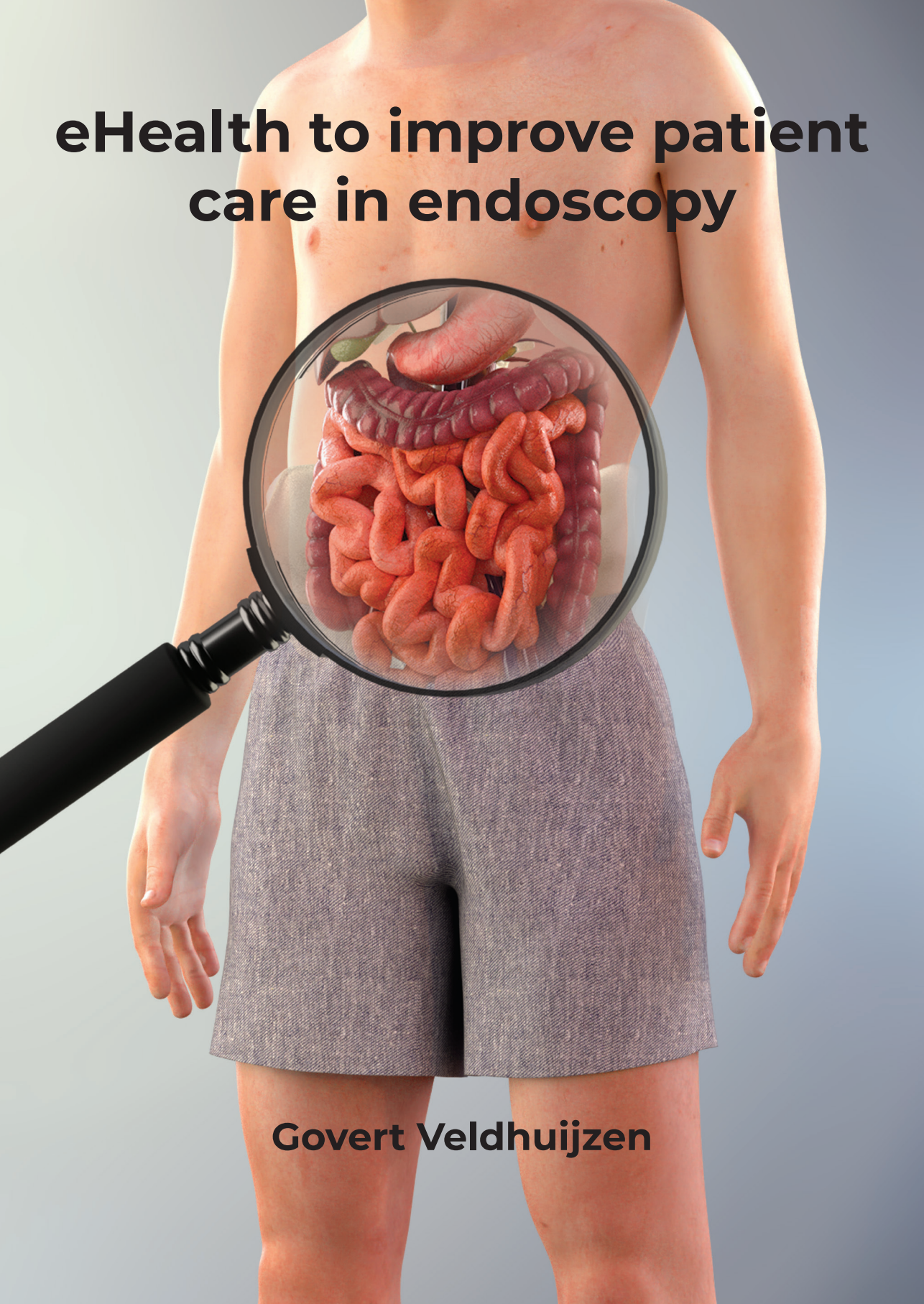
eHealth to improve patient care in endoscopy



Govert Veldhuijzen

eHealth to improve patient care in endoscopy

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Colophon

eHealth to improve patient care in endoscopy

The research in this thesis was performed at the department of Gastroenterology and Hepatology, North West Hospital group Alkmaar, the Netherlands, the department of Gastroenterology and Hepatology, Radboudumc academic hospital, Nijmegen, the Netherlands, the department of Gastroenterology and Hepatology, Jeroen Bosch Hospital, Den Bosch, the Netherlands and the department of Gastroenterology and Hepatology, Bernhoven Hospital, Uden, the Netherlands.

