

## **Influence of perioperative step volume on complication rate and length of hospital stay after colorectal cancer surgery (IPOS trial): study protocol for a randomised controlled single-centre trial at a German university hospital**

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# BMJ Open Influence of perioperative step volume on complication rate and length of hospital stay after colorectal cancer surgery (IPOS trial): study protocol for a randomised controlled single-centre trial at a German university hospital

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## ABSTRACT

**Background** Perioperative mobilisation and physical activity are critical components of postoperative rehabilitation. Physical inactivity is a significant risk factor for complications and prolonged hospitalisation. However, specific recommendations for preoperative and postoperative physical activity levels are currently lacking. Evidence suggests that daily step count before and after surgery may impact the length of hospital stay and complication rate.

The goal of this study is to determine the effectiveness of perioperative step volume recommendations, measured by pedometers, in reducing the length of hospital stay and complication rate for patients undergoing colorectal cancer surgery.

**Methods** This study is a single-centre randomised controlled trial with two arms, allocated at a 1:1 ratio. The trial includes individuals undergoing colorectal surgery for either suspected or confirmed colorectal malignancy. A total of 222 patients will be randomly assigned to either an intervention or a control group. Step counts will be measured using a pedometer. Patients assigned to the intervention group will be given a predetermined preoperative and postoperative step count goal. The analysis will be conducted on preoperative and postoperative physical activity, quality of life, health, duration of hospitalisation, complication rate and bowel function, among other factors.

**Ethics and dissemination** The trial was approved by the ethics committee of the Ludwig-Maximilians-University of Munich, Germany (reference number: 22-0758, protocol version 2022.02). Results will be published in peer-reviewed journals and shared at academic conferences. After the publication of the results, a fully anonymised data set and the statistical code can be made available on justified scientific request and after ethical approval has been granted.

**Trial registration number** DRKS00030017.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The intervention is non-invasive, easily available, not prone to bias and easy to integrate into the clinical routine.
- ⇒ Electric pedometers will provide direct feedback to the patient, thereby all patients will likely profit from participation.
- ⇒ A randomised double-blinded design will reduce bias.
- ⇒ Could improve perioperative care for one of the most common tumour diseases worldwide.
- ⇒ Data will be derived from a single institution with a limited number of treating physicians.

## INTRODUCTION

Colorectal cancer is one of the most common cancers worldwide and a global health burden.<sup>1</sup> Surgical resection is the only curative treatment for colorectal cancer.<sup>2</sup> Onco-logical bowel resection is a common, yet often complicated procedure with complications occurring in around 30% of cases.<sup>3</sup> Specifically, pulmonary complications, anastomotic insufficiency and bowel paralysis complicate the postoperative period. Complications are linked to longer hospital stays, greater morbidity and mortality, as well as lowered quality of life.<sup>3</sup> Prevention is vital, not just for the individual but also to reduce healthcare expenditure.<sup>4</sup> However, the ideal approach to complication prevention has yet to be determined. It should be safe, easily manageable, accessible to all patients, cost-effective and initiated before hospital admission. Numerous prehabilitation interventions, including nutrition and exercise,

have been implemented to improve patient outcomes.<sup>5 6</sup> The literature indicates a favourable impact of exercise prehabilitation, specifically the number of daily steps taken.<sup>5–8</sup> Fitness trackers that measure activity and step volume are readily accessible and utilised in public health research. A meta-analysis indicates that taking 2337 steps reduces overall mortality risk, and taking 3867 steps daily reduces cardiovascular mortality risk.<sup>9</sup> A progressively decreasing risk of mortality has been demonstrated for up to 6000–8000 steps among adults aged 60 years and older.<sup>10</sup> Incorporating step count into preoperative care and prehabilitation is a simple, easily accessible and non-invasive method for optimising outcomes. A low preoperative step count is associated with higher postoperative morbidity as demonstrated by Richards *et al.*<sup>11</sup> However, research results may vary and be affected by potential biases, such as patients' tendency to overestimate their physical activity levels.<sup>6 7 12–14</sup>

Physical therapy and early mobilisation after surgery, which include passive and active exercises, sitting and walking, are crucial components of perioperative patient management.<sup>15</sup> Physical activity should ideally commence immediately after surgery to minimise postoperative complications associated with immobility such as cardiovascular and muscular compromise.<sup>16</sup> Despite the high significance of early postoperative mobilisation, it is an often-neglected part of clinical care. The main reasons include staff and time shortages. Early ambulation depends on the patient's preoperative mobility, physiotherapeutic assistance as well as analgesia and motivation. Monitoring and quantification of patient ambulation is challenging. Despite the importance of postoperative mobilisation, few recommendations exist to guide patients and staff. At present, there are no guidelines for determining the optimal level of mobilisation before or after surgery.

