**A mobile application to improve adherence to an Enhanced Recovery Pathway after colorectal surgery**

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**LIST OF ABBREVIATIONS**

ERAS®: Enhanced Recovery After Surgery

ERP: Enhanced recovery pathway

LOS: Length of stay

POD: Postoperative day

RCT: Randomized controlled trial

CCI: Comprehensive complication index

PRO: Patient reported outcome

TRD: Time to readiness for discharge

TED: Thromboembolic disease

NG: Nasogastric

IV: Intravenous

**Abstract**

Introduction: Enhanced Recovery Pathways (ERP) include multiple evidence-based interventions in the preoperative, intraoperative and postoperative periods that together reduce morbidity and length of stay after colorectal surgery. Increased adherence to these interventions is associated with better postoperative outcomes, but adherence is lower in the postoperative period. Some postoperative elements require patient participation and educating patients is a recommended strategy to improve engagement and adherence. Mobile digital applications are increasingly used in health care education. The objective of this research is to estimate the extent to which a novel mobile app affects adherence to an ERP for colorectal surgery in comparison to standard written material.

Methods: This was a superiority, parallel-group, assessor-blind, sham-controlled randomized trial involving patients undergoing colorectal resection in a single institution. All participants received standard preoperative education during a visit with a specialized ERP nurse, including an illustrated brochure designed by patient education specialists. On the day of surgery, participants were randomly assigned with a 1:1 ratio into one of two groups: (1) iPad including a novel mobile device app for postoperative education and self-assessment of recovery, or (2) iPad without the app. The primary outcome measure was mean adherence (%) to a bundle of 5 postoperative ERP elements requiring patient participation on postoperative days 1 and 2: mobilization, chewing gum for gastrointestinal motility stimulation, breathing exercises, consumption of oral liquids and consumption of nutritional drinks. Secondary outcomes included: (1) length of hospital stay, (2) postoperative complications, and (3) patient satisfaction.

Results**:** Ninety-seven patients completed the study, 50 in the intervention group and 47 in the control group. There was high utilization of the app; 94% of the patients used the app on POD 0 and 82% on POD 1. Median (IQR) hospital stay was 4 days (2-6) in the intervention group and 3 days (2-5) for the control (p=0.33). There was no difference in mean overall adherence to the bundle between the intervention and the control groups (59% vs 62%, p= 0.5). After adjustment for confounders, the impact of the app on overall adherence remained not significant (Coefficient 2.4 (95%CI -5 to 10) p= 0.53). Patient experience was similar in both groups with an overall median score of 4 out of 5 in degree of feeling well-informed, motivation, confidence and satisfaction with care.

Conclusions: In this randomized trial, use of a mobile health application did not improve adherence to a well-established ERP in colorectal surgery patients, when compared to standard written patient education. App usage was high in the first 2 postoperative days suggesting an interest in the use of the technology. Future research should evaluate the impact of applications integrating novel behavioral change techniques that create a more personalized approach to patients and its use should be particularly assessed in contexts where adherence is low.

**Résumé**

Introduction: Les voies de rétablissement améliorées (ERP) comprennent de multiples interventions fondées sur des preuves dans les périodes préopératoires, peropératoires et postopératoires, qui, ensemble, réduisent la morbidité et la durée du séjour après une chirurgie colorectale. Une adhérence accrue à ces interventions est associée à de meilleurs résultats postopératoires, mais l'adhérence est moindre dans la période postopératoire. Certains éléments postopératoires nécessitent la participation du patient et l'éducation des patients est une stratégie recommandée pour améliorer l'engagement et l'adhérence. Les applications numériques mobiles sont de plus en plus utilisées dans l'enseignement des soins de santé. L'objectif de cette recherche est d'estimer dans quelle mesure une nouvelle application mobile affecte l'adhésion à un ERP pour la chirurgie colorectale en comparaison à un document écrit standard.

Méthodes: Un essai randomisé, contrôlé par un évaluateur à l'aveugle, et en groupes parallèles de supériorité, impliquant des patients subissant une résection colorectale dans un seul établissement. Tous les participants ont reçu une formation préopératoire standard lors d'une visite avec une infirmière spécialisée en ERP, y compris une brochure illustrée conçue par des spécialistes de l'éducation des patients. Le jour de la chirurgie, les participants ont été assignés au hasard avec un ratio de 1: 1 dans l'un des deux groupes suivants: (1) iPad incluant une nouvelle application mobile pour l'éducation postopératoire et l'auto-évaluation de la récupération, ou (2) iPad sans l'application . Le résultat primaire était l'observance moyenne (%) à un ensemble de 5 éléments ERP postopératoires nécessitant la participation du patient aux jours 1 et 2 postopératoires: mobilisation, gomme à mâcher pour la stimulation de la motilité gastro-intestinale, exercices respiratoires, consommation de liquides oraux et consommation de

boissons nutritionnelles. Les critères secondaires comprenaient: (1) la durée de l'hospitalisation, (2) les complications postopératoires et (3) la satisfaction des patients.

Résultats: Quatre-vingt-dix-sept patients ont terminé l'étude, 50 dans l'intervention et 47 dans le groupe témoin. Il y avait une utilisation élevée de l'application, avec 94% des patients utilisant l'application sur POD 0 et 82% sur POD 1. La durée d'hospitalisation médiane (IQR) était de 4 jours (2-6) dans le groupe d'intervention et de 3 jours (2 -5) pour le contrôle (p = 0,33). Il n'y a pas eu de différence dans l'observance globale moyenne au groupe entre l'intervention et les groupes de contrôle (59% vs 62%, p = 0,5). Après ajustement pour les facteurs de confusion, l'impact de l'application sur l'observance globale n'a pas été significatif (coefficient 2,4 (IC à 95% -5 à 10) p = 0,53). L'expérience des patients était similaire dans les deux groupes avec un score médian global de 4 sur 5 en ce qui concerne le degré de bien-être, de motivation, de confiance et de satisfaction à l'égard des soins.

Conclusions: Dans cet essai randomisé, l'utilisation d'une application mobile de santé n'a pas amélioré l'adhésion à une voie de rétablissement améliorée bien établie chez les patients ayant subi une chirurgie colorectale, par rapport à la formation standard écrite des patients. L'utilisation des applications était élevée au cours des deux premières journées postopératoires, suggérant un intérêt pour l'utilisation de la technologie. Les recherches futures devraient évaluer l'impact des applications intégrant de nouvelles techniques de changement comportemental qui créent une approche plus personnalisée avec les patients, et son utilisation devrait être particulièrement évaluée dans des contextes où l'adhésion est faible.

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Also, I must thank everyone who was involved in the many different efforts required for the completion of this trial. I want to thank Ms. Pepa Kaneva for her constant assistance and organization and Dr. Nicolo Pecorelli, whose ideas and advice were always timely and very helpful.

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## AUTHOR CONTRIBUTIONS

Dr. Juan Mata Gutierrez: Protocol development, project design, implementation, data collection and entry, analysis, drafting and revision of manuscripts.

Dr. Liane S Feldman: Supervisor. Protocol development, project design, review of manuscripts.

Dr. Julio Fiore: Co-supervisor. Protocol development, project design, review of manuscripts.

Dr. Nicolo Pecorelli: Protocol development, and project design. Data analysis.

Pepa Kaneva: Implementation, data collection/extraction.

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Dr. Sender Liberman: Colorectal surgeon. Review of manuscripts.

**STATEMENT OF ORIGINALITY**

The work presented in this thesis represents original contributions to the evidence base supporting enhanced recovery postoperative management for patients undergoing colorectal surgery.

While I have received support from my supervisors and committee members, and input from co-authors for each study, the data presented in the following chapters represent my original work.

**STATEMENT OF SUPPORT**

This thesis was supported mainly through three sources. I am very grateful to have received salary support from the Fonds de Recherche du Québec – Santé and the Regie de L'Assurance Maladie du Québec. The project was funded by a grant from the Society of American Gastrointestinal and Endoscopic Surgeons.  These scholarships and awards provided me with the necessary support, without which this research would not have been possible. I would also like to acknowledge the support from the Steinberg-Bernstein Centre for Minimally Invasive Surgery and Innovation. Their support was also instrumental in the completion of the studies contained in this thesis.

