MOBILE APPLICATIONS IN COLORECTAL SURGERY

digitally advancing patient care

Sebastiaan Laurentius van der Storm

Mobile applications in colorectal surgery: digitally advancing patient care

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TABLE OF CONTENTS

INTRODUCTION

GENERAL INTRODUCTION AND OUTLINE OF THE THESIS

Smartphones have marked a digital transformative era in our society, fundamentally reshaping the way we live, communicate, work, and entertain ourselves. Notably, one of the most profound transformations was the revolution in communication. These handheld devices have facilitated constant and instantaneous connectivity, making information more accessible, and dismantling geographical barriers on a global scale. Messaging apps and video calls have refined both our personal and professional relationships, while social media provided individuals a platform for self-expression and activism. This has rapidly spread trends influencing culture globally and it has also introduced challenges such as misinformation and algorithm bubbles.[1]

Furthermore, the rise of mobile applications has transformed various aspects of our lives, from how we shop and bank to how we navigate, and even date. Smartphone users can be productive and engage in learning from virtually anywhere using a variety of productivity apps, educational resources, and collaborative tools. Smartphones enable us to carry our office, entertainment, and social networks in our pockets, blurring the borders between work and leisure in a shift towards a mobile-centric society. This transformation has, in turn, altered societal norms.[2] Economically, smartphones have driven explosive growth in e-commerce and significantly influencing consumer behaviour.

Digital literacy has emerged as a fundamental skill in the rapidly evolving smartphone era, characterized by the continual advancement of mobile applications. Digital Literacy can be referred to the ability to find information, understand and use software, technical problem solving and safe use of digital devices or software (data privacy).[3] It empowers individuals to navigate through mobile applications effectively, critically assess information, and engage responsibly with mobile technology.

Digitalizing of healthcare

The digital transformation of healthcare is catching up with societal advancement. Regulatory frameworks designed safeguarding patient privacy and the quality of care, inadvertently pose significant challenges to novel technologies.[4] While many healthcare providers will advocate for implementations of new technologies, there will also be those who consider it as a disruption to current clinical practices and workflow, or may have a preference for traditional methods.[5]

However, the landscape of health and medical applications has witnessed rapid growth over the past decade. In times of limited resources, healthcare is actively exploring the strategic utilization of digital solutions such as mobile applications. Fitness and wellness applications promote healthy living, while medical apps are considered to be used for medical or clinical purposes.[6] Medical applications may facilitate not only patients but also

healthcare professionals or their institutions. These applications can affect several aspects of healthcare such as information provision, communication, clinical decision-making, and monitoring. Although medical applications can be convenient, their use comes with inherent risks concerning data privacy and safety. Wrongful use of applications or use of unvalidated applications may be potentially harmful.[7]

Colorectal surgery

Colorectal surgery may be required for the treatment of diseases affecting the colon and rectum, such as inflammatory bowel disease, diverticulitis, or colorectal cancer. In some cases, a stoma must be created, which is a surgically created opening in the abdominal wall that allows for diversion of defecation. Undergoing colorectal surgery is often a stressful and complex process as patients have to cope with the diagnosis, the surgical procedure itself, or the potential lifestyle adjustments.[8] Support systems, both within the healthcare and patient's social circle, play an important role in guiding patients through this process.[9] However, the overload of information in this limited timeframe, covering aspects of the disease, the surgical procedure, potential complications, and postoperative instructions, can be overwhelming.[10] In this context, effective communication between healthcare providers and patients is essential for ensuring informed decision-making, improving patient empowerment and ultimately influencing patient outcomes.[11]

As colorectal surgical care continues to advance, it becomes paramount to adopt comprehensive and patient-centred approaches. Mobile applications have emerged as a promising tool to enhance patient care throughout the colorectal surgery journey.[12] These applications have the potential to provide a comprehensive platform for perioperative guidance, continuous monitoring, and valuable resources tailored to the unique needs of patients undergoing colorectal surgery.

AIM OF THIS THESIS

This thesis aims to provide an overview of the current perspectives on the use and development of medical mobile applications, assess patients' perspectives on stoma care, and evaluate the clinical effectiveness of patient-centred mobile applications in colorectal surgical care.

OUTLINE OF THIS THESIS

Chapter 1 provides an overview of current regulations relevant to mobile applications used in healthcare and medical research, discusses the responsibilities and liability of medical professionals, and discusses the most practical considerations they should know when using or building a mobile application.

In **Chapter 2**, a systematic review identifies mobile applications that have been described in literature for use in gastrointestinal surgical care. The identified apps are evaluated based on their prospects for providing surgical care.

Chapter 3 investigates patients' satisfaction with stoma care, identifies potential shortcomings, and assesses their attitudes towards a supporting app. This chapter also evaluates the association between patient characteristics, satisfaction concerning received stoma care, and willingness to use an app.

Chapter 4 provides a deeper understanding of the problems that patients face in stoma care and discusses how an app can improve these problems.

In **Chapter 5**, the protocol of the Stoma APPtimize trial is described**,** which investigated whether the self-reported quality of life of patients with a stoma can be enhanced by offering personalized and timed guidance, as well as peer contact, in the Stoma App. **Chapter 6** describes the results of the Stoma APPtimize trial.

Chapter 7 describes the ERAS APPtimize trial which investigates whether patient compliance with the ERAS protocol could be improved by the ERAS App. The mobile application is designed to enhance patient education, participation, and activation within the ERAS colorectal pathway.

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PART I

CURRENT PERSPECTIVES

CHAPTER 1

Apps in healthcare and medical research; European legislation and practical tips every healthcare provider should know

van der Storm SL, Jansen M, Meijer HAW, Barsom EZ, Schijven MP.

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ABSTRACT

Background: The use of apps in healthcare and medical research is increasing. Apps in healthcare may be beneficial to patients and healthcare professionals, but their use comes with potential risks. How to use apps in clinical care is not standard part of medical training, resulting in a lack of knowledge. As healthcare professionals and their employers can be held accountable for the wrongful use of medical apps, this situation is undesirable. This article addresses the most important European legislation regarding medical apps from the perspective of healthcare providers.

Methods: This review provides an overview of current and changing regulations, focusing on apps used in healthcare and medical research. Three topics are discussed: 1) the relevant European legislation and its enforcement, 2) the responsibilities and liability of the medical professional when using these apps, and 3) an overview of the most practical considerations medical professionals should know when using or building a medical app.

Results: When using and developing medical apps, data privacy must be guaranteed according to the GDPR guidelines. Several international standards make it easier to comply with the GDPR, such as ISO/IEC 27001 and 27002. Medical Devices Regulation was implemented on May 26, 2021, and as a result, medical apps will more often qualify as medical devices. The important guidelines for manufacturers to comply with Medical Devices Regulation are ISO 13485, ISO 17021, ISO 14971 and ISO/TS 82304-2.

Conclusion: The use of medical apps in healthcare and medical research can be beneficial to patients, medical professionals, and society as a whole. This article provides background information on legislation and a comprehensive checklist for anyone wanting to start using or building medical apps.

BACKGROUND

The use of mobile applications ('apps') has gained solid ground in healthcare. Currently there are over 400.000 health apps available on app stores worldwide.[1] Health and wellness apps can be defined as apps operating on smartphones that process health-related data or information, as medical apps are considered to be used for medical or clinical purposes.[2] Medical apps may thus facilitate not only patients, but also healthcare professionals (HCPs), their institutions, and society as a whole. Medical apps can aid in access to, distribution, exchange, management and maintenance of information and even facilitate clinical decision making.[3] An important benefit of using an app on a personal mobile device is the possibility of (inter-)connectivity. The use of apps on mobile devices enables the use of integrated sensors like the gyroscope, accelerometer, camera or microphone.[4] Although the use of apps in healthcare and medical research can be convenient and may improve quality of care, there are associated risks. Before using or developing an app, it is important to decide what objective needs to be met and to investigate if the app is truly the best and a reliable solution. Wrongful use of an app, or rightful use in the wrong context, is potentially harmful.[5] This is especially applicable to medical apps that fail to provide any evidence of its effectiveness or safety.[6]

How to critically appraise an app or how to use an app responsibly, is not a standard part of the medical curriculum. As a result, HCPs including medical researchers, often lack knowledge of the safe use of medical apps. This is an unwanted scenario, as HCPs can be held accountable for the wrongful use of nonconfirmative medical apps. Although this problem has existed for longer, the social-cultural discussion has been accelerated by both the covid-19 pandemic as well as the implementation of the Medical Device Regulation (MDR).[7] MDR safeguards stringent requirements for technical development, validation, quality surveillance, and manufacturing.

This study serves three purposes. First, to provide an overview of current and relevant European legislation applicable to medical apps and the institutes responsible for legal enforcement. Second, this study gives an overview of responsibilities and liabilities relevant to the medical professional who use medical apps. Finally, to provide the reader with a framework to critically appraise existing medical apps including a comprehensive checklist for those building and/or using medical apps. Several studies on the safe use of medical apps have been published, however most of them focus on the framework provided by the FDA.[8,9] To our knowledge, this is the first study to focus on the contemporary European regulations.

PART IA: EUROPEAN LEGISLATION

General Data Protection Regulation

In several apps, personal data is used as input and sometimes even as output. For example: the covid-19 status of someone passing through the street, including the date and time of the encounter. Using or processing personal data has to be done in compliance with the General Data Protection Regulation (GDPR).[10] The GDPR was adopted on April 14th 2016 and came into effect on May 25th 2018. The GDPR is a regulation on data protection, based on the principle that the individual is and remains the owner of their data. The GDPR unifies law on European level superseding the Data Protection Directive 95/46/EC.[11]

Most patient data qualifies as special personal data. Under the GDPR the processing of health data is prohibited, unless one of the exceptions in Article 9 of the GDPR is applicable.[10,12] For example; the subject - in this scenario the patient - gives unambiguous consent to use their data and the reasons for processing the data outweigh the risks related to processing the data. It is necessary to have appropriate protection measures when processing data. The GDPR rests upon pillars like the 'Data protection by default' and 'Data protection by design' principles (Art. 25 of the GDPR).[10]

Sometimes, data is only used temporarily as input to generate output, such as a risk score, prognostic value, or therapeutic advice. It is important to keep in mind that software manufacturers, or the hosts of the server where the data is processed, can have temporary access when processing data and as a result becoming the data processor.[9,] As an organization or health institution providing a medical app (defined as the data controller), it is important to have a *data processing agreement* with the processor in place.[10,13]

It is also possible that data is stored longer or even permanently. Data storage usually takes place on a server, which is sometimes owned by the health institution itself. However, commercial applications often rely on third parties to facilitate use of apps and the related data storage. The server where data is stored must be compliant with the requirements formulated within the GDPR, see Table 1. Companies offering data storage in compliance with the GDPR can be recognised by certain certifications. These certifications are granted for a standardized period by certifying bodies if companies comply with the standards published by the International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC). ISO/IEC developed and published worldwide standards for the GDPR requirements. Examples of such certifications include ISO/IEC 27001 for information security management. ISO/IEC 27002 provides control mechanisms for creating the information security as described in ISO 27001.

Not all software manufacturers have experience building in medical apps and their associated specific guidelines regarding the protection of patient data. Therefore, it

is advisable to work with a software manufacturer who is experienced in working in the medical app domain or to involve someone to oversee the project and advise on requirements. The Data Protection Officer of an institute can serve as a starting point.[10]

Table 1: Requirements for data collection, processing and storage according to the GDPR

Lawfulness, fairness and transparency	Personal data should be processed in a lawful, fair and transparent manner
Limited purpose	Personal data should only be collected for a specified use
Confidentiality and integrity	Personal data should be processed according to the appropriate security level and should be protected against unauthorized access, accidental loss, destruction or damage
Data minimisation	The collection of personal data should be limited, only data relevant to accomplish the specific purpose should be collected
Storage limitation	Data should not be stored longer than needed to accomplish the specified use
Accuracy	Personal data should be accurate and kept up to date when applicable

Medical Device Regulation

The Medical Device Regulation (MDR) came into force on May 26th 2021, after a prolonged transit period of four years in total.[7,14,] The MDR is effective in all members of the European Economic Community (EEC), including Switzerland, Norway, Iceland, Liechtenstein and excluding Great-Britain. The MDR replaced the Medical Device Directive (MDD) (93/42/EEC).[15] As the MDD was a European directive, its implementation in national laws varied among members of the EEC. Legislation became non-transparent, making it difficult and time-consuming for manufacturers to release new products onto the market, and regulation of medical devices was problematic. The new MDR should improve transparency, decrease time from innovation to market and provide a better overview of available medical devices.

As a HCP, the MDR is important to be aware of, as health apps easily meet the definition of a medical device. According to the MDR, 'medical device' means:

"any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations…"

(Fragment of the official definition of a medical device as provided in the MDR)[15]

In the new regulation, software is specifically addressed. Software includes all programs and other operating information used by a hardware device. Software can be stand-alone, such as a computer program or a medical app, or part of a medical device such as an infusion pump. If an app is defined as a medical device, it must meet corresponding standards to ensure safety, quality and performances. One of the required standards is the application of CE-marking.

CE-marking

The manufacturer is responsible for determining the risk class of the medical app and for the application of the Conformité Européenne (CE)-marking. The mark guarantees that the medical device is in concordance with the MDR and that the appropriate conformity assessment procedures have been followed in order to determine so. The CE-marking is valid in all members of the EEC. It is important to note that it is a compliance mark, and not a quality mark. Every medical device has an intended purpose, wherefore it was specifically designed by the manufacturer. The conformity assessment procedure is specifically followed for the intended purpose; therefore, the CE-mark is only applicable for the intended purpose.

The conformity assessment procedure depends on the risk class to which the medical device belongs. Class I indicates the lowest risk and class III indicates the highest risk. To determine the risk category of a medical device, the manufacturer should follow the "Implementing rules" in chapter II and the "Classification rules" in chapter III of Annex VIII of the MDR. If a medical device belongs to risk class I, the manufacturer itself can assess the new medical device and apply CE-marking when all requirements from the conformity assessment are met. Whenever a medical device belongs to any other risk class, only a relevant Notified Body (NB) can perform the conformity assessment procedure. Notified bodies are designated organisations to assess the conformity of products, and in this specific scenario, medical devices. The member states of the European Union can designate an organisation within their own state. The Nando-database (New approach notified and designated organisations) lists all notified bodies that are designated to perform conformity assessment procedures according to the MDR.[16] It is important to realise, that products that were already on the market under the MDD will not be revoked, however they should meet the MDR when the current CE-marking expires.

PART IB: ENFORCEMENT

Enforcement of the GDPR

The GDPR provides rules that are directly applicable in all Member States as of May 25th 2018. Under the previous Data Protection Directive (DPD), each EU Member State had to transpose the directive into internal law, resulting in differences in the enforcement of these laws (Art. 4, DPD).[9] Enforcement of the GDPR is facilitated by the European Data Protection Board (EDPB). This board consists of 28 Data Protection Authorities (DPA's) from all Member States and the European Data Protection Supervisor (EDPS). The EDPS is appointed by a joint decision of the European Parliament and the Council for a five-year term. The current term started on December 6th 2019.[17] Under the GDPR, it is possible for the national DPA's to make binding decisions including the option to impose a fine (Art. 83 and 84 GDPR). The national DPA's handle reports of data breaches, they can mediate in disputes between data processors and controllers, but they can also undertake their own research.[10]

Enforcement of the MDR

The NB's and Competent Authorities (CA's) as indicated by the European Commission are entrusted with the enforcement of the MDR. One of the topics of MDR is the increased post-market surveillance. This implies that the manufacturer should continue to meet requirements during the entire lifecycle of the product. NB's and CA's can perform an unannounced audit to enforce the MDR (Chapter 7, Art. 80, 90). In many cases annual performance and safety reporting will be mandatory.[15] It is important to note, that only manufacturers of medical devices with risk II and higher are audited by NB's. NB's can implement their own audit processes; however, they are required to follow the ISO 17021 standard for the MDR. Most NB's will create a quality management system (QMS) following the ISO 17021, ISO 14971 and ISO 13485 standard (see Table 2).[18,19] The aforementioned standards are not legally valid on their own, however they provide guidelines for the practical implementation of the MDR.

To keep track of all available medical devices and to improve coordination between EU member states, every medical device should have an Unique Device Identifier (UDI) and be registered within the European database on medical devices (EUDAMED).[20]

Wrongly applying or not applying CE-marking, or uncomplying to the standards for post market surveillance, is ground for penalization. The most common reasons for failing an audit are: providing an incomplete search strategy, providing an incomplete audit trail, using ad hoc processes, questionable data integrity and providing non-transparent documentation. The NB usually gives the manufacturer an opportunity to revise documentation and visit again, sometimes even several times. When standards are not met after the re-audit, a manufacturer can be fined and ultimately, the NB can decide

that CE-marking should be revoked. Consequently, the medical device should then be withdrawn from the market.

Table 2: Overview of relevant International Standards when implementing the updated GDPR and MDR

ISO 27001	Provides requirements for an information security management system (ISMS)
ISO 27002	Is an information security standard that provides best practice recommendations on information security controls for use by those responsible for initiating, implementing or maintaining an ISMS.
ISO 14971	Specifies terminology, principles and a process for risk management of medical devices, including software as a medical device. The standard helps manufacturers to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
ISO 13485	Provides the requirements for a comprehensive quality management system for the design and manufacture of medical devices.
ISO 17021	Contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems.

PART II: RESPONSIBILITY AND LIABILITY OF THE END-USER

The manufacturer is the legal person responsible for compliance with the GDPR and the MDR of an app. However; any person, organization or company that puts a name or trademark on a medical device is stated as the manufacturer. In healthcare it is imaginable that a HCP has an idea for an app and then starts looking for a manufacturer. In large healthcare organisations, this may be facilitated in-house, but in smaller organisations this may be an external party. In the first scenario, the healthcare organisation is also the manufacturer. In the second scenario, where the app was built by an external party, the issue of who is deemed the manufacturer is more complex. For example, when the healthcare organization publishes an externally built app in the app stores, it is the healthcare organisation who legally becomes the manufacturer. When a healthcare organization uses a pre-existing app, but rebrands the app to match the corporate identity, the healthcare organization might become the manufacturer as well. In those scenario's it is important to be aware of the responsibilities attached to being the manufacturer, or legally transfer them to the organization or party that actually built the app.[21]

When considering using a pre-existing app it is important to realise that the HCP using or advising the medical app can be held responsible when any harm occurs to the end user. Imagine a HCP considering a diagnostic test for a specific patient. The HCP uses a medical app to aid his/her decision and decides not to perform a diagnostic test based on the outcome advice of the app. What if the HCP misses an important finding or diagnosis? When the HCP uses an app that has been thoroughly tested and complies with all applicable legislation, the HCP cannot be held responsible as an individual healthcare provider, but the manufacturer can be. A manufacturer can also be held responsible for an app on which a CE-marking is wrongly applied or does not comply with the standards for post market surveillance. When HCPs decide to use an app which is not CE-marked it is their miscalculation to choose this app and therefore both the HCP and the organization they are working in, can be held responsible. Every medical device has a clearly stated intended use; the medical device is tested and certified for this use. When the HCP uses the app for purposes other than the intended use, the manufacturer cannot be held responsible. Manufacturers will therefore be very specific in formulating the intended use of a medical device. In this regard, it is essential that apps to be used are assessed on their quality and safety conformity and intended use, which may be done by several frameworks as discussed in the next section.

PART III: WHERE TO START AND WHAT TO DO WHEN USING OR DEVELOPING AN APP AS A MEDICAL DEVICE

In this part of this article, theoretical knowledge from the previous sections is translated into a practical checklist for using or developing an app as a medical device.

Critical appraisal of medical apps

Within the overwhelming amount of apps, it is challenging to find the apps with peer reviewed content and in compliance with the GDPR and MDR. Medical apps should be assessed on several aspects. A frequently used framework to assess medical apps are the Health on the Net (HON)-criteria.[22] The HON foundation was founded in May 1996 and promoted the effective and reliable use of the new technologies for telemedicine in healthcare worldwide. Unfortunately, this non-profit organisation was not able to maintain their foundation and has discontinued their services as of December 15, 2022. The mHealthHUB, supported by the European Union's Horizon 2020 research and innovation programme, has published a knowledge tool reviewing available frameworks in 2021.[23] In August 2021 a new standard was published regarding the quality requirements for health and wellness apps, the ISO/TS 82304-2. The standard covers the entire life cycle of a medical app (post market surveillance and quality control). Apps are scored on four different domains, as shown in Figure 1. An overall quality score is also provided.[24]

Building custom medical apps

When there is a healthcare scenario that cannot be addressed using an existing medical app meeting the necessary requirements, one can decide to build a new app. In order to do so the right way, the following aspects must be considered (see also Figure 2).

Conditions

Any medical app must meet specific healthcare-oriented privacy, design, and functionality criteria. To ensure that the app meets these conditions, content experts are needed, next to functional and graphical design specialists. If an app is designed to be used by patients, it is recommended that they be involved early in the development process. "Human factor engineering" or "patient included innovation" will improve the community support amongst intended users and decreases the risk of (wrong) usage of medical devices. An appropriate and well-functioning "User Interface" (UI) and "User Experience" (UX) of the app, designed together with the intended users, will help in presenting information effectively. Usability tests within the intended user group are important because only 30 to 60% of people can be considered health literate.[25] To validate the quality and safety of the app, user trials or tests must also be incorporated in the development process, which is also specifically stated in the MDR.

Intellectual property

If an app is developed by a contracted external developer, a good contract must be in place. It must be clearly defined who is the data processor of the app and who is the manufacturer, and thus who is responsible for compliance to the GPDR and the MDR. Furthermore, it is advisable to record specifically in writing who will have the intellectual property (IP). The party funding the app development will not automatically be the owner of the source code of the app or the IP. If the initiator of the app fails to record the IP, the manufacturer will automatically become the owner of the app.[26] This situation can be problematic, when considering the transfer of the app to another external developer, especially if the current developer fails to comply with the agreements or legislations.

Privacy and safety

Medical apps have to comply to the GDPR and the MDR. When employed in a healthcare facility, you can rely on the expertise of Data Protection Officer (DPO) who is familiar with current rules and regulations regarding data protection. A DPO can help to make sure the app complies with the required legislation. Otherwise, external expertise must be sought to comply to the GDPR. An external app designer/developer that regularly works in the healthcare setting, will be familiar with the processing of personal data and is therefore obliged to have employed a DPO. Additionally, healthcare facilities often employ a MDR expert who can provide support. The ISO 27001, ISO 27002, EN ISO 13485, EN ISO 14971 and ISO/TS 82304-2 standards provide more practical guidelines for building apps that are compliant with the MDR and GDPR.

Other agreements

It is also advisable to decide on arrangements for situations that one would rather not consider. These situations include bankruptcy of an external manufacturer or a dissatisfying cooperation. In case of bankruptcy, the development and maintenance of mobile applications will stop. The source code will be transferred to a curator or another party (in the case of a takeover of the company). To ensure app development can continue at another chosen manufacturer, the source code must be transferred to the buyer/client/initiator. Predetermined arrangements, such as a vendor lock, or an escrow agreement must be drawn up.

CONCLUSION

The discussion on the use of medical apps in healthcare and research is more vivid than ever. Apps have considerable potential for various purposes in healthcare, however it is crucial that apps are developed and used in a responsible manner and comply with relevant legislation. It is imperative for both app manufacturers and healthcare providers to be well-informed about diligent guidelines pertaining to privacy and medical device regulations. Healthcare providers should be aware of their responsibilities and liabilities when developing or using a medical app in healthcare or research. Through a comprehensive understanding of the legislations, responsibilities and liabilities, both manufacturers and healthcare providers can contribute to the responsible and ethical use of medical apps, thereby maximizing their benefits while minimizing potential risks.

Figure 1: Quality label of health and wellness apps as published in the ISO/TS 82304-2

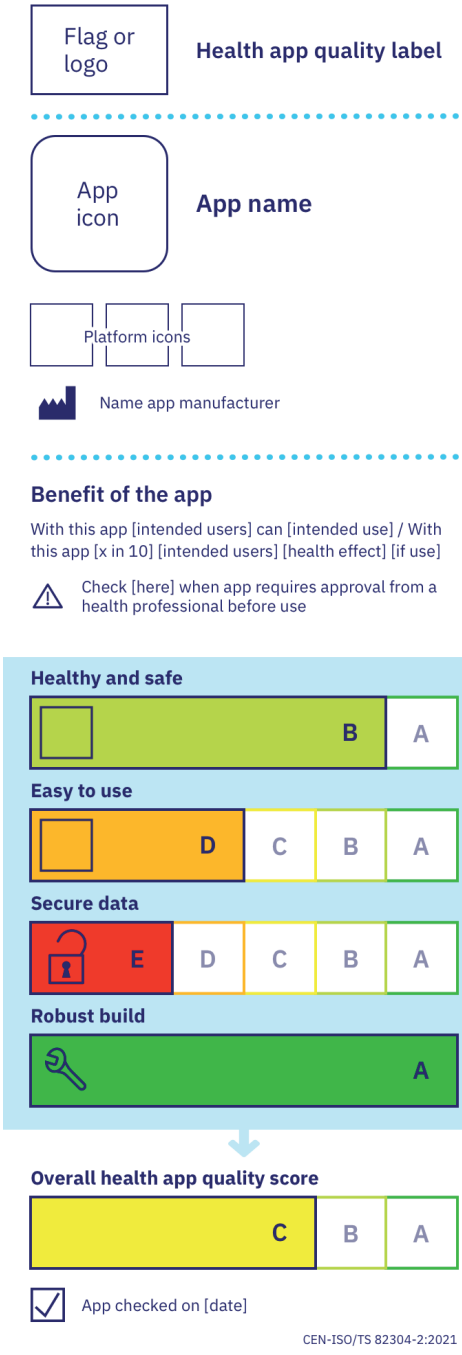
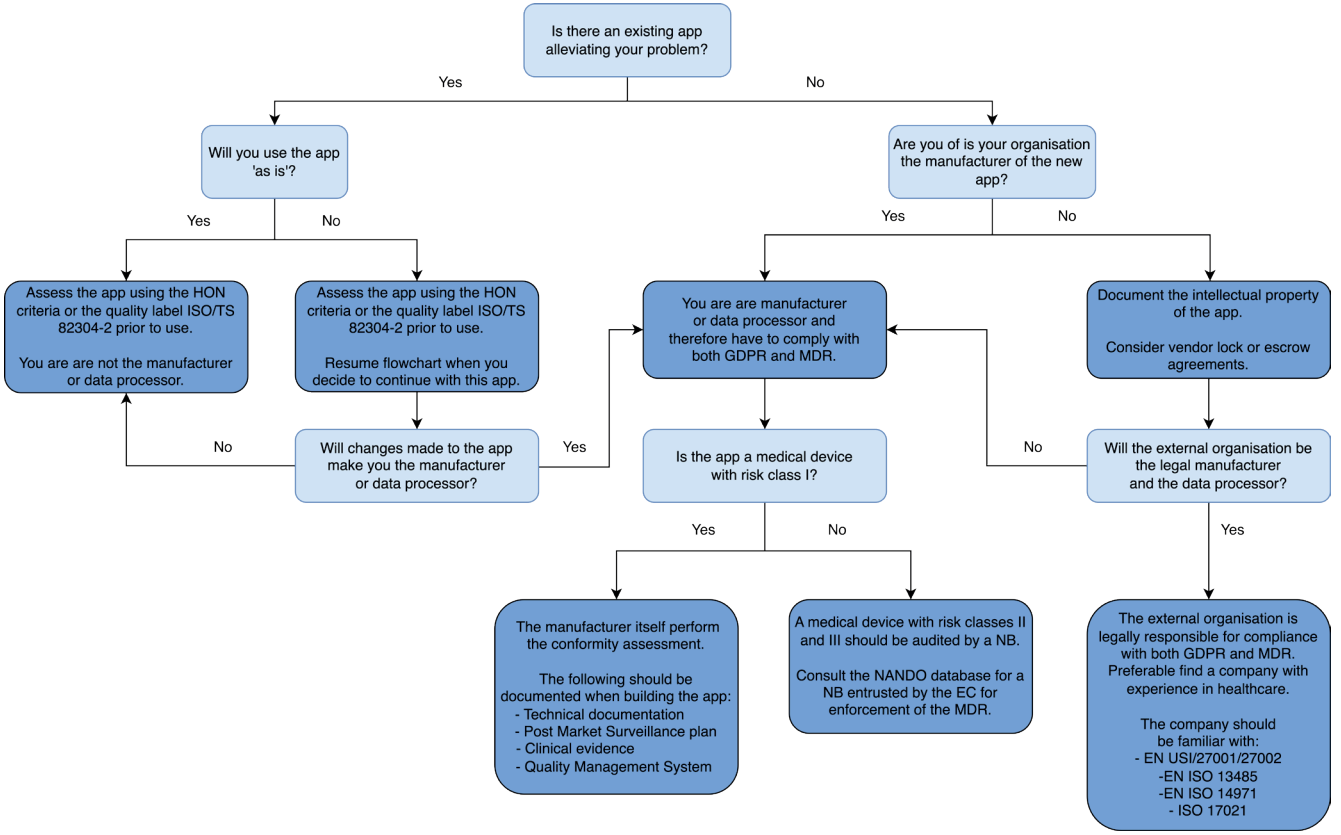


Figure 2: Checklist of the most important considerations when using or developing a medical app



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CHAPTER 2

Mobile applications in gastrointestinal surgery: a systematic review

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ABSTRACT

Background: Mobile applications can facilitate or improve gastrointestinal surgical care by benefiting patients, healthcare providers, or both. The extent to which applications are currently in use in gastrointestinal surgical care is largely unknown, as reported in literature. This systematic review was conducted to provide an overview of the available gastrointestinal surgical applications and evaluate their prospects for surgical care provision.

