

# BMJ Open 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-randomised clinical phase II study

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## 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% and 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-randomised, 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.

**Trial registration number** NCT05776381.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ 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 CPR.
- ⇒ No incentives provided to local investigators or participants for enrolment.
- ⇒ This is a non-randomised trial.

## 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.

## Background

The most recent annual reports from the Danish Colorectal Cancer Group (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.<sup>1-3</sup> During the 3 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.<sup>3</sup>

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.<sup>4 5</sup> In larger published series, roughly 75% of the subsequent bowel resection specimens are without residual cancer.<sup>6</sup> 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.<sup>6</sup> Hence, it seems that many patients are overtreated.<sup>7</sup> Moreover, surgery is not without risk as bowel resections entail a 15%–20% complication rate, 4% anastomotic leakage rate and a considerable cost.<sup>8</sup> 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.<sup>9</sup> 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.<sup>9</sup> 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.

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.

SDM, thus, helps patients to more actively participate in treatment decisions.

Patient decision aids (PtDAs) are tools used in SDM to illustrate and inform patients about the choice and different options in a standardised way, to empower and invite the patient to participate in the decision-making process, considering their personal values.<sup>10</sup> 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.<sup>11</sup> Stacey *et al* evaluated the use of PtDAs in a Cochrane review from 2017.<sup>10</sup> 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.<sup>10</sup> An 'effective' PtDA requires evidence that the PtDA improves the quality of the SDM process and the decision itself.<sup>12 13</sup>

Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences.<sup>10</sup> PtDAs were also shown to reduce the number of people choosing major elective invasive surgery in favour of more conservative options.<sup>10 14</sup> Of the 18 studies included in the review focusing on the choice of major elective surgery, only 5 were studies on patients with cancer: two studies on prostate cancer and three studies on breast cancer. Two of these five studies showed statistically significant reductions in surgical rates.<sup>10</sup>

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 SDM and informed impartially with the use of a PtDA, 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 SDM approach on patient-reported outcome measures (PROMs), patient-reported experience measures (PREMs) and on the change in long-term outcomes compared with historical data.

## MATERIALS AND METHODS

### Study design and setting

The study is a clinical multi-institutional, non-randomised, 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](https://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<sup>2</sup> to obtain a reliable estimate of the true effect. A table describing the study according to the WHO Trial Registration Data Set has been added as online supplemental material 1 and the Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT) guideline 2013 checklist has been added as online supplemental material 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  $\geq 2$ , poor differentiation, lymphovascular invasion or tumour budding density  $\geq 2$ . 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.<sup>15</sup>

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, that is, 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.

### 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 multicentre 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.

### 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 on 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 PtDA can be used in the consultation to facilitate SDM. 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.

### 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 SDM and the PtDA. The PtDA used in this study was developed in a previous study in accordance with International Patient Decision Aids Standards (IPDAS) criteria,<sup>13</sup> using current Danish national guidelines as

the evidence informing the PtDA,<sup>4</sup> and using the generic PtDA template developed and clinically tested by the Center for Shared Decision Making, Vejle Hospital, Denmark.<sup>16 17</sup> The 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 Stacey *et al.*<sup>18</sup> Feedback, responses and insights collected from participants were collated by the principal investigator and subsequently used 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 online supplemental 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 SDM from the principal investigator. The introduction will entail classroom teaching defining and explaining SDM and PtDAs based on the evidence in the current literature, such as the latest Cochrane review on decision aids.<sup>10</sup> 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 SDM.<sup>19 20</sup> The tailored PtDA will then be introduced to the surgeons, who will be asked to actively practice using it in a simulation setting.<sup>21</sup> 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 customise to offer personalised information to each patient. The estimated duration of the study is 4 years, comprising a 1-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.

## Data collection and methods

### 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](#).

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

Data collection outcome measure	Data collection outcome unit	Data collection method –study anno 2024–2025	Data collection method –retrospective data anno 2018–2023
Primary outcome			
Subsequent bowel resection	Proportion (No of patients undergoing a subsequent bowel resection out of the total number of patients with an endoscopically resected malignant polyp included in the study)	Danish Colorectal Cancer Group database	Danish Colorectal Cancer Group database
Secondary outcomes			
Resection without tumour or lymph node metastases	Proportion (No of patients with a subsequent bowel resection without residual tumour or lymph node metastases divided by the total no of patients with an endoscopically resected malignant polyp included in the study phase)	National Pathology Database	National Pathology Database
Patient-reported experience measures and patient-reported outcome measure	See <a href="#">table 2</a>	Questionnaires	N/A
30-day and 90-day morbidity and mortality	Proportion	Danish Colorectal Cancer Group database and National Patient Register	Danish Colorectal Cancer Group database and National Patient Register
Recurrence and overall survival 3 years	Proportion	National Patient Register	National Patient Register
N/A, not available.			

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-day 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](#).

- ▶ Other secondary outcomes are PREMs and 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.<sup>20</sup> PROMs measure the patient's perspective of symptoms and health related quality of life in different stages of treatment in order to identify changes.<sup>20</sup> 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 and 60–70).

A schematic diagram of the study plan can be seen in [table 4](#).