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Voor mama

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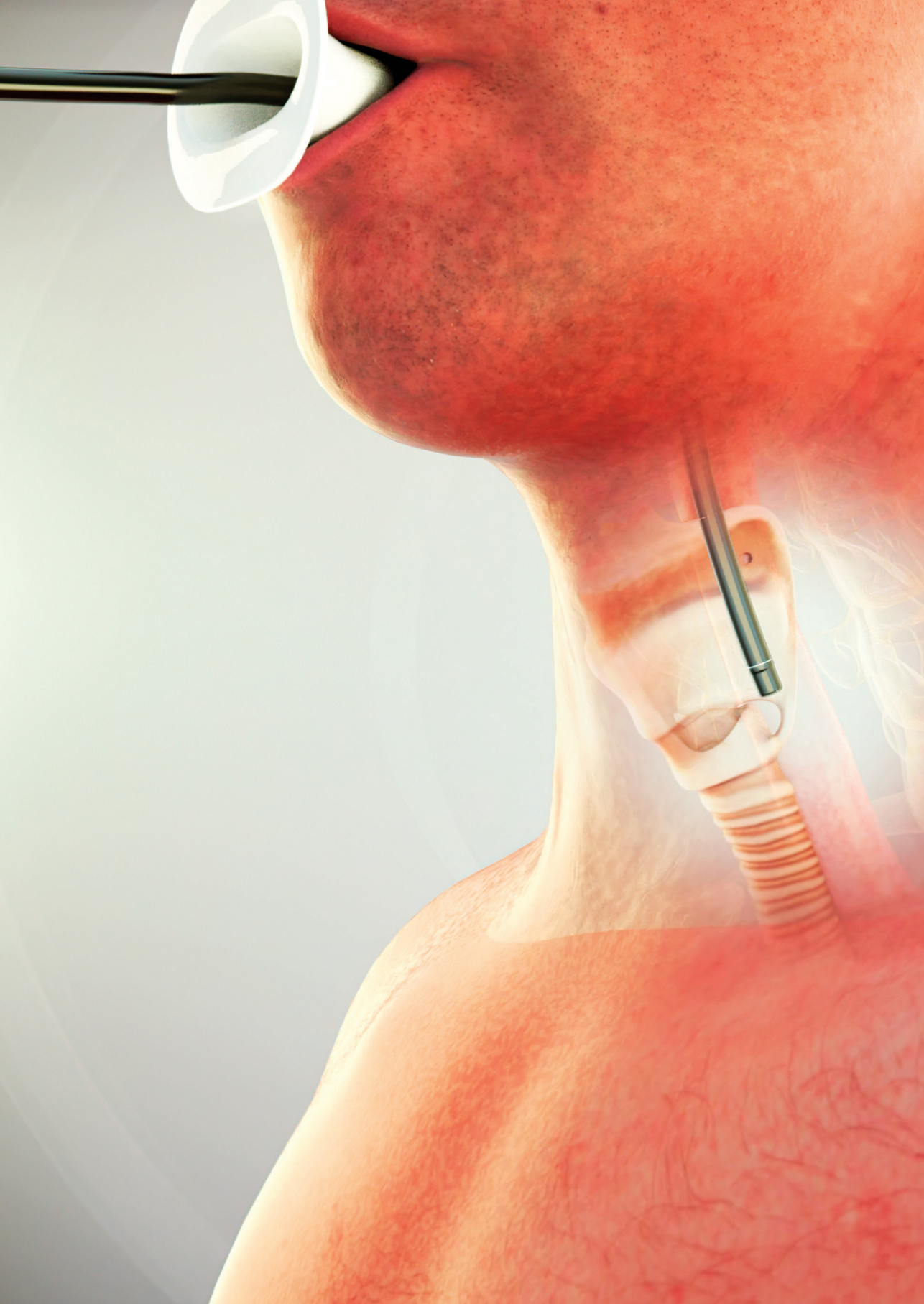