The randomised controlled trial aims to investigate whether recommendations on perioperative step volume can reduce the length of hospital stay and complication rate in patients undergoing colorectal cancer surgery compared with patients who do not receive recommendations on perioperative step volume.

## METHODS

### Trial design

The trial is designed as a single-centre randomised controlled trial with 1:1 allocation. The trial flow chart is depicted in [figure 1](#).

Individuals undergoing colorectal surgery for a clinically suspected or biopsy-proven colorectal malignancy at the University Hospital Augsburg who meet the inclusion criteria will be recruited for this study. All patients will be randomised and assigned to an intervention or control group 1–6 weeks prior to surgery. The intervention group will receive a predetermined preoperative and postoperative daily step count goal in addition to standard physiotherapy. The control group will receive

standard postoperative physiotherapy without a specific step count goal. All steps will be measured by a pedometer and documented daily from the day of inclusion until the day of discharge from the hospital. All patients will receive the International Physical Activity Questionnaire (IPAQ), European Quality of Life 5 Dimensions 5 Level (EQ-5D-5L) and Quality of Life Questionnaire Core 30 (QLQ-C30) questionnaires on physical activity, quality of health and life preoperatively as well as on days 14, 30 and 90 after surgery, respectively.<sup>17–19</sup>

### Informed consent

Informed consent is required from all patients included in the study. The informed consent form will be obtained prior to participation by physicians of the University Hospital Augsburg.

### Eligibility criteria

All patients undergoing colorectal surgery for a suspected or confirmed colorectal malignancy who do not meet any of the below-mentioned exclusion criteria will be included in the study.

### Exclusion criteria

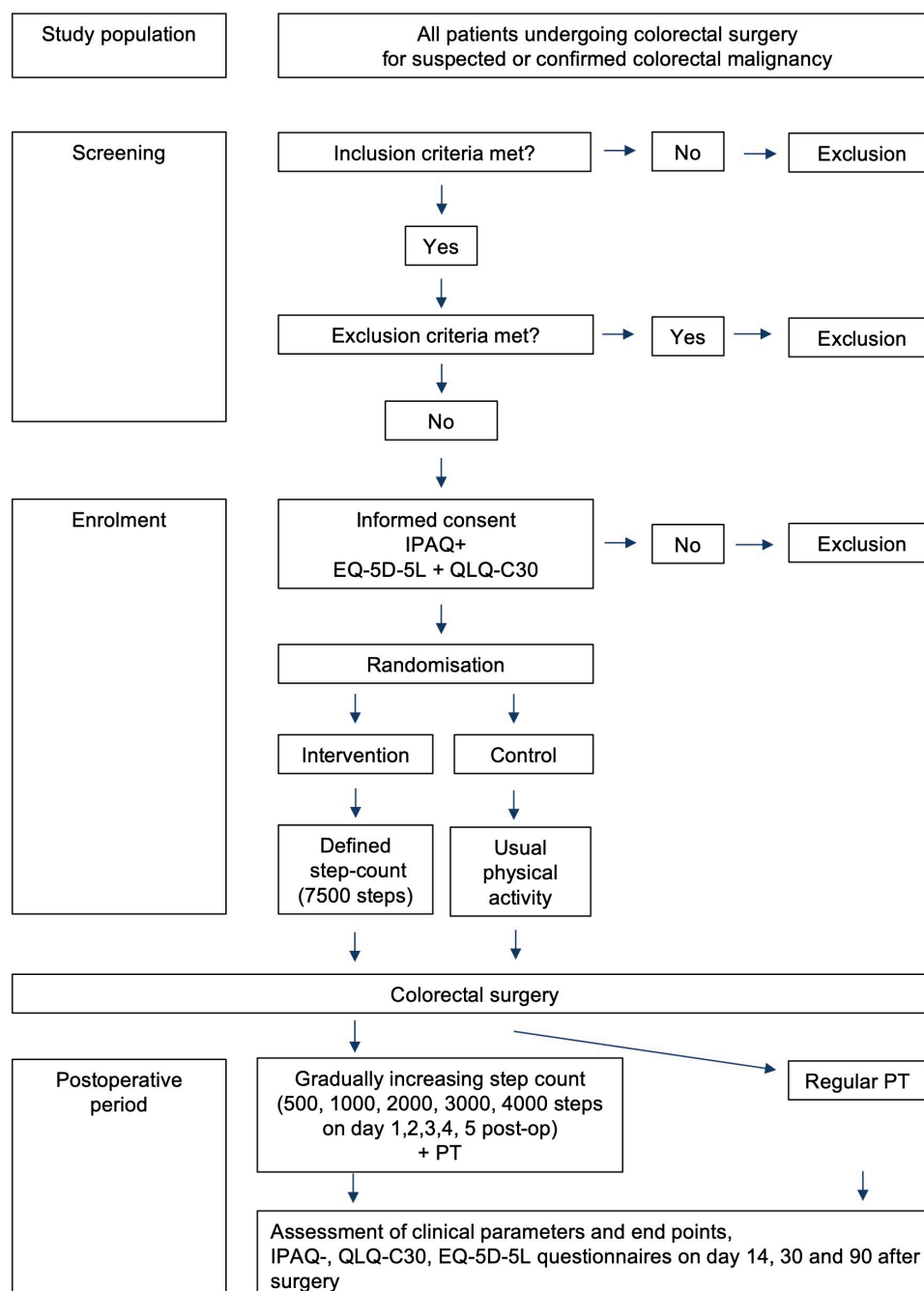
The following exclusion criteria are characterised by immobility, inability to provide written informed consent or pre-existing medical conditions that will greatly affect the primary and secondary endpoints of the trial.

