection methods

The primary outcome is the change in proportion of subsequent bowel resections in management of malignant colorectal polyps in the PtDA exposed cohort when compared with the
participating hospitals’ own retrospective data retrieved from the Danish Colorectal Cancer Database, the National Pathology database and the National Patient Register, as shown in Table 1.

The retrospective comparator data will be retrieved from February 2018 to the end of 2025. In addition to comparing the participating hospitals' study data with their own retrospective data, we will compare with hospitals not participating in our study to control for any general developments or practice changes with time.

Secondary outcomes are:

- The change in the proportion of subsequent bowel resections without residual tumour and/or lymph node metastases in the PtDA cohort when compared with historical data.
- The differences in distribution of patient characteristics associated with choosing major elective surgery versus conservative management, 30- and 90-day postoperative morbidity and mortality, and recurrence and overall survival in the 3-year follow up period.

Further details concerning the outcome measures and collection methods are described in Table 1.

Table 1. Details concerning data collection outcome measure, unit and collection methods

<table>
<thead>
<tr>
<th>Data collection outcome</th>
<th>Data collection Outcome Unit</th>
<th>Data collection method – study anno 2024-2025</th>
<th>Data collection method – retrospective data anno 2018-2023</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subsequent bowel resection</td>
<td>Proportion (number of patients undergoing bowel resection out of the total number of patients with an endoscopically resected malignant polyp included in the study)</td>
<td>Danish Colorectal Cancer Group database</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resection without tumor or lymph node metastases</td>
<td>Proportion (number of patients with a subsequent bowel resection without residual tumour or lymph node metastases divided by the total number of patients with an endoscopically resected malignant polyp included in the study phase)</td>
<td>National Pathology Database</td>
<td>National Pathology Database</td>
</tr>
<tr>
<td>Patient Reported Experience Measures and Patient Reported Outcome Measure</td>
<td>See Table 2</td>
<td>Questionnaires</td>
<td>N/A</td>
</tr>
<tr>
<td>30- and 90-day morbidity and mortality</td>
<td>Proportion</td>
<td>Danish Colorectal Cancer Group database &amp; National Patient Register</td>
<td>Danish Colorectal Cancer Group database &amp; National Patient Register</td>
</tr>
<tr>
<td>Recurrence and overall survival 3 years</td>
<td>Proportion</td>
<td>National Patient Register</td>
<td>National Patient Register</td>
</tr>
</tbody>
</table>
• Other secondary outcomes are Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs). PREMs measure the patient’s experiences throughout a treatment process, such as how well information was explained to them or perceived level of involvement in the clinical encounter [20]. PROMs measure the patient’s perspective of symptoms and health related quality of life in different stages of treatment in order to identify changes [20]. These measures are collected through the questionnaires described in detail in Table 2, including distribution, measures and scoring of each measure.

• Other secondary outcomes are significant predictors for treatment choices, recurrence, survival and morbidity. Predictors will be sought in patient demographic, morbidity, tumour and surgery-related variables. These variables and collection methods are presented in Table 3.

Demographic data on participating surgical consultant will also be collected. The consultants will be asked to fill out a background data form consisting of the following questions: years of experience as colorectal surgeon (number in years), participated in the SDM training (yes/no), gender (male/female), age group (20-30, 30-40, 40-50, 50-60, 60-70).