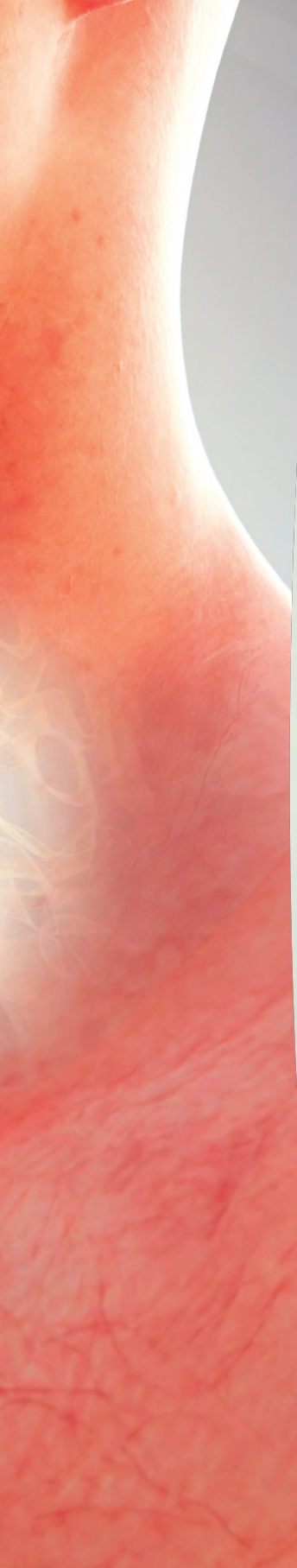

1

General introduction, summarizing history of patient education in endoscopy, aim and outline of the thesis

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GENERAL INTRODUCTION

The explosive development of flexible endoscopy in the 1960s and 1970s brought a new diagnostic modality to the stage equipped to diagnose gastrointestinal diseases, in particular (pre)malignant oesophageal, gastric and colorectal lesions.[1,2] Endoscopy not only serves as a diagnostic tool but also as a therapeutic tool as endoscopic removal of polyps prevents cancer.[3] In particular, endoscopy of the colon, referred to as colonoscopy, has developed as the gold standard to detect and remove neoplastic lesions. As a relevant number of these lesions, such as adenomas, can have a precancerous nature, this practice has clearly shown to reduce colorectal cancer mortality.[4] This led to introduction of large scale polyp surveillance and colon cancer screening programs which enjoys wide support from the population as well as policy makers.[5]

The diagnostic accuracy and therapeutic safety of colonoscopy is influenced by several prerequisites. Important is the quality of the endoscopist who performs the colonoscopy. This is expressed in the number of adenomas found per procedure, or the adenoma detection rate (ADR). In 1 out of 4 colonoscopies, the doctor should find an adenoma.[6]

To achieve a high ADR one of the key requirements is optimal bowel preparation, next to adequate training of endoscopists, sufficient endoscope withdrawal time and optimal scheduling of the procedure.[7] Inappropriately cleaned colons result in less detection of relevant lesions. This warrants repeated colonoscopies and shorter surveillance intervals.[8,9] Indeed, a clean colon during colonoscopy reduces cancer morbidity and mortality.[10]

There are a number of patient related factors associated with poorly prepared colons such as incomplete laxative regimes, age, gender and comorbid disease.[11] Important reasons not to complete the intake of purgatives for patients are the inability in following instructions, reduced awareness of health behaviour and health illiteracy.[12] Consequently it is paramount to inform and instruct our patients prior to a colonoscopy.[13] Several strategies that bank on optimizing patient education to improve bowel cleanliness have been examined; and I describe these below in more detail.[14,15]

The patients journey towards endoscopy deserves optimal patient education on how to follow instructions on bowel preparation. But another pivotal element before endoscopy is that every patient is thoroughly informed about risks and benefits of the procedure (the concept of informed consent).[16] A complete informed consent contains the following elements: the nature of the procedure, its risks, its benefits and its alternatives. The patient should be given adequate time to deliberate and ask

questions.[17] It is the responsibility of the endoscopist to discuss this with the patient and to document this prior to every procedure.[18]

Due to the invasive character colonoscopy is associated with patient reported outcomes like embarrassment, pain and discomfort.[19] Sedatives to relieve anxiety is the method of choice used in order to mitigate discomfort patients experience during colonoscopy.[20] In addition to optimal patient education and obtaining informed consent, the routine use of sedative and analgesics requires a risk assessment of the individual patient.[20,21] This warrants more than just sending an invitational appointment letter to the patient before endoscopy.

The effect of any information transfer is influenced by patient dependent factors such as educational level, comprehensive capacities, and cultural aspects.[22] This results in a mixed understanding of the information that can negatively affect compliance to instructions.[23] Many hospitals rely on personal counselling by nurses or doctors to resolve this issue and at the same time obtain informed consent prior to the procedure. This leads to improved adherence to the instructions for bowel preparation.[24] Whilst effective, it is time-consuming for the counsellor, repetitive, and can result in variability in information distributed to patients. More importantly, it demands an extra hospital visit for the patient that implicates travelling costs and taking a leave absence from work.[25] Derived from these factors, it is associated with costs for the endoscopy unit (nurse wages), the patient (travel costs) and society (leave absence from work). These elements are relevant to patient education.