Methods: The PubMed, EMBASE and Cochrane databases were searched for articles up to October 6th 2022. Articles were considered eligible if they assessed or described mobile applications used in a gastrointestinal surgery setting for healthcare purposes. Two authors independently evaluated selected studies and extracted data for analysis. Descriptive data analysis was conducted. The revised Cochrane risk of bias (RoB-2) tool and ROBINS-I assessment tool were used to determine the methodological quality of studies.

Results: Thirty-eight articles describing twenty-nine applications were included. The applications were classified into seven categories: monitoring, weight loss, postoperative recovery, education, communication, prognosis, and clinical decision-making. Most applications were reported for colorectal surgery, half of which focused on monitoring. Overall, low-quality evidence was found. Most applications have only been evaluated on their usability or feasibility but not on the proposed clinical benefits. Studies with high quality evidence were identified in the areas of colorectal (2), hepatopancreatobiliary (1) and bariatric surgery (1), reporting significantly positive outcomes in terms of postoperative recovery, complications and weight loss.

Conclusion: The interest for applications and their use in gastrointestinal surgery is increasing. From our study, it appears that most studies using applications fail to report adequate clinical evaluation, and do not provide evidence on the effectiveness or safety of applications. Clinical evaluation of objective outcomes is much needed to evaluate the efficacy, quality and safety of applications being used as a medical device across user groups and settings.

INTRODUCTION

The use of smartphones and mobile application software (apps) is deeply integrated into society and their potential is being increasingly recognized in healthcare. In the past decade, the development of healthcare apps has rapidly increased, with the intention of providing medical solutions to some extent. At present, over 400.000 healthcare apps are available for download in mobile app stores worldwide.[1] To date, the number of apps used in gastrointestinal surgical care is limited compared with that in other surgical disciplines.[2] This may change rapidly. Apps are believed to offer great possibilities to support or improve gastrointestinal surgical care, and overall healthcare is on the lookout of the smart use of digital solutions in times of limited resources. Apps may facilitate patients, healthcare providers (HCP), or both. Apps have the potential to improve information provision, communication between patients and HCP, clinical decision-making, perioperative guidance and monitoring, and education/training. In addition, apps may be used to register clinically relevant variables as apps can be developed to connect with sensors or other measurement devices such as a camera, an activity tracker, a biosensor, or a blood pressure monitoring device.[3,4,5.]

The use of apps in healthcare is not without controversy or debate.[6,7] As apps may influence patient-reported or clinical outcomes, they must be properly developed and validated. Apps or software in general to be used as a medical device must comply with standards as described by the European Medical Device Regulation (MDR) or the American Food and Drug Administration (FDA), safeguarding the quality and safety of the app.[8,9] However, the distribution of apps is limitedly regulated by the app stores, with minimum supervision on whether these specific legislations are indeed met. Even if they are met, it is not guaranteed that the use of the app will lead to valid and reliable results across situations and user settings.[7,10] For that, scientific research validating apps with well-designed research protocols is required. To date, a clear overview of properly validated gastrointestinal surgical apps is lacking. Therefore, this systematic review focuses on the following research questions: (1) Which apps that are used in gastrointestinal surgical care have been described in literature? (2) Are these apps clinically evaluated on objective outcomes and able to improve gastrointestinal surgical care?

METHODS

This systematic review was conducted in line with the Cochrane Handbook for Systematic Reviews of Interventions version 6.0 and reported according to PRISMA 2020.[11] This study was registered in Open Science Framework (number X56RA). Studies were considered eligible if they assessed or described mobile apps used in a gastrointestinal surgery setting and were published in 2010 or later. The search was last updated October 6th 2022. A mobile app is defined as a software program which operates only on a smartphone or tablet (and thus, not web-based software). Keywords related to mobile apps and gastrointestinal surgery were incorporated into the search strategy. The search string is presented in the appendix. The included articles were cross-referenced to identify any additional relevant studies. Studies were excluded if (1) the described mobile app was only used to register study outcomes (e.g., number of complications and operation time), (2) the articles were conference proceedings or study abstracts, as they do not provide adequate insights into the app or its evaluation, (3) reviews, and (4) the results were published in a language other than English. Two reviewers (SvdS and MB) independently assessed all titles and abstracts according to the inclusion and exclusion criteria in the software tool "Rayyan". Studies were included in the full-text evaluation when both reviewers agreed on inclusion. Disagreements were resolved through appraisal by a third reviewer (EB).

The methodological quality of the randomized controlled trials was assessed using the Revised Cochrane risk of bias tool for randomized trials (RoB-2).[12] This tool determines the overall risk of bias that is based on the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes and selection of reported results. The ROBINS-I tool was used to determine the methodological quality of non-randomized studies, in which the overall risk of bias is based confounding, participant selection, intervention classification, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results.[13]

Data were extracted independently by two reviewers (SvdS and MB) in a standardized form that included: year of publication, country, study design, number of participants, characteristics of included participants, type of surgery, name of the app, platform of the app, functionalities of the app, and study outcomes. All study outcomes on usability, satisfaction and clinical outcomes were included because apps may have heterogeneous aims and functionalities. Conflicts among reviewers were resolved by consensus. The results of studies were summarized according to the apps described. The apps were categorized based on their functionalities to provide a structured overview of available apps. The apps were described within these categories and were assessed on their outcome evaluations.

RESULTS

In total, 477 studies were screened for eligibility based on their title and abstract. After a full-text assessment, 38 studies were included of which 29 apps were described (Fig. 1). Patients were targeted as users in all apps except in three apps which were used by surgeons.[45,48,53] The apps were classified into seven categories: monitoring, weight loss, postoperative recovery, education, communication, prognosis, and clinical decision-making. The majority of the studies focused on colorectal surgery and monitoring (Fig. 2). An overview of the study's characteristics is presented in Table 1. Due to the heterogeneity of the study designs and apps, a meta-analysis was impeded. In total, seven randomized control trials and seven comparative cohort studies were included. Only four studies had an overall low risk of bias as summarized in Tables 2, 3.[33,38,42,53]

Figure 1: The PRISMA flow diagram

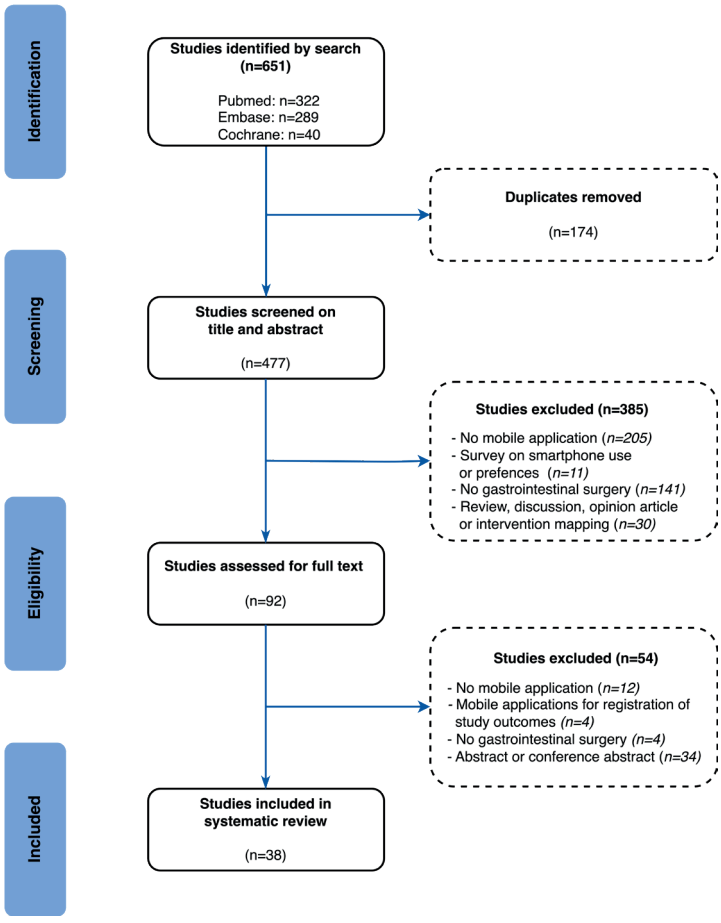

Figure 2: Seven categories of apps in the gastrointestinal surgical domain (N=29)

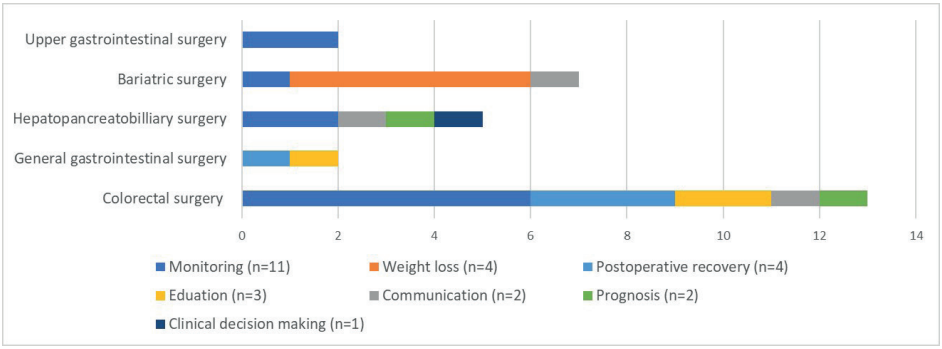

Table 1: General characteristics of included studies

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Keng 2020 [a]	Canada	Cross-sectional	No	30 days	Colorectal surgery	Patients	82	43	Monitoring	- Self-reported assessment on symptoms - Informative library - Photograph function	- Overall completion of daily assessments 41-64% - 92% patients with a good overall satisfaction (26% completed the questionnaire) - 30-day readmission rate of 6%
Pooni 2022 [a]	Canada	RCT	Yes	30 days	Colorectal surgery	Patients	128; 125	41; 50	Monitoring	- Self-reported assessment on symptoms - Informative library - Photograph function	- No difference in postoperative outcomes - Improved patient reported outcomes (satisfaction, well-being & anxiety)
Anpalagan 2022. [a]	Canada	Study protocol RCT	Yes	30 days	Colorectal surgery	Patients	670	-	Monitoring	- Self-reported assessment on symptoms - Informative library - Photograph function	- Unplanned hospital visits within 30 days - Quality of life
Lee 2021 [a]	Canada	Pros-pective cross-sectional survey	Yes	30 days	Colorectal surgery	Patients	48; 73	60; 57	Monitoring	- Self-reported assessment on symptoms - Education material - Photograph function - Chat functionality with HCP's	- Completion of a daily assessment at least once 57% - 80% patients with a good overall satisfaction - Similar postoperative outcomes with control group

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Lee 2022 [a]	Canada	Pros-pective Cohort	Yes	30 days	Colorectal Surgery	Patients	70; 35	59; 55	Monitoring	- Self-reported assessment on symptoms - Education material - Photograph function - Chat functionality with HCP's	- Similar postoperative outcomes with control group
Eustache 2021 [a]	Canada	Pros-pective & retro-spective cohort	Yes	30 days	Colorectal surgery	Patients	94; 256	55; 56	Monitoring	- Self-reported assessment on symptoms - Education material - Photograph function - Chat functionality with HCP's	- Usability score of 84.5 (0-100) - Significant decrease in potentially preventable 30-day emergency visits (incidence rate 0.34) - Significant decrease in length of stay (3.2 vs 4.6 days) - No difference other postoperative outcomes
Agri 2020	Switzerland	Retro-spective Cohort	No	30 days	Colorectal surgery	Patients	43	54	Monitoring	- Self-reported assessment on symptoms - Informative library - Alert messages which was send to HCP's	- Overall completion of daily assessments of 72% - 4/5 level of patient satisfaction (30% completed the questionnaire) - All postoperative outcomes were detected - Median response time of 90 minutes of the HCP

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants Type	N=	Age	App category	Main app functions	Study outcomes
Symer 2017	USA	Pilot Study	No	30 days	Colorectal surgery	Patients	21	52	Monitoring	- Self-reported assessment on symptoms - Alert messages - Photograph function - Connection with activity tracker	- 84% patients completed at least 70% daily task - 2,7/5 level of patient satisfaction - 26,7%patients received alerts based on symptom assessments - Mean return to baseline activity of 30 days.
Diehl 2021 [b]	US	Pilot Study	No	30 days	- Colorectal surgery 68% - Oncological surgery 32%	Patients	50	50	Monitoring	- Education materials - Notifications - Self-reported assessment on symptoms reviewed by HCP's	- Engagement with individual app features 48-81%
Diehl 2021 [b]	US	Study protocol RCT	Yes	180 days	- Colorectal surgery - Oncological surgery - Transplant surgery	Patients	300	-	Monitoring	- Education materials - Notifications - Self-reported assessment on symptoms reviewed by HCP's	- Hospital readmission - Urgent care visits - Complications - Total readmission costs
Valk 2022	Canada	Study protocol Feasi-bility RCT	Yes	42 days	Colorectal surgery	Patients	80	-	Monitoring	Self-reported assess-ment on symptoms - Photograph function	- Usability / app engagement
Gustavell 2019 [c]	Sweden	Pilot Study	No	30 days	Hepato-pancreatobiliary surgery	Patients	6	65	Monitoring	- Risk assessment model for alerts - Self-reported assess-ment on symptoms - Graph of symptoms	- Overall completion of daily assessments 84% - Patient's experiences

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants Type	N=	Age	App category	Main app functions	Study outcomes
Gustavell 2019 * [c]	Sweden	Cohort	Yes historical	6 months	Hepato-pancreatobiliary surgery	Patients	26; 33	67; 66	Monitoring	- Self-reported assess-ment on symptoms - Risk assessment model for alerts - Graph of symptoms	- Overall completion of assessments 83-95% - Significantly less reported hepatic symptoms and higher selfcare - Patient's experiences
2020	Sweden	Cohort	No	6 months		Patients	26	67			
Allenson 2021	US	Pilot study	No	30 days	Hepato-pancreatobiliary surgery	Patients	19	65	Monitoring	- Self-reported assessment of dietary intake - Nutrition goals	- 79% patients completed at least 80% daily task - 89% patients with a good overall satisfaction - Average of 82,4% caloric goals intake
Wu 2019	Taiwan	Feasi-bility study	No	28 days	Upper Gastrointestinal surgery	Patients	43	68	Monitoring	- Education materials - Monitoring of symptoms, body weight, physical activity - Photograph function	- Overall completion of assessments 96%
Chlan 2021	US	Mixed methods	No	1 year	Upper Gastrointestinal surgery	Patients	50	63	Monitoring	- Self-reported assessment on symptoms - Graph of symptoms	- 98% patients reached 90% feasibility threshold - Patient's experiences
Heuser 2021	Canada	Retro-spective Cohort	Yes	30 days	Bariatric surgery	Patients	396; 458	45; 48	Monitoring	- Informative library - Daily recovery milestones - Daily questionnaires	- Completion of daily assessments at least once a week 66% - 90% patients with a good overall satisfaction - 49% patients reported that the app helped to avoid phone calls - No improvement on postoperative outcomes

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Mangieri 2019	US	RCT	Yes	24 months	Bariatric surgery	Patients	28; 28	53; 53	Weight loss	- Nutritional information - Self-reported assessment on intake and weight - Personalized diet program	- Significant more weight loss after 1 year (81.4% vs 74.4%) - Significant more weight loss after 2 years (71.5% vs 59.1%) - No difference in quality of life
Dolan 2019	US	Pros-pective Cohort	No	30 days	Bariatric surgery	Patients	10	38	Weight loss	- Self-reported assessment on intake and symptoms - Informative library - Push notifications - Activity tracker	- 84% patients completed at least 70% of daily task - 2,7/5 level of patient satisfaction
Sysko 2022	US	Pilot RCT	Yes	8 weeks	Bariatric surgery	Patients	25; 25	40; 38	Weight loss	- Informative library - Self-reported assessment on intake and weight - Social challenges and feedback - Activity tracker	- Effect size stress -0.58 - Effect size anxiety -0.62 - No difference in the caloric intake, weight loss or quality of life
Mundi 2015	US	Feasi-bility study	No	4 months	Bariatric surgery	Patients	30	41	Weight loss	- Automatic text messages	- 31% response rate - 7.3 kg weight loss
Bonn 2020	Sweden	Study Protocol RCT	Yes	24 months	Bariatric surgery	Patients	154 (sample size)	-	Weight loss	- Informative library - Daily milestones on activity and vitamin intake - Feedback on activity and vitamin intake - Daily questionnaires - Tracking activity using an accelerometer	- Level of physical activity - Weight loss

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Van der Meij 2018 [d]	Nether-lands	RCT	Yes	6 months	- General gastro-intestinal surgery -Gynaecologic surgery	Patients	171; 173	52; 51	Post-operative recovery	- Informative library - Feedback on the postoperative recovery process - Connection with activity tracker - E-consult direct contact with HCP's	- Significant decrease days return to normal daily activities (21 vs 26) - No difference in postoperative outcomes - Improved satisfaction with care program (7.2 vs 6.3)
Den Bakker 2019 [d]	Nether-lands	Mixed-methods process Inter-view	No	3 months	General gastro-intestinal surgery	Patients	73 14	63 62	Post-operative recovery	- Informative library - Feedback on the postoperative recovery process - Connection with activity tracker - E-consult direct contact with HCP's	- App engagement 63%, activity tracker engagement 67% - Patient satisfaction with the app 7,5/10 - Patients' barriers and facilitators for use of the intervention
Pecorelli 2017 [e]	Canada	Pilot Study	No	28 days	Colorectal surgery	Patients	45	61	Post-operative recovery	- Informative library - Feedback on the postoperative recovery process - Daily recovery milestones - Daily questionnaires	- Usability score of 85 (0-100) - 89% patients with a good overall satisfaction
Mata 2019 [e]	Canada	RCT	Yes	30 days	Colorectal surgery	Patients	50; 47	63; 57	Post-operative recovery	- Informative library - Feedback on the postoperative recovery process - Daily recovery milestones - Daily questionnaires	- Non-significant difference in protocol adherence (59% vs 62%) - No difference in postoperative outcomes

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants Type	N=	Age	App category	Main app functions	Study outcomes
Rauwerdink 2019	Nether-lands	Study Protocol RCT	Yes	42 days	Colorectal surgery	Patients	156 (sample size)	-	Post-operative recovery	- Informative library - Daily recovery milestones - Push notifications - Daily questionnaires - Connection with activity tracker	- Adherence to recovery protocol - Postoperative outcomes - Satisfaction
Bertocchi 2021	Italy	Study protocol obser-vational study	No	-	Colorectal surgery	Patients	270	-	Post-operative recovery	- Education materials - Daily recovery milestones - Push notifications - Self-reported assessment for symptoms	- Confidence using the app - Compliance ERAS elements - Hospital stay, admission rate, complications
Kowalewski 2017	Germany	Vali-dation study	Yes	-	General gastro-intestinal surgery	Surgeons-residents-students	54; 51	NS	Education	- Cognitive task simulation - Practice of surgical procedures	- Surgeons out-performed students (construct validity) - The app aids in the learning and assessment process of the necessary aspects (content validity) - The app represents the reality of the training situation (face validity)
Gaj 2017	Italy	RCT	Yes	-	Colorectal surgery	Patients	63; 63	35; 32	Education	- 3D model of lower abdomen	- Significantly higher degree of clarity doctor (4.4 vs 3.5) - Significantly higher patient satisfaction (4.2 vs 3.5)
Yiğitoğlu 2021	Turkey	Pros-pective cohort	Yes	3 months	Colorectal (ostomy)	Patients	30 60	51; 55	Education	- Education materials	- No difference in psychosocial adjustment - No difference in stoma related problems

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Nardo 2016	Italy	Cohort	Yes	28 months	Hepato-pancreatobiliary surgery	Patients[#]	19; 27	63; 64	Communi-cation	- Text messages - Sending image, or other files	- Averagely 32 communication events a month: clinical questions (54%), instructive comments (32%), administration questions (14%). - No differences in postoperative outcomes
Doğan 2022	Turkey	RCT	Yes	3 months	Bariatric surgery	Patients	26; 25	37 40	Communi-cation	- Live consultation - Informative library - Nutrition and activity diary	- Significant difference in BMI postoperative - No difference in other postoperative outcomes
Moon 2021	Canada	Study protocol RCT	Yes	6 months	Colorectal Surgery	Patients	462	-	Communi-cation	-Online informative modules -Peer support platform	- Quality of life - Patient activation - Bowel function
Gabriel 2015	US	Retro-spective Cohort	No	-	Colorectal surgery	Patients	34.176	69	Prognosis	- Survival rate calculator	- Development of the app (no evaluation of the app)
Low 2021		Pros-pective study	No	60 days	Hepato-pancreatobiliary surgery	Patients	44	66	Prognosis	- Self-reported assessment on symptoms - Collection of smartphone data (location, movement, device use, noise and light levels)	- 73.5% accuracy of the prediction of symptoms during the next day - No evaluation of the app

Study	Country	Study design	Control group	Follow -up	Surgical procedure	Participants **Type**	**N=**	**Age**	App category	Main app functions	Study outcomes
Smits 2022	Nether-lands	RCT	Yes		Hepato-pancreatobiliary surgery	Patients[#]	863; 885	66; 65	Diagnostic and thera-peutic decision making	- Algorithm based on clinical and biochemical variables	- 94% daily data entry - 81% overall adherence - Significant reduction of postoperative complications: bleeding (5% vs 6%), organ failure (5% vs 10%) and 90-day mortality (3% vs 5%)

* Multiple studies using the same database, [#] The app was used by surgeons, [a,b,c,d,e] Studies evaluating the same mobile application,
Abbreviation: RCT: Randomized controlled trial, NA: not applicable, NS: Not specified

Table 2: An overview of the methodological quality assessment of the RCTs according to the Revised Cochrane risk-of-bias tool for randomized trials (RoB-2)

Studies	Bias in randomization process	Deviations from intended interventions	Missing outcome data	Bias in outcome measurements	Bias in reported results	Overall risk of bias
Pooni 2022	High	Some concerns	Low	Low	Low	High
Anpalagan 2022 *	Low	Low	NA	NA	NA	NA
Diehl 2022 *	Low	Low	NA	NA	NA	NA
Valk 2022 *	Some concerns	Low	NA	NA	NA	NA
Mangieri 2019	Low	Low	Low	Low	Low	Low
Sysko 2022	Low	Low	Low	Low	Some concerns	Some concerns
Bonn 2020 *	Low	Low	NA	NA	NA	NA
Van der Meij 2018	Low	Low	Low	Low	Low	Low
Mata 2020	Low	Low	Low	Low	Low	Low
Rauwerdink 2019 *	Low	Low	NA	NA	NA	NA
Doğan 2022	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns
Moon 2021 *	Low	Low	NA	NA	NA	NA
Gaj 2017	Low	Low	Low	Some concerns	Low	Some concerns
Smits 2022	Low	Low	Low	Low	Low	Low

* Study protocols for which the methodological quality could not be fully assessed.
Abbreviation: NA: not applicable

Table 3: An overview of the methodological quality assessment of the non-randomized studies according to the ROBINS-I assessment tool.

Studies	Bias due to confounding	Bias in participant selection	Bias in intervention classification	Bias due to deviations from intended interventions	Missing data	Bias in outcomes measurements	Bias in reported results	Overall risk of bias
Keng 2016	Moderate	Moderate	Low	Low	Serious	Moderate	Moderate	Serious
Lee 2021	Serious	Low	Moderate	Serious	Serious	Moderate	Moderate	Serious
Lee 2022	Moderate	Low	Moderate	Moderate	Moderate	Serious	Moderate	Serious
Eustache 2021	Low	Low	Low	Moderate	Moderate	Moderate	Low	Moderate
Agri 2020	Moderate	Moderate	Moderate	Low	Moderate	Moderate	Moderate	Moderate
Symer 2017	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Diehl 2021	Serious	Moderate	Moderate	Low	Low	Moderate	Moderate	Serious
Gustavell 2019	Serious	Moderate	Low	Moderate	Low	Serious	Serious	Serious
Gustavell 2020 *	Moderate	Moderate	Low	Low	Low	Moderate	Serious	Serious
Gustavell 2019 *	Moderate	Low	Low	Low	Low	Low	Moderate	Moderate
Allenson 2021	Low	Moderate	Moderate	Low	Low	Moderate	Low	Moderate
Wu 2019	Moderate	Moderate	Low	Moderate	Low	Moderate	Serious	Serious
Chlan 2022	Moderate	Low	Serious	Moderate	Moderate	Serious	Moderate	Serious
Heuser 2021	Moderate	Moderate	Moderate	Moderate	Low	Moderate	Low	Moderate
Dolan 2019	Serious	Serious	Serious	Serious	Moderate	Moderate	Low	Serious
Mundi 2015	Moderate	Moderate	Low	Moderate	Low	Serious	Serious	Serious
Den Bakker 2019	Moderate	Serious	Low	Moderate	Moderate	Serious	Low	Serious
Pecorelli 2018	Moderate	Moderate	Low	Low	Moderate	Moderate	Low	Moderate

Studies	Bias due to confounding	Bias in participant selection	Bias in intervention classification	Bias due to deviations from intended interventions	Missing data	Bias in outcomes measurements	Bias in reported results	Overall risk of bias
Berthocchi 2020	Moderate	Moderate	Moderate	NA	NA	NA	NA	NA
Kowalewski 2017	Moderate	Moderate	Low	Low	Low	Moderate	Moderate	Moderate
Yiğitoğlu 2021	Serious	Moderate	Moderate	Moderate	Moderate	Serious	Moderate	Serious
Nardo 2016	Serious	Moderate	Moderate	Moderate	Moderate	Serious	Moderate	Serious
Gabriel 2016	Low	Low	NA	NA	Low	Low	Low	NA
Low 2022	Moderate	Low	Moderate	Moderate	Moderate	Serious	Moderate	Serious

* Multiple studies within the same database
Abbreviation: NA: not applicable

Monitoring

Almost half of the identified apps were used to monitor the clinical condition of patients who underwent gastrointestinal surgery.[14-32] In general, the monitoring apps provided information about the operation, postoperative care, and self-management, contained daily assessments of the surgical wound (image uploading), symptoms and recovery progress, and some apps shared this information with the HCP.

Six apps monitored patients after colorectal surgery. These apps had a completion rate of the daily assessments between 21 and 84%, and had good patient satisfaction.[14-24] The app of Keng et al. had a 30-dayreadmission rate of 6% in comparison with a reported rate of 18% prior to the start of the cohort study.[14] However, postoperative outcomes were not improved in a randomized controlled trial (RCT); only patient-reported outcomes did improve.[15] In another RCT, it will be evaluated whether the app could prevent unplanned hospital visits.[16] The app "Caresense" also had a communication feature. The app was evaluated in combination with the same-day discharge (SDD) protocol. The postoperative outcomes of patients using the app were comparable to patient without the app.[17,18] The app was also evaluated in a retrospective study, in which the patient did not follow the SSD protocol. The app significantly decreased the rate of preventable emergency department visits.[19] The app is available in the app stores, but not freely accessible. The app "Maela" was successfully tested on its feasibility and all post-discharge complications were detected by the app.[20] The app is available in the app stores, but not freely accessible. The app of Symer et al. generated alerts for 26,7% of the patients and one patient within this group was readmitted.[21] The app "MobiMD" was initially developed for several gastrointestinal procedures but its feasibility was successfully tested on mainly colorectal patients.[22] The effect of the app on hospital readmissions will be evaluated in a RCT.[23] The app "how2trak" is focused on surgical wound and symptom surveillance and its feasibility evaluation has not yet been completed.[24]

Two apps monitored patients after undergoing hepatopancreatobiliary surgery and both had a high reporting adherence.[25-28] The "Interaktor" app was evaluated in a cohort, in which patients using the app reported significantly less symptoms and higher self-care activity rates compared to a historical control group.[25-27] The app is available in the app stores. The already available "MyPlate" app monitored postoperative dietary intake and was used by the dietitian to guide patients during counseling visits. Caloric goals were achieved by 82.4% of the patients.[28]

Two apps monitored patients after upper gastrointestinal surgery and both were globally tested on their feasibility.[29-31] The app "SurgeryDiary" had a high overall daily submission rate.[29] The app "UDD" (Upper Digestive Disease) was indicated as a helpful tool for reporting and identifying problems, and enhanced communication with HCP.[30] However, the scoring of dumping-related symptoms and pain which was used in the app was not

yet adequate.[31] One app monitored bariatric patients and provided advice on whether the patients were on track or to seek symptom management by reviewing the educational materials or contacting a HCP.[32] The app was evaluated in a cohort in which clinical outcomes such as hospital stay or readmission did not differ between app users and the control group. Although adherence was relatively low, most patients were satisfied with the app.

Weight loss

Two apps mainly focused on a healthy diet, provided nutritional information and allowed bariatric patients to monitor their intake and weight.[33,34] The already available app "MyfitnessPal" also allowed patients to make a diet program. The app was clinically evaluated in a RCT in which the control group was not allowed to use the app and only received self-monitoring journals.[33] The percentage of weight loss after two years was significantly higher for patients using the app (71,5%) than for those who did not use the app (59,1%). The other app, developed by Dolan et al., had high adherence, but a relatively low patient.[34]

The other three apps were aimed at engagement and stimulation of physical activity and a healthy diet of bariatric patients.[35-37] The extensive app of Sysko et al. was provided in combination with eight weekly virtual check-ins to review weight loss and the overall process before bariatric surgery.[35] The app was evaluated in a pilot RCT. On average, patients opened the app five times per week and entered their weight twice per week. Patients using the app showed a significant moderate decrease instress and anxiety, whereas the effect on the caloric intake, weight loss and quality of life did not improve. The app of Mundi et al. provided automatic text messages stimulating a healthy lifestyle, and patients using this app had an average postoperative weight loss of 7.3 kg.[36] The app "PromMera" monitors and stimulates physical activity and self-registered vitamin intake, but its clinical evaluation in a RCT has not yet been completed.[37]

Postoperative recovery

Four apps intended to improve postoperative recovery, providing perioperative information and feedback on the postoperative recovery process.[38-44] The app "IkHerstel" (I recover) was initially developed for gynaecological patients and adapted to fit a general gastrointestinal surgical population.[38] The app was evaluated in a RCT, in which the control group received access to a placebo website containing standard general information.[39] The time until postoperative return to normal daily activities significantly was shortened of four days in the intervention group (21 vs 25 days), whereas other postoperative complications did not differ. Patients were satisfied with the app and had relatively high involvement with the app and the activity tracker.[40] The app is available in the app stores, but not freely accessible.