## PREFACE

This thesis is presented in a manuscript-based format, evaluating the impact of a novel mobile app on adherence to an enhanced recovery pathway for colorectal surgery in comparison to standard written education. The manuscript has been submitted for publication in the peer-reviewed journal Surgical Endoscopy.

## Chapter 1: Introduction

### 1.1 Enhanced recovery pathways to improve care in colorectal surgery

Colorectal surgery accounts for a sizable proportion of operating room procedures and health care resource utilization. The American College of Surgeons estimates that over 320,000 major colorectal operations are performed every year in the United States alone[1]. In the last 25 years, there have been major advances in the field owing to the introduction of new technologies (e.g. minimally invasive surgery) and improvements in perioperative care (e.g. enhanced recovery pathways (ERPs)). ERPs are evidence-based, multimodal, standardized care plans that integrate multiple interventions throughout the perioperative period to reduce the metabolic impact of surgery and accelerate postoperative recovery[2,3]. By organizing care delivery, ERPs also reduce variability between providers in care processes and outcomes. Meta-analyses of randomized control trials demonstrate that the use of an ERP reduces length of stay and postoperative morbidity without increasing readmissions [4]. This results in significantly decreased costs compared to usual care[5].

Guidelines from the Enhanced Recovery After Surgery (ERAS®) Society and the American Society of Colon and Rectal Surgeons (ASCRS)[6] recommend that patients undergoing colorectal surgery should be treated within an ERP containing up to 23 interventions.

Table 1.1 Perioperative ERP interventions.

| Preoperative | Intraoperative | Postoperative |
|---|---|---|
| Preadmission education | Antibiotic prophylaxis | Early mobilization |

| | | |
|---|---|---|
| Selective mechanical bowel preparation | Epidural anesthesia | Gastrointestinal stimulation with chewing gum |
| Carbohydrate loading | Laparoscopic approach | Consumption of oral liquids on POD 0 |
| Non long-acting sedation | Balanced intravenous fluids | Breathing exercises |
| | PONV prophylaxis | Nutritional drink supplements on POD 0 |
| | No abdominal or pelvic drainages | Opioid sparing analgesia |
| | Normothermia | Early termination of IV fluids |
| | TED prophylaxis | Early termination of urinary drainage |
| | Avoidance of NG tube | Free diet on POD 1 |
| | | Laxatives |

Preoperative interventions include patient education and counseling, smoking and alcohol cessation, reduced period of fasting, consumption of carbohydrate drinks and avoidance of routine bowel preparation. Intraoperative interventions include antimicrobial prophylaxis, minimally invasive surgery whenever possible, fluid optimization and prevention of hypothermia. Postoperative components of ERPs include early oral feeding, multimodal opioid-sparing analgesia, avoidance of drains, early removal of urinary catheters and intravenous (IV) fluids, standard laxatives, use of oral protein supplements, gastrointestinal stimulation with chewing gum, and early mobilization. In a cohort study including more than 300 patients, we found a strong association between compliance with the pathway and successful patient recovery (defined by absence of complications, discharge by postoperative day 4 and no readmission during the following 30 days )[7]. Laparoscopic surgery, early termination of IV fluid infusions and patient mobilization were independent predictors of improved recovery. Adherence varies between the perioperative periods and was shown to be 83% preoperatively, 79% intraoperatively, and decreased to 73% postoperatively[7]. Others have also confirmed lower adherence in the postoperative period[8]. Given that the benefits of ERPs decrease with lower adherence, improving postoperative adherence represents an opportunity for quality improvement[8-10].

**1.2 The challenges in postoperative ERP adherence, education and engagement.**

Achieving completion of every single element of an enhanced recovery program is the result of a joint effort by all parties involved: nursing staff, physicians, clerks and patients. However, the interventions can be broadly divided into those requiring a high degree of patient participation and those that do not. For example, in the postoperative period, early food intake and mobilization require self-management and patient engagement, while the decision to remove IV and urinary catheters is driven by the clinical staff. For elements requiring patient participation, promoting engagement through education is considered a key strategy to increase adherence and ensure the successful implementation of ERPs[11]. In our institution (McGill University Health Center), patient education currently involves a preoperative education session with a surgical nurse during which patients receive an illustrative booklet explaining the pathway and setting specific recovery goals for each postoperative day (http://www.muhcpatienteducation.ca/DATA/GUIDE/170_en~v~bowel-surgery-montreal-general-hospital.pdf). This booklet was created by surgery, anesthesia and the patient education office, consistent with best practices regarding health literacy level and incorporating compelling graphic design. The booklet also includes a log for patients to record their adherence with daily ERP goals as well as their symptoms. This approach was introduced as a way for patients to increase involvement in their own postoperative care by tracking improvement in pain scores, mobility, and fluid intake. Unfortunately, although advised to do so, patients do not always bring the booklet at the time of admission and the log is rarely completed[12]. There is a need for alternative ways to educate and engage patients in order to increase adherence.

### 1.3 Mobile technology and applications for surgery

In the last decade, there has been increasing interest in the use of mobile technology, such as smartphone and tablet computer applications (apps), as platforms to deliver health education material and capture patient-reported outcome (PRO) data[13]. Recent studies suggest that the use of such technology has the potential to foster behaviour change and improve patient compliance with treatment guidelines[14]. When used for data collection, mobile technology may increase administrative efficiency as information entered directly by patients in their mobile device can be transferred automatically to a secure database.

Most mobile applications designed to elicit an effect in the health state of an individual attempt to modify behaviours by either decreasing attitudes that result in a health detriment, or promoting ones that produce beneficial changes. These are called behavioral change techniques and are defined as theory-based methods for changing one or several psychological determinants of behavior such as a person's attitude or self-efficacy[15]. These theories have been abundantly described in the literature and a common feature of them is the use of specific strategies to elicit the intended behavioral changes. The different theories identified several strategies and named them differently despite some of them being very similar, therefore, Abraham and Michie[16] developed a taxonomy of 26 generally applicable behavior change techniques extracted from 6 behavior change theories: information-motivation-behavioral skills model, theory of reasoned action, theory of planned behavior, social cognitive theory, control theory, and operant conditioning[17]. Specifically, in mobile health apps, this taxonomy is useful in determining which techniques are used in the app delivery method when the design intends to promote a behavioral change[13].

The published literature on mobile health apps interventions as the mean to elicit behavioral changes is vast and very heterogeneous. However, in a scoping review of the literature [18], we found very few mobile device health applications (five in total)[18-22] designed to improve care or outcomes of a surgical condition. We also found that most healthcare applications trials were not effective in modifying the desired patient behavior.

From 81 trials identified, 31 had positive clinical outcomes, and, of those, only 5 had surgical patients as subjects. Five behavioral techniques were used in the 31 positive trials. The larger difference in frequency of usage of a specific behavioral technique between positive and negative trials was the one called “Provide feedback on performance” technique, or “tailored feedback”. This technique provides the app user with specific feedback based on the user generated data. The feedback provided by the app is based on accepted guidelines or expert consensus. In contrast, simple feedback provides a summary of the user’s own data. Specific goal setting was another technique frequently used in successful trials. This technique prompts users to specify their own goals, based on their self-identified capabilities. This serves to personalize the goals, adjusting them to the individual user characteristics rather than applying general goals to a heterogeneous user group.

This research suggests that features that personalize mobile health apps, such as these two behavioral change techniques (tailored feedback and personalized goal setting), may improve the chance of impacting positively a behavioral change attempt[23].