For a full overview of the topic I start with the historical development of patient education in endoscopy and describe the lessons learned. Shortly I will explain the concept of eHealth and discuss where these two entities meet. Then I conclude this introduction by stating the starting points of the research we conducted in this thesis.

HISTORICAL OVERVIEW OF PREPARING PATIENTS FOR ENDOSCOPY

To get insight in the historical development of a medical topic it is useful to check the PubMed “results by year” interface and obtain a tally of the number of hits. Using the term “patient education endoscopy” renders 1035 hits in total (June 2020), but just a handful in the 1980s and 1990s. In this overview I mainly report on articles regarding use of endoscopy in gastroenterology.

The following paragraphs describe the insights from literature in chronological order up to the 2000s. This preliminary work set the stage for thinking about patient education

in endoscopy. From 2000 onward, I present the body of research on three types of interventions on patient education. I sought to outline how research in patient education in endoscopy evolved with respect to the following elements: determining patient reported and procedural outcomes, informed consent and the design of interventions to improve education.

Overview 1979 – 2000, 'preliminary work'

The first publication on patient education prior to upper gastrointestinal endoscopy was published in 1979 in Japanese literature. This article focused on advice from nursing staff to influence the psychological state of the patient.[26] Soon, more publications followed in 1981, outlining the important role of education of patients before endoscopy from a psychological perspective too.[27,28] Even in those years, the concept of using endoscopic colour video's to enhance the information content of the instruction was already utilized in urological endoscopy.[29]

The first paper on the need for proper education prior to upper gastrointestinal endoscopy that used patient reported data, was published in 1982.[30] In the same year, a study examined an educational tool (a pamphlet) to alleviate anxiety before endoscopy.[31] Here, for the first time, a patient related outcome – anxiety - for these types of studies was introduced. This acknowledged that patient anxiety can be a relevant problem.

In 1985, two German authors recognized the need to obtain informed consent and organize pre- and post-endoscopy care.[32,33] In the following year, several publications addressed the need to explain the risk of complications (e.g. perforation) as a responsibility of the endoscopist with special attention for the needs of elderly patients.[34,35] Also, the role of nurses came into focus with respect to informing the patient but also to obtain informed consent.[36,37]

Indeed, the literature from the 1980s indicated the need for a structured pre-endoscopy patient education counselling session, with several key ingredients: informed consent, addressing patient anxiety, information about complications and special care for the elderly patient.

Subsequent efforts led to the design of an educational intervention trial with four comparative arms. The aim of this 1989 study was to reduce the anxiety level prior to upper endoscopy.[38] This ranged from explaining the procedure by 1. the referring physician, 2. an endoscopist, 3. using photos of every step of the procedure or 4. a video of the procedure. Most interestingly, the authors used the State-and-Trait Anxiety Inventory validated tool to more objectively establish the effect of their intervention on this measure.[39] They found no difference between groups, concluding that "more effective means are needed to accomplish this objective".[38] On the basis of this

information, the American Gastroenterology Nursing Association produced several viewpoint papers on items concerning informed consent and patient education prior to endoscopy.[16,40,41]

In the 1990s, the first informative booklet was presented as an intervention; also new was the introduction of the Visual Analogue Scale (VAS) to identify differences in the pain patient experience undergoing gastroscopy.[42] Special attention was also given to preparing children before endoscopy and providing sedation to them during endoscopy, a before derelict field of knowledge.[43,44]

These initiatives led to a better understanding by patients of endoscopy. A cohort study from 1991 among 102 patients found that 93% of referred patients for endoscopy understood the indication for their endoscopy and 93% comprehend the procedure itself.[45] Importantly, nurses expressed that patient teaching activities were extremely rewarding for both patient and nurse teachers.[46] Implementing best practices in patient education is paramount; in 1994 the high yield of a regional audit system with proper patient education benchmarks prior to endoscopy was published.[47]

A trial, also in 1991, comparing a videotape with a physician explaining informed consent items before endoscopy, showed that 1. the videotape alone was even as good as 2. the video plus physician and better than 3. the physician in person.[48] This stipulates the problem of patient-to-patient variability of information when a single individual must repeat the same message repeatedly.