A schematic diagram of the study plan can be seen in Table 4.
<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Distribution</th>
<th>Measures</th>
<th>No. Items</th>
<th>Item Range</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared Decision Making Questionnaire 9 (SDMQ-9) [22]</td>
<td>At baseline after encounter</td>
<td>A patient-reported experience measure of the perceived level of involvement in decision-making in the clinical encounter</td>
<td>9</td>
<td>6 point Likert scale with extremes (Completely Disagree= 1 to Completely Agree= 6)</td>
<td>Raw total sum of 45. Transformed score: summed score, multiplied with 20/9. Range from 0 = lowest possible level of SDM to 100= highest level of SDM</td>
</tr>
<tr>
<td>Shared Decision Making Process-4 (SDMP-4) [23]</td>
<td>At baseline after encounter</td>
<td>A short patient-reported measure of the amount of SDM that occurs around a medical decision (Questions regarding: Options, pros, cons and preferences)</td>
<td>4</td>
<td>Q 1 &amp; 2: 4 point Likert scale (Not at all= 0 to A lot= 1) Q 3 &amp; 4: (Yes= 1 point, No= 0 points)</td>
<td>Total sum 0-4, with higher scores indicating more shared decision making</td>
</tr>
<tr>
<td>CollaboRATE [24]</td>
<td>At baseline after encounter</td>
<td>A patient-reported measure of patient experienced involvement in the decision-making process (regarding provider communication)</td>
<td>3</td>
<td>10 point Likert scale with Top score approach: extremes (Not at all= 0 points to Very much =9 points)</td>
<td>Reported as the percentage with the top score (27 points) versus anything less.</td>
</tr>
<tr>
<td>Decisional Conflict Scale (DCS) [25, 26]</td>
<td>At baseline after encounter</td>
<td>A patient-reported perceived measure of 5 dimensions of decision making (uncertainty, informed, values clarity, support, effective decision).</td>
<td>16</td>
<td>5 point Likert scale with extremes (Strongly agree= 0 points to Strongly disagree= 4 points)</td>
<td>Mean of sum Total score: summed score, divided by 16 and multiplied by 25. Ranges from 0 = no decisional conflict to 100 = extremely high decisional conflict.</td>
</tr>
<tr>
<td>Decision Regret Scale (DRS) [27]</td>
<td>3 &amp; 6 months after clinical encounter</td>
<td>A patient-reported experienced measure of distress or remorse after a medical decision</td>
<td>5</td>
<td>5 point Likert scale with extremes (Strongly agree= 1 point to strongly disagree= 5 points)</td>
<td>Mean of sum Total converted score: Mean sum of the 5 items, however, reversing items 2 and 4 as they are phrased in a negative direction. Then subtracting the mean sum by 1 and multiplying by 25. Ranging from 0 = no regret to 100 = high regret</td>
</tr>
</tbody>
</table>
Quality of Life (EORTC QLQ-C30) [28]

At baseline after encounter & 3 months & 6 months after clinical encounter

- A patient-reported outcome measure of health-related quality of life with three subscales: **functional scales/items, symptom scale and global health status**.
- Incorporated are nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social); three symptom scales (fatigue, pain and nausea and vomiting); and a global health and quality of life scale. Six additional single items, which are categorized as functional items: five single items assessing additional symptoms commonly reported by cancer patients (dyspnoea, sleep disturbance, appetite loss, constipation and diarrhoea) and perceived financial impact of the disease.

5 point Likert scale with extremes (Not at all= 1 to Very much= 4)

Scores can be calculated for each scale/item or as a mean sum for each subscale:

**Functional scales score:** \( \frac{1}{3}(\text{sum subtracting 1 and dividing by range of 3}) \times 100 \). Range in score from 0-100, a higher score indicates high level of functioning.

**Global health status score:** \( \frac{1}{1}(\text{sum subtracting 1, divided by range}) \times 100 \). Range in score from 0-100, where a high score represents high QOL.

**Symptom scales/items score:** \( \frac{1}{2}(\text{sum subtracting 1, divided by range}) \times 100 \). Range in score from 0-100, where a high score represents a high level of symptomology or problems
Table 3. Patient, tumour and surgery-related variables and method of collection

<table>
<thead>
<tr>
<th>Variable category</th>
<th>Variables</th>
<th>Collection methods for study and historical data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-related</td>
<td>Sex, age, diagnosis, height, weight, Tumour location, stage and TNM category, Tobacco and alcohol use, ASA score, performance status, Charlson Comorbidity Index (CCI) score</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td></td>
<td>Socioeconomic and demographic data</td>
<td>Statistics Denmark</td>
</tr>
<tr>
<td>Disease-related</td>
<td>Screening status, polyp histology, localization of polyp, reason for choice of conservative management as registered in the database, Histopathological risk-factors according to national guidelines</td>
<td>Danish Colorectal Cancer Group database</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Pathology Database</td>
</tr>
<tr>
<td>Surgery-related</td>
<td>Operative approach, procedure, reason for surgical subsequent bowel resection</td>
<td>Danish Colorectal Cancer Group database</td>
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<tr>
<td></td>
<td>Outcome of subsequent bowel resection according to national guidelines</td>
<td>National Pathology Database</td>
</tr>
</tbody>
</table>
2.5.2 Adherence

Patient and surgical consultant adherence to the study protocol will be sought by explaining the importance of the study when recruiting.

In order to monitor care provider adherence to the use of the PtDA in the actual consultation, the surgeon and the patient will be asked to fill out a questionnaire after the consultation describing to what degree the PtDA was used during this particular consultation.