The other three apps were more focused on improving compliance to the recovery protocol after colorectal surgery, providing daily recovery milestones, and questionnaires to track patient compliance and assess patient-reported outcomes.[37-40] The app of Pecorelli et al. had a high usability score and patient satisfaction.[41] Subsequently, the app was evaluated in a RCT in which overall adherence to the postoperative recovery protocol and other postoperative outcomes did not improve.[42] The app "ERAS APPtimisation" specifically targets patient related elements of the Enhanced Recovery After Surgery (ERAS) protocol, and daily activity was monitored and simulated using an activity tracker.[43] The clinical evaluation in a RCT has not yet been completed. The comparable "IColon" app which incorporated slightly different ERAS elements, will be clinically evaluated in an observational study.[44]

Educational apps

The "Touch Surgery" app facilitated three modules for laparoscopy to practice surgical procedures and cognitive tasks. Although the app was successfully validated based on its construct, face and content, training with the app did not improve students' performance on a VR trainer.[45] The app is freely available in the app stores.

The app "Iprocto" provided a 3D model of various structures in the lower abdomen to improve the information provision to patients during the preoperative consult.[46] The intervention group used this app during consultations, whereas the control group did not use the app. The intervention group reported significantly higher scores of the clarity on the doctor and satisfaction regarding the proctologic visit than the control group.

The "Stoma-M" app provided educational information and contact details of stoma care units and associations in Turkey.[47] The app was evaluated in a quasi-experimental study, in which the intervention group received the app on a provided Android phone, while the control group received a booklet containing the same content as provided in the app. The app did not improve psychosocial adaptation and stoma-related problems.

Communication

The commonly known app "WhatsApp" was evaluated as a communication tool among surgeons.[48] In this study, surgeons treated patients in two cohorts:1) surgeons who communicated using traditional procedures, such as e-mail, phone calls, and collegial meetings, or 2) surgeons who used the "WhatsApp Surgery Group", in which surgeons could communicate with each other. No differences in surgical clinical outcomes were reported between the two groups.

The app of Doğan et al. enabled bariatric patients to have a live consultation with researchers and contained educational materials.[49] The app did not improve self-care, quality of life and the self-body image. Although significant differences in BMI were reported between the intervention and the control group, the weight loss towards the preoperative weight was not analysed.

Moon et al. developed a peer support app for patients with low anterior resection syndrome.[50] The app consisted of information modules and a peer support forum in which patients could communicate with mentors monitored by a team of HCP's. The app will be evaluated in a RCT on its impact on patients-reported outcomes.

Prognosis

The app of Gabriel et al. contained a prediction model of the 5 years overall survival of postoperative patients with stage II or III colon cancer which was based on a large retrospective cohort study.[51] However, the app itself has not been tested on its usability, effectiveness and reliability in clinical care.

The already available "AWARE" app collected behavioural data of patients after pancreatic surgery, which was used in combination with an activity tracker to predict postoperative symptoms with a 73.5% accuracy.[52] However, the prediction was calculated afterwards and was not included in the app. Thus, the clinical relevance of the app has not been evaluated.

Clinical decision-making

The app "Pancreatic Surgery" contained a multimodal algorithm for early recognition and minimally invasive management of postoperative complications after pancreatic surgery, in which the HCP were instructed to enter data daily. The app was evaluated in a RTC, and patients who were treated in accordance with the algorithm in the app had significantly less postoperative complications than those who received usual care.[53] The app is freely available in the app stores.

DISCUSSION

Healthcare apps may offer great possibilities to support or improve gastrointestinal surgical care, provided that the development and validation process are properly conducted and the app itself complies with professional standards and medical device regulations [8,9]. This systematic review showed that most the gastrointestinal apps, which have been described in literature, at best had low-quality evidence and were limited in their evaluation methodology. Small sample sizes, lack of comparison with a control group and subjective outcomes defined were common limitations. Most of the identified apps were only assessed on their usage, usability, satisfaction and feasibility, which was rarely measured with a valid and reusable questionnaire. Studies of higher-level evidence in the area of colorectal.[38,42] Hepatopancreatobiliary[53] and bariatric surgery[33] reported mostly positive outcomes on postoperative recovery, complications and weight loss.

In total, the review retrieved 29 apps developed for use by patients, surgeons, or both. In the selected studies, there was a predominant focus on monitoring the patient's postoperative condition and symptoms in the area of colorectal surgery. Apps that fall within the same category share many similar functionalities, with minimum variance in functionality. It is fair to state that apps that fall into different categories are not mutually exclusive in their functionalities regarding their category inclusion. Across all app categories, studies have indicated a potential benefit of apps, except for the categories of communication and prognosis. Users of apps generally seemed to be satisfied with the apps, while reported patient engagement was highly variable across the categories and domains. Patient engagement with the app is, of course, a driver of the potential clinical effect of apps aimed at patient care. Patient engagement not only depends on the specific features that the app offers but also relates to the context and phase of care the patient is receiving, the patients' digital literacy, and the apps' overall usability and stability. Most studies did not report participants' digital literacy, although it can be assumed that participants had sufficient proficiency, as patients with insufficient proficiency probably did not participate. It is important to acknowledge digital literacy and to compensate for digital literacy as well as possible, as the effectiveness of apps may be substantially less.

Although over 150 gastrointestinal surgical apps for use on a smartphone or tablet are available in the app stores, only a limited amount (29) is reflected in studies as could be retrieved from scientific literature by this systematic review. [54-56] Non-validated or poorly validated apps are potentially harmful, especially if they may have a direct effect on clinical outcomes such as diagnosis or decision support tools. This underlines the need for high quality clinical research to safeguard the effectiveness and safety of apps, and to provide HCP's a better understanding of the potential impact of an app on surgical care. It is important to realize that apps can be published in the app stores claiming to be effective or reliable without presenting a snippet of evidence to support clinical safety

or efficacy. There are no specific rules or regulations in the submission guidelines for the app stores, which is an important issue.[57,58] When scientific evidence is needed to safeguard the efficacy, quality and safety of apps to be in clinical settings, and with the medical device regulations in place, the public should at least be able to discern apps that are built and proofed reliable from those that are not before they are downloaded and granted permission from the user. App stores are encouraged to change their submission guidelines for apps that act as a medical device.

Healthcare apps which are used to monitor, guide, diagnose, or treat patients must be regarded as a medical device and thereby have to comply to medical device regulations (FDA or MDR).[8,9] The regulations have strict requirements for the (technical)development, validation and quality surveillance of the app, and the manufacture itself. Even with legislation in place, HCP's or manufacturers may be unaware of the importance of such legislation, which may impede the quality and safety of apps. Although apps evaluated in a clinical study do not have to fully comply to the regulations, it is worthwhile to note that only one author has mentioned the regulations.[39] It is unclear if other apps would be allowed under the medical device regulations. However, it is not guaranteed that the app will lead to valid outcomes if they have met the regulations.[7,10] Therefore, well-designed scientific research validating apps are needed. As with researching medical devices or drugs, conducting research with healthcare apps is time-and cost-consuming. The role of app manufacturers with commercial interests and eagerness of the public to use apps are potential hazards. It is essential that an expert HCP is involved in the development and validation of healthcare apps. Not only to safeguard content, but also to ensure that apps are well researched and vetted before they become accepted in clinical practice. Although the development process of the apps identified in this review has been rarely or obscurely described, the involvement of HCP is presumed. HCP's are mostly not involved in unvalidated apps which are available in the app stores, resulting in a potential higher risk.[51] Moreover, apps that collect and/or process medical data must comply with data privacy regulations.[59,60] Specific standards needs to be followed, but not all app manufacturers are familiar with them.[61] Most of the included apps collect or process patient data (25/29), however, only three have mentioned privacy measures.[30,48,50] This does not have to imply that these apps do not comply with data privacy regulations as the development process was generally obscurely described.

Since the use of apps in healthcare has grown rapidly, hospitals and health insurers are increasingly demanding that apps are adequately validated before deployment in clinical care. However, they struggle with the minimum required proof of evidence. Conventionally, a RCT is the golden standard, and is especially applicable for high-risk apps which are classified as medical devices. But there are also other methods to validate apps of which mixed methods studies are an excellent example.[62] It is important that all evaluations are

published, to shape the proof of evidence of apps. It is recommended that medical apps used in research or clinical practice comply with the suggestions summarised in Table 4.

Table 4: Suggestions for future research and/or practice.

Process	Suggestions
App development	An 'expert' healthcare provider should be involved to safeguard medical content and to ensure that apps are well researched and vetted.
	Medical apps should also be compensated for patients with low digital literacy.
App evaluation in clinical research	All medical apps should be evaluated on their effectiveness and safety in quality studies in which a control group, objective outcomes on effectiveness of apps and valid and reusable questionnaires are used.
	The development process of medical apps should be completely described so that it is possible to assess whether all conditions are met.
Regulations in app stores	All medical apps should provide evidence on their effectiveness and safety before the app stores accept their publications.
Clinical practice	Healthcare providers and patients must be aware of the level of evidence of apps that they prescribe or use.
	Only well-validated medical apps should be used in clinical practice, as high level of evidence is needed to guarantee their efficacy, quality and, safety.

CONCLUSION

Healthcare providers and patients must be aware of the level of evidence of apps that they prescribe or use. Although apps may offer great potential to improve gastrointestinal surgical care, only a limited number of available gastrointestinal surgical apps have been researched and described in peer-reviewed literature to date. It is of great concern that most studies evaluating gastrointestinal surgical apps fail to generate a high level of scientific evidence, needed to guarantee the efficacy, quality and safety of apps. To fully utilize the potential of gastrointestinal surgical apps in standard surgical care, more and higher quality of research is needed.

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PART II

PATIENT PERSPECTIVES

CHAPTER 3

Patient satisfaction with stoma care and their expectations on mobile apps for supportive care

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ABSTRACT

Introduction: Self-efficacy in stoma care is essential, as it reduces morbidity and psychosocial problems. Mobile applications (apps) may optimise patients' self-efficacy. This article investigates patients' satisfaction with stoma care, their attitudes towards a supporting app aiming to promote self-efficacy and evaluate which functionalities are desired.

Method: A survey was sent to members of the two stoma-related patient associations in the Netherlands. Associations between patients' characteristics, satisfaction concerning received stoma care, and willingness to use an app were evaluated.

Results: The survey was completed by 1868 patients. Overall satisfaction was scored as 6.6, with shortfalls reported in the preoperative information provision, stoma site selection, and postoperative care. Patients of older age, who were unaware of getting a stoma, had an ileostomy, a low quality of life or psychosocial problems, were less satisfied. An app was expected to be of added value by 59.4% of the patients having a stoma for less than three years, compared to the significantly lower 43.8% expectation rate of the remaining study population ($p<0.001$). Moreover, patients with a high frequency of physical or psychosocial problems expressed higher levels of interest.

Conclusion: Patients were only moderately satisfied with their received stoma care. A supportive app is most likely beneficial for patients who had a stoma for less than three years, were in an acute situation, and/or have stoma-related problems. Most patients prefer information via internet or on paper, although apps may offer additional benefits. It is important to acknowledge digital literacy and to council patients appropriately about the benefits, and help them to use apps.

INTRODUCTION

It has been estimated that over 750.000 people in the United States have an ostomy.[1] In the Netherlands, this number is estimated to be 40.000.[2] For some patients, a stoma may improve quality of life. [3] For others, having a stoma may negatively impact one's self-image and daily functioning, resulting in reduced quality of life.[4-6] Coping with a stoma may result in insecurity, leading to various psychosocial problems.[7] Patients who are unable to manage their stoma well are at risk of encountering stoma-related morbidities, such as skin irritation, leakage, parastomal hernia, or prolapse, with an incidence varying from 20-80%.[8,9] Patients with a high self-efficacy in stoma care had fewer psychosocial problems and stoma-related morbidities.[10,11] Hence, tailored patient education and guidance are essential for improving patients' ability to cope with a stoma and their quality of life.

Providing targeted and adequate stoma care can be challenging. Even when a stoma is given in an elective situation with patients receiving proper counselling, they may be unable to retain and replicate the given information due to the shock of having to undergo an operation and the news of getting a stoma. Hence, even if counselling is well done, it is very important for patients to have access to stoma-related information. Several educational stoma care programs have been described in the literature, all of which have shown positive results in terms of psychosocial skills, self-efficacy, and quality of life.[12,13] Surprisingly, it is largely unknown whether the current preoperative information routine and stoma care yield sufficient patient satisfaction and whether patients' needs are met. A mobile application (app) may provide a sustainable solution fitting patients' individual needs, situations and daily routines, and stimulating self-management.[14-16] Apps may offer important benefits, such as personalisation of information, connectivity or monitoring functionalities, wound-care videos, and information availability on a hand-held device. However, understanding patients' opinions on current stoma care and their specific needs in care and their preferred pathway of information is necessary. Only then, it becomes clear whether there actually is a need for improvement and additional support, and moreover, in what format.

METHODS

Study design

A national retrospective survey study was conducted in cooperation with the two Dutch stoma-related patient associations ('Stomavereniging' and 'Stichting Stomaatje'). This study was conducted according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).[17] Ethical approval was waived by the local Ethics Committee of Amsterdam UMC.

Development of the questionnaire

The questionnaire used in this study was based on the Consumer Quality Index Stoma Care" (CQISC) which assesses the medical status of patients with stoma and their experiences with overall healthcare.[18] The questionnaire was compiled by our research team and included clinical experts in stoma care and stoma patient associations. The questionnaire consisted of three parts: 1) patient characteristics and medical status, 2) current stoma care including possible improvements and patient satisfaction, and 3) patients' experiences with mobile technology, assessing the needs for the desired functionalities of an app. Satisfaction was evaluated with the Satisfaction concerning Stoma Care Questionnaire (SSCQ), which was validated to evaluate perioperative stoma care. [19] The SSCQ contains three domains: 'preoperative care and information', 'postoperative care and guidance', and 'contact with stoma nurse' with a total of 20 questions (total score: minimum of 20 and maximum of 100).

Study population

The two patient associations sent invitational e-mails to their members. The members of the Dutch Stoma Association, 'Stomavereniging', were already part of an active panel, regularly participating in patient-related surveys, and received a closed-unique and personal invitation link. Members of the Dutch Patient Foundation 'Stomaatje' received an open – not unique–invitation link. The inclusion criterion was patients with a stoma (e.g., ileostomy, colostomy or urostomy), which was also stated in the invitation e-mail and the introduction of the survey. Most members of both associations had a stoma; however, a minor portion also had an ileoanal pouch. Patients with a pouch that did not have a stoma were excluded from the analysis if they returned the survey. To our best estimate, approximately 5270 patients (including patients with a pouch) were invited to complete the survey.

Data collection

Potential participants received an open or closed invitation and possibly one reminder to complete the web-based survey using SurveyMonkey®. Data was collected between 21th

February and 17th March 2020. Collected data were anonymized by the Dutch Ostomy Association, and subsequently provided for analysis.

Statistical analysis

Statistical analyses were performed using SPSS (version 27). Descriptive statistics were used to assess baseline characteristics. Missing data were accounted for using imputation by chained equations for variables with missing data. The pooled results of the five multiple iterations were used for the analysis. For further analysis, the frequencies of ten potential physical and nine potential psychological problems were respectively added together, so the total scores ranged 10-50 and 9-45. Multiple linear regression analysis was performed to investigate the association between the patient characteristics and patient satisfaction. As recall bias for patient satisfaction may be strongly present, the analysis was also conducted separately for each time group (< 1 year, 1-3 years, 3-5 years, 5-10 years and > 10 years having a stoma). Multinominal logistic regression analysis was conducted to investigate whether willingness to use an app could be predicted by patient characteristics, satisfaction, or experience with mobile technology. To discriminate between patients' willingness and unwillingness, we trichotomized the outcomes to 'willing' (with choices 'very willing' and 'willing'), 'neutral', and 'unwilling' ('unwilling' and 'very unwilling'). The reference category for the logistic analysis was the neutral option. For both regression analyses, all determinants were chosen a priori, based on the literature and expectations. Dummy variables were created for nominal and ordinal variables, and measured relative to their default reference categories (the highest frequency in this study population or the most clinically relevant). A stepwise backward selection method was used to correctly select and remove covariates that were not associated with the outcome. Therefore, only the significant variables ($p \leq 0.05$) remained in the prediction model.

RESULTS

A total of 1868 patients who met the inclusion criteria completed the web-based survey; 1692 via closed invitation (response rate 40%), and 198 via open invitation (estimated response rate 19%) Thirteen patients with a pouch but without a stoma were excluded from the analysis. The baseline characteristics are summarised in Table 1. Most patients were male (n=1011, 54.1%), had a colostomy (n=983, 56.3%) and had an operation indication related to a malignant disease (n=1116, 59.7%). The mean age was 67.5 years. Most patients had a stoma for at least five years (n=1141, 61.1%). The most frequently reported physical and psychosocial problems were leakages, skin issues, stomal hernias, fear of leakages, sexual problems, and insecurity (Figure 1, 2). As expected, stoma nurses were the main source of information and stoma-related questions. Stoma nurses were mainly contacted regarding stoma materials (47.0%), leakage (42.6%), and skin problems (37.0%).

Table 1: Baseline characteristics

Variable	Total n= 1868
Gender:	
Male	1011 (54.1%)
Female	857 (45.9%)
Age	67.5 (11.6)
Nationality	
Dutch	1837 (98.3%)
Other	31 (1.7%)
Level of education	
Low	824 (44.1%)
Medium	325 (17.4%)
High	719 (38.5%)
Family situation	
Single without children	240 (12.8%)
Single with children	152 (8.1%)
With partner and with children	636 (34.0%)
With partner without children	818 (43.8%)
Other	27 (1.4%)
Quality of life	
Bad	34 (1.8%)
Moderate	302 (16.2%)
Good	970 (51.9%)
Very good	426 (22.8%)
Excellent	137 (7.3%)
Stoma type	
Colostomy	983 (56.3%)
Ileostomy	461 (26.5%)
Urostomy	300 (17.2%)
Other	124 (6.6%)

Variable	Total n= 1868
Time having a stoma	
<1 year	169 (9.0%)
1-3 years	291 (15.6%)
3-5 years	269 (14.4%)
5-10 years	507 (27.1%)
>10 years	632 (33.8%)
Permanent or temporary stoma	
Permanent	1630 (87.3%)
Temporary	238 (12.7%)
Indication for surgery	
Malignancy	1121 (59.9%)
Benign	749 (40.1%)
Aware of stoma before surgery	
No, acute situation	260 (13.9%)
Stoma was unexpected or unlikely	286 (15.3%)
Yes, elective surgery	1322 (70.8%)
Hospital	
Regional hospital	1415 (75.7%)
University hospital	453 (24.3%)
Satisfaction concerning stoma care (SSCQ)	
Total score	72.4 (13.6)
Domain preoperative care and information	17.6 (5,2)
Doman postoperative care and guidance	30.9 (7,4)
Domain contact with stoma nurse	23.8 (4,6)
Internet use for information regarding stoma	
Never	600 (32.1%)
Yearly	538 (28.8%)
Monthly	571 (30.6%)
Weekly	124 (6.6%)
Daily	33 (1.8%)
Mobile technology experience	
Excellent experience	362 (19.4%)
Much experience	661 (35.4%)
Some experience	598 (32.0%)
Little experience	188 (10.1%)
No experience	59 (3.2%)
Use of mobile apps	
Yes including medical apps	380 (20.3%)
Yes but no medical apps	1127 (60.3%)
No apps	88 (4.7%)
No mobile phone	272 (14.6%)

Continuous data: mean ± standard deviation. Categorized data: frequencies and percentages.

Figure 1: Patients' self-reported physical and psychosocial problems related to their stoma

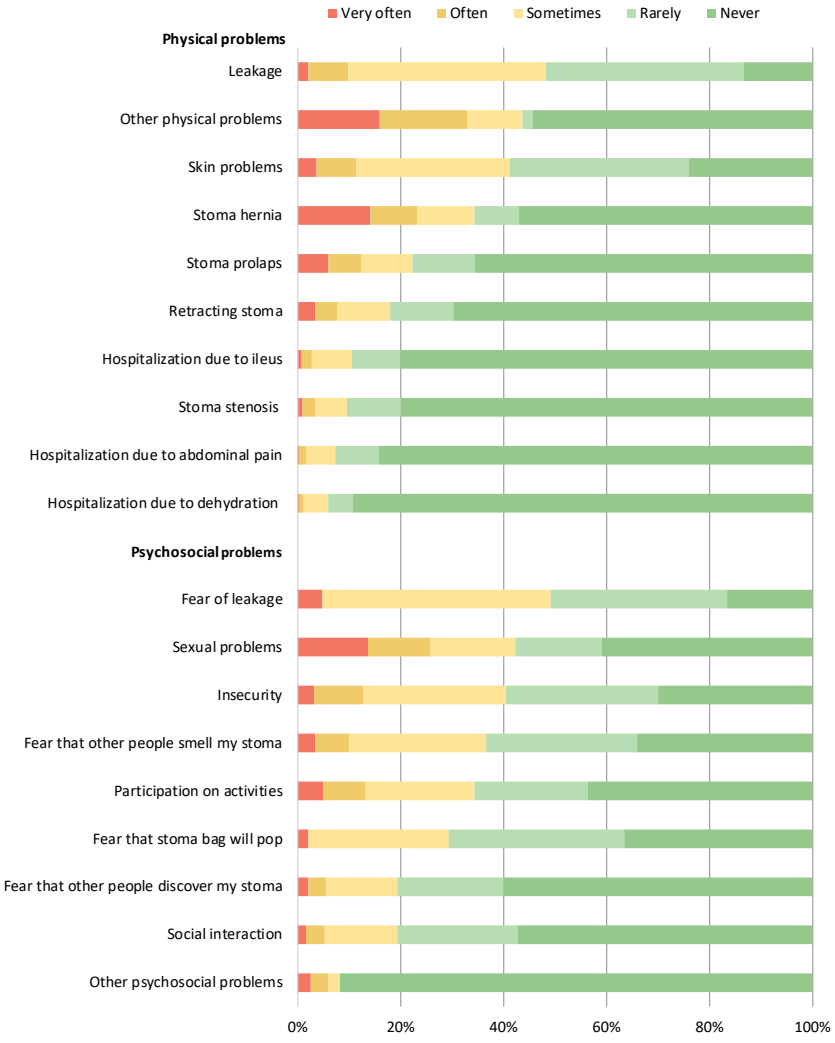

Figure 2: Patients' self-reported physical and psychosocial problems regarding their stoma, stratisfied on years of having a stoma

Patients' view on their received stoma care

The patients were moderately satisfied with their received stoma care. The mean total SSCQ score was 72.4 (± 13.6), which was converted to 6.6 on a scale of 0-10. The SSCQ score of the five 'time having a stoma' groups showed no difference. This may be explained by the fact that stoma care has not improved over the years or that recall bias may disguise possible improvements. A total of 40.6% of the patients indicated that they did not need any additional support or care, and 63.8% reported that further improvements were unnecessary. However, additional care was most desired after hospital discharge, and the most frequently reported potential improvements were preoperative information provision (16.9%), stoma site selection (14.1%), information about stoma-related problems (20.3%), and stoma materials (19.4%).

Multivariate linear regression analysis showed that the satisfaction score was significantly associated with the patient-related factors: sex, age, and education; the care-related factors: hospital type, stoma permanency, and preoperative unawareness of stoma; and the postoperative factors: quality of life and frequency of psychosocial problems (Table 2). Preoperative awareness, quality of life, and frequency of psychosocial problems mostly influenced satisfaction. Hospital type and stoma permanency did not have a clinically relevant influence. The stratified analysis for time having stoma yielded two additional variables which were not significant in the general regression analysis; patients with an ileostomy had significantly less satisfaction in the group 'stoma less than 1 year' and patients with a benign operation indication had significantly less satisfaction in the group 'stoma 3-5 years'. The other yielded variables differed in significance between the groups and it was notable that the influence of a high education was substantially increased in the group 'stoma less than 1 year'.

Table 2: Association of patient characteristics and overall satisfaction concerning stoma care

	B	SE B	95% CI		*p*-value
Constant	94.41	.73	89.03	99.79	<0.001
Gender					
Male *	-	-	-	-	-
Female	- 2.44	0.66	-3.74	-1.14	<0.001
Age	-0.14	0.03	-0.20	-0.08	<0.001
Education					
Low*	-	-	-	-	-
Moderate	-0.54	0.92	-2.37	1.29	0.559
High	-1.75	0.69	-3.09	-0.41	0.011
Quality of life					
Bad	-2.69	2.39	-7.39	2.01	0.261
Moderate	-2.23	0.90	-4.07	-0.53	0.011
Good*	-	-	-	-	-
Very good	2.45	0.77	0.96	3.96	0.001
Excellent	4.49	1.21	2.13	6.89	<0.001
Hospital type					
Regional hospital*	-	-	-	-	-
University hospital	-1.87	0.81	-3.47	-0.26	0.024
Stoma					
Permanent *	-	-	-	-	-
Temporary	-2.13	0.95	-3.99	-0.27	0.025
Aware of stoma					
No, acute situation	-7.20	1.01	-9.22	-5.18	<0.001
Unexpected or unlikely	-2.33	0.91	-4.12	-0.53	0.011
Yes, elective surgery *	-	-	-	-	-
Frequency psychosocial problems #	-0.50	0.05	-0.61	-0.40	<0.001

R2 0.161, Adjusted R2 0.155 F 27.4 Sig. ANOVA <0.001

* Reference category. # score is ranging 9-45. Abbreviations: B Beta coefficient for total SSCQ score; SE Standard Error; CI Confidence interval

Table 3: Association of patient characteristics and overall satisfaction concerning stoma care stratified for time having a stoma

	B	SE B	95% CI		*p*-value
<1 year (n=169) R2 0.175, Adjusted R2 0.144 F 11.6 Sig. ANOVA <0.001					
Constant	106.53	8.83	89.21	123.86	<0.001
Age	-0.220	0.10	-0.43	-0.01	.036
Education					
Low*	-	-	-	-	-
Moderate	-1.09	3.07	-7.11	4.93	0.722
High	-6.28	2.60	-11.40	-1.17	0.016
Stoma					
Urostomy	0.21	3.27	-12.60	-2.35	0.59
Ileostomy	-7.47	2.61	-5.92	6.34	0.004
Colostomy*	-	-	-	-	-
Frequency psychosocial problems #	-0.72	0.18	-1.07	-0.37	<0.001
1-3 years (n=294) R2 0.292, Adjusted R2 0.267 F 11.6 Sig. ANOVA <0.001					
Constant	96.22	6.02	84.35	108.10	<0.001
Gender					
Male *	-	-	-	-	-
Female	-5.33	1.61	-8.49	-2.17	<0.001
Age	-0.15	0.07	-0.28	-0.01	0.034
Quality of life					
Bad	-8.41	3.95	16.16	-0.66	0.034
Moderate	-2.69	2.31	-7.29	1.86	0.245
Good*	-	-	-	-	-
Very good	4.81	1.95	0.98	8.64	0.014
Excellent	7.64	3.04	1.68	13.60	0.012
Hospital type					
Regional hospital*	-	-	-	-	-
University hospital	-5.43	1.88	-9.16	-1.70	0.005
Aware of stoma					
No, acute situation	-6.21	2.30	10.72	-1.70	0.007
Unexpected/unlikely	-0.22	2.24	-4.65	4.21	0.923
Yes, elective surgery *	-	-	-	-	-
Frequency psychosocial problems#	-0.49	-0.49	0.13	-0.76	<0.001

	B	SE B	95% CI		*p*-value
3-5 years (n=268) R2 0.263, Adjusted R2 0.240 F 12.0 Sig. ANOVA <0.001					
Constant	81.75	2.72	76.42	87.09	<0.001
Quality of life					
Bad	-4.46	6.25	-16.80	7.88	0.476
Moderate	-0.45	2.19	-4.72	3.85	0.842
Good*	-	-	-	-	-
Very good	3.23	1.93	-0.55	7.01	0.094
Excellent	6.64	3.48	9.81	23.48	<0.001
Stoma indication					
Malign *	-	-	-	-	-
Benign	-3.72	1.69	-7.04	-0.42	0.027
Aware of stoma					
No, acute situation	-8.63	2.55	-13.67	-3.59	<0.001
Unexpected/unlikely	-4.79	2.39	-9.49	-0.10	0.045
Yes, elective surgery*	-	-	-	-	-
Frequency psychosocial problems#	-0.43	0.13	-0.68	-0.180	<0.001
5-10 years (n=515) R2 0.148, Adjusted R2 0.143 F 29.1 Sig. ANOVA <0.001					
Constant	86.31	1.83	82.72	89.91	<0.001
Aware of stoma					
No, acute situation	-9.34	1.78	-12.86	-5.81	<0.001
Unexpected/unlikely	-2.41	1.67	-5.70	0.89	0.151
Yes, elective surgery*	-	-	-	-	-
Frequency psychosocial problems#	-0.69	0.10	-0.88	-0.50	<0.001
>10 years (n=640) R2 0.119, Adjusted R2 0.107 F 12.1 Sig. ANOVA <0.001					
Constant	98.12	4.64	88.97	107.27	<0.001
Gender					
Male *	-	-	-	-	-
Female	-3.36	1.13	-5.58	-1.15	0.003
Age	-0.18	0.05	-0.28	-0.07	0.001
Education					
Low*	-	-	-	-	-
Moderate	-1.71	1.59	-4.85	1.43	0.284
High	-2.40	1.19	-4.74	-0.06	0.045
Aware of stoma					
No, acute situation	-6.16	1.59	-9.28	-3.03	<0.001
Unexpected/unlikely	-2.92	1.43	-5.73	-0.11	0.042
Yes, elective surgery *	-	-	-	-	-
Frequency psychosocial problems#	-0.49	-0.49	0.13	-0.76	<0.001

* Reference category, # ranging 9-45, Abbreviations: B Beta coefficient for total SSCQ score; SE Standard Error; CI Confidence interval

Patient preference regarding e-health

Of all patients, 39% stated that they consulted the internet at least once a month to search for information regarding their stoma. This percentage was 64.8% for patients with a stoma of less than three years. Patients stated that their most preferred way of consulting information would be using the internet (55.9%), on paper (46.3%), or via a yet to be developed mobile app (33.5%). The preference for an app increased to 47.4% for patients aged 50 years or younger. Experience with mobile technology was moderate to high for the majority of patients (86.8%), and this was also largely present in patients above 80 years of age (70.9%). A mobile app would be expected to be of benefit for them, as reported by 47.6% of the patients, as they expected it to help them cope with a stoma. However, this percentage was significantly increased for patients with a stoma less than three years, 59.5% compared to 43.8% of the remaining study population ($p<0.001$). Table 4 presents the patients' preferences for the functionalities of an app, in order of popularity. Most items were assessed as useful, except for a sensor measuring stoma production. The most popular items were advice on stoma-related problems and information on stoma care, stoma materials, instructions at discharge, and lifestyle.