Excluded from the trial are as follows:

- ▶ Patients not able to provide written informed consent (eg, patient under legal guardianship).
- ▶ Minors below the age of 18.
- ▶ Pregnant patients.
- ▶ Patients admitted for emergency surgery.
- ▶ Patients undergoing surgery without curative intent (eg, tumour debulking or ostomy for tumour-associated bowel obstruction).
- ▶ Patients with significantly impaired mobility (eg, bedridden patients, amputation of one or both lower extremities or parts of the lower extremity, permanent dependence on a wheelchair, current bone fractures, neurodegenerative diseases).
- ▶ Patients with pre-existing severe chronic heart failure (New York Heart Association (NYHA) III–IV) or other untreated cardiac and/or pulmonary conditions significantly impairing daily physical activity.
- ▶ Patients suffering from dementia or other conditions influencing the patient's compliance.
- ▶ Participation in other clinical studies with a potential influence on the primary endpoint of this study.

### Randomisation

Randomisation will be conducted using block randomisation with a variable block size to reduce selection bias and ensure comparable group sizes. A 1:1 allocation ratio will be applied. An internet-based randomisation tool available at <https://www.randomizer.at> will be used. The randomisation process will be conducted only by medical staff not involved in data collection, analysis or



**Figure 1** Trial flow chart. EQ-5D-5L, European Quality of Life 5 Dimensions 5 Level Version Questionnaire; IPAQ, International Physical Activity Questionnaire; PT, Physiotherapy; QLQ-C30, EORTC Quality of Life Questionnaire Core 30.

participant supervision. Stratification based on tumour location (middle and lower rectum or colon and upper rectum) will be performed.

### Blinding

Patients and study personnel will be blinded. Blinding efficiency of patients will be randomly checked in 30 consecutive patients in the postoperative period. Patients will be specifically asked whether they believe to be randomised to the intervention or control group.

Medical staff involved in treatment of study patients, physiotherapists, nurses and personnel involved in data acquisition and analysis will be blinded.

### Sample size

Sample size estimation is based on the average postoperative length of stay (11.57 days) and SD (7.35) of patients receiving surgery for colorectal cancer at our institution.

Given the mean length of stay in our population and data from other studies, that reported up to 33% reduction in length of stay using rehabilitation programmes we chose an average reduction in length of stay of 3 days as an endpoint.<sup>20</sup> Using a two-sided significance level of 5% and a power of 80%, a case number of 96 participants per group was calculated. To account for inaccuracies in the calculation, lost to follow-up or lack of compliance,



15% additional cases are included. A total of 111 patients will be assigned to each study group. Calculations were performed using the G\*Power V.3.1 software.<sup>21</sup> If consent is withdrawn prior to completion of data collection, or if a participant requests deletion of their study data, an equivalent number of additional patients will be recruited.

### Study groups

All patients undergoing colorectal surgery for a suspected or confirmed colorectal malignancy who do not meet exclusion criteria will be recruited. Perioperative anaesthesia management will follow institutional standards and will not vary between groups. Peridural catheter use, which may impact postoperative mobility, will be registered and its impact calculated.