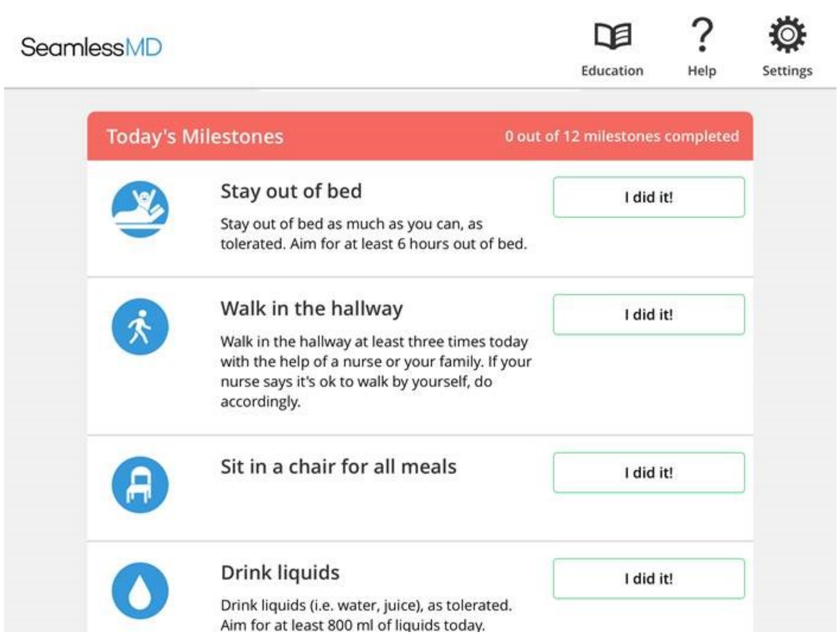
### 1.4 A novel mobile app for colorectal ERP

In order to support patient engagement and collection of PROs, we developed a custom mobile app for colorectal surgery. This app provides educational material and captures patient-reported information regarding ERP adherence and achievement of recovery milestones during hospital stay[24]. In a pilot study, 45 patients used this app on a tablet computer (iPad, Apple®) during the first 3 postoperative days. The app had high usability and user satisfaction with high agreement between patient-reported information and information obtained by a clinical auditor. This suggests that the novel mobile app has the potential to reliably collect patient-reported recovery information and engage patients in their recovery process[24], particularly with respect to interventions that require significant patient participation for completion.

The app was designed in collaboration with a medical information and technology company (Seamless MD) and was initially conceived as a digital version of the educational booklet. As the design evolved, new elements were added including a daily overall score of the number of elements completed per day. Visually attractive icons and illustrations were designed for the app and a module for patients with a stoma was added.

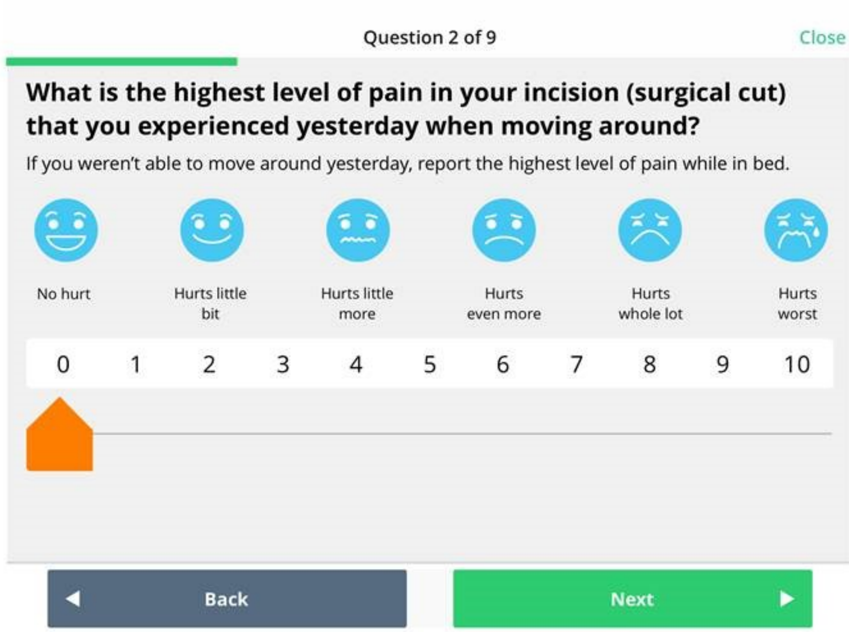
The new colorectal ERP app consists of 3 major sections.

1) Milestones checklist: The app informs the patient of a number of milestones to be achieved on each specific postoperative day. These were called “recovery goals” and included a detailed description of the requirements needed to complete each specific milestone. (e.g. Drink at least 1.5 liters of water today (3 red cups)). The cumulative score of the goals achieved over the total number of milestones is always on display on the main screen of the app, providing the patient a constant reminder of the pending goals for the day. At the end of each postoperative day, the app generates a brief summary of the daily achievements and displays an encouraging statement.

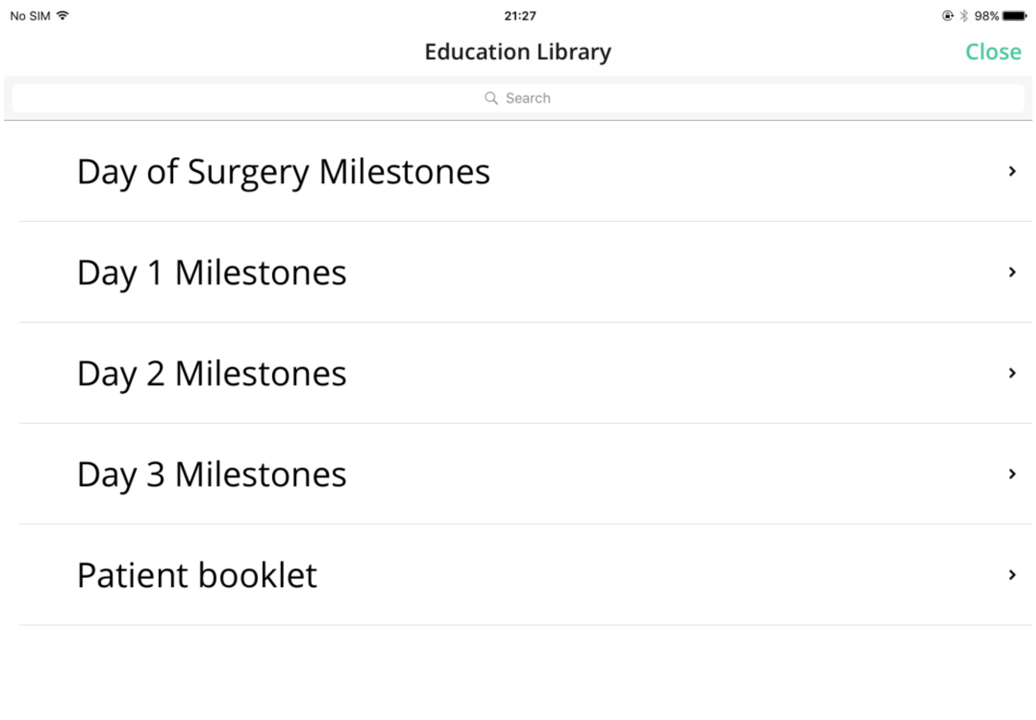



2) Daily clinical questionnaires: Every morning, the app prompts the user to complete a questionnaire about the previous day (e.g. How many laps of the corridor did you walk yesterday?). This also includes symptoms and outcomes of surgical recovery (e.g. rate your pain; did you pass gas?). The items are identical to those in the standard patient

education booklet patient log. At completion of the questionnaire, the patient receives a cumulative score from the previous day called "number of milestones met" and advice on how to improve on the present postoperative day (Example: when a patient reports too much pain, the advice would read "call your nurse, tell them your pain is not controlled"). Items regarding bowel function and passage of gas were modified for the group of patients with a stoma (i.e. Did you pass stool? Or, did your bag have stool?). The daily clinical questionnaire scores are always accessible from the main menu of the app.




3) Education: An icon in shape of a book is always on display in the corner of the main screen and provides access to an education module. It provides information about every element of the postoperative pathway and their respective importance. The information is identical to that contained in the paper booklet they had received in the preoperative clinic.




The daily use of the app with the 3 modules was designed to encourage engagement of patients in their own recovery thus increasing adherence to the clinical pathway elements.