The multinominal logistic regression analysis in table 5 showed that willingness to use an app was significantly influenced by experience in mobile technology, frequency of psychosocial and physical problems, time having a stoma, and the independent domains of SSCQ. Patients who have a stoma for less than 3 years are more willing to use an app. Other cut-offs of time having a stoma were studied, but were not significant or more clinically relevant. Interestingly, patients who have a high satisfaction score on the SSCQ domains: 'preoperative care and information' and 'contact with stoma nurse' are more willing to use an app.

Table 4: Assessment of functionalities of a mobile application

Functionalities	Useful (%)	No opinion (%)	Not useful (%)	N
Advice for stoma related problems	89.6	8.6	1.8	1238
Information on stoma care	84.7	12.4	2.9	1246
Information on stoma materials	84.7	12.8	2.5	1234
Information on instructions at discharge	84.4	12.2	2.5	1218
Information on life style	82.0	15.4	2.5	1224
Direct contact with healthcare providers	75.7	19.9	4.4	1229
Preoperative information	75.5	21.1	4.5	1214
Contact details of healthcare providers	75.2	19.8	5.0	1223
Personalised information	71.2	23.3	4.5	1236
Information on stoma site selection	71.1	23.2	5.7	1206
Videos on stoma care	69.1	25.2	5.7	1228
Links to other websites	67.1	26.4	6.5	1203
Frequent asked questions	63.2	29.7	7.2	1214
Feedback	61.2	31.6	7.2	1206
Receiving daily information	45.9	39.8	14.3	1209
Contact with peer patients	42.6	43.3	14.1	1216
Sensor measuring stoma production	29.4	45.8	25.4	213

Table 5: Association of patient characteristics and their willingness to use a mobile app

	OR #	95% CI		p-value
Not willing to use an app				
Experience in mobile technology				
No	1.56	0.56	4.30	0.374
Some *	-	-	-	-
Moderate	0.59	0.35	0.99	0.047
A lot	0.47	0.25	0.90	0.024
Excellent	0.47	0.25	0.87	0.017
Willing to use an app				
Experience in mobile technology				
No	0.58	0.21	1.64	0.302
Some *	-	-	-	-
Moderate	1.39	0.83	2.31	0.207
A lot	2.23	1.27	4.16	0.008
Excellent	3.12	1.62	6.02	0.002
SSCQ: Preoperative care and guidance	1.03	1.00	1.06	0.021
SCCQ: Postoperative care and guidance	0.96	0.94	0.98	<0.001
SCCQ: Contact with nurse	1.03	1.00	1.07	0.046
Time having a stoma				
<3 year *	1.59	1.18	2.14	0.003
>3 years	-	-	-	-
Frequency of psychosocial problems (ranging 9-45)	1.03	1.00	1.05	0.035
Frequency of physical problems (ranging (10-50)	1.03	1.00	1.07	0.037

* Reference category, # Reference category = no opinion. Abbreviations: OR Odd ratio; CI Confidence interval

DISCUSSION

Although stoma care is of critical importance to the well-being and quality of life of patients, it is largely unknown whether current stoma care yields sufficient patient satisfaction and meets patients' needs. It is necessary to understand patients' perspectives and evaluate whether additional support to improve patient care is desired, and in what format. An app may provide a sustainable solution fitting patients' individual needs, offering possible benefits such as push notifications and peer support- additional to information on paper. Assessing determinants influencing the willingness to use an app is essential to ensure proper design and implementation.

Overall, patients scored their satisfaction with their received stoma care as 6.6 (scale of 0-10). Patient satisfaction was mostly influenced by being unaware of the chance of getting a stoma, indicating improper preoperative counselling, or an acute situation in which counselling could not take place. Patients who received a stoma in an acute situation were significantly less satisfied. These patients did not have or had limited preoperative counselling, and immediate postoperative care by a stoma nurse or a stoma-competent ward nurse could be limited, for instance, for patients who underwent surgery at the weekend. Hence, these patients missed much information and counselling, most likely to be given in an elective situation. In addition to acute situations, other variables also influenced satisfaction. The perioperative clinical condition and mental state may also negatively impact patients' perception of the actual received stoma care in the immediate pre- and postoperative phase. In addition, patients who underwent surgery for a benign indication with underlying chronic disease reported lower satisfaction. These patients may have had a more severe and/or lengthy disease course or recovery, possibly influencing their reported satisfaction. In addition, patients who received an ileostomy were less satisfied. These patients likely experience more frequent changes in stoma materials, leakages, peristomal skin problems, and water/electrolyte imbalances, all of which impact daily life. Although these two associations were significant only in the two subgroups of the stratified analysis, they were expected to substantially affect patient satisfaction. Overall, men showed higher patient satisfaction than women, which is comparable with literature and may be explained that men and women value aspects of care differently.[20-22] Older and highly educated patients were generally less satisfied. This may be explained by the fact that younger patients are likely to experience fewer comorbidities and complications, be more active, and participate in their own care; thus, young patients may have a more positive perception of the received care. Patients with decreased quality of life or psychosocial problems showed lower overall satisfaction. The psychological state may affect the patients' expectations and experiences.[23,24]

Although most patients had a stoma for many years, they still consulted the internet regularly to search for information regarding their stoma and how to cope with it. A mobile

app may be a good alternative for internet (or responsive websites), offering additional functionalities such as personalisation of information or peer contact, and information on a hand-held device is considered to be both easily accessible and convenient by many. Surprisingly, our study showed that most patients prefer to have additional stoma-related information via the internet or on paper, which raise the question if an app is a needed addition for all patients. As reported in this study, patients with no or limited experience with mobile devices are significantly hesitant to use an app for their personal stoma care. It is important to acknowledge digital literacy, especially, since healthcare information and accessibility are digitalising fast and, in many aspects, with most hospital patient portals are now electronically operated. Patients may be still unaware of benefits of apps as described above, or just not used to accessing medical information via apps, as there is simply not much out there for them. An app is expected to be most commonly used by patients with a sufficient smartphone experience, and who had a stoma for less than 3 years, a high frequency of psychosocial or physical problems, or those who are not satisfied with their postoperative care. These patients were significantly more willing to use an app to provide additional information and support. It could be argued that an app would also be beneficial for patients undergoing emergency surgery, who usually receive less care and are, therefore, less satisfied. Although patients with low digital literacy are hesitant to use apps, an app should also suit the needs of those patients and be optimised for use by them. Adequate preoperative preparation and good contact with stoma nurses are important when implementing an app, as patients are more motivated to use an app. It is important to advocate the app as an information source that integrates in normal preoperative counselling.

This is the first study to focus on patient satisfaction concerning stoma care and assess whether e-health may be beneficial. The strength of this study lies in the extensiveness of the questionnaire covering all relevant aspects of stoma care and determinants for an e-health intervention, and this study had a large sample size (N = 1868). Results may be biased, as participants were members of patient associations who may be more involved in their own stoma care, or perhaps better educated or skilled when compared to their peers who have decided not to join a patient association. Nevertheless, asking all members of stoma societies to give their opinions is the best way to include a significant number of patients, providing the best possible representation of the general stoma population.

This study had some limitations. First, many patient questionnaires had incomplete data owing to the length of the questionnaire. Missing data was increasingly present over the course of the questionnaire. To improve the validity of the results, missing data used in the statistical analysis were corrected by multiple imputation. Second, most patients had a stoma for at least five years. This might implicate recall bias in the assessment of patient satisfaction concerning stoma care in the perioperative period. However, patient satisfaction was comparable across all time periods. Stoma care may not have improved

over the years, or recall bias may have disguised possible improvements. A third limitation might be the questioning of patients' willingness to use an app. A description of its potential functionalities was not provided, although it could be assumed that the app would contain stoma-related information. Some patients will not have a concept of a mobile app, as it might be difficult to think in all potentials, while the remaining patients will have a different concept from each other. Therefore, the interpretation of these results requires caution because willingness is likely to be underestimated. Presenting a clear description of a well-designed app using visual images or videos will improve patients' willingness to use an app. Finally, it can be argued that the variance of the satisfaction analyses was low, only determining the outcome to a small extent (see Tables 3, 4). However, the variance in patient satisfaction usually is less than 20%.[25-27]

CONCLUSION

Patients are only moderately satisfied with their received stoma care, with shortcomings reported in the provision of preoperative information, stoma site selection, information on stoma-related problems, and material and postoperative care. For many patients, especially those with high proficiency in using smartphones, an app is considered an important addition to regular stoma care or support groups. Digital literacy should be a focus point of health and patient organisations, counselling patients appropriately about the benefits and helping them to use the apps. Further qualitative research on how to best support patients in building such an e-health solution is needed to provide additional in-depth insights that could be used as a blueprint for the development of an app and how to disseminate this well. Subsequently, it is highly recommended that the app will be evaluated on its safety and effectiveness in clinical research, and compensates for digital literacy as much as possible, involving patient groups who are not proficient in using apps in the app development.

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CHAPTER 4

Supporting stoma patients' self-efficacy with a mobile application - a focus group interview study

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ABSTRACT

Background: Being able to care for and cope with one's stoma adequately may significantly impact patient's wellbeing. A well-designed mobile application (app) may improve and solve some of the difficulties patients encounter. This study aims to gain a better understanding of the problems patients face in stoma care and to determine how to improve these problems by an app.

Method: A qualitative study using six focus group interviews was conducted between March and April 2020. Patients with a stoma, representatives of patient associations and stoma-related healthcare providers participated to provide insights. A thematic content analysis method was used to analyse the transcripts.

Results: Participants indicated that perioperative information could be improved, information should be applicable for all patients and the amount of stoma materials to be overwhelming. Moreover, the contact with fellow peers could be utilised more and it was unclear which healthcare provider should be contacted. All participants expected an app would be beneficial. The app should provide reliable and up-to-date information which is presented in a visually attractive manner, and facilitate peer contact in which patients can support each other.

Conclusion: Adequate self-care and coping is essential for patients' quality of life. A personalised, mobile app may be promising to overcome some of the problems related to adequate self-provision of stoma care at home, improving self-efficacy and overall well-being.

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INTRODUCTION

In the Netherlands, it has been estimated that annually, over 7000 patients undergo stoma surgery to treat various diseases.[1] Getting a stoma is likely to impact one's body image and daily functioning, which may lead to insecurities affecting mental health.[2-4] As coping might be difficult, patients may face several psychosocial problems such as depression, stress, anxiety, less social participation and sexual problems.[5] Moreover, the incidence of stoma-related morbidities varies between 20-80%.[6,7] Due to its broad impact, the quality of life is significantly decreased.[8] Patients with high self-efficacy have decreased risk of psychosocial problems and stoma-related morbidities.[9,10] Therefore, providing good preoperative and postoperative stoma care is essential for patients to adequately cope with a stoma and achieve a good quality of life.[11]

To date, patients have been moderately satisfied with their received care in the Netherlands.[12] Several shortcomings in the information provided during the pre-operative workup routine, in postoperative care, and especially during care in unforeseen acute situations have been reported. Even if patients have years of experience with having a stoma, they still regularly browse the internet to search for stoma-related information. In an increasingly digitalising society, a mobile application (app) for use on mobile phones may be an easy-access route to health-related information for patients. An app with on-demand information may better fit patients' individual needs and daily routines, and can improve patients' self-management.[13-15] Compared to providing information on paper or via internet, apps may offer additional functionalities such as easy access to information, personalisation of information, and the possibility of online peer-to-peer contact. Indeed, representatives of Dutch patients with a stoma feel that an app with these functions is of interest and possibly beneficial.[12] However, it is not yet known how such an app should be developed to best support and accommodate patients.

METHODS:

Design

A qualitative study using semi-structured focus group interviews was conducted between March and April 2020. The study was reported in accordance with the Standards for Reporting Qualitative Research (SRQR).[16] This study aimed to gain a better understanding of the perceptions and experiences of patients and caregivers regarding stoma-related problems, and how an app should be designed aiming to help stoma patients to best cope with their stoma in real life setting.

Sampling and participant

Patients, representatives of patients (e.g. from patient associations), and healthcare providers were invited to participate. The patient associations ("Ostomy Association" or "Foundation Stomaatje") recruited patients aged 18 years or older who had an ileostomy or colostomy among their members. Patient were selected using purposive sampling to acquire a broad scope and a wide range of perspectives, taking into account sex, age, operation indication, and stoma type.[17] To help broaden the perspectives of patients, representatives of the aforementioned associations were also present. In addition, healthcare providers, including doctors or nurses, working in the field of stoma care were recruited from a large university and a teaching hospital in Amsterdam, the Netherlands. This approach ensured a diverse range of perspectives from multiple stakeholders.

In total, 23 participants were recruited to assure for a balanced distribution of patients, healthcare providers, and representatives. Participants were assigned to one or multiple focus groups based on their availability. We intended to include between 6 and 8 participants in each focus group interview to ensure every participant had the chance to discuss their experience.[18] Insights on the participants' experiences in stoma care and their perspectives on what a good 'stoma app' should entail above the currently available information were collected. Participants had no previous work or care-related relationship with the first author, except for the last author who participated three focus groups. She had a work-related relationship serving as surgeon, not as primary surgeon but involved in supervising care of patients admitted at the surgical wards. The participants provided oral and/or written informed consent and received a travel allowance for participating in the face-to-face interviews.

Data collection

Four focus group interviews were planned based on a semi-structured interview schedule (see Table 1). The topics of focus groups 1 and 2 and those of groups 3 and 4 were the same. To ensure data saturation and expand upon the insight gained, two additional focus groups were organised to acquire further, detailed information on peer contact and the design of information timeline in the app (see Table 1). The first three interviews were conducted at a large university hospital in the Netherlands, and the last three interviews were conducted online due to COVID restrictions. The first author moderated all six interviews, and had some prior experience in qualitative research. To create a comfortable atmosphere, the participants had 10 minutes to chat with each other before the interviews. The interviewer empowered the participants to speak freely and instructed them not to condemn the other participants. The participants were asked to share their experiences with stoma care and their thoughts on the possible functionalities of the app to solve some of the problems. Questions regarding peer contact and the functionality of the app were more direct. The interviewer interrupted the conversations if the participants drifted too much off topic

for longer durations, or a topic was discussed enough. During the interviews, field notes on striking topics or emotions were made.

Data processing and analysis

All data were collected, analysed, and reported anonymously. The interviews were audio-recorded and transcribed verbatim by the second author. To ensure credibility, all participants received summarised transcripts and were asked for comments or corrections. The transcripts were checked repeatedly for mistakes by the first author. Relevant quotes have been added to the focus group data table.

All data were analysed using the thematic content analysis method described by Sundler (2017).[19] The transcripts were read multiple times to establish a global overview of the topics discussed and familiarity with the data. The first two authors interpreted the quotes of the participants and searched for meanings and underlying themes. Quotes were jointly coded into topics using the software 'MAXQDA 2020 plus (version 22.0.2). Patterns were sought in the identified topics, and were iteratively organised into the subthemes. In addition, some subthemes were divided into overarching themes. After coding, the data were reduced by the second author by removing quotes that had no contribution or were merely repetitions of previous quotes. The first two authors read the reorganised text, including the coding, independently, and in several consensus meetings, themes were critically examined, further refined, and reduced to main themes. Field notes and the results of our qualitative study were re-read to contextualise and check the coding. This triangulation deepened our understanding of the patients' experiences and needs and increased the credibility of our results. Subsequently, the categorised quotes were analysed. All the steps were performed under the supervision of the last two authors, both with previous experience in qualitative research.

Table 1: Interview schedule

Focus group 1 & 2:
- What impediments do you experience in stoma care? - How can a mobile application improve or solve certain of these problems? - In which phase of the care pathway will an app be applicable and could it be of any support? - Which functionalities should be implemented in the mobile application?
Focus group 3 & 4:
- Are there any impediments to stoma care not discussed in the previous focus group? - Are there any ideas of the functionalities of the mobile application that were not discussed in the previous focus group? - How should the app be personalised? In other words, what characteristics should the information be specially adapted for in the mobile application? And, how should the information be adapted? - When should specific information be provided? In other words, what information should be provided before surgery, during hospital admission, and after hospital admission?
Focus group 5
- How is fellow peer contact organised by the patient associations? - How should a mobile app provide peer contact?
Focus group 6
- When should you notify the patients of certain information? Which information is important before and after surgery? - Which information should be provided before surgery for patients who will undergo an emergency operation? Which information should be provided after surgery for patients who will undergo an emergency operation? When should this be provided? - Which type of information should be repeated? When should it be repeated, and in what time span? - What is the maximum number of messages a patient should receive?

Interview schedule of the six focus groups. Focus group 1 and 2 contained the same questions, which also implies for group 3 and 4.

Table 2: The participants

Participant	Groups attended	Years of experience	Gender	Age	Stoma	Disease
Patient 1	1,4,6	0.5	Female	40-50	Ileostomy	IBD
Patient 2	2,4	2	Female	20-30	Ileostomy	IBD
Patient 3	2,4,6	8	Female	50-60	Colostomy	CR cancer
Patient 4	1,4,6	8	Male	60-70	Colostomy	CR cancer
Patient 5	1,4,	4	Female	20-30	Ileostomy	IBD
Patient 6	1,3	1.5	Male	40-50	Colostomy	CR cancer
Representative 1	5	± 1	Male	N/S	N/A	N/A
Representative 2	2,4,5	± 10	Female	N/S	N/A	N/A
Representative 3	3	± 5	Male	N/S	N/A	N/A
Representative 4	4,5	± 15	Female	N/S	N/A	N/A
Representative 5	4,5	± 15	Female	N/S	N/A	N/A
Nurse 1	1,6	± 30	Female	N/S	N/A	N/A
Nurse 2	3,6	± 15	Female	N/S	N/A	N/A
Nurse 3	1,3,6	± 20	Male	N/S	N/A	N/A
Nurse 4	1,6	± 20	Male	N/S	N/A	N/A
Nurse 5	2	± 10	Female	N/S	N/A	N/A
Nurse 6	2,5,6	± 25	Female	N/S	N/A	N/A
Surgeon 1	2,4,6	± 25	Female	N/S	N/A	N/A
Surgeon 2	3	± 25	Female	N/S	N/A	N/A
Surgeon 3	1	± 40	Male	N/S	N/A	N/A
Surgeon 4	2,3	± 10	Female	N/S	N/A	N/A

All participants who attended at least one focus group. To preserve the animosity of the participants, age is only presented (in ranges) for patients, as age of the other participants is not relevant. Abbreviation: CR colorectal; IBD Inflammatory bowel disease; NS not specified; NA not applicable

RESULTS

The focus group interviews 1-4 lasted an average of 77 min (ranging from 74 to 81 min), and the in-depth interviews of groups 5 and 6 lasted 50 min and 122 min, respectively. As presented in Table 2, twenty-one participants attended the interviews, including six patients, five patient representatives, six nurses, and four gastrointestinal surgeons. Of the nurses, three were specialised in stoma care, two were head of the surgical ward, and one worked in the surgical ward. Patients had a mean stoma care experience of three years (ranging 0.5-8 years), while caregivers and patient representatives had a mean experience of 18 years (ranging 1-40 years).

Thematic qualitative analysis of the interviews identified five themes 1) perioperative information provision, 2) the need for information applicable to all patients, 3) the shortage of opportunities for peer contact, 4) contact with healthcare providers, and 5) information about stoma materials (see Figure 1). For the (sub)themes, it was discussed whether a mobile app would be beneficial, and this was supported by quotes. Participants were hopeful that a mobile app could solve some of the problems discussed, and expressed their insight into important aspects of developing an app and the functionalities it should have.

1. Perioperative information provision

1.1 Inadequate or contradictory information provision

Stoma nurses reported that patients tend to forget a lot of provided information during patient counselling, and they often had to replicate the information multiple times and / or on multiple occasions; in diverse settings. Patients recognised this and explained that they are under a great amount of stress when a surgeon explains they have to undergo surgery. This message is often so impactful, that having any other information just cannot be processed. Hearing about their disease and the surgery itself is a lot of information to take on at once, it simply prevents them from capturing or remembering additional information about dealing with a stoma. Not being able to process information about getting a stoma, inevitably results in patients unable to remember what is needed with respect to their stoma care, possible preparations before surgery, and how to set up adequate care at home. Patients also reported that different, but sometimes also the same healthcare providers at different times; give inconsistent, and even contradictory advice, which makes them feel insecure. Therefore, patients felt compelled to ask for the same or more information multiple times.

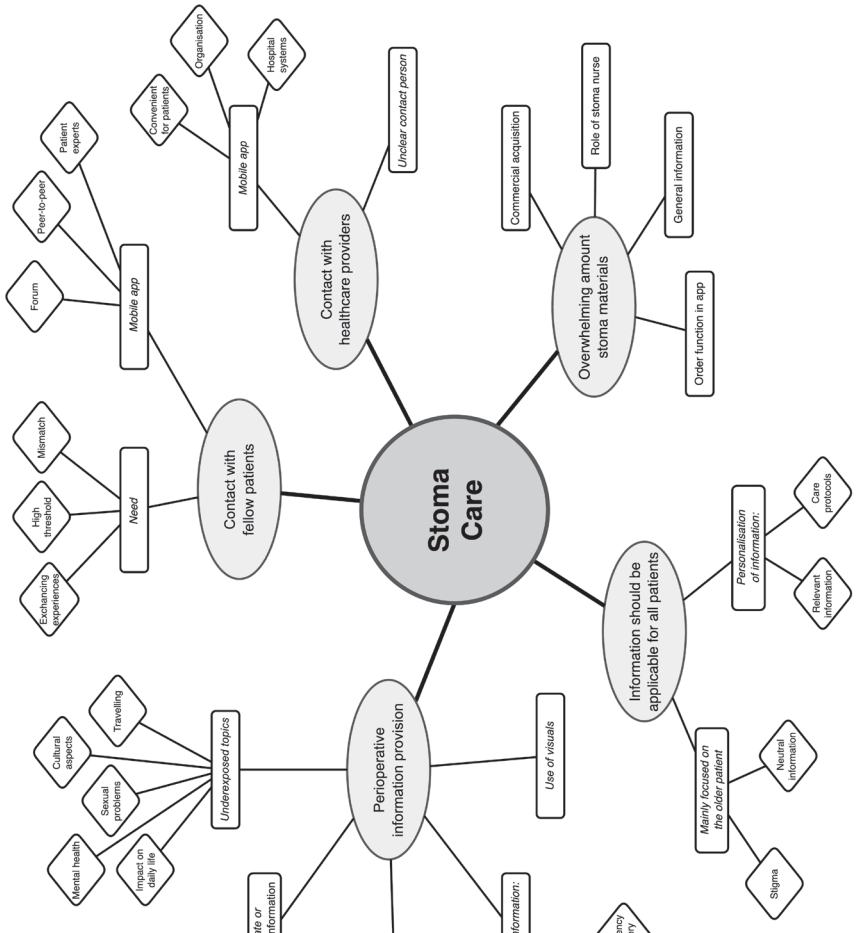

Figure 1: Thematic diagram

Patient 1 (FG4): *"One doctor says: 'You have to put the stoma bag on the left side' and the other doctor says otherwise. You know, this confuses people and they will get them in trouble".*

1.2 Underexposed topics

Patients who are new to a stoma face many challenges and questions during their care pathway. For instance, how should a stoma normally look, how do they recognise stoma-related problems in a timely manner, and how will a stoma impact daily life? Moreover, patients explained that healthcare providers fall short of advice on mental health, sexuality, and overall stoma care, and that it led to insecurity. Patients wished to have had better advice regarding these topics and emphasised the importance of providing adequate information on the impact of having a stoma on their mental health. Following that, patients indicated that psychosocial aspects and sexuality should be discussed in the app to prepare patients for their lives after surgery and how to cope with possible mental health problems. Cultural aspects can influence one's acceptance of a stoma, and should therefore be discussed in the app as well.

Patient 1 (FG1): *"..if there is a problem with my stoma... And, these problems are never told to me, how should I know how to solve them?*"

Patient 4 (FG1): *"I was once directed to that topic [sexuality] by a radiologist, and he discussed it with us. I found that very pleasant. None of the other doctors I have encountered paid any attention to this matter."*

Some patients had experienced uncomfortable situations with customer employees when travelling abroad, in which patients have to explain what a stoma is. They recommended that the app should provide a brief explanation of what a stoma in several languages. Moreover, they recommended a small 'tips & tricks' function for the most common problems abroad, such as obstipation, dehydration or not having enough stoma materials.

Patient 3 (FG2): *"Things like 'I have a stoma or I have stoma materials with me', if that could be translated in a few languages, it would be very helpful."*

1.3 Providing reliable and easy to find information in the app

Participants suggested that reliable up-to-date information in the app could benefit many patients, as inaccurate, contradictory and confusing information can be given by various caregivers. According to them, patients should be properly educated on how to prepare themselves for the operation, what happens during the operation itself, and what is considered appropriate after-care. Participants recommended that stoma care, stoma problems, self-management, and choice and use of different stoma materials should all be major topics in the app.

Representative 3 (FG3): *"…What is the moment you have to contact someone, so, what are dangerous situations? In that way, patients can be more aware and if they have a problem, they can see in the app: 'If you have this problem, you should immediately contact a healthcare professional, and if you have this problem, you can wait and see."*

Participants suggested a 'search function' which helps patients to easily find desired information without searching through the entire app, and an index list from A to Z. One patient suggested that the search function should include a 'descriptive function' that enables patients to describe the word or concept they are trying to find. However, one surgeon explained that implementing this function is difficult and expensive.

Patient 5 (FG 4): *"Suppose you have 'skin irritation', and you type 'skin irritation ' and the color of the skin. That can be searched through the text in the app."*

1.4 Timing of information:

Participants discussed that the timing and quantity of information in the app should be carefully considered and ideally, triggered when most likely to be relevant. Some recommended that patients receive information up to 6 months prior to surgery, while others recommended a timeline of only a few weeks before surgery, arguing that patients would most likely forget information when given too early. Information provided just before surgery ('just in time') was considered problematic too, as patients reported considerable stress just before surgery. Participants agreed that general information such as 'what is a stoma' and 'importance of exercise before surgery' could be given weeks or months before surgery, and topics such as stoma care, stoma materials, and fluid intake could be given only a few days before and after surgery. In this way, the information provided will be more relevant to the patient's situation and will therefore be more beneficial.

Patients who undergo emergency surgery cannot be provided with information weeks or months before surgery. For these patients, the information provision after surgery must be different. During hospital admission, emergency patients must be able to receive a limited amount of essential information, whereas less essential information should be provided later. Participants agreed that only important topics should be provided during the hospital phase, such a basic information of a stoma ('what is a stoma', and 'what does it look like'), and information on stoma care. All other information would be better to provide over the next few weeks. Participants emphasised that the information should be repeated multiple times.

Patient 3 (FG2): *"It is the own choice of patients what to with it, but…. It is a great start if patients can be notified with information or exercises before or after their surgery, or when they are back home."*

1.5 Presenting information with a good balance between videos, pictures, and texts

Most participants preferred pictograms, pictures, videos, and not too much text. Although one patient preferred the opposite: "I do not like to watch videos, I always skip them. I always read the text." All participants agreed that the visual aspect is important. Having too much text would increase the risk of the app not being appealing and the app would look like a textual website, rather than use the opportunities of an app. An app should be inviting, easy to use and appealing.

> Patient 3 (FG 2): *"You should provide multiple options, because one may like to read a text, and someone else prefers a video or pictures."*

2. Information should be applicable for all patients

2.1 Mainly focused on the older patient

Patients noticed that written information was often focused on older patients, thus not adequately addressing the needs of younger patients. Often, only older patients are displayed in flyers, websites, and other resources. Patients mentioned that there is a stigma that only 'older' people have a stoma. Younger patients felt that they are invertedly placed in the category of older patients, which feels unjust and may revoke a younger patient from further reading. Younger patients wanted more 'neutral' information, which is not specifically focused on the older patient. Representatives involved in stoma-related information resources recognised this problem.

> Surgeon 4 (FG2): *"Of course, I have seen these websites myself and the information is focused on the older patients. However, there are so many young patients with a stoma. I get what you [the patients] are saying."*

2.2 Personalisation of information

Some participants recommended providing personalised information in the app, because some information may be less important to some patients than others. For example, information regarding urostomy is not informative for patients with an ileostomy. Participants agreed that information should be personalised based on stoma type, age, sex, and underlying disease. In this way, all information provided is relevant, as information shown is tailored to the situation. However, some doubted the benefit of a personalised app because they felt that it may be too difficult to cater to all individual needs. Participants recommended that all information should be accessible so that, if needed, patients could read topics that were not included in their personalised app.