2.5.3 Databases

The data collection outcome sources listed in Tables 1 and 3 are described in further detail below:

- The DCCG database is a high-quality national database hosted by RKKP (Regional Clinical Quality Control Program) holding clinical, demographic and histopathological data on patients with a first-

<table>
<thead>
<tr>
<th>Event / Time</th>
<th>Prior to consultation</th>
<th>Intervention (time=0)</th>
<th>Surgery after intervention</th>
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<th>3 months later</th>
<th>6 months later</th>
<th>3 year follow-up</th>
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<td>Shared Decision Making Questionnaire 9</td>
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<td>Quality of life questionnaire</td>
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<td>Recurrence and overall survival</td>
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<td></td>
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</table>
time diagnosis of colorectal cancer in Denmark with >95% completeness [29]. Prospective registration in the
database is compulsory for Danish surgeons and pathologists.

- The Danish National Pathology Database contains detailed nationwide records of all
pathology specimens analysed since 1997 and a database with a high quality and high level of completeness
of almost 100% [30].

- The Danish National Patient Registry contains information on all inpatients admitted to
somatic hospital departments since 1977. Since 1995 persons admitted to psychiatric departments,
outpatients and contacts in the emergency department have also been recorded. International Classification
of Diseases (ICD) codes, procedure codes, examination codes and surgical procedures are among the data
that have been registered since 1995 [31].

- Statistics Denmark is the central authority on national statistics. All socioeconomic and
demographic data can be found in this database.

- The common key to all these databases is the personal registration number (CPR) assigned to
all Danish citizens at birth or immigration.

2.5.4 Questionnaires

At the end of the consultation, the patient will be asked to complete the outcome
questionnaires and at different points during the study, which are described in detail in Table 2.

The PREMS and PROMs will be retrieved by electronic questionnaire feedback. The REDCap
platform (copyright Vanderbilt, Nashville, Tennessee, U.S., version 12.0.19) will be used [32] to build a study
database from which the electronic questionnaires are sent automatically to e-Boks with the correct intervals.
e-Boks is a personal digital mailbox for secure mail used in Denmark by public and private senders,
including the health authorities. All Danish citizens have this digital mailbox unless they have actively
declined electronic mail and asked for ordinary mail. The system is used in several countries and has over 21
million users globally [33].

License to use the questionnaires before start of the study will be sought where necessary.

2.5.5 Retention

Participants may withdraw from the study for any reason at any time. To promote retention
patients will be asked for consent to use their email address and telephone number for the follow-up period;
in this way we will be able to remind them to complete the study questionnaires.

The patient will receive a reminder to complete the follow-up questionnaire 2 weeks later if
the questionnaire has not been completed, and a telephone call 3 weeks after the first questionnaire was sent,
if the questionnaire is still not completed.

In the case of non-retention, outcome data recorded are analysed according to intention-to-
treat principle, however, missing data will be described for transparency.

2.5.6 Data management

All paper forms related to the study will be kept in locked cabinets. The data will be stored on
the secure online servers of the Region of Southern Denmark at REDCap, which prevents unauthorized
access to participant data. Single data entry will be entered by the primary investigator and the data will be
stored for 5 years after the end of the study.
Information about potential and enrolled patients will be collected by the local investigators and entered in the aforementioned secure database in REDCap. The local investigators will have login permission to enter data regarding their own department only. Access to the study database will be restricted to the investigators involved in the study and data management, and the Region of Southern Denmark who own the database. The principal investigator is responsible for the storage and use of data.

2.6 Sample size

The trial is based on Simon’s two-stage mini-max design [34]. According to the DCCG database, approx. 45% of all patients with a small polyp cancer are currently treated with a subsequent bowel resection. The hypothesis is that the use of SDM principles and a PtDA will reduce the number of subsequent bowel resections by 30% (to 0.7x45% = 32%; absolute risk reduction (ARR) of 13%). In other words, the target is to increase the percentage of non-resected patients from 55% to 68%; With a significance level of 5% and power of 80%, the trial must initially include 51 patients in stage 1 of Simon’s two-stage design. If 27 or fewer of these patients end up being treated conservatively (i.e., without resection), the trial will be terminated owing to insufficient effect. However, if more than 27 patients are treated conservatively, the study will move on to stage two and include a further 36 patients. The total number of included patients will amount to 87, and if more than 56 of these are treated conservatively, we will conclude that the PtDA intervention is sufficiently promising to warrant a phase III trial. To account for a dropout rate of 20%, a total of 110 patients will be included. Data from stage 1 will be analysed using interim analyses and if the trial continues to stage 2, data will be further analysed using inference analyses.