## 1.5 Measuring adherence and postoperative recovery

### 1.5.1 Measuring adherence

Among the postoperative elements included in our evidence-based ERP, five were considered to be especially dependent on patient participation. Completion of each care process was defined according to published guidelines (Table 1.2)[6]. Adherence to each care process was determined on POD 1 and POD 2. We excluded the day of surgery (POD 0) from data analysis given the variability in time of ward admission and known lower adherence to the ERP associated with arrival to the wards after 6 P.M.[25].

Table 1.2 Criteria to define adherence to patient-dependent ERP elements on POD1 and POD2[6]

| | |
|---|---|
| Early mobilization | Out of bed for 4 hours on POD 1 and 6 hours on POD 2 |
| Gastrointestinal stimulation with chewing gum | Chewing gum for 30 minutes three times per day |
| Consumption of oral liquids | Consumption of $\geq$800 ml water per day |
| Breathing exercises | Using the spirometer at least 3 times per day |
| Nutritional drink supplements | Consumption of at least 2 protein drinks per day |

Adherence to each of the five elements was evaluated on both POD 1 and 2, producing 10 data points on which to assess overall adherence. This was the primary outcome of the study.

### 1.5.2 Clinical outcomes

There is no single accepted universal measurement of in-hospital postoperative recovery. Patients, clinical staff, and society may place emphasis on different aspects of recovery[26]. We included three standard clinical measures as secondary outcomes of the study:

1. Length of stay (LOS): The number of days a patient remains in hospital after the surgical procedure. This is the most commonly used measure of short-term recovery in ERP studies[27]. Length of stay is highly impacted by adverse events, surgical complications, or patient symptomatology. It is also affected by non-clinical factors unrelated to recovery, such as patient expectations, social support, distance from the hospital and health care system organization[28]. Recent literature suggests that the time to achieve discharge

criteria ("time to readiness for discharge", TRD) may be a better measure of in-hospital recovery, in that it discounts organizational factors accounting for longer LOS[29]. However, within a well-established ERP, we found that LOS was an equally construct-valid measure of in-hospital recovery compared to TRD[30]**.**

2. Postoperative complications: These are defined as any deviation from the normal postoperative course[31]. Commonly occurring complications of colorectal surgery were defined *a priori*[7]. A complication grade from was assigned to each patient based on their most severe complication using the Clavien-Dindo system[26] (Table 1.3).
3. Comprehensive complication index (CCI): The CCI is an evolution of the Clavien-Dindo classification that summarizes all complications occurring in a single patient, weighted for severity. The final score ranges from 0-100 and may be a more sensitive endpoint in assessing morbidity compared to the traditional Clavien-Dindo classification[27,28].

**Table 1.3 Clavien-Dindo system for classifying postoperative complications.**

| Grade | Definition |
|---|---|
| Grade I | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions |
| Grade II | Requiring pharmacological treatment with drugs other than such allowed for grade I complication |
| Grade III | Requiring surgical, endoscopic or radiological intervention |
| Grade IIIa | Intervention not under general anesthesia |
| Grade IIIb | Intervention under general anesthesia |
| Grade IV | Life-threatening complication (including dialysis) |
| Grade IVa | Single organ dysfunction |
| Grade IVb | Multiorgan dysfunction |
| Grade V | Death of a patient |

## Thesis objectives

Our primary research question was: Does the use of a mobile device app specifically designed for patient education and self-assessment of recovery after colorectal surgery impact on adherence to ERP elements in comparison to standard preoperative education? Our primary hypothesis was that the use of this mobile device app will result in greater adherence to postoperative ERP care processes that require a significant degree of patient participation.

We will also test the exploratory hypotheses that, in comparison to standard preoperative education, the mobile device app will: (1) reduce LOS, (3) reduce postoperative complications, and (4) improve patient satisfaction.

## CHAPTER 2: Manuscript

# A mobile device application (app) to improve adherence to an enhanced recovery program for colorectal surgery: a randomized controlled trial

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## 2.1 ABSTRACT


**INTRODUCTION:** Increased adherence with enhanced recovery pathways (ERP) is associated with improved outcomes. However, adherence to postoperative elements that rely on patient participation remains suboptimal. Mobile device apps may improve delivery of health education material and have the potential to foster behaviour change and improve patient compliance. The objective of this study was to estimate the extent to which a novel mobile device app affects adherence to an ERP for colorectal surgery in comparison to standard written education.

**METHODS:** This was a superiority, parallel-group, assessor-blind, sham-controlled randomized trial involving 97 patients undergoing colorectal resection. Participants were randomly assigned with a 1:1 ratio into one of two groups:(1) iPad including a novel mobile device app for postoperative education and self-assessment of recovery, or (2) iPad without the app. The primary outcome measure was mean adherence (%) to a bundle of 5 postoperative ERP elements requiring patient participation: mobilization, gastrointestinal motility stimulation, breathing exercises and consumption of oral liquids and nutritional drinks.

**RESULTS:** In the intervention group, app usage was high (94% completed surveys on POD0, 82% on POD1, 72% on POD2). Mean overall adherence to the bundle on the two first postoperative days was similar between groups: 59% (95%CI 52 to 66%) in the intervention group and 62% (95%CI 56 to 68%) in the control group [Adjusted mean difference 2.4% (95%CI -5 to 10%) p= 0.53].

**CONCLUSIONS:** In this randomized trial, access to a mobile health application did not improve adherence to a well-established enhanced recovery pathway in colorectal surgery patients, when compared to standard written patient education. Future research should evaluate the impact of applications integrating novel behavioral change techniques, particularly in contexts where adherence is low.

## 2.2 Introduction

Over 300,000 major colorectal operations are performed each year in the United States, accounting for approximately 6.5 billion dollars in annual health care cost[1]. Enhanced recovery pathways (ERPs) are evidence-based, multimodal, standardized care plans that integrate multiple interventions throughout the perioperative period. When compared to traditional care, ERPs reduce complications, length of stay and cost of colorectal surgery without increasing readmissions.[2-5] Guidelines recommend that patients undergoing colorectal surgery be treated within an ERP comprising more than 20 elements, including preoperative patient counselling, reduced preoperative fasting, early mobilization out of bed, opioid sparing analgesia and early oral nutrition [6,7]. Observational studies suggest that higher adherence to these elements is associated with improved outcomes[8,9] and that benefits may decrease with lower adherence.[10]

Adherence in the postoperative period may pose particular challenges[11]. The reasons are likely multifactorial; for example, adverse postoperative symptoms can prevent adherence (e.g. nausea and vomiting interfering with early oral nutrition, presence of postoperative pain influencing physical activity) while staffing may impact the availability of personnel available to assist patients to achieve ERP goals (e.g. mobilization out of bed). Nevertheless, a distinction can be made between interventions that require patient participation (e.g. early food intake, mobilization out of bed) and those that are initiated and completed entirely by the clinical staff (e.g. early removal of intravenous fluid and urinary drainage catheters)[12]. For ERP elements that are dependent on patient participation, patient education is considered a key strategy to increase adherence and ensure successful ERP implementation[13]. Guidelines recommend preoperative counselling supplemented by written instructions to explain the pathway and set specific recovery goals for each postoperative day.[7] In our institution, patients are advised to use this written resource during hospital stay and complete a log to record milestones, encourage engagement and record symptoms interfering with adherence. However, patients do not always use the booklet and the log is rarely completed.[14] In addition, information about patient symptoms that may require modification of the pathway are not available in real-time to clinicians. Electronic and mobile technology such as smartphone and tablet computer applications (apps) are newer platforms with the potential to improve delivery of health education material and capture patient-reported outcome (PRO) data. This technology may foster behaviour change and improve compliance.[15]

To support our ERP for colorectal surgery, we developed a customized mobile app to provide educational material and capture patient-reported information regarding symptoms and achievement of recovery milestones during hospital stay. In a pilot study, the app had high usability and user satisfaction scores, with high agreement between patient-reported information and information obtained by a clinical auditor[16]. The present study is a randomized controlled trial to estimate the extent to which this app impacts adherence to postoperative ERP elements in comparison to standard written education. Secondarily, we explored the association of the intervention with overall adherence to the pathway, length of hospital stay, postoperative complications and patient satisfaction.