In addition, stoma care protocols can differ among hospitals, and, therefore, it can be challenging to inform patients about certain themes, as there is not always an 'apply to all'. For example, one nurse explained that patients should contact their hospital if they

have a stoma output of > 900 ml, whereas another nurse defined a high-output stoma as an output of more than 1200 ml. To prevent patients becoming confused about possible contradictions between the information in the app and the information given by their caregivers, participants agreed that the app should contain a statement that patients should always follow the protocol given by their own caregivers.

> Surgeon 2 (FG3): *"Can I go to a festival?' Those questions I get from younger patients. But there are also 35 years old patients who are sitting home with their three children, so... It is difficult to personalize something so specific, because it will never include every patient."*

3. Contact with fellow patients

3.1 The need for peer contact

Patients and their representatives explained that contact with fellow patients is important. Patients can benefit from exchanging their experiences and useful information. To date, patients have experienced difficulties in contacting fellow patients. Some participants mentioned that the threshold to get in contact could be too high, or that patients were not matched according to their personal situation and preferences. One patient reported that he was connected to a 30 years older patient whose interests and experiences did not match with his as a result of their age gap. Patients expressed that contact with fellow patients should be easier, preferably with patients of the same age and interests.

> Patient 4 (FG4): *"If I look at what I wanted back then, I had the desire to talk to someone. Not on a forum, there is sufficient information on the internet. I just wanted to talk to someone who shared the same experience as me, but the threshold was too high."*

3.2 Peer contact in a mobile app

Participants expressed that contact with fellow patients facilitated in an app would be helpful. Three types of fellow peer contact in an app were discussed. A forum could be implemented in the app, in which a patient can ask a specific question and all other patients can respond to share their experience or knowledge on this topic. A forum can provide access to opinions and insights of many patients, rather than just one opinion. However, participants suggested that patients have less privacy if specific questions can be read by all other patients, and the representatives of patient associations explained that they already have an online forum on their website and in Facebook groups and recommended using the forum on the existing platforms instead of building it in the app.

The possibility of integrating a platform with peer-to-peer contact in the app was discussed, so that patients could interact with others to give or receive advice, or with

the intention to become friends. As such, patients can bond and share experiences and feelings that non-peers may not understand easily. Another option would be to provide patients with a one-to-one chat selected expert patients, who have more experience in giving advice to other patients and dealing with difficult questions. Here, the goal is to ask about stoma-related problems and advice, and not to become friends. This option would require an extensive budget, as expert patients should be hired, trained, and managed. Representatives of stoma-related associations expressed their preference for experts in a controlled environment.

> Patient 6 (FG1): *"I really missed having some fellow patient contact." Interviewer: "How can we solve this problem though a mobile application?" Patient 6: "I think… a sort of community chat group. So, you can ask questions."*
>
> Representative 4 (FG5): *"We have two possibilities: there are people wishing to become friends with other ostomy-patients, or get a relationship. But if they know they did a special course and are trained, then they are more like semi-professionals."*

4. Contact with healthcare providers

4.1 Unclear contact person in case of issues/problems

Patients expressed that it can be difficult to know which healthcare providers should be contacted to address a specific question. Normally, a stoma nurse is the first contact person for all stoma-related questions. However, patients see many healthcare providers during the perioperative period, and they struggle to have a good overview which healthcare providers should be contacted. An overview in the app is considered helpful.

> Patient 2 (FG2) *"There are so many channels you can ask questions. This also creates a problem. You think 'To who am I going to ask that question?' because I have so many contacts at once right now. If there is perhaps such an overview in an app… "*

4.2 Contact a healthcare provider in a mobile app

Patients suggested that direct contact with stoma nurses would make it easier for patients to ask questions and prevent unnecessary hospital appointments. However, a surgeon explained that it would demand that nurses answer in a short period, putting too much pressure on them, and that the system should be waterproof, guaranteeing that all questions indeed arrive at a nurse. It would not be possible to create such a large organisation for this app. Furthermore, hospital systems do not advocate patient information to 'land' outside the hospital record in an independent app, risking lost to follow-up of information in the patient file. Therefore, participants suggested a list of nurses, dieticians, and physiotherapists, so that patients could find these healthcare professionals more easily if needed.

Representative 1 (FG2) *"Actually, you would like to have a page somehow. So, you know the physiotherapists described in this app really understand it. This applies for dieticians as well."*

5. Overwhelming amount stoma materials

Patients experience the choice of stoma materials and suppliers as excessive and overwhelming. After surgery, patients often receive a large amount of stoma materials from different suppliers in an attempt to acquire more customers. A stoma nurse explained that over 300 types of stoma plasters are available, and patients were indeed overwhelmed by the choice of materials, unknowing what type of material fits best. Stoma nurses stated that hospitals purchase stoma materials from only a few suppliers, which makes it difficult for them to council patients about all materials. In addition, a stoma nurse explained that insurance companies determine which material from which supplier is reimbursed, resulting in a limited choice for the patient. And on top of that, patients may have different insurance providers and packages. Therefore, it is difficult for nurses to have a full overview, and also difficult for patients to switch suppliers -based on their preferences.

Patient 4 (FG1) *"You are talking about a convex skin plate. Well, I don't know what that is. I can imagine it, but I don't know what it is. That should be in the app, it should say that there is a one-piece system: what it is, what the advantages are, what the disadvantages are, and there are two-part systems, what the advantages are, what the disadvantages are. But it doesn't have to be that there are green, yellow or blue, or dots."*

Participants agreed that general information about stoma materials and suppliers should be provided in the app. Stoma nurses indicated that too much detailed of information would be unnecessary and may even increase the problem of patients feeling overwhelmed. They expressed that patients need to be properly informed by a nurse on different materials fitting their requirements. In addition, patient suggested an ability to order stoma material through the app to be of high value. This, to ease the process of ordering material, and obtain a better overview of all suppliers and materials. Other participants also stated this could be used to create funding to maintain the app by asking suppliers for a fee for an order.

Representative 3 (FG2): *"If you have an app where you can see if the stoma material is a right fit for you and you get a web-link to the supplier, it could be a funding."*

DISCUSSION

Providing adequate stoma care is essential for patients' well-being and quality of life. This enables them to cope adequately with a stoma and reduces psychosocial problems and stoma-related morbidity. Although patients were generally satisfied with their received stoma care, several shortcomings were identified in preoperative information and care in acute and postoperative situations. As patients indicated that a mobile app may be beneficial, it may provide a sustainable solution to improve stoma care.

Our findings identified five key themes in stoma care: 1) perioperative information provision, 2) the need for information applicable for all patients, 3) the shortage of opportunities for peer contact, 4) contact with healthcare providers, and 5) information about stoma materials. These problems, especially when combined, may affect patients' insecurity and self-efficacy, and thereby their quality of life. All participants expected that an app would be useful, and be able to improve information provision and peer contact. They emphasised that it is essential that the app provides up-to-date and reliable information which can be consulted and searched anytime, and that the information is presented in a visually attractive way. Topics on mental health and sexuality deserve attention in the app, as this is usually insufficiently explained by caregivers, which has also been reported by other studies.[5,20-22] Personalisation of the information could improve the relevance and user convenience of the app, mainly for the younger patients. However, it is challenging to consider all individual needs or hospital-specific protocols; therefore, it should be considered to limit personalisation to a few factors; triggered by important moments such as time of surgery and hospital discharge. Furthermore, patients expressed that fellow patient contact is important and that the app can improve peer contact. In other studies, patients also indicated that peer contact is essential.[23] Peer contact in the app should considered to be designed as peer-to-peer chat contact next to the existing platforms in the Netherlands.

Developing and maintaining a medical app is costly, as it must comply with the European Medical Device Regulation (MDR), incurring additional expenses.[22] Therefore, spending of available budget to build app functionality is something to consider carefully. It's crucial to prioritize functionalities when allocating the limited available budget. What is nice to have, and what is a need to have? Participants suggested that cooperation with different stoma material suppliers could increase options in case of budget constraints. During the interviews, several expensive functionalities were suggested, such as the possibility to have direct contact with a stoma nurse, a 'descriptive' search function, and contact with expert-patients. Although the wish of having a 'direct line' with a stoma nurse is understandable, one should be careful not to build an app that interferes with the regular caregiver interaction or hospital policy in terms of having all patient advice solely being routed via the hospital electronic patient file; not accepting alternative routes.

To date, healthcare is on the lookout for the smart use of digital solutions in times of limited care provider availability and -resource. A well-designed mobile app has the potential to support healthcare, contributing to several aspects, such as information provision, communication between patients or between patients and their healthcare provider, and perioperative guidance.[2] Research indicates that a Chinese app improved patient outcomes for those with a stoma, while a Turkish app did not.[13,26] However, both apps had limited functionality that did not fully align with patients' desires described in this study, with the Chinese app primarily focused on appointment scheduling, chat communication with stoma nurses, and photo uploading, while the Turkish app offered information and contact details for Turkish stoma care units. The clinical effectiveness of an app is reliant on proper design and development. To ensure usability, we conducted a quantitative study[12] and this qualitative research on stoma care, studying patients' specific needs and desired functionalities. It's crucial to involve the target group and stakeholders actively in the development process to guarantee usability. Additionally, recognizing patients' varying levels of digital literacy is important, as not all may have the necessary proficiency with mobile devices.[12] As such, the app should cater to this as much as possible and provide support for patients who need help in using it.

Although not reported in literature, a strong opinion, role or verbalism of a sole participant in a focus group may influence others in the same group - or even prevent others from verbalising their thoughts.[27] Such risk was mitigated by strong focus on creating a comfortable atmosphere on forehand, a group leader aware of this and asking all participants for their opinions during the interviews. We did not notice any limited expressions of the participants. In addition, the setup of the participants was different in every interview, as it was not possible to organise interviews with the same participants. This could have led to different dynamics between the participants in the interviews and, ultimately, to different outcomes. It is important to note that participating patients may not be a good representative of the 'average' patient. Most likely, our participants were more actively involved in their own stoma care, or perhaps better educated or skilled as they were members of patient associations. Purposive sampling was used to minimize this limitation. Finally, the last three interviews were conducted online because of Dutch COVID-19 restrictions. Based on previous studies showed virtual focus groups may result in participants being more relaxed and involved in the group discussion.[28] However, in our study, we experienced that discussions in online meetings were less fluent because of connectivity or audibility problems.

CONCLUSION

Stoma care can be much improved to date, as patients face important problems that cannot be well addressed in the traditional care pathway. They are in need of on-demand, and reliable information they can revisit when needed, fitting their personal circumstances. In this study, we discovered some key problems that the participants thought could be overcome by the development of an app. The app must provide up-to-date and reliable information, be visually attractive, and facilitate peer contact. After development, the safety and effectiveness of the app should be evaluated in clinical research.

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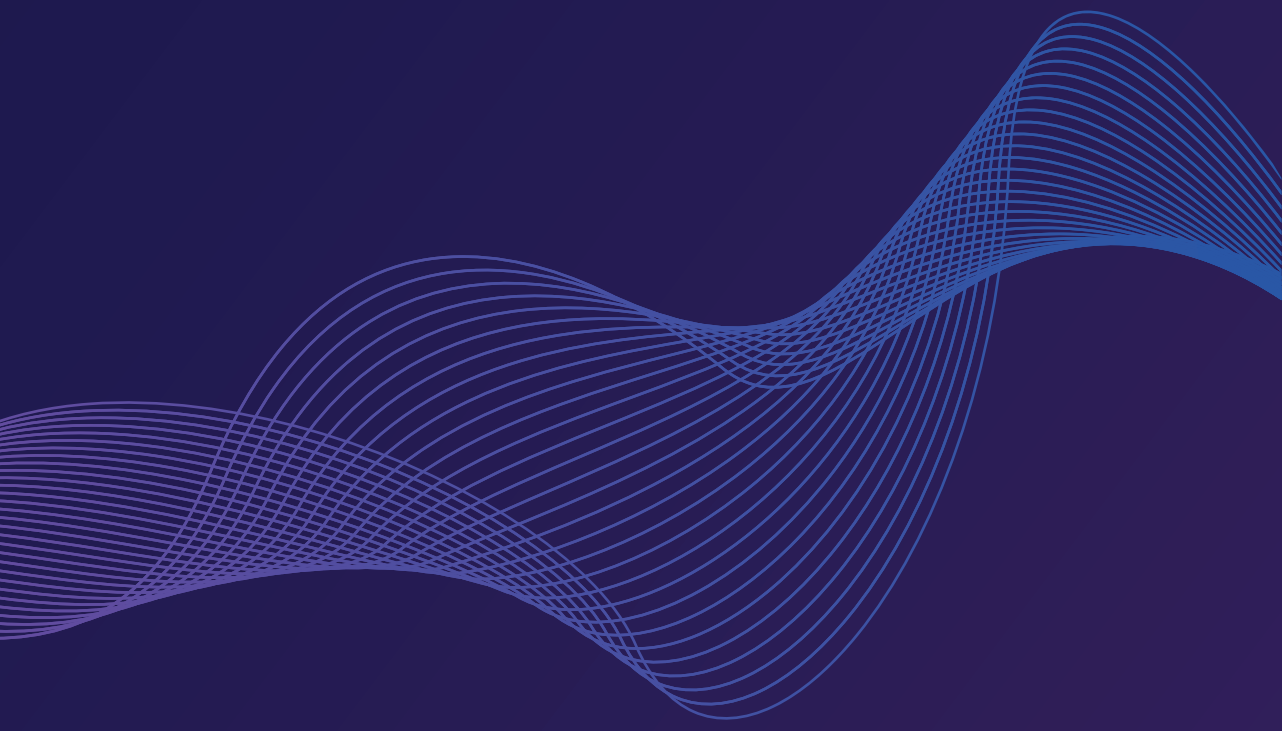
PART III

CLINICAL TRIALS

CHAPTER 5



A personalized app to improve quality of life of patients with a stoma: A protocol for a multicentre randomized controlled trial

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ABSTRACT

Introduction: Proper education, guidance and support is crucial before and following creation of a stoma. Patients with a stoma and their close relatives need to adapt to and cope with this new – and sometimes unforeseen – situation, which may result in insecurities and a variety of psychosocial problems. Self-efficacy is associated both with a reduction in psychosocial problems and with improved quality of life. The main objective of this study was to investigate whether self-reported quality of life of patients with a stoma can be enhanced by offering personalized and timed guidance, as well as peer contact, in a patient-centred mobile application.

Method: A multicentre, double-blind, randomized controlled trial will be conducted. Consented adults >18 years of age who will receive an ileostomy or colostomy and possess an eligible smartphone will be included. The intervention group will be given the full version of the application (containing personalized and timed guidance, such as operation-specific information and information on the associated care pathway) to install on their smartphone. In addition, the intervention group has access to a protected peer-support platform within the app. The control group will receive a restricted version of the application that contains only generic (non-personalized) stoma-related information. The primary outcome is quality of life, 3 months postoperatively. Secondary outcomes are Patient Reported Outcome Measures (PROMs), such as psychological adaption, as well as number of complications, re-admission and re-operation rates and the length of hospital stay.

Results: Patient enrolment began in March 2021. Data collection was not complete when this protocol was submitted.

Conclusion: We hypothesize that patients with a stoma who are supported by the intervention version of the app will report a significantly higher quality of life than patients with a stoma who are supported by the control version of the app (i.e., are not offered personalized and timed guidance and information and do not have access to peer support in the app).

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INTRODUCTION

It is estimated that over 7000 new stomas are created annually in the Netherlands.[1] The creation of an ileostomy or colostomy may be required for colorectal malignancy or inflammatory bowel disease. For the patient, having a stoma may negatively affect their self-image and daily functioning, which most likely will result in a reduced quality of life.[2-4] Especially in the initial postoperative period, patients must adapt to the new situation. Coping with a stoma may be difficult, resulting in insecurities that can lead to psychosocial problems, such as depression, stress, anxiety, decreased social participation and sexual problems.[5] Patients are also at risk of stoma-related morbidity (the incidence of which varies from 20% to 80%), with peristomal skin problems and leakages being the most common complications.[6,7] Self-efficacy is associated with a reduction in psychosocial problems and stoma-related morbidities.[8,9] Hence, patient education and guidance are crucial both pre- and postoperatively. Several educational stoma-care programs have been described in the literature, all of which have shown positive results in terms of psychosocial skills, self-efficacy and quality of life.[10,11] However, providing personal and adequate stoma care both in and out hospital settings can be challenging. In general, Dutch patients were only moderately satisfied with the stoma care they received, and several shortcomings were reported in information provision, the postoperative care and contact with fellow peers.[12,13]

A tailored personalized mobile application (app) may be an important and eligible addition to regular stoma care to improve information provision and contact with fellow peers. [12,13] An app, if properly designed in terms of content and regulations, has great potential to provide support, whenever needed, to patients with a stoma. It is essential that the app provides up-to-date and reliable information which can be consulted and searched at any time, and that the information is presented in a visually attractive way.[13] Reliable and easy to understand information on how to cope with a stoma and what is considered 'normal' and what is not, and the possibility for peer-to-peer contact between patients, may be very important in the perioperative phase, but also to fall back upon later. Access to such information at any time may facilitate acceptance, self-confidence and self-efficacy, and may help a patient regain control over their new situation, possibly resulting in a decreased demand for caregivers. By conducting this double-blind randomized controlled trial (RCT), we aimed to investigate whether personalized and timed guidance, as well as peer contact, in a patient-centred mobile application can significantly improve the quality of life of patients following placement of a stoma compared to patients with no personalized and timed guidance or peer contact.

METHOD

Study setting

The Stoma APPtimize trial is a double-blind multicentre RCT that will be conducted in the Netherlands. APPtimize is a blended word, combining 'APP' and 'timize' from 'application' and 'optimization'. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement will be followed, and the trial will be reported in accordance with the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth (CONSORT-EHEALTH) statement. The Stoma APPtimize study will be conducted in accordance with the Declaration of Helsinki. A written informed consent form is required to participate in this study. Approval for this study was obtained from the local Medical Ethics Committee (registration number NL75119.018.20), and the study is registered on the International Clinical Trial Registry Platform (NL8895).

Study population

The study population consists of patients scheduled for elective or emergency ileostomy or colostomy. Patients must be 18 years of age or older and possess a smartphone operating either iOS 9 or Android 8.0, or more recent versions. Patients who meet one or more of the following criteria will not be considered for inclusion:

- A Karnofsky score of ≤ 40
- Unable to understand the Dutch language
- Visual impairment, unless well corrected with visual aids
- Physical disabilities limiting the use of a mobile application, such as Parkinson's disease
- Patients with pre-existing skin conditions, such as pemphigus, para-pemphigus and psoriasis.

Investigational intervention

Content development

We conducted a survey study among members of stoma-related patient associations to assess patients' satisfaction and their specific needs in stoma care.[12] In a focus group interview study, we aimed to gain a deeper understanding of the problems faced by patients and to determine how to improve these problems by using an app.[13] Both studies were used to develop a blueprint for the mobile application. The content of the app is based on the Dutch Ostomy Care Guidelines and on information already available from the patient associations.[1] The blueprint was iteratively evaluated by 'expert' healthcare providers and patient representatives.

Technical development

The application is developed by a third party. The application works on smartphones compatible with the operating systems either iOS 9 or Android 8.0, or more recent versions. Smartphone applications influencing the diagnosis, treatment and monitoring of diseases are considered as medical devices and need to meet additional quality and safety requirements.[14] The 'Stoma App' application is developed specifically for patients undergoing ileostomy or colostomy surgery with the aim of providing personalized and timed guidance and facilitating peer contact and is therefore considered a medical device. The app is CE-marked (NL-CA002-2020-53630). The app is built to comply with the General Data Protection Regulation and follows the data and security guideline ISO 27001.[15]

Usability testing

The usability of the application was tested by a group of patients, representative of two stoma-related patient associations and the Dutch Ostomy Nurse Association, and health-care providers. The usability and weaknesses of the application were evaluated in several walkthrough sessions, and adjustments were made. Furthermore, the application will be monitored continuously during the trial.

Intervention group

Patients in the intervention group use the application immediately after inclusion until 1 year postoperatively or stoma reversal. The main goals of the application are: (1) to provide reliable information, (2) to stimulate self-management and self-confidence, (3) to monitor the progress of self-care and self-management, and (4) to provide support to patients from fellow peers. Figure 1 shows the layout of the application. The information will be provided in an information library, including illustrations and videos, and in a personalized timeline, both based on the Dutch guideline for stoma care.[1] The timeline is personalized based on the type of stoma (ileostomy or colostomy), type of surgery (elective or emergency) and operation indication (malign or benign) and is timed based on the date of the operation and the date of discharge from hospital. As these dates can change due to unexpected circumstances, patients can change these dates when necessary. To prevent the patient from becoming overwhelmed by unnecessary information, the timeline shows information only when it is relevant. All information received by the participant can be recalled at any time. Questions or notifications will be pushed through the application to inform and prompt the patient. The questions also function as a registration tool for fluid intake and stoma output and for the elements of stoma self-care that are fulfilled. This may improve the insight of patients regarding their progress in self-management. Patients will also be able to have peer contact with other patients using the public (restricted) version of the application. A suggestion list of peers, all of whom can be contacted, is generated based on the type of stoma, operation indication, and age and sex of the patient. Only

patients with a declaration by their general practitioner, surgeon or ostomy nurse will be given access to the platform in the public version of the application.

Control group

Patients in the control group use the application immediately after inclusion until 1 year postoperatively or until stoma reversal. The control group receive a restricted version of the application that contains generic stoma-related information, which is not personalized and timed. This information is comparable with the standard patient information folders developed by the Dutch Stoma Association and based on the Dutch guideline.[1]

Outcomes

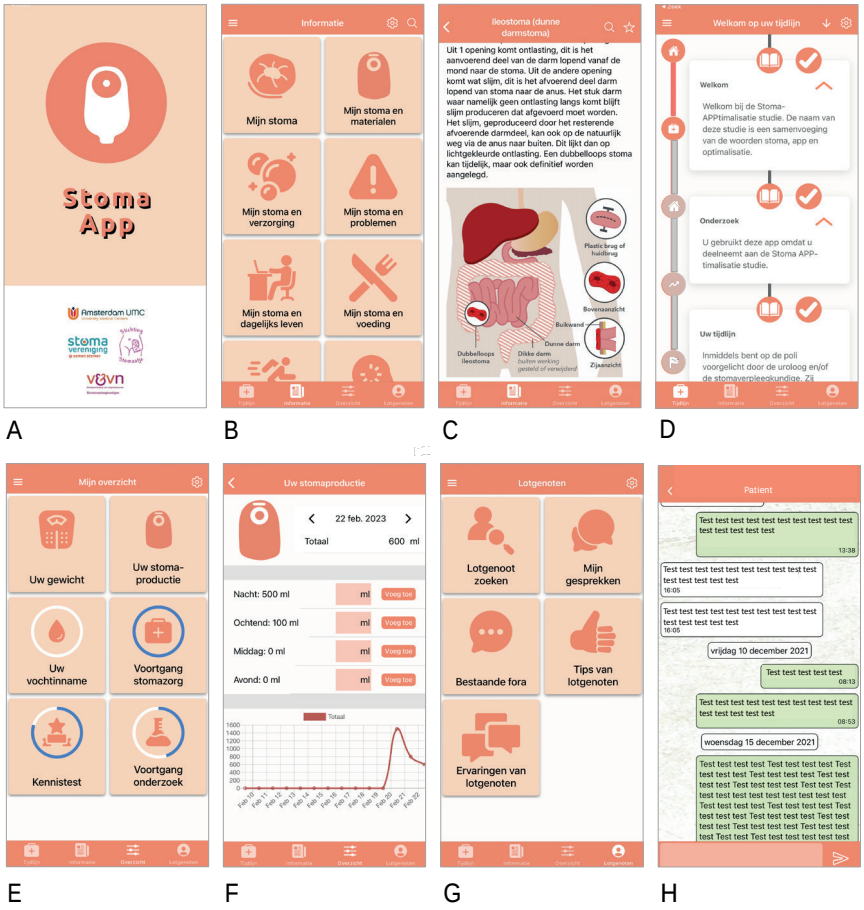
The primary outcome is stoma quality of life. As the application is patient-centred, providing personalized and timed guidance and a peer-support platform, the Patient Reported Outcome Measures (PROM's); patient satisfaction and psychological adaption, are considered as important secondary outcomes. Other secondary outcomes are postoperative outcomes, stoma-related problems and number of contacts with the ostomy nurse at the outpatient clinic. Table 1 describes all the study outcomes and how and when they will be measured.

Trial recruitment

1. Elective surgery that preoperatively is expected to result in creation of a stoma:

Preoperatively, the treating colorectal surgeon or supervised surgical assistant will introduce the Stoma-APPtimize trial; if the patient is interested in participating in the trial, they will be given the Patient Information Form (PIF). At the following outpatient visit, the ostomy nurse will explain the study and address any questions the patient may have after reading the PIF. Patients will be granted at least 24 h to decide whether they want to participate. After providing written informed consent, patients are randomized to either the control group or the intervention group.

Figure 1: Screenshots of the Stoma App



Screenshots of the Stoma App (in the Dutch language). A) The splash screen when starting up the app shows the cooperating patient and professional associations, B) The information library containing relevant information, C) Information and illustration of an ileostomy, D) The personalised information timeline which is personalised based on the type of stoma, operation setting, and operation indication, and timed based on the operation and hospital discharge dates read text boxes are ticked off and the left bar illustrates the patients process in the pathway (in this case, in admission), E) "My overview" in which patients can enter their process, F) Registration of the stoma production, G) Peer-support platform, the app provides a suggestion list of peers which is based on the type of stoma, operation indication, age, and sex, all of which can be contacted H) One-one peer chat.

2. Elective surgery that preoperatively was not expected to result in creation of a stoma, or stoma creation in emergency setting:

From 12 h after surgery, the treating colorectal surgeon or supervised surgical assistant will explain the Stoma-APPtimize, if the patient is well awake and the clinical condition permits. If the patient is interested in participating in the trial, they will be given the Patient Information Form (PIF) and will be allowed at least 24 h to decide whether they want to participate. After providing written informed consent, patients are randomized to either the control group or the intervention group.

Randomization and blinding

After inclusion in the study, the participant will be added to the application system by the ostomy nurse or the coordinating researcher. The system generates a unique personal access code which also randomly allocates participants to either the intervention group or the control group. Allocation will be performed in a 1:1 ratio, with stratification according to indication for surgery (benign or malignant) and type of stoma (ileostomy and colostomy). Random block sizes of two, four and six will be used. Participants and health-care providers will be blinded to the allocation outcomes. The coordinating researcher will provide instructions and is therefore unblinded. Participants will be instructed not to tell other participants or patients about the content of their version of the application.

Data collection

Data from the intervention and control groups will be mostly automatically collected and stored in a database. Self-reported questionnaires and reminder push notifications to fill them in will be sent automatically. Some data, such as baseline characteristics or clinical outcomes, will be retrieved from the electronic health record by the coordinating researcher and entered into electronic case report forms. Trial findings will be stored in accordance with local data protection regulations. A data protection impact assessment was included in the protocol.

The following baseline characteristics will be collected preoperatively: sex, age, American Society of Anesthesiologists (ASA) classification, body mass index, alcohol intake, smoking, Karnofsky scores, operation indication, comorbidity and mobile device proficiency.

Major per- and postoperative complications, prolonged hospital stay, readmission and comorbidities are considered as potential confounders. Healthcare personnel are instructed to register all potential confounders in the electronic health record. The coordinating researcher will screen potential confounders during follow-up of the participants.

Table 1: *Study outcomes and time points.*

Data measurements	T0	T1	T2	T3	T4	T5
Baseline characteristics						
General characteristics	x					
Disease related characteristics	x					
Postoperative outcomes						
Length of hospital stay			x			
Overall morbidity			x	x	x	x
Complications			x	x	x	x
Reoperations			x	x	x	x
Readmission			x	x	x	x
In-hospital mortality			x	x	x	x
Number of outpatients visits			x	x	x	x
Self-reported problems			x	x	x	x
Patient reported outcomes (PROMS)						
Mobile proficiency (MDPQ-16)	x					
General quality of life (WHOQol)	x		x			x
Stoma quality of life (Stoma-QoL)		x	x	x	x	x
Disability (WHODAS2)	x			x	x	x
Psychosocial adaption (OAI-23)		x	x	x	x	x
Patient satisfaction questionnaire						x

T0: At informed consent, T1: 2 weeks after surgery, T2: 1 month after surgery, T3: 3 months after surgery, T4: 6 months after surgery, T5: 12 months after surgery or end of follow-up

Sample size calculation

The quality of life of patients with stomas has been well described in the literature. In the study by Sier et al., the study population and the data analyses share similarities with the study proposed here.[16] In the study by Sier et al., patients received additional stoma care, in terms of home visits by a stoma nurse. The results from the study by Sier et al. were used as the best estimated reference values to calculate the optimal sample size in the present study. The average quality-of-life score in the study by Sier et al., measured using the stoma quality-of-life tool (Stoma-QoL), was 63.4 (SD = 10.5) for the intervention group and 56.6 (SD = 10.9) for the control group. We assumed that a patient-centred application would be of greatest benefit in the immediate postoperative phase, when patients need to learn how to cope with a stoma. We hypothesize that the QoL of patients in the group allocated Stoma-APPtimize would increase with 5.0 point, compared with 56.6 in the control group. Using a sample size calculation with 90% power, a two-sided alpha of 0.05 and an SD of 10.7, we estimated that 98 participants per study group are needed. A loss to follow-up rate of 10% was also estimated. Therefore, the total target sample size was set at 208 participants ((2 × 98)/0.9 = 208).