An editorial from 1994 on video education choose almost prophetic words: "As we approach the dawn of the establishment of the information highway, the informed consent process appears to me to be outdated and outmoded …. It would be a simple matter to extend [this videotape] into a videotape that would more fully demonstrate the procedure, including graphs, schematics, and other video wizardry. The next logical extension would be to include an interactive program. This would allow the viewer to actively participate in the learning process."[18] One year later other authors developed an interactive video disc as suggested.[49] Three years later, in 1998, the first computer assisted concept for explaining information proved useful in an Swiss practice.[50] A 1999 Lancet paper reports a strong decrease in preprocedural anxiety scores when patients were shown a video prior to endoscopy.[51] In 2000 this was also confirmed in a small sample using physiological measures (haematocrit).[52]

To help nurse counsellors to reduce anticipatory anxiety, it proved helpful to consider patient demographics, asking about previous experiences with endoscopy, and eliciting special concerns.[53] To this end, a comprehensive instruction program to teach the nurse counsellor was published.[54] In a 1998 study there was specific attention for two main coping styles of patients: information seekers or avoiders. Seekers approach threatening

situations by intellectualization and by seeking information to make events more predictable, whereas "avoiders" use defensive mechanisms of avoidance and denial, preferring the event to remain unpredictable. When information seekers were given additional sensory information (what the patient was likely to see, hear, or feel during each stage of the procedure) there was a reduction of anxiety, recovery time, and observed behavioural indices of pain of colonoscopy. But there was no effect seen on sedation dose or patient perception of pain. Avoiders on the other hand scored higher satisfaction rates when just procedural information (facts) were presented.[55]

Overview 2000-2020, 'research along three different lines'

From the 2000s onwards, there still was wide variety in Europe in how patient education to obtain informed consent was embedded in endoscopy.[56] So the research continued on this topic, spreading out in three main directions: 1. nurse counsellors, 2. written materials and 3. audio-visual guided strategies. (Figure 1.)

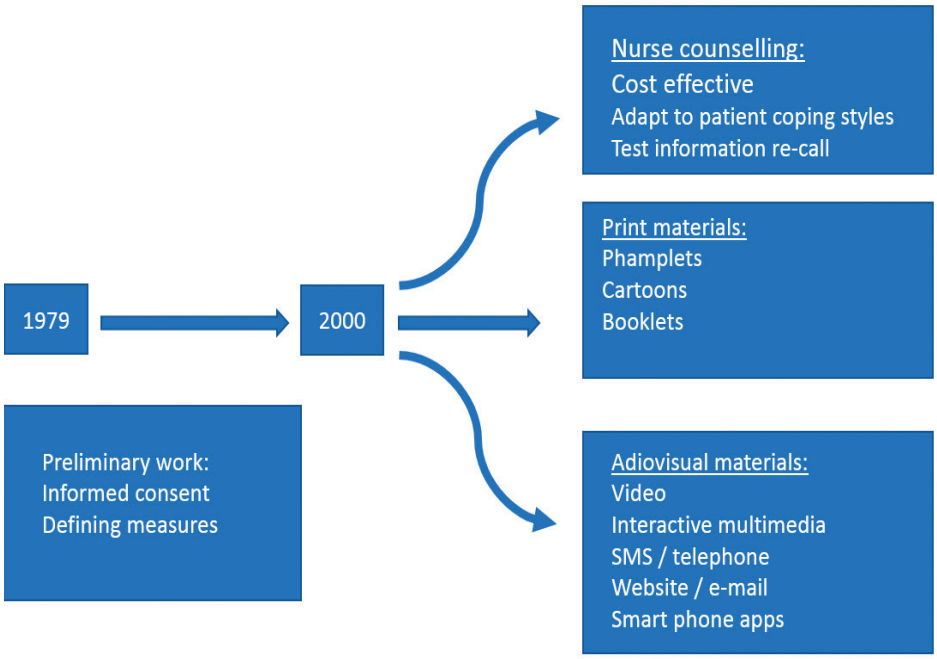

Figure 1. Research directions before and after the millennium

A noteworthy publication in the first group concerning research on nurse counselling was a 2001 cost effectiveness trial. Nurse counselling prior to endoscopy showed to be cost effective because it reduced the need for repeat procedures after initially failed attempts due to poorly cleansed colons.[24] For patients who poorly tolerated endoscopy, a counselling session by a surgeon and psychiatrists reduced the need for midazolam given during the subsequent endoscopy.[57] In 2003 endoscopists in Thailand established

high patients satisfaction scores when a counselling visit was offered the evening before endoscopic biliary interventions.[58]