### 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.

### 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 Programme) holding clinical, demographic and histopathological data on patients with a first-time diagnosis of colorectal cancer in Denmark with >95% completeness.<sup>22</sup> 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%.<sup>23</sup>
- ▶ 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 codes, procedure codes, examination codes and surgical procedures are among the data that have been registered since 1995.<sup>24</sup>
- ▶ 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 assigned to all Danish citizens at birth or immigration.

### 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, USA, V.12.0.19) will be used<sup>25</sup> 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.<sup>26</sup>

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

### 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

**Table 2** Details of questionnaire distribution, measures and scoring

Questionnaire	Distribution	Measures	No items	Item range	Scoring
Shared Decision Making Questionnaire <sup>g29</sup>	At baseline after encounter	A patient-reported experience measure of the perceived level of involvement in decision-making in the clinical encounter	9	Six point Likert scale with extremes (completely disagree=1 to completely agree=6)	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
Shared Decision Making Process-4 <sup>30</sup>	At baseline after encounter	A short patient-reported measure of the amount of SDM that occurs around a medical decision (Questions regarding: options, pros, cons and preferences)	4	Q 1 and 2: Four point Likert scale (not at all=0 to a lot=1) Q 3 and 4: (yes=1 point, no=0 points)	Total sum 0–4, with higher scores indicating more shared decision making
CollaboRATE <sup>31</sup>	At baseline after encounter	A patient-reported measure of patient experienced involvement in the decision-making process (regarding provider communication)	3	Ten point Likert scale with extremes (not at all=0 points to Very much=9 points)	Top score approach: Reported as the percentage with the top score (27 points) vs anything less.
Decisional Conflict Scale <sup>32 33</sup>	At baseline after encounter	A patient-reported perceived measure of 5 dimensions of decision making (uncertainty, informed, values clarity, support, effective decision).	16	Five point Likert scale with extremes (strongly agree=0 points to strongly disagree=4 points)	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.
Decision Regret Scale <sup>34</sup>	3 and 6 months after clinical encounter	A patient-reported experienced measure of distress or remorse after a medical decision	5	Five point Likert scale with extremes (strongly agree=1 point to strongly disagree=5 points)	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
Quality of life (QOL) (EORTC QLQ-C30) <sup>35</sup>	At baseline after encounter and 3 months and 6 months after clinical encounter	A patient-reported outcome measure of health-related QOL 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 QOL scale. Six additional single items, which are categorised as functional items: five single items assessing additional symptoms commonly reported by patients with cancer (dyspnoea, sleep disturbance, appetite loss, constipation and diarrhoea) and perceived financial impact of the disease.	30	Five 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: 1 minus (sum subtracting one and dividing by range of 3) multiplied by 100. Range in score from 0 to 100, a higher score indicates high level of functioning. Global health status score: (sum subtracting 1, divided by range) multiplied by 100. Range in score from 0 to 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 to 100, where a high score represents a high level of symptomatology or problems

EORTC, European Organisation for Research and Treatment of Cancer; QLQ-C30, Quality of Life Questionnaire- Cancer 30 items; SDM, shared decision-making.

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.

### 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 unauthorised 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

**Table 3** Patient, tumour and surgery-related variables and method of collection

Variable category	Variables	Collection methods for study and historical data
Patient related	Sex, age, diagnosis, height, weight, tumour location, stage and TNM category, tobacco and alcohol use, ASA score, performance status, Charlson Comorbidity Index score	Danish Colorectal Cancer Group database
	Socioeconomic and demographic data	Statistics Denmark
Disease related	Screening status, polyp histology, localisation of polyp, reason for choice of conservative management as registered in the database	Danish Colorectal Cancer Group database
	Histopathological risk factors according to national guidelines	National Pathology Database
Surgery related	Operative approach, procedure, reason for surgical subsequent bowel resection	Danish Colorectal Cancer Group database
	Outcome of subsequent bowel resection according to national guidelines	National Pathology Database

ASA, American Society of Anesthesiologists; TNM, Tumour, Node, Metastasis.

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.

### Sample size

The trial is based on Simon's two-stage mini-max design.<sup>27</sup> 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  $0.7\% \times 45\% = 32\%$ ; absolute risk reduction 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 (ie, 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 2 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 drop-out rate of 20%, a total of 110 patients will be included. Data

**Table 4** Study plan

Event/time	Prior to consultation	Intervention (time=0)	Surgery after intervention	1 month later	3 months later	6 months later	3 years follow-up
Eligibility screening	x						
Informed consent	x						
Enrolment		x					
Evaluation of resected specimen			x				
Shared Decision Making Questionnaire 9		x					
Shared Decision Making Process 4		x					
CollaboRATE		x					
Decision Conflict Scale		x					
Decisional Regret Scale					x	x	
Quality of Life Questionnaire		x			x	x	
Recurrence and overall survival							x
Morbidity and mortality				x	x		

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.

### 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,  $\chi^2$  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.<sup>27</sup> A  $p < 0.05$  will be considered statistically significant. Statistical analysis will be performed using Stata V.17/BE (StataCorp).

A 30-day 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 ORs with 95% CIs. 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.

### 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 two 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<sup>28</sup> as described above.

### 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 online 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 suggests 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.

### 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.

### 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 SDM 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 SDM 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-randomised, 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.

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