Data analyses

Statistical analyses of differences between the two groups will be performed using SPSS for Windows version 26 (SPSS Inc.). Data will be analysed according to the intention-to-treat protocol and any missing data will be imputed. Continuous data will be reported as mean and standard deviation for a normal distribution and as median and 95% CI for a non-normal distribution. Whether the data follows a normal distribution will be determined by visual inspection of the histograms and by analysing the data using the Kolmogorov–Smirnov test. The analysis will be performed using linear regression. Values of $p < 0.05$ will be considered statistically significant. Categorical data will be displayed as numbers and percentages and analysed using the chi-square test.

Trial discontinuation and withdrawal

The participants will be informed of their right to withdraw from the trial at any time and without any explanation. There will be no further follow-up of participants who have withdrawn, and data that have already been collected will be used. The follow-up of participants will end upon the reversal of their stoma (anastomosis of the intestine and stoma closure). After stoma closure surgery, participants will be invited to complete the questionnaires 12 months after surgery or at the end of follow-up. In the app participants will register themselves when their stomas are reversed. Participants who did not receive an ileostomy or a colostomy during surgery will be withdrawn from the study and replaced with a new participant.

DISCUSSION

Providing adequate stoma care enables patients to cope better with their stoma and therefore it is essential for improving their quality of life. Although the importance of stoma care has been reported, it falls short in several aspects. Innovative mobile applications have significant potential to overcome these shortcomings. To our knowledge, the Stoma APPtimize trial is the first study to evaluate a patient-centred mobile application that is truly based on patients' needs and desires. This is also the first study in which the control group used a (restricted) version of an app. Self-efficacy and patient engagement can be improved by using mobile apps.[17,18] A Chinese app specifically developed for stoma patients improved patient-related outcomes, such as self-efficacy, whereas a Turkish app did not improve any outcomes.[17,19] However, both apps have different functionalities and are less extensive than our app. In our opinion, the Stoma APPtimize trial is the only study that has conducted a proper process for the design and development of a stoma mobile application. Before development, we assessed the problems experienced in stoma care, in addition to patients' specific needs and desired functionalities. The target group and stakeholders were involved in the development of the app to guarantee its usability and relevance.

Moreover, to optimize its future implementation in standard care, the app is provided by ostomy nurses via the trial and publicized by patient and professional associations.

CONCLUSION

We hypothesize that patients supported by the intervention version of the mobile app 'Stoma App' are better supported and have more self-efficacy in their stoma care, and therefore will have a better quality of life than patients with a stoma who are supported by the control version of the app (and not offered personalized and timed guidance and information, or have access to peer support in the app). By simulating patients' self-efficacy, other clinical outcomes might also benefit.

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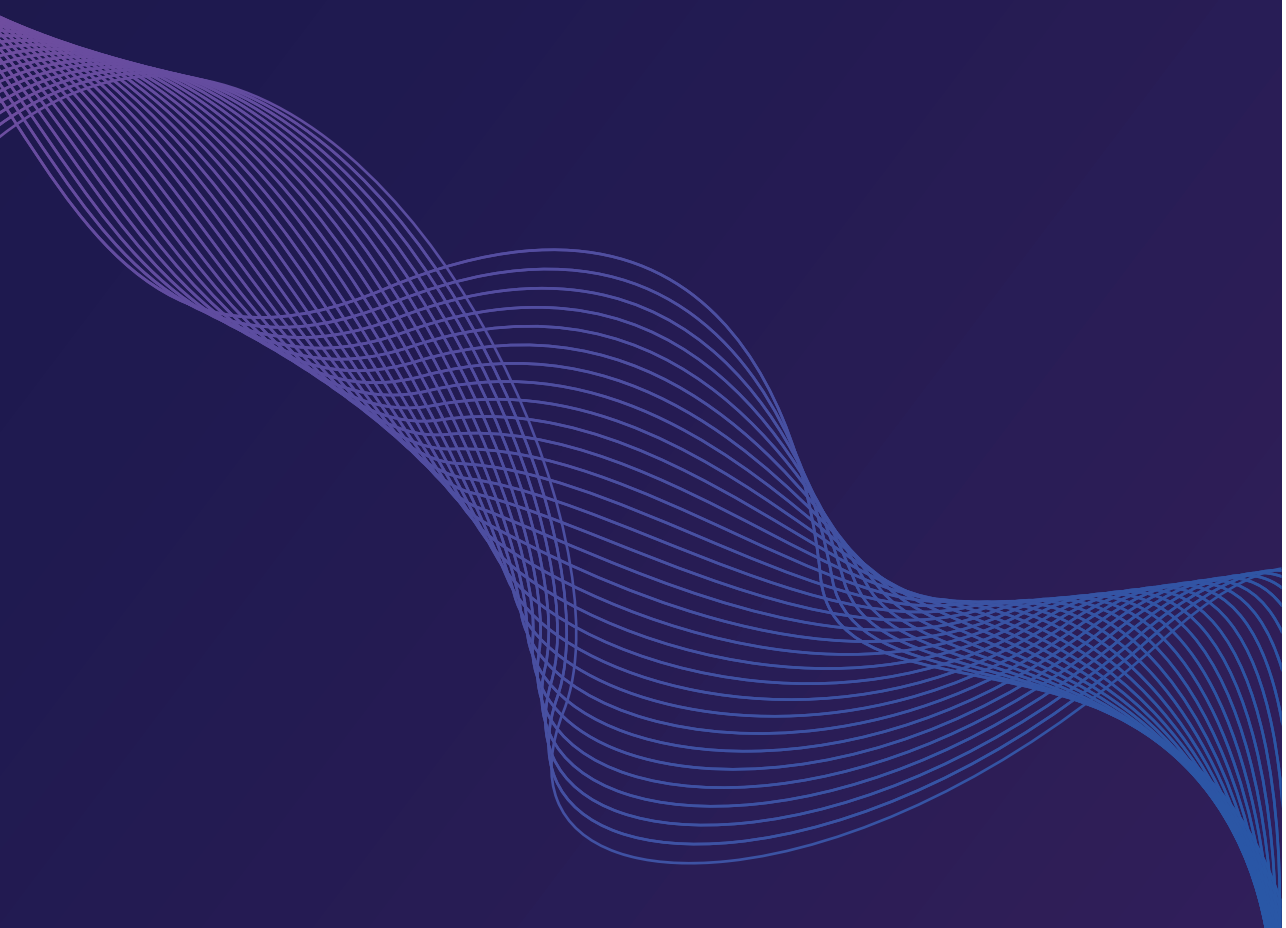
CHAPTER 6



Better Stoma Care using the Stoma App – does it help? A first randomised double-blind clinical trial on the effect of mobile healthcare on quality of life in stoma patients.

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ABSTRACT

Introduction: Receiving a stoma significantly impacts patients' quality of life. Coping with this new situation can be difficult, which may result in a variety of physical and psychosocial problems. It is essential to provide adequate guidance to help patients cope with their stoma, as this positively influences self-efficacy in return. Higher self-efficacy reduces psychosocial problems increasing patient's quality of life. This study investigates whether a new mobile application, the Stoma App, improves quality of life. And if personalized guidance, timed support, and peer contact offered as an in-app surplus makes a difference.

Methods: A double-blind, randomized controlled trial was conducted between March 2021 and April 2023. Patients aged > 18 years undergoing ileostomy or colostomy surgery, in possession of a compatible smartphone were included. The intervention group received the full version of the app containing personalized and time guidance, peer support and generic (non-personalized) stoma-related information. The control group received a restricted version with only generic information. Primary outcome was stoma quality of life. Secondary outcomes included psychological adaption, complications, re-admittance, reoperations and length of hospital stay.

Results: The intervention version of the app was used by 96 patients, the control version by 112 patients. After correction for confounding, the intervention group reported a significant 3.1-point improvement in stoma-related quality of life one month postoperatively (p=0.038). On secondary outcomes, no significant improvements could be retrieved of the intervention group.

Conclusion: The Stoma App improves the quality of life of stoma patients. Peer-support and personalized guidance are of significant importance in building self-efficacy. It is to be recommended to implement Stoma app –freely available software qualifying as a medical device- in standard stoma care pathways for the benefits of both patients and healthcare providers.

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INTRODUCTION

In the Netherlands, it is estimated that over 7,000 new stomas are created every year.[1] Ileostomies or colostomies may be necessary for patients with colorectal malignancy, inflammatory bowel disease, or to resolve or mitigate intestinal leakage for other reasons. Getting a stoma may negatively impact patients' self-image and daily functioning, leading to a reduced quality of life. [2-4] In the initial postoperative period, patients must learn to cope and adapt to the new situation which can be challenging. This may result in several psychosocial problems such as insecurity, depression, stress, anxiety, decreased social participation and sexual problems.[5] Patients are also at risk of stoma-related morbidity which has an incidence of 20-80%, the most common complications are peri-stomal skin problems and leakages.[6,7] Complications themselves can exert a significant negative impact on the mental and social well-being of patients.[8]

Self-efficacy has been found to be very important for patients having a stoma. When self-efficacy is high, psychosocial problems and stoma-related morbidities are effectively reduced. [9-10] Therefore, it is crucial to provide adequate patient education and guidance, especially in the immediate preoperative and postoperative period. Several educational interventions have demonstrated positive results in terms of enhancing psychosocial skills, self-efficacy, and quality of life.[11,12] However, providing adequate stoma care or obtaining information in the out-of-hospital setting can be challenging. In general, Dutch patients reported only moderate satisfaction with the stoma care they received, highlighting several shortcomings in information provision and postoperative care. Also, they express a need to be in contact with peer patients.[13,14]

A mobile application (app) may act as a medical device and have great potential to improve and support healthcare.[15] Introducing a personalised app as an addition to regular stoma care can provide stoma patients with important benefits. These benefits include easily accessible information that relates to specific circumstances, and the opportunity to engage in peer-to-peer contact with other patients in a safe, anonymous environment, if one should desire so.[13,14] Providing reliable and understandable information on stoma management is very important for patients. This should include what is considered to be 'normal' and what is not, along with the possibility for patients to interact and learn from other patients in the same situation (peers). Having access to such information at any time may contribute to acceptance, self-confidence, and self-efficacy, enabling patients to regain control of their new situation. In turn, this may reduce the demand for caregivers and potentially avoid returning to the clinic.

The app 'Stoma App' offers a wide range of relevant stoma-related information. It provides personalised and timed guidance and facilitates peer-to-peer patient contact. It includes –among others- step-by-step videos on how to take care of a stoma, information on stoma

materials, nutrition, exercise, emotional and sexual wellbeing and travelling. One is also able to self-monitor progress in stoma self-care. The layout of the full version of the Stoma App is depicted in Figure 1 in Chapter 6. The Stoma App is based on the Dutch Ostomy Care Guidelines and built with patients and providers, and caters to various patients' needs.[12,13] By conducting this double-blind randomized controlled trial (RCT), we aimed to investigate whether personalised and timed guidance, and peer contact in a patient-centred app significantly improves the Stoma quality of life (Stoma QoL).

METHODS

Study setting

The Stoma APPtimize trial is a double-blind multicentre randomized controlled trial that was conducted since March 2021 in two academic hospital centres and across twelve teaching hospitals in the Netherlands. Data collection for the short-term outcomes was completed in April 2023. The study was approved by the local medical ethics committee of Amsterdam UMC registration number NL75119.018.20). The study protocol has been published previously.[16] The study is reported according CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth) checklist.[17]

Study population

Patients were eligible if they received an elective or emergency ileostomy or colostomy, were aged 18 years or older and had a smartphone operating on at least iOS 9 or Android 8.0. Patients who met one or more of the following criteria were not considered for inclusion:

- Patients with a Karnofsky performance score ≤40
- Incompetence of understanding the Dutch language
- Visual impairment, unless well corrected with visual aids
- Physical disabilities limiting the use of a mobile app, such as Parkinson's disease
- Patients with pre-existing skin conditions, such as pemphigus, para-pemphigus, and psoriasis.

Group allocation and blinding

After inclusion, participants were provided with an unique generated access code that blindly randomized them to either the intervention or the control (1:1) group using block sizes of two, four, and six. Randomization was stratified for indication for surgery (benign or malignant) and type of stoma (ileostomy or colostomy). Only the coordinating researcher was unblinded as he provided the app's instructions. Participants were instructed not to

tell other participants or patients about the content of their version of the app. Participants used the app according to their own preferences without any intervention of the research team, however, they had the option the contact the research team for technical support if needed.

Procedures

Participants were supported by the app 'Stoma App' immediately after inclusion until three months postoperative or until stoma reversal. The intervention group had access to the full version of the app. In this version, information is provided in a generic information library, and personalised timeline triggering push notifications. These push notifications were used to inform and activate patients at specific times. All information could be recalled at any moment in time. Participants could watch instruction videos on stoma care, and register their weight, fluid intake, stoma production, and the process of stoma self-care. Participants also had the option to interact anonymously with other patients (who used the public, restricted version of the app).

The control group received a restricted version of the app that contained generic stoma-related information, lacking personalization and timing. This information was comparable with the standard patient information folders typically used in the Netherlands. Both groups were required to complete questionnaires through the app. The Stoma App is CE-marked (NL-CA002-2020-53630), complies with the General Data Protection Regulation, and follows ISO 27001 data and security guidelines.[18]

Outcome

The primary outcome is Stoma QoL. To correct for potential cofounding on digital literacy, participants completed a questionnaire on their mobile proficiency. Secondary outcome measures included psychological adaptation, postoperative outcomes, stoma-related problems, and number of contact moments with the ostomy nurse at the outpatient clinic.

Statistical analysis

The sample size was calculated based on the Stoma QoL score of 56.6 as retrieved as baseline from a previous study and the hypothesis that the Stoma QoL of the Stoma-APPtimize group would increase to 61.6. Using a sample size calculation with 90% power, a 2-sided alpha of 0.05, and a standard deviation of 10,7, we estimated that 98 participants per study group are needed. A loss to follow-up rate of 10% was also estimated. Therefore, the total target sample size was set at 208 participants ((2 × 98) / 0.9 = 208). Participants who did not receive an ileostomy or colostomy during surgery were excluded and substituted with new inclusions. Data was analysed according to the intention-to-treat protocol.

Statistical analyses of differences between the two groups were performed using IBM SPSS for Windows version 28.0. Baseline characteristics were summarized using descriptive statistics and compared between the intervention and control groups. Continuous data were reported as mean and standard deviation in case of normal distribution and as median and 95% confidence intervals in case of non-normal distribution. The normality of data distribution was analysed by visually inspecting the histograms. Categorical variables were presented as frequencies and percentages. Independent t-tests, Mann-Whitney U tests, Chi-squared tests, and Fisher's exact tests were used to assess differences between groups as appropriate. Multivariate linear regression with stepwise backward selection was used to account for the potential confounding and stratifying factors. A two-tailed p-value ≤ 0.05 was considered statistically significant.

Patient history was categorized as: none, minimal or extensive, with minimal history defined as one or two diseases generally not affecting or debilitating current quality of life (e.g., hypertension, appendectomy), and extensive history defined as having chronic diseases or several abdominal surgeries affecting or debilitating current quality of life.

Patient Reported Outcome Measurements (PROMs) were included in the analysis if the patient completed at minimum 80% of the PROM related questionnaires per domain. Missing data were corrected using the participants' mean outcome of the (domain of the) PROM. For missing values, a cut-off value of 20% was applied.

RESULTS

A total of 263 participants provided informed consent and were randomized. Of these participants, 36 participants did not receive the treatment allocation (did not download or use the Stoma App), 96 participants received the full version Stoma App (intervention group) and 112 received the restricted version of the Stoma App (control group, figure 2). The baseline characteristics of the participants, as presented in Table 1, were similar between the two groups except for a significantly worse overall preoperative performance score in the intervention group (87.0 vs 89.6, p=0.041). The mean age of the study population was 56 years; the majority received a colostomy (59.6%) and the majority was operated upon in a non-acute, elective setting (63.5%). Both groups expressed overall sufficient scores on the mobile proficiency questionnaire. On average, patients in the elective setting started using the app 21 days before surgery, while patients in the emergency setting started using the app 5 days after surgery. From the patients in the intervention group, 20.1% utilized the peer contact function at least once.

The results on the Stoma QoL questionnaire at two weeks, one month and three months postoperatively are presented in Table 2. At first sight, it appears that there were no significant improvements in the Stoma QoL for the intervention group. However, after adjusting for confounding factors using multivariate linear regression analysis, a significant improvement in reported quality of life was observed at the timestamp of one month postoperative (Table 3). Confounders included the quality of life at baseline, the readmission rate, and reported psychological problems.

Patients in both groups had five contact moments (face-to-face or telephonic) at the outpatient clinical with a stoma nurse in the postoperative phase. Patients in academic medical centres had significantly fewer contacts in total, compared to patients in teaching hospitals (2.1 vs. 2.8 at one month p=0.019; 1.5 vs 2.8 at three months p<0.001). This was independent from the incidence of stoma related problems, suggesting different postoperative pathways or low-threshold contact in teaching hospitals. Self-reported problems were present in both the intervention and control groups. Physical problems were reported by 74.3% vs. 69.4% of patients at one month (p=0.500) and 68.5% vs. 65.6% at three months interval (p=0.411). Similarly, psychological problems were reported by 72.2% vs. 73.2% of patients at one month (p=1.000) and 68.1% vs. 64.8% at three months (p=0.740). The readmission rate of the intervention group was significantly higher at one month after surgery (20.4% vs 10.0%, p=0.047). Most readmissions were due to intra-abdominal abscesses (7.2%) or ileus (2.4%), see Table 4. The number of reported comorbidities in the intervention group was significantly lower (9.7% vs. 20.9%). Other clinical and patient-reported outcomes were comparable between the groups (Table 5).

Figure 2: Treatment assignment and study flow

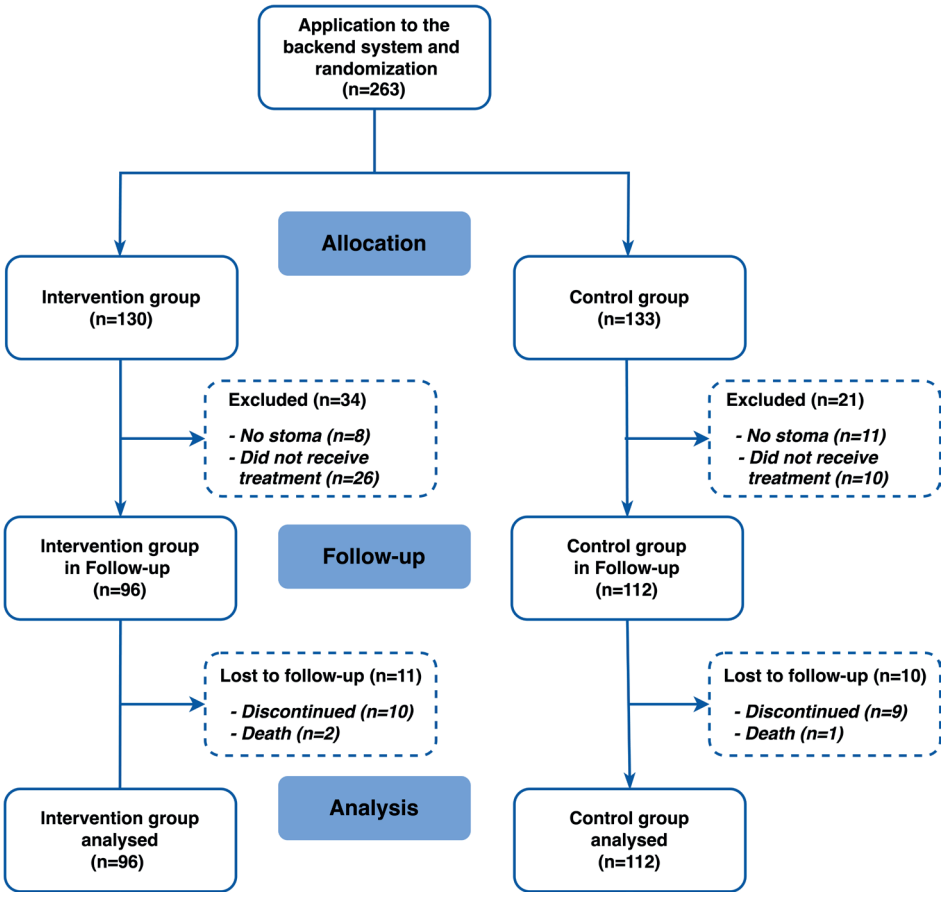

Table 1: Baseline characteristics of study population

Variable	Intervention (n=96)	Control (n=112)	*P*-value
Male Gender	54 (56.3%)	53 (47.3%)	0.213
Age	56.0 (13.4)	56.7 (14.8)	0.716
BMI	25.7 (4.5)	26.0 (4.7)	0.596
Karnofsky performance score	87.0 (9.2)	89.6 (9.4)	0.041
ASA			0.265
1	7 (7.4%)	17 (16.0%)	
2	67 (71.3%)	70 (66.0%)	
3	19 (20.2%)	17 (16.0%)	
4	1 (1.1%)	2 (1.9%)	
Patient history			0.377
No patient history	23 (24.0%)	20 (17.9%)	
Minimal patient history	26 (27.1%)	39 (34.8%)	
Extensive patient history	47 (49.0%)	53 (47.3%)	
Indication			0.578
Benign	46 (47.9%)	59 (52.7%)	
Malignant	50 (52.1%)	53 (47.3%)	
Setting			0.506
Elective expected ostomy	57 (59.4%)	60 (53.6%)	
Elective unexpected ostomy	5 (5.2%)	10 (8.9%)	
Emergency	34 (35.4%)	42 (37.5%)	
Type of ostomy			0.258
Colostomy	53 (55.2%)	71 (63.4%)	
Ileostomy	43 (44.8%)	41 (36.6%)	
Hospital			1.000
Academic	26 (27.1%)	30 (26.8%)	
Teaching	70 (72.9%)	82 (73.2%)	
Days to operation			
Elective	-21.1 (42.8)	-21.1 (43.8)	1.000
Emergency	4.8 (9.6)	2.7 (4.7)	0.227
Mobile proficiency*	68.4 (54.8-70.0)	65.4 (53.8-70.0)	0.219
General QoL			
Physical QoL	65.3 (20.6)	64.7 (24.0)	0.839
Psychological QoL	71.9 (14.7)	72.3 (14.0)	0.838
Social relationships *	83.3 (75.0-100)	83.3 (72.9-100)	0.404
Environment QoL	79.1 (13.5)	79.7 (14.7)	0.768
Disability score*	19.5 (15.0–27.5)	21.0 (15.0–30.3)	0.658

* Data presented as median (IQR).

Table 2: The Stoma QoL of the intervention and control group

Stoma-QoL	Intervention	Control	*P*-value
2 weeks postoperative	55.5 (11.1)	53.9 (11.2)	0.357
1 month postoperative	56.3 (10.9)	54.9 (12.0)	0.416
3 months postoperative	58.4 (12.1)	56.9 (12.3)	0.401

The Stoma QoL is presented as mean with the standard deviation.

Table 3: Multiple linear regression analysis of Stoma QoL.

Variable	B	95.0% CI		Standard error	*P*-value
Stoma QoL at two weeks					
(Constant)	30.738	21.894	39.583	4.479	<0.001
Intervention					
Intervention	1.929	-1.116	4.973	1.542	0.213
Control*	-	-	-	-	
Operation indication					
Benign	-1.801	-4.998	1.396	1.619	0.268
Malign*	-	-	-	-	-
Stoma					
Ileostomy	-2.081	-5.181	1.018	1.570	0.187
Colostomy*	-	-	-	-	-
Psychological QoL at baseline	0.361	0.251	0.472	0.056	<0.001
Patient history					
No history	-0.532	-4.659	3.595	2.090	0.799
Minimal history	-3.495	-6.986	-0.005	1.767	0.050
Extensive history *	-	-	-	-	-
Stoma QoL at one month					
(Constant)	39.182	28.8717	49.646	5.295	<0.001
Intervention					
Intervention	3.064	0.174	5.953	1.462	0.038
Control*	-	-	-	-	-
Operation indication					
Benign	0.989	-2.112	4.089	1.569	0.530
Malign*	-	-	-	-	-
Stoma					
Ileostomy	1.123	-1.858	4.103	1.508	0.458
Colostomy*	-	-	-	-	
Psychological QoL at baseline	0.167	0.032	0.302	0.068	0.016
Environment QoL at baseline	0.148	0.009	0.287	0.070	0.037
Readmission within 1 month	-6.628	-10.955	-2.301	2.189	0.003
Self-reported psychological problems	-11.791	-15.250	-8.333	1.750	<0.001

Variable	B	95.0% CI		Standard error	*P*-value
Stoma QoL at three months					
(Constant)	66.699	54.890	78.507	5.970	<0.001
Intervention					
Intervention	2.039	-0.747	4.825	1.408	0.150
Control*	-	-	-	-	-
Operation indication					
Benign	1.870	-1.289	5.030	1.597	0.244
Malign*	-	-	-	-	-
Stoma					
Ileostomy	0.568	-2.337	3.472	1.468	0.150
Colostomy*	-	-	-	-	-
Psychological QoL at baseline	0.147	0.033	0.262	0.058	0.012
Self-reported psychological problems	-8.445	-11.475	-5.415	1.532	<0.001
Disability score at three months	-0.762	-1.013	-0.512	0.127	<0.001
Operation setting					
Elective *	-	-	-	-	-
Unexpected ostomy	-0.780	-6.138	4.578	2.709	0.774
Emergency	-3.440	-6.622	-0.257	1.609	0.034

Abbreviations: B, beta coefficient for Stoma QoL; CI, confidence interval. * Reference category.

Table 4: The indications for readmission

Indication for readmission	**N=208**
Intra-abdominal abscess	14 (7.2%)
Ileus or no stoma output	5 (2.4%)
Nausea	2 (1.0%)
Revision stoma	2 (1.0%)
Dehydration and/or electrolyte imbalance	2 (1.0%)
Pneumoniae	1 (0.5%)
Anastomotic leakage	1 (0.5%)
Wound infection	1 (0.5%)
Other	2 (1.0%)

Table 5: Secondary outcomes

Variable	Intervention	Control	*P*-value
Length of admission in days *	7.0 (5.0-11.5)	7.0 (5.0-11.3)	0.674
Ostomy related complications			
1 month	28 (32.2%)	34 (31.8%)	1.000
3 months	19 (23.2%)	24 (23.1%)	1.000
Other complications			
1 month	34 (38.6%)	34 (31.8%)	0.366
3 months	2 (2.4%)	4 (3.9%)	0.695
Comorbidities			
1 month	9 (9.7%)	23 (20.9%)	0.034
3 months	24 (28.2%)	29 (26.6%)	0.871
Readmissions			
1 month	19 (20.4%)	11 (10.0%)	0.047
3 months	18 (21.2%)	16 (14.7%)	0.258
Reoperations			
1 month	5 (5.4%)	13 (11.8%)	0.139
3 months	6 (7.1%)	9 (8.3%)	0.794
Outpatient contacts with stoma nurse*			
1 month	2.5 (1.8)	2.7 (2.0)	0.296
3 months	2.6 (2.3)	2.4 (2.0)	0.211
Self-reported physical problems			
1 month	55 (74.3%)	68 (69.4%)	0.500
3 months	50 (68.5%)	61 (65.6%)	0.411
Self-reported psychosocial problems			
1 month	52 (72.2%)	71 (73.2%)	1.000
3 months	49 (68.1%)	59 (64.8%)	0.740
General Quality of life (at 1 months)			
Physical QoL	64.7 (16.8)	62.3 (20.5)	0.400
Psychological QoL	68.5 (14.5)	68.2 (14.3)	0.875
Social relationships *	83.3 (66.7-100)	83.3 (66.7-83.3)	0.292
Environment QoL	77.4 (13.1)	76.1 (15.4)	0.556
Psychosocial adjustment			
2 weeks	69.6 (7.9)	69.2 (7.3)	0.702
1 month	68.9 (7.5)	68.4 (7.3)	0.652
3 months	68.7 (8.6)	68.5 (8.6)	0.845
Disability Assessment (3 months) *	17.0 (14.0-22.0)	17.5 (14.0-24.3)	0.812

* Data presented as median and interquartile range

DISCUSSION

Providing adequate stoma care is essential to help patients cope with their stoma and improve their quality of life. To date, it is reported in literature that patients experience a lack of adequate and personalized information provision, postoperative care, and support, and are in need of contact with peer patients especially when they are out of hospital.[13,14] To address these shortcomings and optimize stoma-care, a patient-centred mobile app tailored to meet the needs and preferences of stoma patients holds significant potential. This study examined the effects of having timely, individualised information and peer contact available via the Stoma App on patients with ileostomies or colostomies, as well as the value of having information that is both accessible and trustworthy.

The intervention version of the Stoma App demonstrated a significant improvement in the stoma quality of life by 3.1 (p=0.038) in the multivariate analysis, at one month after surgery. This finding holds significant importance, especially considering that the immediate postoperative period is often characterized by various insecurities and psychosocial challenges.[21] In this period, patients may not always have adequate self-efficacy, which may result in insecurity, social impairment, or isolation. In return, this may lead to an increase in emergency department visits without readmission (patients being insecure),[22] or in contrast, and even worse, to an increase in readmission (patients waiting too long to present themselves). [23] In our study, the Stoma App showed significant improvement in the primary outcome measurement 'quality of life' after correction for confounders, but not in the secondary outcome measures. Interestingly, the intervention group had a significantly higher readmission rate one month after surgery. This was primarily due to operation related complications such as intra-abdominal abscess or ileus (Table 4). It is highly unlikely that stoma-related guidance or peer-contact have any influence on these complications. The significantly lower Karnofsky performance score before surgery in the intervention group may attributed to the higher readmission rate. Co-morbidities were less frequently reported in the intervention group in the same period. This may result from underreporting in the intervention group, as complications or readmissions are likely to obscure other problems.

Two stoma-related apps have been described in literature with inconsistent user outcomes.[24,25] These apps were less capacious in content and user interface than the Stoma App, lacking a proper (user-) design and development testing process. In contrast, development of the Stoma App was based on an assessment of the actual problems that patients themselves reported to encounter in stoma care and their specific needs and desired functionalities.[13,14] To that end, we involved both patient associations and the stoma nurse association intensively. [26-28] Indeed, the target group and stakeholders were involved in the development of the app and in pilot testing, to ensure its usability and relevance. Possible features that the apps can offer to patients were explored in beta

testing before the app was registered in the app stores. This is a vital step in building good apps, as apps can provide many ways of providing information.