A three-armed trial compared different patient routes: 1. a 12-minute nurse counselling session prior to upper endoscopy, 2. cognitive and behavioural interventions like breath exercises and swallowing techniques and 3. a control group with verbal instructions alone. This showed a positive impact of both interventions 1. and 2. compared to controls in 3. on patient distress during endoscopy.[59] A Dutch trial performed by psychologists compared patient coping styles (information seekers versus avoiders). A potential disadvantage was demonstrated, as this study showed that information overload unexpectantly burdens even the information seeking patient as no beneficial effect on anxiety, pain or experience was seen.[60] Information recall improved with a dedicated visit.[61]

In most studies patient related outcomes were used to define the effect of the intervention. But in 2009 the first study evaluated an procedural outcome: bowel preparation.[62] This aspect of colonoscopy was often used in trials to compare laxative medication prior to colonoscopy. Several scales were used to define adequate bowel preparation during endoscopy, these are mentioned in table 1.

In the 2009 study written information and a physician visit were compared to a short questionnaire identifying knowledge gaps in participants which were subsequently addressed in the same visit. This failed to improve the bowel preparation score on the Universal Preparation Assessment scale (UPAS). One year later, better bowel preparation was seen in inpatient colonoscopies when prior counselling and written instructions were given.[9]

A comparative Turkish trial proved the superiority of verbal information to written or no additional information in lowering anxiety, although this might be due to literacy levels as only 55% had secondary or higher educational levels.[63] This finding was also confirmed in a Chinese and Indian cohort.[64,65] In a 2019 Saudi cohort of children undergoing upper endoscopy, the opposite was found after broad verbal explanation. Authors stated that the procedural stress is significantly less, as measured by the s-cortisol levels in saliva and the anxiety questionnaire.[66]

In 2019, Australian research matched 76 poorly prepared patients with adequately prepared controls to find specific risk factors -opioid / constipating agents use and low socioeconomic status - for poor bowel preparation. Second, they developed a screening tool to guide the nurse counsellors on the level of education needed. As a result, a 61.6% to 33.5% drop in outpatient visits was achieved after implementation, clearly making more efficient use of education resources in endoscopy.[67]

The second main direction of research is written information. A wide variety of options in printed materials was studied. A key element is that printed information may or may not be read. In a cohort only 52% of patients referred for endoscopy actually reads the provided text completely.[68] Also the quality and the content of printed information varies considerably. For instance in an Northern Ireland sample of seven hospitals some leaflets even lacked vital information such as optional sedation or risks of endoscopy.[69] Despite these shortcomings, patients were generally satisfied with the information.[70]

Several options to provide information have been explored since. Adding written information to oral explanation by a physician yield higher patient satisfaction scores compared to oral explanation alone.[71] In 2010, a general information sheet showed high patient satisfaction rates using the Global Rating Scale (GRS).[72] Written information showed significant decrease of anxiety before endoscopy.[73] Importantly, a Dutch trial showed that coping styles are not relevant when evaluating an information brochure. This did not significantly affect anxiety or satisfaction scores.[74]

Adding a leaflet with endoscopic images of an badly prepared colon to explain the rationale of purgative use did not affect bowel preparation, as examined with the Boston Bowel Preparation Score (BBPS).[75] A booklet explaining this same concept by using the metaphor of driving through a snowstorm when advancing through a badly prepared colon did improve the bowel preparation, here examined with the Ottawa Bowel Preparation Score (OBPS).[76] A cartoon depicting a concerned physician when shown a dirty colon in a Korean cohort of patients did improve the bowel preparation scores.[77]

An American study on a multilingual (English and Spanish) booklet was published in 2016, showing a beneficial effect of implementation of this strategy when evaluating bowel preparation.[78] Endoscopic tissue sampling is common, but withholds usually around one week waiting time before the pathology report is completed. The effect of specific patient education about endoscopic biopsies reduced the anxiety levels in patients that received biopsies during endoscopy.[79] When more targeted information on the risk to fall after sedation is provided to vulnerable patients in print prior to endoscopy, the adherence to safety instructions rises from 33% to 100%.[80]

The third main direction of research after 2000 are audio-visual interventions followed by more sophisticated computer based interventions that finally could be delivered as web based solutions via internet. These were studied exhaustingly and thereby formed the largest body of science. In 2001, the first landmark trial showed that computer-assisted instruction helps physicians meet their duty to inform and to disclose with no decrement to the interpersonal aspects of the patient-physician relationship.[81] Another approach used digital visualization on a bedside laptop as an adjunct to a physician visit. This was timed prior to cardiological and endoscopic examinations in a combined cohort

of patients. This study showed an increase of satisfaction and level of knowledge of the patients, scored by a ten-item questionnaire, without significant consuming more time.[82]

Allowing room for choice for patients to see an instructive video showed no significant improvement in patient satisfaction; the authors therefore suggest to fully implement video education if available.[83] However, Danish investigators reported no effect of a thorough video information module on improving anxiety, pain, tolerability or willingness to return for repeat colonoscopy.[84] The reason why their trial was negative compared according to the authors in comparison to earlier trials centred on the inability to tailor this modality to the individual patient.