### Intervention group

Patients in the intervention group will receive a pedometer and a daily goal of achieving 7500 steps before their scheduled surgery. Patients will record their daily step count until the day of their surgery. The intervention will begin at the time of indication for surgery, which can be up to 6 weeks to 1 week prior to surgery. Patients will be recruited in the surgical outpatient clinic. Postoperative mobilisation is facilitated by nurses and physical therapists who are unaware of group allocation and step count goals. All patients in the intervention group are provided with a structured exercise plan that includes mobilisation in bed, walking within the patient's room and trips to the bathroom on the day of the surgery. Beginning from 500 steps on day 1 postsurgery, the goal is to escalate this figure to 1000 steps on day 2, 2000 steps on day 3, 3000 steps on day 4 and finally to 4000 steps on day 5. The objective is to enhance the number of steps taken by patients undergoing postoperative recovery on a daily basis. Every patient's progress in terms of the number of steps taken will be documented. Standard physical therapy, which includes breathing and mobility exercises, will be provided to all patients.

### Control

Patients assigned to the control group will receive a pedometer preoperatively without a step count target. Postoperatively, there is no daily step volume target for patients in the control group. Mobilisation efforts and physical therapy will be equivalent to those in the intervention group. The preoperative and postoperative daily step volume will be documented.

### Assessment of physical activity, quality of life and health outcome

Preoperative and postoperative physical activity is analysed by the IPAQ. The questionnaire reliably registers daily physical activity as well as sedentary time. Quality of life and health will be assessed by the Euroqol EQ-5D-5L and European Organisation for Research and Treatment of Cancer QLQ-C30 questionnaires.<sup>17–19</sup>

### Outcomes

#### Primary endpoint

- Postoperative duration of hospitalisation.

#### Secondary endpoints

- Overall complication rate (Clavien-Dindo  $\geq$  III and Comprehensive Complication Index).
- In-hospital mortality and mortality in the 30-day interval.
- Time until postoperative onset of bowel function.
- Length of time to build up food before reaching the solid food stage.
- Need for gastric tube placement and postoperative vomiting.
- Physical activity 14 days, 30 days and 90 days postoperatively (assessed by IPAQ).
- Health status 14 days, 30 days and 90 days postoperatively (assessed by EQ-5D-5L).
- Quality of life 14 days, 30 days and 90 days postoperatively (assessed by QLQ-C30).
- Length of stay in the intensive care unit.
- Average number of steps achieved preoperatively.
- Average number of steps achieved postoperatively.
- Thromboembolic complications.
- Association between number of steps and complication rate and length of hospital stay.

### Data collection and management

Participants will be assigned a random four-digit numerical code to store data in a pseudonymised manner. Analysed data will include demographics, preoperative and postoperative physical condition (step count, IPAQ), health and life status (EQ-5D-5L and QLQ-C30 questionnaire), tumour-specific factors (location, histological data), type and duration of surgery, intensive care monitoring, length of hospital stay, complications (with or without further need for intervention), physiotherapeutic treatment as well as the daily cumulative step volume. All data will be collected in case report forms and manually transferred to an electronic SPSS sheet (SPSS for Windows, V.28, IBM). Statistical analysis will be performed by using SPSS and R (R Foundation for Statistical Computing, Vienna, Austria). Only personnel directly involved in the study will be granted access to the data.

### Statistical analysis

Normally distributed variables will be analysed by Student's t-test. Non-normally distributed variables will be analysed by Mann-Whitney U test. Categorical data will be compared by  $\chi^2$  testing or by Fisher's exact test if requirements for the  $\chi^2$  test are not met. A two-sided  $p \leq 0.05$  will be considered significant. Questionnaires are analysed according to the authors recommendations.<sup>17–19</sup> Demographic factors and risk factors for complications are evaluated regarding a possible association with the primary endpoint and analysed in a multivariate manner.

### Subgroup analysis

Planned evaluations of subgroups are performed. The subgroups will be formed based on the following parameters

- ▶ Type of surgery (minimally invasive/open).
- ▶ Type of tumour rectum/colon.
- ▶ Patient age (<65/≥65 years).
- ▶ Gender (male/female)

### Interim analysis

Due to the low burden and low risk posed by the intervention, an interim analysis will not be performed.

### Adverse events

Despite the proposed intervention being a very low-risk intervention, any adverse events attributable to the study intervention as well as any surgical and non-surgical complications will be assessed.