The yearly numbers of registered endoscopically resected malignant colorectal polyps have been identified in the DCCG database for each department in Denmark. The departments participating will be selected based on this patient flow and their number of cases per year. With an estimated accrual rate of 70% the participating departments will be able to recruit the estimated number of patients within approximately 12 months.

2.7 Statistical analysis

Descriptive statistics will be used to describe the study population and surgical consultant demographics (mean, SD, range and frequencies). For binary outcomes analyses, Chi2 test or Fisher’s Exact test will be employed as appropriate, and for ordinal outcomes analyses Mann-Whitney U test will be used. Analyses on the total sample population will take into account the adaptive nature of the sampling while considering both the planned and actual sample size [34]. A p-value of <0.05 will be considered statistically significant. Statistical analysis will be performed using Stata version 17/BE (StataCorp, College Station, TX, USA.).

30- and 90-day postoperative morbidity and mortality and 3-year recurrence and overall survival will be analysed using Cox regression models using time since SDM-consultation as time scale. Results from regression analysis will be presented as odds ratios (OR) with 95% confidence intervals (CI). Time-to-event-analyses will be displayed, if possible, using Kaplan-Meier survival curves. In the case of fewer than 10 events per group, Cox regression cannot be used, and the mortality and recurrence rates will be shown.

2.8 Missing, monitoring and auditing data

The number of missing items will be described for each variable for transparency.

There will be a data monitoring committee independent of the study steering group comprising of at least 2 independent researchers and at least one patient. The committee will review the accumulating data every 6 months to determine whether the trial needs to be modified or discontinued. It
will report the outcome to the steering committee. The trial has also been designed with interim analysis and stopping guidelines according to Simon's two-stage design [35] as described above.

3. Ethics

Participants will receive both written and oral information and will be requested to sign an informed consent before inclusion in the study, which will be scanned and stored in the electronic database. The patient information and consent form has been added as Supplementary Material 4.

Our study underwent evaluation by the Regional Committees on Health Research Ethics for Southern Denmark (file number 20232000-47), concluding that formal approval was not required for this kind of research. According to Danish law, only studies involving an intervention with the use of human biological material or within the definitions of the Committee Act need approval by the Committee on Health Research Ethics (CHRE).

The CHRE suggest that participants have at least 24-hour deliberation time, if possible, before signing an informed consent form before inclusion in the study. The participants will therefore receive an invitation to be part of the study concerning the use of SDM in the consultation setting. However, the participants cannot receive detailed information about the study as these patients are not informed of their cancer diagnosis before attending the clinic. The consultation nurse or surgical consultant will recruit the patient using oral and written information on the project and informed consent will be ensured before the consultation is started. After the consultation the patients will receive a detailed description of the study. The study will follow the ethical standards of the Declaration of Helsinki. Important modifications of the study protocol which has an impact on the study design, aim, patient inclusion or significant administrative aspects will be documented in the submitted study article for transparency and also sent to the Editor of the journal in which the study protocol has been published to be added as supplementary material. Lastly, it will also be registered in clinicaltrials.gov.

The permission to store study data according to the Danish rules on protection of personal data will be approved by the Danish Data Protection Agency before inclusion of patients, and all data will be deleted 5 years after end of study.

There are no conflicts of interest for principal or local investigators in any of the study sites.

The Danish Patient Compensation offers the opportunity to seek formal compensation if the patients should suffer any harm due to the study.

4. Dissemination

All results will be published at Danish and international meetings, and in English language scientific peer-reviewed journals. The recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals as described by the International Committee of Medical Journal Editors will be followed. Professional writers will not be used.

5. Discussion

The potential for overtreatment of thousands of patients each year despite compliance with national guidelines calls for improvement of standard consultation practice. Patients must be empowered and invited to participate in the decision-making process, taking their personal values into consideration, making sure that they understand the pros and cons of each choice, and supporting them in making an informed preference-sensitive decision. The shared decision-making concept can assist us in achieving this.
Our results will show whether a change in the proportion of subsequent bowel resections occurs when consultation management is exposed to the use of SDM and an in-consult PtDA, perhaps with more patients opting for a more conservative approach. Our results will also give us important details concerning patients’ experiences of shared decision-making in these consultations with a preference-sensitive choice that needs to be made. This may help optimise SDM consultations in the future by helping us to understand how SDM and the PtDA are perceived by the patient and in turn giving us the opportunity to tailor our consultation approach or making changes to the PtDA. Finally, disclosing any demographic or socioeconomic predictors for treatment choices may help us in developing better support for vulnerable and deprived patients.