Although apps have great potential to improve and support healthcare, it is crucial that these apps are thoughtfully designed in terms of content and user-interface, maintain technical stability, and adhere to privacy and medical device legislation to ensure their effectiveness and safety. [29] When developing an app, one must realize that app features are sometimes costly to build, protect and maintain; and there is a 'nice to have' and 'need to have' that needs to be explored. It is important to acknowledge that apps are at risk of poor implementation and underutilization in healthcare if not built well. Addressing these concerns is crucial, as apps have additional features and benefits in comparison to a website or digital paper, which may positively impact patient care.[16] Therefore, to optimize and prepare for future implementation in standard care, the Stoma App was provided by ostomy nurses to their patients in this trial. And also, our partner in development and spreading insights -the Dutch patient associations- propagated the app and patient stories about it on their website and in their newsletters.

We deliberately chose not to compare the full version of the app with 'care as usual' –as we expected this outcome evaluation would be biased. Normal routine of stoma care consists of a one-time informative conversation with a physician or stoma nurse before surgery, possibly supported by a paper folder or a referral to a website. Providing information on a stoma -especially if the conversation immediately follows a conversation in which the message is given that one is diagnosed with cancer or another illness, is often not remembered by patients.[30] Thus, it is highly likely that having easily accessible information in an app on the own smartphone as an extra to normal routine will be valued more highly than not having such an app. Therefore, we compared two versions of the app to strengthen the evidence supporting the app's impact and adequately evaluate the effectiveness the design's add-ons, as suggested by patients. As the app was built with a subsidiary that is to be depleted, insurers require robust evidence to financially support an app built as 'software as a medical device'. We aim to keep offering this app free of charge to all stoma patients, in and outside of the Netherlands for many more patients to benefit from. For that, one needs evidence on the effect of the app as a medical device in patients as a whole; whilst considering the proposed benefits of the costly elements.

Although there was a significant increase in the quality of life of patients using the intervention version of the Stoma App, the uptake and utilization of the app can be further optimized. It is important to acknowledge that the Stoma App suffered from technical issues during the trial. Some of these were not adequately addressed or resolved in a timely manner by the app developer. These technical issues mainly affected the timed information feature of sending out push notifications to patient. This must be considered a crucial component of the timed intervention version of the app. This issue has now been

resolved in further development scaling-up the app, including migration of the app and choosing a different app developer. This needed to be done in order to futureproof and sustain the app, fitting current and future technical and legal requirements and operational stability. Building an app and researching it -even after committing to a pilot testing phase for technical issues- is a journey in itself. New insights are bound to be derived and are generated by actual use and implementation research itself. It is important to acknowledge this phenomenon, be transparent about it and act accordingly. It is encouraging that despite the technical issues, on the primary outcome measurement significant difference was noted. This strengthens our belief that with optimal functionality, the value of personalization and peer-support is likely to be higher than now visible.

The need for peer contact is frequently reported in literature by patients having a stoma.[11,13,14,22]. However, only one out of five patients in the intervention group used the peer contact function. This may indicate that, when asked, patients may have responded socially desirable to the question of whether peer support is important for them. It seems that for the majority of patients in our study, the opportunity to have peer contact via an app is not a 'need to have' feature, but rather a 'nice to have'. That said, one out of five patients used this feature, being either curious or in need of the support or opinion of a peer. It would be interesting to know, if these patients have a weaker social network than the ones who did not use it, but that could not be retrieved from data. And one may argue that one- out –of five is relevant number in itself to support the need for this feature.

Although the app is freely available in the app stores and publicized by patient associations, the involvement of local stoma nurses proved to be key in the process and success of the Stoma App.[30] The stoma nurses recruited and onboarded the patients for the trial, which took approximately 15 minutes. In addition, stoma nurses helped patients not familiar with app installation, and with overcoming some digital literacy issues using the app. We consider this to be a best-fit in the normal work routine, as patients in both groups needed a code to access the app. Of course, we needed to ensure that there were only patients having or getting a stoma as users in the app. Throughout the study, the participating stoma nurses were updated about course of the study and new app insights. Also, non-participating stoma nurses were informed about the trial and the app on national stoma congresses, many of them expressing interest in the app. In our study, as in many multicentre trials, patient recruitment varied between the study sites. That can be explained because some nurses actively integrated the app into the standard care pathway, while others did not and sometimes forgot about the app.

This study has several limitations. Mostly importantly, it is highly likely that the results were significantly and negatively influenced by technical issues within the intervention version of the app. When developing a mobile app, careful consideration should be given to selecting a qualified app developer. But one should also clearly agree on what is

included in app maintenance –and what are agreeable timeframes for maintenance- when an app is in trial. This, to ensure adequate support also after build and registration in app stores.[15] Although the developer possessed relevant certifications to ensure compliance to privacy and quality requirements, as well as having prior experience in the development of medical apps, the technical support and timely reaction time for this app proved to be inadequate. Especially for apps in medical trials, it is crucial to establish a solid agreement that obligates the developer to promptly detect and correct any technical problems that may arise. That said, even with the technical impairments now resolved, the intervention version of the app proved to be superior in supporting quality of life of stoma patients. Second, the intervention group had a significantly slightly worse preoperative clinical condition (and higher readmission rate) which may have negatively impacted the results. Third, the distribution of participants between the intervention and control groups was unequal, resulting from exclusions before receiving treatment (withdrawal, did not receive treatment), or because they did not receive an anticipated stoma. Consequently, this imbalance might have influenced the statistical significance of the results, as the differences in outcomes would need to be more substantial to be significant. Lastly, results may be biased as questionnaires were to be completed in the app itself. This method allowed participants to "click through" the questions quickly, potentially leading to less thoughtful answers and influencing the accuracy and reliability of the data collected.

To further explore and address the need for optimization of the uptake and utilization of the app, we are investigating facilitators and barriers in patients' and stoma nurses' engagement using semi-structured interviews. It is advised by our participating stoma nurses and authors incorporate the app into the care pathway, as the app requires limited time from personnel, it simulates consistent engagement and utilization by stoma nurses. By doing so, to provide more patients with the benefits of the app.

CONCLUSION

The Stoma App – software as a medical device- improves the quality of life of stoma patients. This is a significant step forward in the optimization of stoma care. The app provides patients with ileostomies or colostomies with personalized support, peer contact if they need or desire to have such contact on a voluntary basis and a reliable, easily accessible base of information. This study demonstrated the app's effectiveness in improving stoma quality of life in the critical postoperative period. Considering the study outcomes and the minimal time commitment required from healthcare personnel, it is highly recommended that the app be integrated into standard stoma care pathways.

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CHAPTER 7

Improving Enhanced Recovery After Surgery (ERAS): The Effect of a Patient-Centred Mobile Application and an activity tracker on Patient Engagement in Colorectal Surgery.

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Submitted

ABSTRACT

Introduction: The Enhanced Recovery After Surgery (ERAS) protocol improved perioperative colorectal care. Although the protocol is firmly implemented across hospital settings, there are benefits to gain by actively involving patients in their recovery. The main objective of this study was to investigate whether compliance with selected items in the ERAS protocol could further improve by using a patient-centred mobile application.

Method: This multicentre, randomised controlled trial was conducted between October 2019 and September 2022. Patients aged 18 years or older who underwent elective colorectal surgery, and in possession of a smartphone were included. The intervention group used a mobile application combined with an activity tracker to be guided and supported through the ERAS pathway. The control group received standard care and wore an activity tracker to monitor their daily activities. The primary outcome was overall compliance with selected active elements of the ERAS protocol.

Results: In total, 140 participants were randomised to either the intervention (n=72) or control group (n=68). The use of the ERAS App demonstrated a significant improvement in overall compliance by 10%, particularly in early solid food intake by 42% and early mobilization by 27%. Postoperative or patient reported outcomes did not differ between groups.

Conclusion: Supporting and involving patients is of great importance in optimizing perioperative care and best possible outcome of surgery. The smartphone application 'ERAS App' is able to significantly improve adherence to the active elements of the ERAS protocol for colorectal surgery; and thus, may be of importance in optimizing care for patients.

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INTRODUCTION

To optimize outcome for patients having to undergo colorectal surgery, the Enhanced Recovery After Surgery (ERAS) Study Group was formed.[1] This group published the first evidence-based consensus protocol for colonic surgery in 2005 and rectal surgery in 2009, both outlining and stressing the importance of a multidisciplinary and multimodal approach. The ERAS protocol consists of 24 core elements in the preadmission, preoperative, intraoperative, and postoperative phases.[2] ERAS elements can be categorized as requiring contribution from healthcare providers (passive elements), patients (active elements), or both (passive/active elements).[3] All elements work together in an effort to reduce surgical stress, maintain postoperative physiological function, and enhance mobilization after surgery,[4-8] resulting in a faster recovery, shorter hospital stay, and reduced rates of morbidity.[9-11]

High adherence to the ERAS protocol is significantly associated with markedly improved outcomes, such as shorter hospital stay, lower rates of postoperative complications, reduced 30-day morbidity, and lower readmission rates.[12-15] However, local implementation of ERAS protocols differ across medical centres. Even when clinical pathways are based on the same ERAS guidelines, implementation of the protocol and outcomes vary.[16] Protocol adherence were 69%, 72% and 53% during the preoperative, perioperative and postoperative phase respectively.[17] ERAS protocol compliance may be most essential in the early postoperative phase, as it stimulate early mobilization and resumption of oral intake, avoid discharge delay and minimize the overall risk of complications.[16] The provider-initiated part of the pathway include most ERAS elements which usually has high adherence.[3] The elements of the ERAS protocol that require patient involvement have the poorest compliance. There are benefits to gain here, as patient empowerment plays an essential part in improving patient adherence. [18,19]

In recent years, mobile healthcare applications (apps) and wearables have emerged as strategies to improve patients' adherence to treatment.[20-23] Apps can provide information, stimulate desired behaviour, enhance self-efficacy and empower patients allowing patients to take an active role in their own healthcare.[24-26] Several apps for postoperative recovery have been described in literature, however, the level of evidence and outcomes were varying.[23] Regardless of how promising this technology is, it is unclear for many apps whether outcome is properly measured and their use in the medical domain is safe and allowed under current legislation.[23] The “ERAS App” is an innovative app which combines stimulation of patient involvement in the ERAS with a personalised activity recovery program. The ERAS App offers an engaging approach to involve patients actively in their own care, providing timed information and recovery goals during the perioperative period. This randomized controlled trial (RCT) was conducted to assess whether the use of a

patient-centred app can significantly increase compliance with the active elements of the ERAS protocol in patients undergoing colorectal surgery.

METHOD

Study design

The ERAS APPtimize study is a multicentre RCT that was conducted between October 2019 and September 2022 at one academic hospital and four teaching hospitals in the Netherlands. The ERAS protocol was implemented into the care pathways of all centres, initiated at varying time points and accompanied by locally different adaptations. The study was approved by the local medical ethics committee of Amsterdam UMC (registration number NL63874.018.17). The study protocol has been previously published.[27] The trial was prospectively registered on International Clinical Trial Registry Platform (ICTRP); registration number NTR7314. The study is reported according CONSORT-EHEALTH(Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and online TeleHealth) checklist and the Reporting on ERAS Compliance, Outcomes, and Elements Research (RECOvER) Checklist.[28,29]

Study population

Patients were eligible if they underwent elective colorectal surgery for either malignant or benign disease, were aged 18 years or older, and were in possession of a smartphone running at least the operating systems iOS 9 or Android 8.0. Patients were excluded if they met any of the following criteria:

- Palliative surgery or surgery performed after neoadjuvant radiotherapy or chemotherapy
- Karnofsky Performance score ≤40
- Inability to understand the Dutch language
- Visual impairment, unless well corrected with visual aids
- Limitations in using mobile applications due to physical or mental impairments,
- Wheelchair-restricted
- Estimated pre-operatively if post-operative adherence to the ERAS protocol is not feasible
- Resection of multiple organs

Group allocation and blinding

After informed consent, patients were randomly assigned (1:1) using internet block randomization with block sizes of two, four, and six to either the intervention or the control group. Randomization was stratified by disease (benign and malignant) and age

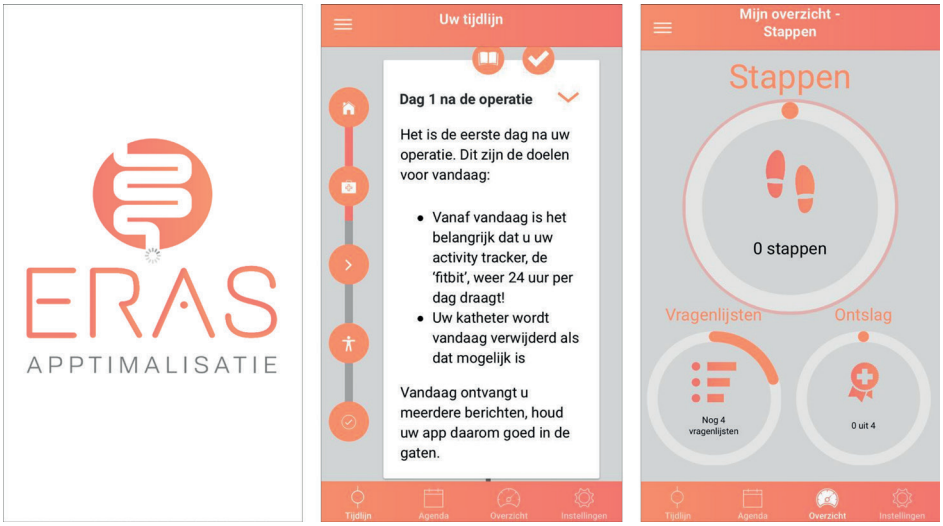
(< 50 years and > 50 years). Participants, their involved healthcare professionals, and outcome assessors of study were not blinded to the treatment allocation as one group received the ERAS App and the other group did not. Participants were instructed not to tell other patients in their ward if they are assigned to the intervention or control group to avoid societal bias.

Procedures

Participants received care in adherence to the local ERAS protocol in their hospital, which were locally different among study centres. Additionally, the ERAS APPtimize intervention group was supported by the ERAS App spanning from 1-3 weeks preoperatively until 42 days postoperatively. The app was based on the generic ERAS protocol and was designed to educate and actively involve patients in their local perioperative care pathway promoting daily activity. The active ERAS elements reported in Table 1 were translated into practical patient-centred features. Push notifications were used to alert patients to new information at specific times to prompt them to complete the necessary actions for each element. All information on the ERAS protocol and required steps could be retrieved and accessed in the app at any time. Daily activity was measured using an activity tracker, starting 7 days prior to surgery or as soon as possible after surgery was scheduled. The average daily step count during the preoperative period of seven days is used to set an individual baseline. During the postoperative phase, daily step goals (Table S1) were offered via push notifications and taken steps were monitored in the app, until 21 days postoperatively. Questionnaires are also completed through the app. In study setting, participants had access to the app, as an access code were provided by the research team or healthcare providers. Participants received instructions at the treatment allocation, had the option the contact the research team for technical support if needed, and used the app according to their own preferences, without any intervention of the research team. Figure 1 displays the app layout. The ERAS App is CE-marked (NL-CA002-2019-47000), complies with the General Data Protection Regulation, and follows ISO 27001 data and security guidelines.[30]

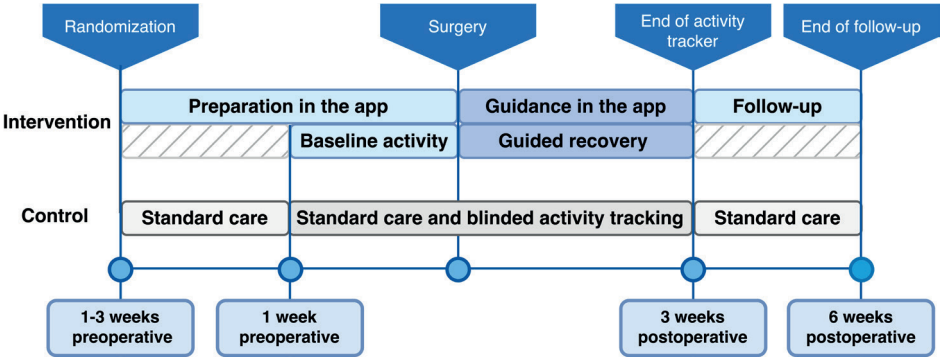
Participants assigned to the control group received the usual care following the local ERAS protocol and were given a blinded activity tracker to monitor activity. Participants received a paper booklet containing the ERAS elements completion checklist and questionnaires. They were instructed to complete the checklists once a day and the questionnaires according to the time points shown in Table S2. Figure 2 illustrates the study pathways for both groups.

Figure 1: Screenshots of the ERAS App



First screenshot: Splash screen. Second screenshot: The app generates a timeline based on the operation date which provides information and daily goals to complete. The timeline gives patients an overview of their own care pathway and supports patients to prepare for surgery. If new information or goals are available, push notifications are sent to stimulate patients to adhere to the protocol. Third screenshot: The app's 'dashboard' displays the completion of three subjects: 1) daily activity goal, 2) active ERAS elements, and 3) self-registered questionnaires throughout the entire study.

Figure 2: Flowchart of intervention and control group



Outcome

The primary outcome was overall average compliance with selected active ERAS elements (Table 1). To correct for cofounding on digital (il-)literacy, participants completed a questionnaire on use of apps and their mobile proficiency. Secondary outcome measures were postoperative outcomes, such as length of hospital stay (LOS), complications, readmissions, and reinterventions, as well as patient-reported outcomes (PROMs), including quality of life (measured with WHOQOL-BREF), disability (measured with WHODAS 2.0), and satisfaction with the app (measured using a self-developed questionnaire).[31,32] Additionally, the activity was assessed from day -7 to surgery, until day 21 post-surgery.

Table 1: The presentation and scoring of the selected active ERAS elements

Selected active ERAS elements	Presentation in application	Scoring	
1. Preoperative nutritional screening and, as needed, assessment and nutritional support	SNAQ scoring tool; information	SNAQ ≥ 3 + no dietician visit SNAQ ≥ 3 + dietician visit SNAQ ≤ 2	0 1 1
2. Preoperative carbohydrate treatment *	Push reminders to finish carbohydrate treatment; checklist	No Yes (1 or 2 bottles) Tube feeding Standard use of nutridrink	0 1 1 1
3. Early mobilization	Information; tailored daily goals and reminders; display of progress	No mobilization on day 1 Mobilization on day 1	0 1
4. Early intake of oral fluids and solids	Information; tailored daily goals and reminders; display of progress	No oral intake on day 1 Oral intake on day 1	0 1
5. Early removal of urinary catheters *	Information, checklist	Not removed on day 1 Removed on day 1 No catheter	0 1 1
6. Use of laxatives	Information, checklist	No laxatives day 1-3 Laxatives day 1-3	0 1

* The element was not present in all local ERAS protocols of the participating hospitals and therefore was not included in the calculation for overall compliance for these hospitals. Each hospital had a minimum of 5 active elements. Abbreviations: SNAQ Short Nutritional Assessment Questionnaire.

Statistical analysis

The sample size was calculated based on a compliance rate to active ERAS elements of 57% in a previous study and the hypothesis that the ERAS App would increase patient compliance to 62%.[17] Using a 2-sided alpha of 0.05, with 90% power and a standard deviation of 9, 140 patients were estimated to be required for the study. Data were analysed according to intention to treat protocol.

Statistical analyses were conducted using IBM SPSS version 28.0. Baseline characteristics were summarized using descriptive statistics and compared between the intervention and control groups and between the included and excluded patients. Continuous normally distributed variables were reported as mean ± standard deviation, and non-normally distributed continuous variables were reported as median and interquartile range (IQR). Distributions were evaluated using visual inspection of histograms. Categorical variables were presented as frequencies and percentages. Independent t-tests, Mann-Whitney U tests, Chi-squared tests, and Fisher's exact tests were used to assess differences between groups as appropriate. A two-tailed p-value ≤ 0.05 was considered statistically significant.

The extent of surgery was categorized as either being major or minor, with minor surgery defined as stoma creation/removal combined with an enterocutaneous fistula correction and major surgery including all the other operations.

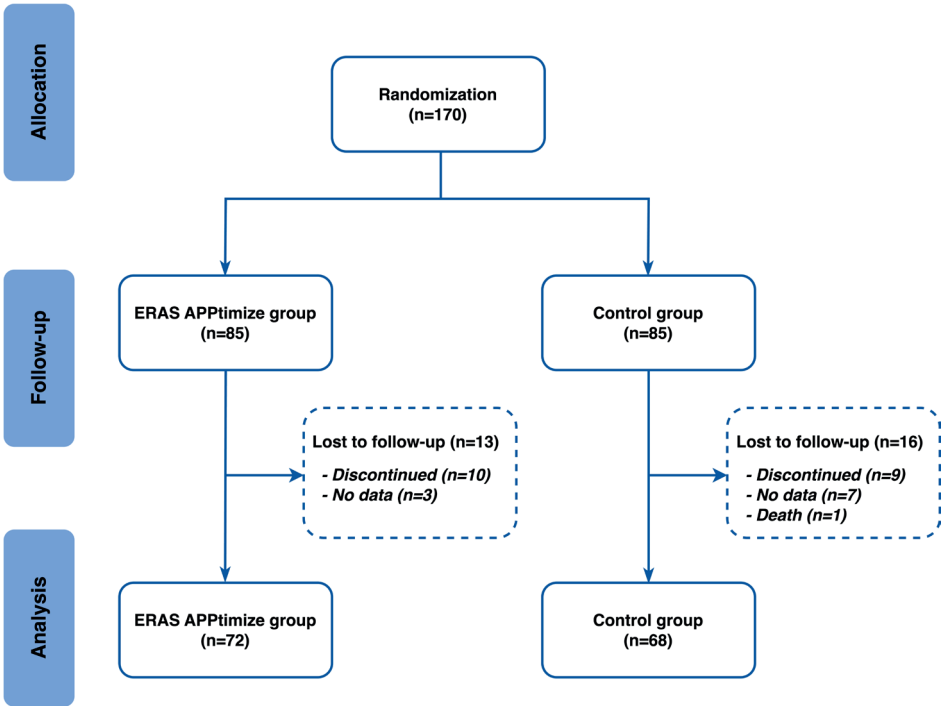
The selected ERAS elements were dichotomously scored as being fully complete or incomplete. The overall compliance is the average of all individual completion percentages. If a specific ERAS element was not present in the local pathway, it was not included into the calculation of overall compliance for these hospitals. Multivariate linear regression with stepwise backward selection was used to account for potential confounding and stratifying factors.

PROMs were only included in the analysis if the patient completed >80% of the questionnaire per domain. Missing data were corrected using the participants' mean outcome of the (domain of the) PROM. Baseline activity was calculated using the mean of the data recorded the week before surgery. For missing values, a cut-off value of 20% was applied. Postoperative activity was analysed using a Toeplitz linear mixed model. Graphs were generated to visualize daily step count.

RESULTS

A total of 170 participants provided informed consent and were randomized. Of these participants, respectively 72 and 68 patients were analysed in the intervention and control groups and 30 participants were lost to follow-up (figure 3). The baseline characteristics of the participants, presented in Table 2, were similar between the two groups, with a predominantly male population (54.9%), a median age of 57 years, and a majority of malignant diagnoses (60.1%). Despite randomization, diverticulitis was significantly more prevalent in the control group (p=0.044). Minimally invasive surgery was the predominant mode of surgery in both groups (91.5%), and both groups had sufficient scores on the mobile proficiency questionnaire. Baseline PROM's are reported in Table 6.

Figure 3: Treatment assignment and study flow



Compliance with the ERAS protocol

Patients in the intervention group had a significantly higher compliance of 10% (76.4%) than patients in the control group (66.4%) ($p = 0.003$) (Table 3). This was mainly due to improved compliance with the early intake of solid foods on day 1 (92%; $p<0.001$) and start with early mobilization on day 1 (41%; $p<0.001$). These two elements were also significantly higher from day 2 to day 7 after surgery. After adjusting for confounding factors in multivariate linear regression analysis, the improvement in compliance was similar (Table 4). The analysis identified an academic hospital, high Karnofsky score, poor physical health score, and high disability score as being significant confounders. It is worth mentioning that patient compliance was 16% higher in teaching hospitals than in academic hospitals. A comparative sub analysis reported that the patient populations of both type of hospital are significantly different (Table S3), however none of these variables were significant confounders.

Secondary outcomes

The median hospital stay was 5 days for patients in both groups. Complications were not reported to be significantly different: 23.5% in the control group and 26.4% in the intervention group. The intervention group demonstrated a noteworthy reduction in reported pain by day 7, as evidenced by a VAS score of 2.5 compared to 3.3 in the control group ($p=0.021$). The other postoperative outcomes were also comparable between groups (Table 5). The PROMs quality of life, disabilities and satisfaction were similar in both groups (Table 6). Patients from teaching hospitals had significant better postoperative outcomes; a hospital stay of 4 days vs 6 days ($p<0.001$), complications 16% vs 34%, and reinterventions 3% vs 14%. ($p=0.018$). The activities of both groups are presented in figure 4. Although not statistically significant, preoperative activity did increase by 946 daily steps with the use of the ERAS app (8491 compared to 7545; $p=0.106$). Postoperative activity in both groups was comparable. However, the intervention group became increasingly active in the last few days of their activity follow-up.

Table 2: Baseline characteristics of included participants.

	Control group (n=68)	***APPtimize group (n=72)***
Male sex	36 (52.9%)	41 (56.9%)
Age (years) [a]	60 (49 - 68)	55 (44 - 68)
ASA classification		
1	10 (14.7%)	8 (11.1%)
2	43 (63.2%)	57 (79.2%)
3	15 (22.1%)	7 (9.7%)
Karnofsky Performance scale [a]	90 (90 - 100)	100 (90 - 100)
BMI (kg/m^2) [a]	25.05 (22.00 – 28.85)	24.00 (22.00 – 27.79)
Smoking		
< 5 pack years	45 (66.2%)	46 (63.9%)
≥ 5 pack years	23 (33.8%)	26 (36.1%)
Alcohol (units/week) [a]	1.0 (0.0 – 4.0)	2.0 (0.0 – 6.8)
Indication		
Benign	26 (38.2%)	31 (43.1%)
Ulcerative colitis	3 (4.4%)	8 (11.1%)
Diverticulitis*	6 (8.8%)	1 (1.4%)
Morbus Crohn	15 (22.1%)	19 (26.4%)
Slow transit	1 (1.5%)	1 (1.4%)
Other	0 (0%)	2 (2.8%)
Malignant	42 (61.8%)	41 (56.9%)
Colon cancer	20 (29.4%)	16 (22.2%)
Rectosigmoid cancer	1 (1.5%)	1 (1.4%)
Rectum cancer	15 (22.1%)	16 (22.2%)
Sigmoid cancer	5 (7.4%)	6 (8.3%)
Other	2 (2.9%)	3 (4.2%)
Procedure		
Minimal-invasive	63 (92.6%)	65 (90.3%)
Open surgery	5 (7.4%)	7 (9.7%)
Extent of surgery		
Minor	11 (16.2%)	9 (12.5%)
Major	57 (83.8%)	63 (87.5%)
Type of Hospital		
Teaching	37 (54.4%)	40 (55.6%)
Academic	31 (45.6%)	32 (44.4%)
Mobile proficiency (MDPQ) [b]	38.5 (33.5 – 40.0)	38.5 (32.5 – 40.0)

[a] Values are median (IQR), [b] MDPQ Mobile Device Proficiency Questionnaire (scale 8-40)
*Significant difference between groups, p=0.044
Abbreviations: ASA American Society of Anaesthesiology; BMI Body Mass Index; IQR inter quartile range.