## 2.3 Methods

### *Study design*

This was a superiority, parallel-group, assessor-blind, sham-controlled randomized trial. Participants were randomly assigned with a 1:1 ratio into one of two groups: (1) standard preoperative education and sham intervention, or (2) standard preoperative education and the use of a mobile device app for postoperative education and self-assessment of recovery. The trial protocol was registered in ClinicalTrials.gov (NCT03277053) and reporting is in accordance with the CONSORT Statement[18].

We considered for inclusion adult patients (>18 years) with colonic or rectal diseases (e.g. neoplasm, inflammatory bowel disease, diverticulitis) planned for surgical resection at the Montreal General Hospital site of the McGill University Health Centre. Criteria for exclusion were medical conditions precluding patients from following the pathway or using the tablet computer (i.e. cognitive, neurological, or musculoskeletal diseases) and inability to understand or read English or French. Patients were approached in the preoperative clinic to assess eligibility for the study and obtain consent.

### *Interventions*

All patients were treated according to a well-established ERP.[8] This includes standard preoperative counseling, comprised of an education session with nursing personnel trained in Enhanced Recovery and an illustrated booklet, including recovery goals for each postoperative day and a diary to record daily activities. The booklet was designed by the hospital ERP steering committee and the patient education office using best practices for health education, at an appropriate health literacy level and with engaging graphic design (http://www.muhcpatienteducation.ca/DATA/GUIDE/170_en~v~bowel-surgery-montreal-general-hospital.pdf).

Postoperatively, participants randomized to the intervention group received a tablet computer (Apple® iPad, Cupertino, USA) containing a novel mobile app. The app was developed by a partner software company (SeamlessMD, Toronto, Canada; https://seamless.md), customized to our pathway, and available in both English and French. The mobile application was previously described[16]. In brief, it included three sections:

1) Milestones checklist: A checklist was always visible in the app's homepage listing the day's recovery goals with a brief description of the requirements to achieve each one. Next to each description, a button icon was available for the patients to press when the milestone was achieved, and an overall score of the number of milestones achieved compared to the total number for that day was constantly visible in the app's main dashboard.
2) Daily clinical questionnaires: A brief questionnaire assessing adherence and outcomes for the previous day. In contrast with the milestones checklist, which assessed progress for the present day, the clinical questionnaire assessed the previous day to give an overall summary. Items regarding bowel function and passage of gas were modified for the group of patients with a stoma (i.e. Did you pass stool? Or, did your bag have stool?). After submitting the information, the app displays a total score of the number of "milestones met" (one for every ERP element of interest they achieved), with a brief phrase of encouragement for goals that were achieved and advice for how to reach the milestones that were not yet achieved. Patients could review this feedback at any time in the app's home page.
3) Education: Access to educational material was always available in the app's home page. Accessing one of the modules produced a detailed description of the milestones for each

postoperative day. An exact replica of the education booklet received in their preoperative visit was also included in the educational module.

Participants randomized to the sham intervention (control) group received a tablet computer (Apple® iPad, Cupertino, USA) with internet access but without the mobile app.

***Randomization process and blinding***

Randomization was conducted centrally using a web-based randomization system provided by an independent contractor (Sealed Envelope, http://www.sealedenvelope.com/). To ensure concealment of allocation, patients were randomized once they arrived at the surgical ward after the surgery. To ensure balance in treatment allocation, patients were randomized in blocks with block sizes randomly assigned (2, 4 or 6). Randomization was stratified by surgery with formation of a new stoma versus surgery without a new stoma, as patients with a stoma are treated within a slightly modified ERP and used a modified version of the app. Once participants were randomized, specific instructions were given depending on their allocation: patients in the usual care group were instructed on how to access the internet using their 'sham' tablet computer, while patients in the mobile app group received detailed instructions on how to use the app.

Since only the patients randomized to receive the app could submit outcomes electronically in real-time, which may introduce bias, a researcher blinded to the participants' treatment allocation recorded all outcome measures. The examiner visited the patients early in the morning to obtain the clinical information corresponding to the previous day (i.e., when the patient was visited on POD 2, the questions referred to POD1). To ensure blinding, participants in the control group had a tablet computer in their room during hospital stay (sham intervention). Participants were asked not to discuss information about their group allocation with the assessor. The codes for group allocation were not revealed until data collection was completed. Any inadvertent unblinding was reported. Due to the nature of the intervention it was not possible to blind the participants to their group assignment.

***Outcome assessment***

Assessments were conducted at the patient's routine visit to the preoperative clinic (within 2 months before surgery), daily during hospital stay, and at 4 weeks after surgery (via telephone follow-up).

The primary outcome measure of the study was overall adherence to a bundle of 5 postoperative ERP elements that depend on patient participation and are therefore potentially modifiable with the use of the app. These elements include early mobilization, gum chewing, consumption of oral liquids, breathing exercises, and consumption of nutritional drinks. The definitions of adherence to these elements are described in Table 1.1. As adherence to these elements on POD0 is highly dependent on the time of arrival at the ward[12], our primary outcome was adherence on POD1 and POD2 (i.e., the total number of elements out of a maximum of ten: 5 on POD 1 and 5 on POD2). We then compared mean percent adherence to this bundle between the two groups.

Other exploratory outcome measures included adherence to each of the five ERP elements on POD1 and POD2, by calculating the number of patients adherent to each element/total number of patients. Length of primary hospital stay (LOS) was calculated as the number of nights spent in hospital during the primary admission from the day of surgery to the day of discharge. Intraoperative and postoperative complications were defined *a priori* as previously reported.[11] Data regarding postoperative complications was obtained from medical records and graded by severity using the Comprehensive Complication Index (CCI), a validated measure that summarizes the complete spectrum of complications and their severity in a single score ranging from 0 to 100.[19,20] Evidence suggests that CCI is a more sensitive endpoint in assessing morbidity compared to the traditional Dindo-Clavien classification.[21] Data on emergency department visits to a hospital within 30 days after surgery was extracted from the electronic medical record and verified with the patient at their 4-week phone follow-up. Patient satisfaction was measured at hospital discharge with 4 items derived from the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS).[22] The four items were: Did I feel well informed? Did I feel confident? Did I feel motivated? and Did I feel satisfied with the care received? Answers ranged in a scale from 1 to 5 where 1 represented a low agreement and 5 a high agreement to the statements presented.

***Statistical analysis***

In previous research, mean adherence to the predefined bundle of patient-dependent ERP elements (i.e. early mobilization, chewing gum, consumption of oral liquids and nutritional drinks) in the immediate postoperative period for patients undergoing colorectal surgery in our hospital was 33%[8]. Sample size requirement for the present study was estimated for an $\alpha$ level of 0.05 and 80% power to detect a 30% increase in this proportion. According to this estimate, a sample of 43 participants per group was sufficient. A sample size of 50 participants per group (total sample of 100) was targeted to account for a possible increase in data variance due to multiple imputation of missing data.

Statistical analysis was performed using STATA version 13.1 software (StataCorp, College Station, TX, USA). Linear regression was used to test the main hypotheses that patients using the app have better adherence to patient-dependent ERP elements. The impact of the app on exploratory outcome measures was analyzed using logistic regression for binary outcomes (i.e. adherence to individual ERP elements, postoperative complications), cox-regression for LOS, and linear regression for overall adherence and CCI. All regression analyses were adjusted for the stratification factor (stoma vs. no stoma) and for established prognostic factors for adherence to ERP elements including older age (75+), gender, ASA score, preoperative diagnosis (malignant disease vs. benign disease), late arrival to the ward (after 6pm on POD0), and surgical approach (laparoscopic vs. open)[23-25]. Mann Whitney test was used to compare median score for each question regarding satisfaction with care. The analyses were performed according to an intention-to-treat principle, with participants being analyzed in the groups to which they were allocated. To minimize potential bias arising from missing data, the primary analysis was conducted using multiple imputations by predictive mean matching through 10 iterations, under the assumption that data were missing at random.