This clinical multi-institutional, non-randomized, interventional Phase II study will be the first to examine whether the exposure to SDM and an in-consult PtDA in the management of an endoscopically resected malignant colorectal polyp can result in a change in the patients’ choice of subsequent bowel resections and key experience outcomes.

Acknowledgement and author contributions: Conceptualization, Helene Würtz, Hans Rahr, Adrian Edwards and Karina Steffensen; Funding acquisition, Helene Würtz and Karina Steffensen; Investigation, Helene Würtz, Jan Lindebjerg and Karina Steffensen; Methodology, Helene Würtz, Hans Rahr, Adrian Edwards and Karina Steffensen; Project administration, Helene Würtz; Resources, Helene Würtz; Supervision, Hans Rahr and Adrian Edwards; Validation, Adrian Edwards; Visualization, Helene Würtz and Karina Steffensen; Writing – original draft, Helene Würtz and Karina Steffensen; Writing – review & editing, Helene Würtz, Hans Rahr, Jan Lindebjerg, Adrian Edwards and Karina Steffensen. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by the University of Southern Denmark scholarship. This funding source had no role in the design, execution, analyses, interpretation of the study nor in the decision to submit the report for publication.

Sponsor: Department of Surgery and Center for Shared Decision Making, Vejle/Lillebaelt, University Hospital of Southern Denmark, Vejle, 7100, Denmark.

Informed Consent Statement: Informed consent will be obtained from all subjects involved in the study.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

References


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### SPIRIT GUIDELINES

**SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents**

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
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<td>Names, affiliations, and roles of protocol contributors</td>
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<td>Roles and responsibilities</td>
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<td>Name and contact information for the trial sponsor</td>
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<td>Roles and responsibilities</td>
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<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
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<tr>
<td>Roles and responsibilities</td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
<td>6,13,14,15</td>
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</table>
Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention 3+4

6b Explanation for choice of comparators 6

Objectives 7 Specific objectives or hypotheses 4+14

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) 4

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained 4

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) 4+5

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered 5

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) 5

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) 12

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A

Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended 4-8

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) 12
Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions N/A

Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned N/A

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions N/A

Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how N/A

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A

Methods: Data collection, management, and analysis

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol 6-11

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols 13
<table>
<thead>
<tr>
<th>Section</th>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>Data management</td>
<td>19</td>
<td>Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol</td>
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<td>Statistical methods</td>
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<tr>
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<td>20b</td>
<td>Methods for any additional analyses (e.g., subgroup and adjusted analyses)</td>
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<td>Methods: Monitoring</td>
<td>21a</td>
<td>Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed</td>
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<td>Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial</td>
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<td>Consent or assent</td>
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<tr>
<td>Ancillary and post-trial care</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Dissemination policy</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>31a</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>15+16</td>
<td></td>
</tr>
<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
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**Appendices**

<table>
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<th>Description</th>
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<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
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<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
<td>N/A</td>
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</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.*
DELTAGER INFORMATION

Projekt om “Brug af Fælles Beslutningstagning i samtaler efter fjernelse af polypper i tarmen ved kikkertundersøgelse.”

Forespørgsel om at deltage

Vi vil spørge, om du vil deltage i et videnskabeligt forsøg, der udføres af Læge og PhD studerende Helene Juul Würtz fra Center for Fælles Beslutningstagning, Vejle Sygehus og Organ- og Plastikkirurgisk afdeling, Vejle Sygehus.


For at kunne træffe beslutningen om du ønsker at deltage i forsøget skal du først have en indblik i hvad studiet går ud på samt hvad der forventes af dig såfremt du vælger at deltage.

Formål, dets betydning og rækkevidde


Hvad forventes af dig?

Såfremt du vælger at deltage i forsøget vil vi under samtalen i dag anvende et beslutningsstøtteværktøj. Efterfølgende vil vi bede dig svare på et spørgeskema som i alt indeholder 62 spørgsmål, som vi vil bede dig svare på umiddelbart efter samtalen i dag. Vi forventer at det vil tage dig 10 minutter at svare på disse spørgsmål, som du vil modtage via E-boks.

Efterfølgende vil du få tilsendt 35 spørgsmål henholdsvis 3 måneder og 6 måneder efter din samtale. Vi forventer at det vil tage 5 minutter at svare på disse spørgsmål.