Table 3: Compliance with the active ERAS elements

	Control group (n=68)	*APPtimize group (n=72)*	*P - value*
Nutritional screening and assessment	89.7 (30.6)	91.7 (27.8)	0.690
Carbohydrate loading	54.4 (50.2)	50.0 (50.4)	0.601
Early mobilization	66.2 (47.7)	93.1 (25.6)	<0.001
Early intake of solid food	45.6 (50.2)	87.5 (33.3)	<0.001
Urinary catheter removed	64.7 (48.1)	63.9 (48.4)	0.920
GI stimulation (Laxatives)	77.9 (41.8)	72.2 (45.1)	0.435
Total score	66.4 (23.7)	76.4 (16.7)	0.003

Mean compliance of the group in percentage. Abbreviations: GI Gastro-intestinal

Table 4: Multiple linear regression analysis compliance to ERAS protocol

	B	*SE B*	*95.0% CI*	*P - value*
Constant	0.245	0.285	-0.318 – 0.808	0.391
ERAS App	0.095	0.041	0.030 - 0.161	0.005
Age, under 50 years*	-0.018	0.043	-0.098 - 0.063	0.666
Benign diagnosis*	-0.001	0.033	-0.086 - 0.085	0.989
Teaching hospital	0.163	0.038	0.088 - 0.238	<0.001
Karnofsky Performance scale at baseline	0.008	0.003	0.002 - 0.013	0.007
Physical QoL at baseline	-0.003	0.001	-0.005 - 0.000	0.030
Disability at baseline	-0.009	0.004	-0.016 - -0.002	0.013

* Stratification factor in randomization. Abbreviations: B Beta coefficient for compliance to ERAS protocol; SE Standard Error; CI Confidence Interval; QoL = quality of life

Table 5: Postoperative outcomes

	Control group (n=68)	***APPtimize group (n=72)***	***P - value***
Length of hospital stay (days) [a]	5.00 (4.00 – 7.75)	5.00 (4.00 – 6.75)	0.997
Pain (VAS)			
Day 1	4.7 (2.1)	4.9 (2.0)	0.655
Day 2	4.2 (2.1)	4.1 (2.0)	0.771
Day 3	3.6 (2.2)	3.7 (1.9)	0.773
Day 4	3.8 (2.3)	3.5 (1.9)	0.477
Day 5	3.7 (2.5)	3.0 (2.0)	0.113
Day 6	3.6 (2.1)	3.1 (2.0)	0.184
Day 7	3.3 (2.1)	2.5 (1.5)	0.021
Complications	16 (23.5%)	19 (26.4%)	0.736
Ileus	2 (2.9%)	4 (5.6%)	0.445
Gastroparesis	2 (2.9%)	4 (5.6%)	0.445
Anastomotic leakage	4 (5.9%)	9 (12.5%)	0.178
Stoma obstruction	1 (1.5%)	0 (0%)	0.302
Urinary tract infection,	2 (2.9%)	2 (2.8%)	0.954
Electrolyte imbalance	2 (2.9%)	2 (2.8%)	0.954
Surgical site infection	1 (1.5%)	3 (4.2%)	0.339
Other, n (%)	6 (8.8%)	4 (5.6%)	0.453
Reintervention	4 (5.9%)	7 (9.7%)	0.523
Readmission	9 (10.6%)	13 (15.7%)	0.228

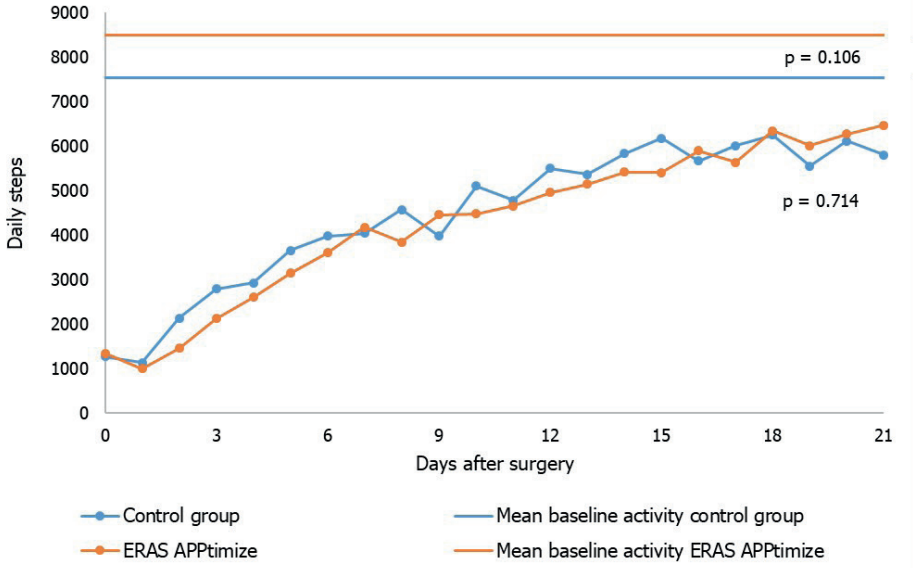
[a] Values are median (IQR)

Table 6: Patient reported outcomes

	Control group (n=68)	*APPtimize group (n=72)*	*P - value*
Physical QoL			
Preoperative (baseline)	63.00 (44.00 – 81.00)	66.00 (44.00 – 81.00)	0.980
One week after surgery	56.00 (38.00 – 69.00)	56.00 (44.00 – 69.00)	0.407
Two weeks after surgery	24.00 (19.00 – 29.00)	24.00 (19.00 – 28.00)	0.683
Six weeks after surgery	66.00 (44.00 – 81.00)	69.00 (56.00 – 81.00)	0.952
Psychological QoL			
Preoperative (baseline)	69.00 (56.00 – 81.00)	69.00 (63.00 – 81.00)	0.522
One week after surgery	69.00 (56.00 – 75.00)	69.00 (63.00 – 75.00)	0.363
Two weeks after surgery	69.00 (56.00 – 81.00)	69.00 (56.00 – 78.00)	0.379
Six weeks after surgery	69.00 (59.50 – 81.00)	69.00 (63.00 – 81.00)	0.515
Social QoL			
Preoperative (baseline)	75.00 (59.25 – 90.75)	75.00 (56.00 – 81.00)	0.124
One week after surgery	75.00 (56.00 – 81.00)	69.00 (56.00 – 81.00)	0.348
Two weeks after surgery	75.00 (56.00 – 81.00)	75.00 (62.50 – 81.00)	0.453
Six weeks after surgery	75.00 (69.00 – 81.00)	75.00 (56.00 – 81.00)	0.199
Environment QoL			
Preoperative (baseline)	88.00 (75.00 – 94.00)	81.00 (69.00 – 94.00)	0.363
One week after surgery	75.00 (69.00 – 88.00)	78.00 (69.00 – 88.00)	0.380
Two weeks after surgery	81.00 (69.00 – 94.00)	75.00 (66.00 – 94.00)	0.391
Six weeks after surgery	84.50 (75.00 – 94.00)	88.00 (75.00 – 94.00)	0.857
Disability			
Preoperative (baseline)	17.00 (14.25 – 22.75)	15.00 (13.00 – 20.75)	0.062
Six weeks after surgery	18.50 (14.55 – 25.00)	18.00 (14.00 – 25.00)	0.963
Overall satisfaction	27.00 (24.00 – 28.00)	27.00 (23.50 – 29.00)	0.387
Intervention satisfaction	8.00 (6.00 – 8.00)	8.00 (6.00 – 9.00)	0.560

Values are median (IQR). Domains of quality of life are measured in a 0-100 scale, Disabilities is measured in a 12-60 scale, Overall satisfaction is measured in a 7-35 scale, and intervention satisfaction is measured in a 2-10 scale. Abbreviations: QoL = quality of life

Figure 4: Postoperative activity, measured in steps taken per day



DISCUSSION

The ERAS protocol has improved perioperative care for patients undergoing colorectal surgery. However, challenges persist in optimizing patient engagement and compliance, prompting exploration into innovative mobile healthcare solutions. This study investigated the effectiveness of a patient-centred app, the ERAS App, designed to enhance patient education, participation and activation within the ERAS colorectal pathway. Notably, the ERAS APPtimize trial stands out as the first study to combine an activity tracker with an interactive mobile application classified as a medical device, underscoring its unique approach to supporting patients through the perioperative journey.

The ERAS App demonstrated a significant improvement in overall compliance with selected active ERAS elements by 10%, particularly in early solid food intake by 42% and early mobilization by 27%. However, other ERAS elements remained unchanged, as these elements relies partially on healthcare providers. Notably, patient compliance was higher in teaching hospitals than academic hospitals. This can suggest that the ERAS protocol was better implemented in teaching hospitals, however other factors may be of influence such as shorter disease courses, fewer comorbidities, or less complicated surgeries. In line with compliance discrepancies, patients in teaching hospitals had shorter length of hospital stay by three days ($p<0.001$). It is important to acknowledge that the study involved only

one academic hospital, and results may vary in other settings. Additionally, factors such as overlapping local studies and healthcare providers' awareness might contribute to compliance variations between teaching and academic hospitals.

Despite, the significant increase in compliance with active ERAS elements, the study did not demonstrated improvement in clinical outcomes. The study was not powered on clinical outcomes, in the context of clinical outcomes which had already seen significant enhancements since the introduction of the ERAS protocol. It is essential to consider potential impact in larger groups where improved adherence to active elements might translate into clinical benefits. Additionally, the quality of implementation of the ERAS protocol may have varied among healthcare providers or institutions, leading to inconsistent results across study sites. This highlights the need for standardized implementation and continuous monitoring to ensure protocol effectiveness.

Furthermore, the ERAS App did not improve patient-reported outcomes (PROMs) or postoperative activity. It is possible that increased adherence to the ERAS protocol may not have a direct impact on PROMs such as quality of life or patient satisfaction. A potential social desirability bias in self-reported questionnaires could have influenced the observed outcomes.[33] The ERAS App did not lead to an activity improvement when compared to the control group. Most patients exceeded their daily step goals, indicating that the goal-setting may have been too simplistic to motivative patients for increased physical activity. The ERAS APPtimize group's increased activity in the final days suggests that the follow-up period might have been too short to capture sustained improvements. Additionally, unusually high baseline activity levels (e.g., 23,000 steps per day), possibly due to preoperative motivation, have led to an unrepresentative baseline level.

Several limitations to this study need to be addressed. Firstly, the exclusion of patients undergoing palliative surgery, surgery after neoadjuvant chemotherapy or radiotherapy, or multiple organ resections, may have resulted in a selection bias. These patients may benefit the most from the app, and their exclusion may underestimate the true impact of the app. Secondly, non-completing participants had significantly more complications (Table S4), which suggests that the ERAS App may not be optimal for patients with complications. This highlights the need for further research. Thirdly, not all participants had optimal postoperative activity goals, as the baseline measurement may have been too short or goals may not have been sufficiently challenging. Lastly, it is important to note that patients in the control group may have been more actively participating in the ERAS care pathway compared to their peers as. This may have resulted in a decreased compliance difference between the two study groups.

Despite the demonstrated effect of the ERAS App, opportunities for further optimization were identified. Dynamic features catering to individual recovery progress and adapting to postoperative complications hold promise. However, it's important to exercise caution

when integrating individual recovery progress because the more personalized the intervention, the less evidence there is to support its overall effectiveness. The integration of prehabilitation with the ERAS App emerges as a potential strategy to improve clinical outcomes.[34] Future research should delve into the feasibility and efficacy of incorporating dynamic features or prehabilitation within the ERAS pathway through the ERAS App. Additionally, exploring barriers and facilitators to the app's implementation in clinical practice can inform strategies for enhancing its adoption and utilization. Overall, further research and development of the ERAS App can lead to better patient engagement, adherence to the ERAS protocol, and improved clinical outcomes.

CONCLUSION

The ERAS App successfully increases patient compliance to the ERAS protocol by actively involving patients into their own ERAS care. Although the ERAS App was unable to demonstrate improved patient-related and clinical outcomes, the app is an important step towards optimizing perioperative care for colorectal surgery patients and enabling patients to optimize being in control of their own recovery. Further research and development are necessary to identify ways to improve the app's efficacy and impact on patient outcomes.

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SUMMARY AND DISCUSSION

SUMMARY OF MAIN FINDINGS

This thesis, entitled "Mobile applications in colorectal surgery: digitally advancing patient care," aimed to (**part I**) provide insights into the current perspectives on the use and development of medical mobile applications, (**part II**) assess patients' perspectives on stoma care, and (**part III**) evaluate the clinical effectiveness of patient-centred mobile applications in colorectal surgical care.

Current perspectives on medical mobile applications

The literature review in **Chapter 1** emphasised the importance of compliance with the General Data Protection Regulation and Medical Device Regulation to ensure data privacy and safety of medical mobile applications. This chapter provided the most practical considerations that medical professionals should know when using or building a medical mobile application. In **Chapter 2**, a systematic review was conducted to identify mobile applications used in gastrointestinal surgical care and to evaluate their prospects for surgical care provision. Although over 150 gastrointestinal surgical mobile applications are available in app stores, only a limited number can be retrieved from the scientific literature. The 29 identified mobile applications were classified into seven categories: monitoring, weight loss, postoperative recovery, education, communication, prognosis, and clinical decision making. Most identified mobile applications were assessed for their usage, usability, satisfaction, and feasibility. This review showed that most studies using mobile applications have failed to provide high-level evidence on effectiveness or safety.

Patient perspectives on stoma care

Chapter 3 assessed patients' satisfaction with stoma care and their attitudes towards a supporting mobile application. The web-based survey involving 1868 patients revealed that patients were only moderately satisfied with their received stoma care, as the overall satisfaction score was 6.6 out of 10. The study showed that patient satisfaction was mostly influenced by being unaware of the chance of getting a stoma or being in an acute situation. However, additional care was most desired after hospital discharge. The perioperative clinical condition and mental state may also negatively impact patients' perception of the actual received stoma care in the immediate pre- and post-operative phases. The most frequently reported potential improvements were provision of preoperative information (16.9%), stoma site selection (14.1%), information about stoma-related problems (20.3%), and stoma materials (19.4%).

Of the patients with a stoma of less than three years, 64.8% stated that they consulted the internet at least once a month for stoma-related information. Although there was a preference for information in a conventional manner, 59.5% of the patients with a stoma for less than three years expressed the potentially added value of a supportive

mobile application. Willingness to use an application was also strongly associated with digital literacy. **Chapter 4** elaborated on stoma patients' perspectives through focus group interviews, identifying key themes such as perioperative information, the need for universally applicable information, lack of peer contact opportunities, communication with healthcare providers, and information about stoma materials. Participants deemed a mobile application useful, emphasizing the importance of up-to-date, visually appealing, and personalized information for enhanced user convenience.

Clinical trials evaluating patient centred mobile applications

As described in **Chapter 2**, mobile applications can be used to improve patient education and postoperative recovery after colorectal surgery. Based on the findings of chapter 3 and chapter 4, the “Stoma App” was developed. The protocol of the Stoma APPtimize trial is described in **Chapter 5**, which investigated whether self-reported quality of life of patients with a stoma can be enhanced by offering personalized and timed guidance, as well as peer contact, in the Stoma App. The intervention group used the full version of the application, while the control group received a restricted version of the application that contained only generic (non-personalized) stoma-related information. The results of the Stoma APPtimize trial are described in **Chapter 6,** which showed that the stoma-related quality of life one month postoperatively improved by 3.1 (p=0.038). Other clinical and patient outcomes did not improve.

Chapter 7 investigated the effectiveness of the ERAS App, designed to enhance patient education, participation, and activation within the ERAS colorectal pathway. The intervention group used the ERAS App combined with an activity tracker to be guided and supported through the ERAS pathway, while the control group received standard care. The mobile application significantly improved overall patient compliance by 10%, particularly enhancing early solid food intake by 42% and early mobilisation by 27%. Other clinical or patient-reported outcomes did not improve.

GENERAL DICUSSION

Mobile applications have the potential to enhance and support colorectal surgical care in several ways. However, despite the substantial number of medical applications available in app stores, only a limited number have been adequately assessed in peer-reviewed literature. This is of great concern, and healthcare providers and patients should be aware of the level of evidence regarding the applications they prescribe or utilize. The use of non-validated or poorly validated applications poses a significant risk, particularly when the application has a direct impact on clinical outcomes. It is important to note that healthcare providers may be held accountable if they use applications that fail to adhere to safety and quality requirements.

However, responsible use of medical applications can be promoted if standards are established and adhered. To address the question of how to enhance the quality and safety of medical applications, it is imperative to evaluate applications in clinical studies, including control groups, objective measures of their effectiveness, and the use of validated and reusable questionnaires. An essential component of this process is the involvement of an 'expert' healthcare provider to safeguard the accuracy of medical content and ensure that apps undergo robust research and vetting. Ideally, app stores should play an active role in assessing the evidence supporting an app's effectiveness and safety before acceptance for publication. The development process of medical applications must be described transparently, allowing for the assessment of whether all necessary conditions have been met.

Building a medical application

Medical applications must be thoughtfully designed in content and user interface and adhere to privacy and medical device safety criteria.[1] It is important to acknowledge the inherent risk of poor implementation and underutilization if applications are not well built or maintained. If an application is designed to be used by patients, it is recommended to involve patients early in the development process, evaluate their perspectives, and assess how an application can provide support.[2] It is imperative to ensure that applications are designed to cater to needs of patient with low digital literacy as well, and their useability is optimized, including a comprehension and intuitive user interface with straightforward navigation supported by visual aids.[3]

The expertise of a qualified developer, possessing functional and graphical design specialists and relevant certifications to ensure adherence to privacy and quality standards, is also required. Ideally, developers should have prior experience in the development of medical applications. After registration in app stores, it is crucial that the application is adequately technically supported, as any technical issues may impact the effectiveness of the application during clinical use or research. It is recommended to establish a solid

agreement that mandates the developer to identify and correct any technical issues within an agreeable timeframe.

Patient-centred colorectal surgical care

Patients undergoing colorectal surgery are faced with processing information and coping with the surgical procedure, recovery, potential complications, and lifestyle adjustments.[4] Transforming to a more patient-centred approach holds the potential to enhance patients' overall experience, promote treatment adherence, and improve outcomes.[5-7] Medical applications can be employed to support colorectal surgical care on various aspects. These applications provide a sustainable solution by informing and guiding patient through in the colorectal pathway, empowering patients in their own care and recovery.[8]

Although stoma care is of critical importance to the well-being and quality of life of patients, they are only moderately satisfied with their received stoma care. They indicated several shortcomings in information provision and postoperative care and the need to be in contact with peer patients. It was expected that patients who were in an acute situation, and/or had stoma-related problems would mostly benefit from additional support from a mobile application. Surprisingly, analysis showed that patients in an acute operation setting did not experience more benefits from the Stoma App in comparison to those in an elective setting. The Stoma App improved the stoma-related quality of life one month postoperatively by 3.1. Although the clinical significance of this difference may be debatable, it should be acknowledged that the technical issues impeded the application's full potential. Despite these issues, the demonstrated effectiveness suggest that the improvement in quality of life would have been more substantial if the application had not been hampered by technical issues. Given the established clinical evidence, minimal time commitment required from healthcare personnel to provide the application, and the resolution of previous technical issues, it is strongly recommended to integrate the application into standard stoma care pathways.

Moreover, challenges persist in optimizing patient compliance within the colorectal surgical pathway in general. The ERAS App actively engaged patients in their own colorectal surgical care and recovery, resulting in a significant increase in patient compliance with the ERAS protocol. Although patient or clinical outcomes did not improve, the application represents an important initial step towards enhancing perioperative care for colorectal surgery patients. Especially so, when local implementation of the ERAS protocol and clinical outcomes differ across medical centres.[9] Exploring the incorporation of dynamic recovery features or prehabilitation within the ERAS App can further enhance patient engagement with the ERAS protocol and potentially improve clinical outcomes. Nevertheless, implementing the current application in the colorectal pathway may benefits patients, and require minimal time from healthcare providers.

The clinical impact of the medical applications is not solely dependent on the specific features they offer but also relies on patient engagement. This is linked to factors such as the context and phase of care during which the application is provided, the patient's digital literacy, and overall usability and technical stability.[10] The connection that patients experience with their treating healthcare provider may be essential for patient engagement.[11] Although digital literacy had no significant effect on the outcomes in both clinical evaluations, it should be noted that this could be influenced by a potential selection bias in the study population. However, an upcoming qualitative analysis of the facilitators and barriers to the uptake of the Stoma App showed that some patients faced challenges related to logging in, remembering credentials, and resetting passwords, thereby highlighting the impact of digital (il)literacy on application usage. Other patients reported that using the application enhanced the feeling of being a patient instead of resuming their normal daily life. This self-stigmatisation could pose a significant barrier for continued application use after surgery.

Digital literacy

Addressing digital literacy is crucial as the digitisation of healthcare information and accessibility is accelerating. Patients with low digital literacy may exhibit hesitancy to use medical applications. Many patients may still be unaware of the potential benefits or may simply not be used to access medical information through applications. Therefore, proactive efforts are required to empower patients to benefit from medical applications.[12] Digital literacy should be a focus point for healthcare organizations, engaging in comprehensive counselling to educate patients on the benefits of medical application, and providing support to facilitate their usage.

Clinical implementation

Despite conducting a thorough predevelopment assessment of the perspectives and needs of the target group, along with a pilot testing phase for the mobile application, true utilization and clinical evaluation are bound to yield valuable new insights. Certain functionalities of the application may be redundant, while others may require adaptation or even inclusion. These insights will prove essential for further refinement of the application to ensure optimal functionality and effectiveness.

Both clinical evaluations showed variations in patient recruitment and integration of the mobile application into the standard care pathway across the medical centres. Healthcare providers play a key role in implementing medical applications. It is essential to advocate the application as an information source, integrated into normal preoperative counselling. The pivotal role played by treating healthcare providers was highlighted in the upcoming qualitative analysis. Those with a positive attitude toward the application are more likely to incorporate the application in their working routine, actively advocating its use. Notably,

younger nurses exhibit greater involvement in recommending the application, suggesting generational differences in attitudes toward the digitalisation of healthcare. Discussing the application briefly or immediately before surgery may result in limited usage.

One of the crucial challenges lies in securing sufficient funding to sustain technical maintenance, periodic updates based on new insights, and the implementation of the app in clinical practice. Generally, medical applications are funded by subsidiaries that cover the costs of development and the initial clinical evaluation. However, a potential risk emerges after clinical evaluation when subsidies are depleted, leaving well-validated medical applications in jeopardy. It is imperative to establish financial support mechanisms for medical applications, ideally to make them freely available to patients. Although certain applications may find additional funds, a more comprehensive and structural assurance is essential to guarantee the continued availability of well-validated applications.

CONCLUSION

This thesis emphasises the feasibility of integrating medical applications into colorectal surgical care, revealing their potential to enhance patient empowerment and other outcomes. However, the prevailing challenge is that the majority of presently available apps lack sufficient clinical evaluation regarding their effectiveness and safety. The journey toward the systematic integration of medical apps into clinical practice demands the overcoming of several hurdles.

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APPENDICES

NEDERLANDSE SAMENVATTING

Dit proefschrift heeft als doel om: (**deel I**) inzicht te geven in de huidige perspectieven op het gebruik en de ontwikkeling van medische mobiele applicaties, (**deel II**) de perspectieven van patiënten op stomazorg te onderzoeken en (**deel III**) de klinische effectiviteit van de patiëntgerichte mobiele applicaties in colorectale chirurgische zorg te evalueren.

Huidige perspectieven op medische mobiele applicaties

Hoofdstuk 1 benadrukt het belang van het naleven van de regelgeving met betrekking tot de gegevensbescherming en veiligheid van medische hulpmiddelen zoals medische applicaties. Het hoofdstuk bespreekt ook de meest praktische overwegingen die medische professionals moeten kennen als zij een medische mobiele applicatie gaan gebruiken of ontwikkelen. **Hoofdstuk 2** vervolgt met een systematische literatuur review om te identificeren welke mobiele applicaties in de gastro-intestinale chirurgische zorg werden gebruikt en om te evalueren wat hun vooruitzichten voor chirurgische zorg zijn. Hoewel er meer dan 150 gastro-intestinale chirurgische mobiele applicaties beschikbaar zijn in app stores, kon slechts een beperkt aantal worden teruggevonden in de wetenschappelijke literatuur. De 29 geïdentificeerde mobiele applicaties werden ingedeeld in zeven categorieën: monitoring, gewichtsverlies, postoperatief herstel, educatie, communicatie, prognose en klinische besluitvorming. De meeste geïdentificeerde mobiele applicaties werden alleen onderzocht op hun gebruik, bruikbaarheid en gebruikerstevredenheid en hadden dus geen hoogwaardig wetenschappelijk bewijs van hun effectiviteit en veiligheid.

Patiëntperspectieven op stomazorg

Hoofdstuk 3 onderzocht de tevredenheid van patiënten over hun ontvangen stomazorg en hun mening ten opzichte van mogelijke ondersteuning van een mobiele applicatie. Uit de enquête onder 1.868 patiënten bleek dat patiënten slechts matig tevreden over hun stomazorg waren, met een score van 6,6 op 10. De tevredenheid werd vooral beïnvloed door onwetendheid om een stoma te krijgen of in een acute situatie te zijn geopereerd. Ook kan de medische conditie voor de operatie of mentale klachten een negatieve invloed hebben op de perceptie van patiënten van de daadwerkelijk ontvangen stomazorg. Patiënten hadden graag meer zorg na de ziekenhuisopname gehad en ze gaven aan dat de volgende aspecten verbeterd konden worden: voorlichting voor de operatie, de stoma plaatsbepalingen informatie over stoma gerelateerde problemen. 64,8% van de patiënten die korter dan drie jaar een stoma hebben, raadpleegden minstens eenmaal per maand het internet voor stoma gerelateerde informatie. Hoewel er een voorkeur was om informatie via een conventionele manier te raadplegen, gaf 59,5% aan dat zij een mobiele applicatie als toegevoegde waarde zouden zien. Uit het onderzoek blijkt ook dat patiënten met digitale geletterdheid meer bereid zijn om de applicatie te gebruiken. Dit geeft aan dat het erg belangrijk is om goede voorlichting te geven over de voordelen van mobiele applicaties

en patiënten ook te helpen bij het gebruik. **Hoofdstuk 4** ging dieper in op de perspectieven van stomapatiënten via focusgroep interviews. De deelnemers vonden dat een mobiele applicatie waardevol zou zijn, mits de applicatie voorzien is van up-to-date, visueel aantrekkelijke en gepersonaliseerde informatie. Uit de interviews kwamen belangrijke thema's over de stomazorg naar voren zoals informatievoorziening rondom de operatie, de behoefte aan universeel toepasbare informatie, gebrek aan mogelijkheden voor contact met lotgenoten, communicatie met zorgverleners en informatie over stomamaterialen.

Klinische onderzoeken naar de effectiviteit van op de patiëntgerichte mobiele applicaties

Zoals beschreven in **Hoofdstuk 2**, kunnen mobiele applicaties worden gebruikt om patiënteducatie en herstel na colorectale chirurgie te verbeteren. Op basis van de bevindingen van **hoofdstuk 3** en **hoofdstuk 4** werd de "Stoma App" ontwikkeld. Het protocol van de Stoma APPtimize trial wordt beschreven in **Hoofdstuk 5**. De studie onderzocht of de kwaliteit van leven van patiënten met een stoma verbeterd kan worden door gepersonaliseerde en getimede begeleiding en lotgenotencontact in de Stoma App aan te bieden. De interventiegroep gebruikte de volledige versie van de applicatie, terwijl de controlegroep een beperkte versie van de applicatie ontving met alleen generieke (niet-gepersonaliseerde) informatie. De resultaten van de Stoma APPtimize trial worden beschreven in **Hoofdstuk 6,** die aantoonde dat de stoma-gerelateerde kwaliteit van leven één maand na de operatie met 3,1 verbeterde (p=0,038). Andere klinische en patiëntuitkomsten verbeterden niet. **Hoofdstuk 7** onderzocht de effectiviteit van de ERAS App, die was ontworpen om patiënteducatie, betrokkenheid en activatie binnen het ERAS-colorectale zorgpad te verbeteren. De interventiegroep gebruikte de ERAS App in combinatie met een stappenteller om te worden begeleid en ondersteund in het ERAS zorgpad, terwijl de controlegroep standaard zorg ontving. Door het gebruik van de ERAS App werd de algehele naleving aan het ERAS protocol met 10% verbeterd, met name wat betreft vroege inname van vast voedsel met 42% en vroege mobilisatie met 27%. Andere klinische of door de patiënt gemelde uitkomsten verbeterden niet.

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Other submitted

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General courses	Year	ECTS
Basic course in legislation and organization for clinical researches (BROK)	2019	1.0
Practical biostatistics	2020	1.5
Entrepreneurship in Health & Life Sciences	2023	0.7
Oral presentations	**Year**	**ECTS**
De waarde van een D3 lymfadenectomie en complete mesocolische excisie bij een colonresectie wegens een coloncarcinoom, Wetenschapsdag chirurgie VUMC, Amsterdam, the Netherlands	2018	0.5
Stoma-APPtimize: Improving quality of life, Stomacongres, Nijkerk, the Netherlands	2019	0.5
Ontwikkeling medische apps en CE markeren, DARQA Symposium, Best, the Netherlands	2019	0.5
ERAS-APPtimize: Improving patient participation in colorectal surgery by using a patient-centred mobile application, Wetenschapsdag chirurgie Amsterdam UMC, Amsterdam, The Netherlands	2019	0.5
Stoma-APPtimize: Improving quality of life of patients having a stoma. Wetenschapsdag chirurgie Amsterdam UMC, Amsterdam, The Netherlands	2021	0.5
Stoma APPtimalisatie studie: informatievoorziening en begeleiding voor de stomadrager via de Stoma App. Stomacongres, Nijmegen, the Netherlands	2021	0.5
Study protocol: Improving quality of life of patients having a stoma. WCES 2021, Barcelona, Spain	2021	0.5
Short term outcomes Stoma-APPtimize: Improving Stoma Quality of Life. EAES 2023. Rome, Italy	2023	0.5
Poster presentations	**Year**	**ECTS**
Improving enhanced recovery after surgery (ERAS): the effect of a patient-centred mobile application on patient participation in colorectal surgery. ECCO 2023. Copenhagen, Denmark	2023	0.5

Attended (inter)national congresses	Year	ECTS
Mobile Healthcare Event	2019	0.25
ECCO Vienna	2020	0.5
The annual congress of the Dutch Society of Simulation and Healthcare (organizing committee)	2021	0.5
WCES Barcelona	2021	0.5
The annual congress of the Dutch Society of Simulation and Healthcare (organizing committee)	2022	1.0
APH Annual conference on Digitalization	2022	0.25
ECCO Copenhagen	2023	0.5
EAES Rome	2023	0.5
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Sebastiaan van der Storm was born on the 2nd of January 1994 in Haarlem, the Netherlands. He graduated from high school at Hageveld College, Heemstede, in 2012. In the same year, he started medical school at Vrije Universiteit in Amsterdam. During his studies, he worked as a nurse assistant in elderly care, took initial steps in medical research, and wrote his first scientific publication.

After obtaining the medical degree in 2018, he started working as a surgical resident not in training in Amsterdam UMC, location AMC. In 2019, he had the opportunity started as a PhD student supervised by Prof. Dr. Marlies Schijven. His research project focused on the integration of medical apps in surgical care. He successfully received several grants and provided essential funding for his research. He developed several apps in collaboration with patient associations and coordinated several multicenter clinical trials. During his research, he enjoyed coaching several scientific interns, worked at a medical IT company as a project manager and medical advisor, and was a council member of the Dutch Society of Simulation in Healthcare.

After completing the research that led to this thesis, Sebastiaan transitioned to a new chapter of his career. He started as a resident not in training in geriatric medicine at Zonnehuis Amstelveen. In March 2024, he started his general partitioner training.

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