### 2.4 Results

A total of 135 patients were assessed for eligibility, of which 100 were randomly assigned to intervention (n=50) or control (n=50) (Figure 1). Ninety-seven patients completed the study (intervention n=50, control n=47). Three patients in the control group did not complete the study: two were admitted to the intensive care unit immediately after randomization, and one had postoperative delirium preventing accurate follow up by the blinded assessor. Two patients (one per group) declined the assessment on POD 1. Data for adherence on POD 2 was not available for 32 patients who were discharged prior to assessment on the morning of POD 3, including 15 in the app group and 17 in the control group.

Patient and surgical characteristics are summarized in Table 2.1 Patients in the intervention group were older (63.3 vs 56.6 years), had a higher comorbidity index (4 vs 2.9) and were less likely to have an operation completed by laparoscopy (70% vs 85%). New stoma creation, rectal surgery, duration of surgery and late arrival to the ward was similar between groups. Ownership of smartphones, tablets and personal computers was high in both groups (86% vs 79%). Postoperatively, length of stay, complication rate and severity, emergency visits and readmissions were similar between groups (Table 2.2).

There was no between-group difference in the main outcome measure, adherence to the 5-element bundle of postoperative interventions requiring patient participation over the two first postoperative days. Mean overall adherence to the bundle was 62% (95%CI 56% to 68%) in the control group and 59% (95%CI 52% to 66%) in the intervention group (adjusted mean difference 2.4% (95%CI -5 to 10), p= 0.53). There were no differences between the groups in adherence to each individual element or overall adherence on each postoperative day (Table 2.3). There was also no impact of the intervention on postoperative clinical outcomes, including LOS, morbidity and comprehensive complication index (CCI) (Table 2.4).

App usage for the patients in the intervention group was high. Ninety-four (94%) percent of patients used the app on POD 0, which decreased in the subsequent days to 82% on POD 1, 72% on POD2 and 48% on POD 3 (Table 2.5). Overall satisfaction was high, with no differences in median score for each item between the intervention and control groups (Table 2.6).

## 2.5 Discussion

We designed a novel health application to provide education and real-time feedback to patients treated within our established colorectal surgery ERP. In a pilot study, this application was well accepted by patients and could be feasibly used to collect patient-reported outcome data in a comparable surgical population [16]. However, in this randomized trial, we found no significant impact of this app on adherence to a bundle of 5 postoperative interventions that are dependent on patient participation. The lack of difference between groups occurred despite high usage of the app during the first two postoperative days.

This study is the first randomized controlled trial estimating the impact of a mobile application to improve surgical care. We identified only 5 studies reporting apps developed for a surgical population. Three provided medication reminders before and/or after surgery [29-31], while another provided a rehabilitation workout after ankle surgery [32]. In the fifth study, a novel iPad-based platform was used to provide a daily care plan and collect patient-reported outcomes after cardiac surgery.[33] None of these studies compared outcomes between patients who used the app and those who did not.

Overall adherence was 62% in the control group which was higher than anticipated. In fact, both groups achieved a level of adherence to the pathway that was expected for the intervention group. In other studies, adherence to postoperative interventions for colorectal pathways ranged from 32 to 73%[6,8,10]. Our sample size calculation was based on data from a study conducted in our institution in 2014, where reported adherence to a similar bundle of ERP elements was only 33%[8]. However, in this previous study, data reflected an unselected cohort of consecutive patients and included the immediate postoperative period (POD 0). During the years between these studies, efforts to improve access to nutritional supplements and early mobilization may have improved adherence to postoperative ERP elements. In addition, in the previous study, data was obtained mainly through medical records, which likely underestimated adherence compared to the present study where data was obtained each day directly from the patient. The patient populations were also different, as this RCT excluded patients who may be at risk for poor adherence, such those with cognitive, neurological, or musculoskeletal impairments and those with language barriers. Nonetheless, while adherence in the control group was higher than anticipated, adherence was not further improved in patients who had access to the app.

The educational content of the app was similar to the written content given to all patients preoperatively. Patient education materials are an integral component of all our ERPs and are created in collaboration with a Patient Education Office using best practices to be understandable and actionable. All participants received the standard preoperative education including written material. The relatively high adherence in the control group suggests that the quality of the information received was sufficient and potentially more important than the vehicle used to convey it. For example, there were no between-group differences in satisfaction scores regarding patient information. This could be a result of the quality of the patient education and accompanying reading material that all patients received preoperatively. We cannot exclude that a similar mobile app could have more impact on adherence outcomes in institutions that do not give as much emphasis on preoperative education.

The interactive content of the mobile application was customized to our pathway with the input of software engineers. Despite being interactive and providing a daily “score” compared to the pathway milestones, it did not include specific behavioral change techniques that might more effectively promote health behavior changes [27]. Some behavioral change techniques that have been successfully applied in health mobile applications include personalized goals, gamification features like rewards for adherence, and tailored (instead of generic) feedback on progress. Behavior change techniques have been proven efficacious in other fields [28] and may be a useful feature for future ERP apps.

Despite randomization, there were some differences between the groups, with patients in the control group being on average 6 years younger than those in the app group. However, there are no reports of specific age threshold for successful utilization of mobile health apps and both groups had similar previous experience with smart gadgets and personal computers. Our screening for the latter demographic characteristic only assessed ownership of a device, but individual patterns of usage should be accounted for in future app intervention trials.

This study has several strengths. It was a randomized trial using data collected by an independent auditor not involved in patient care and who was blinded to group allocation. The app was designed by a multidisciplinary team and used in the context of a well-established ERP with other perioperative interventions standardized. The high frequency of app usage on POD 0 and 1 represented another strength. However, there was a substantial decrease in usage on POD 2 and POD 3. This may reflect the fact that prolonged hospital stay is often associated with the presence of symptoms, complications and/or social situations that may impact willingness (or ability) to use the app. Efforts to assure continuous engagement and interest in mobile applications might improve their effectiveness.

This study also has several limitations. The amount of help required by different patients to set up and use the iPad varied significantly. If daily help with completing the questionnaires is necessary, it defeats the purpose of an app being an independent support for patient self-management. Ideally, mobile health apps should be user friendly enough to make them as self-explanatory and adaptable to patients with various levels of technological knowledge. Second, this was a single-center trial in a hospital with a well-established ERP that includes patient education materials designed in collaboration with a dedicated patient education group. This may have contributed to the higher adherence in the control group. Third, due to the nature of the intervention, the patients could not be blinded, which may have contributed to increased engagement in the control group. Fourth, to avoid the bias inherent in collecting data from one group electronically and the other through an auditor, we collected data about the previous day for all participants. This resulted in inability to collect data for POD 2 in 32 patients who were already discharged by the morning of POD 3. However the proportion of patients discharged early was similar in both groups. Finally, we tested the app only in an inpatient setting. We cannot exclude that possibility that mobile apps would be more beneficial post-discharge, when there is less staff support available to facilitate the process of postoperative recovery.

### *Conclusion*

In this randomized trial, a mobile health application did not improve adherence to a well-established in-patient enhanced recovery pathway in colorectal surgery when compared to standard written patient education. App usage was high in the first 2 postoperative days suggesting an interest in the use of this technology. Future research should evaluate the impact of applications integrating novel behavioral change techniques, particularly in contexts where adherence is low.