The first video based intervention in patient education that showed improvement in bowel preparation as main outcome was published in 2013 and was reconfirmed in 2014.[85,86] The first internet based delivery of video content was investigated in a trial where only 6% of the patients actually watched the video.[87] The apparently main stumble block was the fact that patients received a paper card with the website address and the instruction “go to this website”. This turned out not to motivate patients to visit the website. Nevertheless the message “online education does not work” did reverberate in a subsequent editorial referring to this trial.[88] No less than three subsequent letters to the editor discussed this further. Authors highlighted several important issues such as technical accessibility of the video, the importance of adequate health and digital literacy and the interesting point that computer based interventions “will become more successful over time as successive generations become computer savvy at younger ages”.[89-91]

A Chinese paper in 2014 compared a telephone-based re-education the day before colonoscopy as an add-on to nurse counselling, with superior bowel preparation scores as a result.[92] The impact of this unsophisticated form of telemedicine and the concerns of effectiveness in real life settings led to discussion whether the results would be representative in the Western world.[93]

The link between good information re-call and subsequent better bowel preparation was demonstrated in a Korean cohort, where a video intervention proved superior in both outcomes.[94] Also in Korea, the first trial utilizing short message service (SMS) was performed, yielding better bowel preparation scores than controls. Most interestingly, these authors added a third arm to SMS and controls utilizing telephone calls, with comparable results, leading to the conclusion that SMS could be just as effective, but cheaper and therefore the preferred option.[95] The last paper to date on an SMS based reinforced education intervention in Germany showed significantly higher bowel preparation scores, leading to improved adenoma detection rate.[96]

An elaborate study protocol with the aim to implement evidence based practices to organize endoscopy departments in six units in the United States was published in 2015.[97] They studied very clear cut questions on "what works (intervention effectiveness), for whom it works (influence of Medicaid versus other health insurances), in which contexts it works (setting characteristics that influence implementation), and how it works best (comparison of implementation strategies)" However, for undisclosed reasons, the results remain unpublished until date.

In 2016, a link to a video placed on YouTube was e-mailed to patients, concerning dietary advice alone prior to colonoscopy. This did not affect the bowel preparation.[98] Another study showed that with a website based video available to all patients, approximately 50% of patients studied this material.[99] Bowel preparation scores were higher in this group. This trial included the ADR as a novel measure, but this outcome was not improved in the intervention group. Watching a video in the hospital directly after a visit to the outpatients clinic improved bowel preparation.[100] Another trial in Korea on access to video material on the day before colonoscopy confirmed improvement of bowel preparation. Here, this did not lead to a higher polyp detection rate.[101] A 2020 paper on the quality of colonoscopy videos on YouTube demonstrated overall poor quality, except for videos produced by professional societies.[102]

In Taiwan in 2016, data on the use of CD-ROM with interactive patient education material were published, with significant impact on pain and anxiety.[103] A Chinese application with interactive information, send via a social media app (WeChat) to patients before colonoscopy resulted in improved scores of adequate bowel cleanliness (82.2% vs 69.5%).[104] This platform offered the additional opportunity to ask questions used by 11.3% of the patients. Two more recent studies confirmed the positive effect on bowel preparation of using the same social media app.[105,106], Comparable results were reported by using an application in Korea[107] Also in Asia, requesting patients to watch a video and re-tell it in their own words, proved a successful strategy to improve bowel preparation.[108]

Website information is widely accessible by patients, but the quality is often poor, as found in this 2018 paper.[109] In a low literate group of patients from Philadelphia, USA, a comparative trial with video on colonoscopy preparations showed a dramatic improvement of the rate of adequate bowel preparation. This suggests using video is more appropriate than written materials in illiteracy.[110] In 2018, a paper on a web-based multimedia platform showed both reduction of anxiety and increased information re-call compared to controls.[111] This finding was confirmed with the use of video instruction prior to endoscopic retrograde cholangiopancreatography (ERCP), with higher comprehension of ERCP-related complications and its incidence, leading to higher satisfaction with informed consent process and fewer need for additional explanations.[112]

One focus of research in the years 2000 to 2010 dealt mainly with measurements to improve the adherence to colorectal cancer screening programs as these were introduced in several countries around this time. Because this beholds more than the endoscopic procedure alone, with for instance in-depth information on false negative and false positive findings of diagnostic tests. This therefore was beyond the scope of my research.