Forsøgets nytte

Vi ønsker at undersøge om brugen af Fælles Beslutningstagning og et beslutningsstøtteværktøj i samtalen fremmer Fælles Beslutningstagning i samtaler efter fjernelse af polypper i tarmen ved kikkertundersøgelse, hvorfor vi gerne vil bruge og undersøge dette i din samtale. Derudover vil vi undersøge hvilken indvirkning det har netop efter samtalen, og 3 og 6 måneder efter samtalen.

Fordele og ulemper ved forsøget

Brugen af Fælles Beslutningstagning har vist sig at øge patienttilfredsheden og tidligere forskning har vist at patienter har en tendens til at forstå deres behandlings eller opfølgningsmuligheder og de mulige konsekvenser bedre, når de er aktive inddraget i beslutningen. Fælles beslutningstagning giver også patienter mulighed for at vælge behandlings/opfølgningsmuligheder, der passer bedst muligt til deres personlige præferencer, værdier og livsstil. Fælles beslutningstagning kan muligvis også have en række ulemper, f.eks. kan det tage længere tid end en mere traditionel beslutningsproces, hvilket kan være udfordrende for træve sundhedsfaglige. Ydermere føler nogle patienter sig måske ikke godt nok informeret til at træffe beslutninger om deres behandling og foretrækker, at lægen træffer valget.
Behandling af personoplysninger

Ved at underskrive samtykkeerklæringen giver du tilladelse til at forskergruppen får direkte adgang til oplysninger fra din patientjournal mv., herunder elektroniske journaler, med henblik på at se oplysninger om dine helhedsforhold (det kan eksempelvis være oplysninger om tidligere og nuværende sygdom og behandling, blodprøveresultater, røntgenundersøgelser osv.), som er nødvendige som led i forsøget.


Resultaterne af undersøgelsen forventes at kunne gøres op i år 2026 og vil i anonymiseret form blive søgt offentliggjort i et internationalt, videnskabeligt tidskrift. Du er også velkommen til at kontakte undegygnede til den tid for at få et uddrag af resultaterne.

Godkendelser

Forskningsprojektet er anmeldt til fortegnelsen over sundhedsvidenskabelig forskning i Region Syddanmark. Videnskabsetisk komité har vurderet at der ikke er grundlag for at dette forskningsprojekt skal anmeldes.

Økonomi

Forskningsprojektet er en del af et PhD uddannelsesforløb som blandt andet er finansierer via Syddansk Universitet samt Vejle Sygehus, Sygehus Lillebælt. Ingen af de involverede læger eller forskere har nogen kommerciel interesse i undersøgelsen.

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad forskningsprojektet går ud på, og at du føler dig rustet til at tage beslutningen om vi må bruge din samtale og dine data i forskningsområderne. Så frem du ønsker at deltage vil jeg bede dig underskrive samtykkeerklæringen nedenfor og udfylde din alder, køn og fuldført uddannelse.

De Bedste Hilsner,

Læge og Phd studerende Helene Juul Würtz

Organ og Plastikkirurgisk afdeling, Vejle Sygehus samt Center for Fælles Beslutningstagning, Vejle Sygehus

Kontakt information: helene.juul.wurtz3@rsyd.dk
Informert samtykke til deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel: "Brug af Fælles Beslutningstagning i samtaler efter fjernelse af polypper i tarmen ved kikkertundersøgelse."

Erklæring fra forsøgspersonen:
Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.
Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.
Jeg giver samtykke til, at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn (blokbogstaver): ___________________________________________________

Dato: _______________   Underskrift: ____________________________________________

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?:

Ja _____ (sæt x)         Nej _____ (sæt x)

Erklæring fra den, der afgiver information:
Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.
Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information (blokbogstaver) _________________________________________

Dato: _______________   Underskrift: ____________________________________________

Projektidentifikation: (clinicaltrials.gov NCT05776381, versions 1./August 2023)
Informeret samtykke til deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel: "Brug af Fælles Beslutningstagning i samtaler efter fjernelse af polypper i tarmen ved kikkertundersøgelse."

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Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information (blokbogstaver)____________________________

Dato: _______________   Underskrift: ____________________________________________

Projektidentifikation: (clinicaltrials.gov NCT05776381, versions 1./August 2023)

Såfremt denne samtykkeerklæring og patient grund data arket ikke ligger i forskningsmappen skal den underskrevne samtykke erklæring afleveres til den forskningsansvarlige på kirurgisk afdeling til opbevaring.
Patient Decision Aid for *Management of endoscopically resected malignant colorectal polyps.*