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**Figure 1.- CONSORT Flow Diagram**

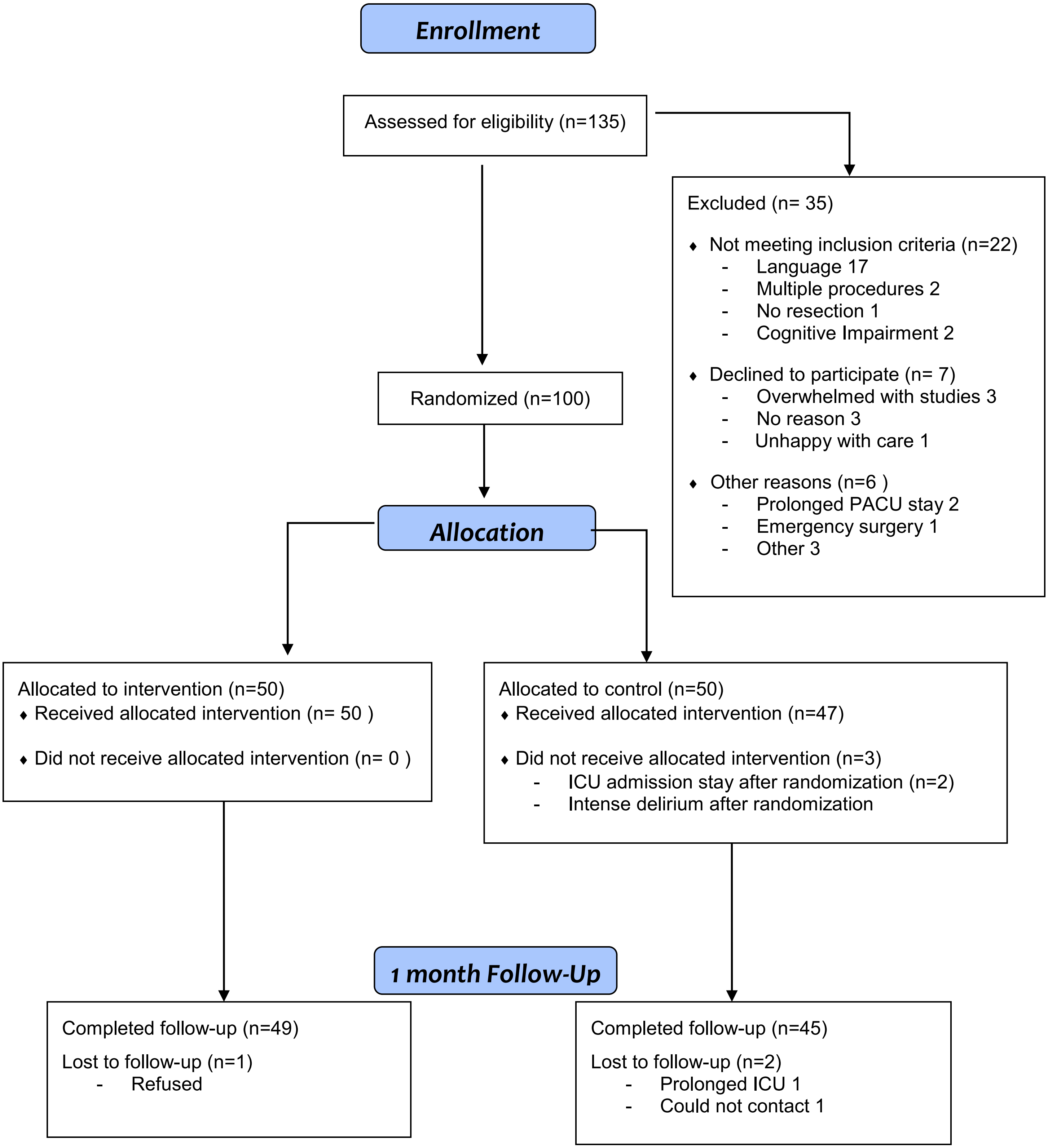

Table 2.1 Characteristics of patients included in the study. Values are number of patients (%) unless otherwise stated.

| Variables | Control (n=47) | Intervention (n=50) |
|---|---|---|
| Age, years, mean (95% CI) | 56.6 (53.2 to 60) | 63.3 (60 to 66) |
| Female | 20 (43) | 23 (46) |
| ASA | | |
| 1 | 4 (9) | 1 (2) |
| 2 | 29 (62) | 34 (68) |
| 3 | 14 (30) | 15 (30) |
| Charlson Comorbidity Index, mean (95% CI) | 2.9 (2.3 to 3.4) | 4.0 (3.5 to 4.4) |
| Diagnosis | | |
| Malignancy | 23 (49) | 30 (60) |
| Inflammatory bowel disease | 13 (28) | 6 (12) |
| Diverticular disease | 4 (9) | 5 (10) |
| Other | 7 (15) | 9 (18) |
| Owners of smartphone/tablet or personal computer | 37 (79) | 43 (86) |
| Laparoscopic approach | 40 (85) | 35 (70) |
| Procedure performed | | |
| Right hemicolectomy | 13 (28) | 12 (24) |
| Low anterior resection | 7 (15) | 12 (24) |
| Sigmoid resection | 8 (17) | 8 (16) |
| Left hemicolectomy | 2 (4) | 6 (12) |
| Ileocecal resection | 8 (17) | 6 (12) |
| Abdominoperineal resection | 2 (4) | 3 (6) |
| Proctocolectomy | 2 (4) | 1 (2) |
| Total / subtotal colectomy | 5 (11) | 1 (2) |
| New stoma creation | 5 (11) | 7 (14) |
| Rectal resection[a] | 10 (21) | 13 (26) |
| Surgery duration (mins) (mean, 95%CI) | 206 (192 to 220) | 228 (212 to 234) |
| Arrival at ward after 6pm | 20 (43) | 19 (48) |

[a] Includes total proctocolectomy, Low anterior resection, Abdominoperineal resection,
ASA, American society of Anesthesiologists

Table 2.2 Postoperative outcomes. Values are number of patients (%) unless otherwise stated.

| **Variables** | **Control (n=47)** | **Intervention (n=50)** | **p** |
|---|---|---|---|
| Length of primary hospital stay | | | |
| median (IQR) | 3 (2–5) | 4.0 (2-5.8) | 0.33 |
| mean (95% CI) | 6.4 (2.6-10.2) | 4.6 (3.8-5.4) | |
| 30-day postoperative complications (any) | 19 (40) | 25 (50) | 0.32 |
| During primary stay | 12 (25) | 16 (32) | 0.44 |
| Post-discharge | 7 (15) | 9 (18) | 0.70 |
| Type of postoperative complication | | | |
| Medical complications | 5 (10) | 12 (24) | 0.06 |
| Cardiovascular | 1 (2) | 1 (2) | 1.00 |
| Respiratory | 1 (2) | 2 (4) | 0.52 |
| Other[a] | 3 (6) | 9 (18) | 0.07 |
| Infectious complications | 3 (6) | 5 (10) | 0.47 |
| Surgical complications | 14 (30) | 19 (38) | 0.40 |
| Anastomotic leak | 1 (2) | 1 (2) | 1.00 |
| Bleeding | 5 (10) | 6 (12) | 0.75 |
| Ileus | 7 (15) | 9 (18) | 0.69 |
| Other | 3 (6) | 4 (8) | 0.70 |
| 30-day reoperation | 2 (4) | 4 (8) | 0.41 |
| 30-day emergency department visits | 9 (19) | 10 (20) | 0.90 |
| 30-day hospital readmissions | 0 (0) | 4 (8) | 0.05 |

[a] Renal, hepatic, neurologic, psychiatric.