### Data monitoring and data handling

External monitoring will be conducted by an independent auditor before the recruitment of the first patient (kick-off audit), and after the completed follow-up of the last patient (close-out audit).

There is annual internal monitoring by an internal data monitoring committee, this is, composed of individuals not involved in patient recruitment and data collection. The results of the monitoring are discussed with the study coordinator and investigators and a report is prepared.

To improve data quality and avoid transcription errors during manual transfer of raw data and case report forms into the electronic database, all collected study data will be entered into two electronic data sets by different persons. These two parallel data sets are compared using a computerised procedure. Any discrepancies between the two data sets are manually checked and corrected.

### Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this trial.

### Ethics approval and dissemination

The trial was approved on 26 October 2022, by the ethics committee of the Ludwig-Maximilians-University of Munich, Germany (reference number: 22-0758, protocol version 2022.02). Any future amendments to the study protocol will be submitted to an ethics committee for review. We plan to publish the findings in peer-reviewed journals and share our findings at academic conferences. After the publication of the results, a fully anonymised data set and the statistical code can be made available on justified scientific request and after ethical approval has been granted. Depending on the extent of the data use and the planned research, either appropriate credit or coauthorship must be granted to the authors of this study.

### DISCUSSION

Physical activity is an important aspect both in the development and recovery from colorectal cancer.<sup>22</sup> This study aims to analyse the impact of perioperative step volume on hospital stay duration. Second, postoperative complications, bowel function, the psychological and physical effect of enhanced physical activity will be investigated. Third, patients' physical well-being and quality of life will be assessed.

Reducing postoperative complications remains a challenge in cancer surgery. However, data on efficacy, optimal amount and type of exercise are limited.<sup>13</sup> An observational study conducted by Richards *et al* found a correlation between a low preoperative step count and an increased risk of postoperative morbidity.<sup>11</sup> This new study aims to supplement the existing data by including an intervention group and step count target for patients. The preoperative step goal exceeds patients' daily average of 5000 steps by 2500 steps to encourage physical activity.<sup>11 23</sup> Recommendations for postoperative mobilisation do not typically include specific information on the degree of mobilisation and are frequently disregarded.<sup>24</sup> Information on the average number of steps taken during the perioperative period, potential thresholds for a beneficial outcome and stratification based on cancer location could aid in developing a customised exercise programme for patients. Implementation of such programme could positively impact both physical and mental health of patients and lead to economic benefits by decreasing hospital stays and complication rates.

Tracking the daily step counts with wearables is an accessible tool to motivate patients and objectify perioperative activity levels. Fitness trackers are easy to use and provide constant feedback. A significant increase in the average step count has already been observed in patients who received feedback on their step volume via an activity tracker after laparoscopic surgery.<sup>25</sup> The use of fitness trackers allows for objective measurement of physical activity levels. This provides reliable data that can be used to evaluate compliance with the prescribed step count recommendations, as well as monitor the patients' progress throughout the perioperative period. It also empowers patients to take control of their health, which can lead to better outcomes and a sense of empowerment and well-being.

A critical factor in postoperative mobilisation is the availability of staff.<sup>26</sup> The implementation of fitness trackers and a mobilisation protocol in postoperative care could reduce staff time and aid in staff-independent mobilisation of patients. In addition, monitoring daily step counts will help nurses and physicians assess whether mobilisation targets are met, and it could contribute to patient motivation.

This study aims to evaluate the impact of a defined perioperative step volume recommendation on the length of hospital stay and postoperative complications. The proposed study takes a pragmatic approach to setting a target for preoperative and postoperative mobility

to reduce both the length of hospital stay and the incidence of complications in patients undergoing colorectal surgery. Step count recommendations and fitness trackers could serve as motivational tools and encourage patients to participate in their recovery process. The evidence from this study could inform clinical practice and potentially contribute to the development of standardised protocols.

### Trial registration and status

The trial was prospectively registered in a primary registry of the WHO (German Clinical Trials Register (registration number: DRKS00030017) on 27 January 2023. Recruitment is expected to start in July 2023.

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**Contributors** MCS and LA developed the study concept. MCS, LA, FS and SW designed the study protocol. MCS, SS, TTA and FS developed the evaluation plan and conducted the statistical analysis. LA drafted the initial manuscript. DV, MH, MA and SW critically revised the manuscript for important intellectual content. Final approval of the version to be published was given by all authors. MCS, LA and FS took responsibility for the work and controlled the decision to publish. The corresponding author attested that all listed authors meet the authorship criteria and that no others meeting the criteria have been omitted.

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