Table 2.3 Intervention impact on overall mean adherence to the elements of the postoperative bundle

| **Variables** | **Control** | **Intervention** | **Adjusted regression coefficient (95%CI)**[a] | **p** |
|---|---|---|---|---|
| %Adherence POD1 and 2, mean (95%CI) | 62 (56 to 68) | 59 (52 to 66) | 2.4 (-5.2 to 10.1)[b] | 0.5 |
| POD1 %adherence, mean (95% CI) | 65 (62 to 68) | 63 (59 to 67) | 0.75 (0.5 to 1.7)[b] | 0.67 |
| Mobilization (n,%) | 20 (42) | 23 (48) | 1.37 (0.6 to 3.2)[c] | 0.68 |
| Chewing gum (n,%) | 30 (63) | 30 (62) | 1.13 (0.4 to 2.9)[c] | 1.00 |
| Oral fluids (n,%) | 38 (80) | 37 (77) | 1.12 (0.4 to 3.4)[c] | 0.80 |
| Spirometry (n,%) | 42 (89) | 42 (88) | 0.31 (0.1 to 1.3)[c] | 1.00 |
| Protein drink (n,%) | 23 (49) | 19 (40) | 0.58 (0.2 to 1.5)[c] | 0.41 |
| POD 2 %adherence, mean (95% CI) | 55 (51 to 59) | 52 (47 to 56) | 1.08 (0.4 to 2.4)[b] | 0.53 |
| Mobilization (n,%) | 10 (33) | 11 (33) | 0.29 (-0.8 to 1.4)[c] | 1.00 |
| Chewing gum (n,%) | 16 (53) | 12 (36) | 0.17 (-0.9 to 1.2)[c] | 0.21 |
| Oral fluids (n,%) | 22 (73) | 21 (64) | 0.64 (-0.4 to 1.7)[c] | 0.43 |
| Spirometry (n,%) | 25 (83) | 30 (91) | 0.45 (-1.3 to 2.2)[c] | 0.46 |
| Protein drink (n,%) | 3 (10) | 3 (9) | 0.97 (-1.2 to 3.1)[c] | 1.00 |

[a] Adjusted by: Age (75+), ASA, gender, stoma, malignancy, surgical approach, late arrival.

[b] Adjusted mean difference (linear regression)

[c] Adjusted odds ratio (logistic regression)

Table 2.4 Impact of intervention on clinical outcomes.[a]

| **Variable** | **Adjusted regression coefficient (95%CI)** | **p** |
|---|---|---|
| Length of stay, HR (95%CI) [b] | 1.17 (0.8 to 1.8) | 0.48 |
| Postoperative complications, OR (95%CI) [c] | 1.37 (0.5 to 3.5) | 0.50 |
| CCI[d], Coefficient (95%CI) [e] | 0.18 (-0.5 to 0.8) | 0.57 |

[a] Adjusted by: Age (75+), ASA, gender, stoma, malignancy, surgical approach, late arrival.

[b] Hazard ratio (Cox regression)

[c] Odds ratio (logistic regression)

[d] Comprehensive Complication Index

[e] Adjusted mean difference (linear regression)

Table 2.5 App usage in the intervention group.

| Days | Eligible patients | Completed surveys | % of eligible patients |
|---|---|---|---|
| POD0 | 47 | 44 | 94% |
| POD1 | 46 | 38 | 82% |
| POD2 | 33 | 24 | 72% |
| POD3 | 29 | 14 | 48% |

POD: postoperative day

Table 2.6 Impact of intervention on satisfaction scores for each item.

| Satisfaction questionnaires, median (IQR) | **Control** | **Intervention** | **p** |
|---|---|---|---|
| I felt well informed | 4 (4 – 5) | 4 (4 – 5) | 0.80 |
| I felt confident | 4 (4 – 5) | 4 (4 – 5) | 0.96 |
| I felt motivated | 4 (4 – 5) | 4 (4 – 5) | 0.54 |
| I felt satisfied with the care received | 4 (3.5 – 5) | 4 (4 – 5) | 0.70 |

## CHAPTER 3: Discussion

In this trial, adherence to an enhanced recovery pathway in colorectal surgery was not improved by use of a mobile health application as compared to standard written patient education.

Several important questions remain unanswered: Is there a better way to design mobile applications with the objective to incite behavioral changes in surgical patients? Would a similar intervention be successful in a setting with less established postoperative care pathways? Should effective mobile applications in a medical or surgical setting be targeted to a certain age group or to individuals with technological knowledge?

The results of our research indicate that the great majority of patients utilized the mobile application. This suggests an interest in mobile devices for information delivery, even in the immediate postoperative period. However, there has been very little research evaluating mobile apps in surgical patients. In our scoping review, we found 81 health applications targeting 31 aspects of health, but only five[29-33] addressed surgical conditions and none of them were comparative studies. Overall, most apps were not successful in eliciting a change in patients' behaviour. Two techniques were used more frequently in successful apps: tailored feedback and goal setting. The interface of our mobile app was not designed with any theory-based behavioral change techniques. It simply provided generic feedback and recommendations that were consistent with evidence-based recommendations but were not specifically tailored to the individual patient. Also, individualized goal setting was not considered during the design phase which would represent an additional form of personalization. Based on the findings of the randomized trial and the literature review, having a simple function that incorporates the patient's own motives/goals may create a sense of collaborative effort between the app and the patient (i.e. in terms of laps of a hallway, or time out of bed) since the interface adjusts to the patient's needs. The app's feedback could be designed to incorporate the patient's stated capabilities/goals and reward behaviour that exceeds self-identified limits. For example, a patient who anticipated walking for 1 hour would receive positive reinforcement if he/she walks 1.5 hours despite not achieving the pathway goal. Our literature review of existent mobile apps indicates that efforts in personalizing the interface increases the chance of having a successful intervention, and this should inform future efforts in mobile app design for surgical patients[23].

The postoperative enhanced recovery pathway within which we tested our mobile app is a very well-established program with highly trained, experienced personnel. Our research revealed that, in comparison to the study on which we based our power calculation[7], the postoperative adherence to the ERP has substantially increased and approaches some of the highest reported in the literature. We cannot pinpoint a specific reason for the noted increase in measured adherence however it may be due to both significant improvements in our ERP and important differences in study methodology, as discussed in the manuscript.

The high adherence to the ERP found in the overall trial population creates a system in which it becomes increasingly difficult to further improve the adherence with additional interventions, hence, we cannot exclude the possibility that similar mobile apps can improve adherence in settings with less successful ERP. One of the strengths of the ERP of our institution is the quality of the pre-operative information sessions and the written material given to every patient. This material has been reviewed in several phases to ensure that it is accessible to patients at all levels of literacy. In keeping with the results of our trial, it may be that it is the quality of information delivered, and not the mode of delivery that is the most important.

Another strength of our institution's ERP that impacted the development of this trial was the number of patients who were discharged home early on POD 2, preventing the trial staff from evaluating them. Due to early discharge, the total number of missing data points on POD 2 was 32, which is a large portion of the overall number of subjects. However, among those who were discharged early, an equal number was enrolled in each of the randomization groups. In the setting of less successful ERP implementation and prolonged LOS, the impact of a similar intervention might be significant.

The processes of randomization and assessor blinding were adequate during the trial; there were no violations of the randomization process, nor breaks in concealment in the allocation or assessment process. Nonetheless, two demographic characteristics (age and 30-day hospital re-admission) were different between the two groups. With respect to the difference in age, it is possible that the higher age of the intervention group could have reduced the impact of the app, but we lack evidence to support this claim. Information about mobile technology dexterity in certain age groups and among patients with a certain level of technological knowledge would define a population in which app interventions might be effective. This data could be obtained by detailed usage information generated by the mobile app (such as periodicity and duration of the individual usage). Hence, the knowledge produced in this thesis contributes important venues for future research and app design.

Length of stay and 30-day readmission were longer for the intervention group. Based on current knowledge and the results of our trial, the use of a mobile app in hospitalized patient cannot explain these differences. It is possible that the aforementioned age difference between the groups could account for them.

## CHAPTER 4: Conclusion and future direction

Patient education is considered a key aspect of a successful implementation of an ERP, since it improves engagement and gives tools to the surgical patient to become an active participant in their own recovery after a procedure[11]. This thesis investigated a novel way to deliver information to patients, using a mobile application. The objective was to increase adherence to a selection of postoperative interventions that require a degree of patient participation and are associated with improved surgical outcomes. The app had no significant impact on adherence to the aforementioned bundle in the context of our well-established ERP.

Even though no difference was detected in our trial, important knowledge was generated that could inform future efforts for similar technology. The usage of behavioral techniques should be part of the design of any app intended for patients and in particular for those recovering from surgery. Better real-time data generation and analyses of the usage details of mobile health apps regarding the age and the health literacy of the patients could identify specific populations that benefit from mobile health applications.

The aforementioned improvements in the design, integration and information quality of a mobile health application for recovering surgical patients could have a significant positive impact, in particular in programs and pathways where adherence is low.

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