The heterogeneity of the trials in the literature discussed above about interventions and outcome measures precludes proper meta-analysis. In recent years three publications still strived to do so, but they were either limited to assessing effect of education on anxiety alone or focused on bowel preparation scores alone.[14,15,56]

Therefore, I summarized all relevant endpoints used in the literature above in table 1.

Table 1. Outcome measures in patient education research in endoscopy

	Outcome measure	Scales	Year of entry	Author
1.	Anxiety	Likert	1982	Kamakura, Y. et al
		STAI	1989	Levy, N.et al
2.	Pain / stress	VAS	1990	Lanius, M. et al
	Physiological measures	Haematocrit	2000	Neumann, J. et al
		Heart rate	2004	Van Vliet, M. et al
		Skin conductance	2004	Van Vliet, M. et al
		S-cortisol levels in saliva	2019	Volkan, B et al
3.	Cost effect	n/a	2001	Abuksis, G. et al
4.	Satisfaction	Likert	2002	Bassi, A. et al
	Willingness to return	Likert	2007	Bytzer, P et al
5.	Bowel preparation	UPAS	2009	Modi, C. et al
		BBPS	2011	Calderwood, A. et al
		OBPS	2011	Spiegel, B. et al
		Arondchick	2014	Hseuh, F. et al
6.	Information re-call	Validated questionnaire	2015	Cho, Y. et al
7.	Adenoma detection rate	ADR	2016	Hayat, U. et al
8.	Polyp detection rate	PDR	2016	Park, J. et al

A topical editorial emphasized the “ceiling effect” that is part of these interventions to reach 90% adequate bowel preparation scores in an endoscopy unit.[113] As a result, these interventions will be beneficial in underperforming units with scores well below the 85% benchmark advised by the U.S. Multi-Society Task Force on Colorectal Cancer Screening.[114] By contrast, in better performing units the ceiling effect prevents to detect meaningful differences.

Many valuable lessons can be drawn from the literature as summarized in this introduction. The main take home messages were 1. how the content of education should be designed, 2. what the most optimal strategy is to present this to the patient and 3. how this will affect the patient in several clinically relevant outcomes.

The following section describe briefly the definition, history and use of eHealth interventions.

DEFINITION AND BACKGROUND OF eHEALTH

The history of eHealth started with 'Telemedicine'; remote care for patients with no physical contact between patient and caregiver. In 1929 the first telemedicine publication was on *Flying Doctors* in Australia, that provided a telegraph service using Morse code for emergency medicine.[115] This is a good example of the fact that the first prerequisite is adequate communication technology before eHealth implementation can follow. A further relevant historical overview is depicted here. (Figure 2.)

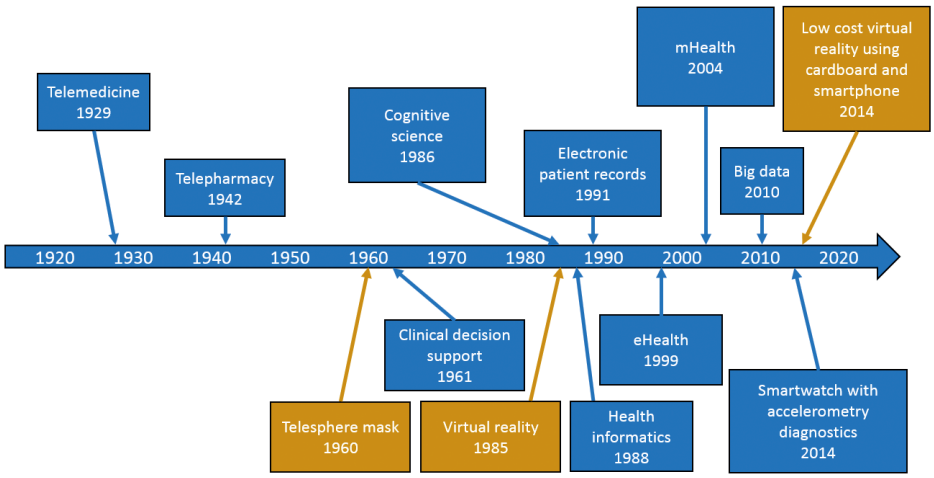

Figure 2. Timeline of eHealth development (blue) and virtual reality (gold)

The advent of the Internet came with new challenges. Efforts to use this technology from 1999 onwards are referred to as eHealth. But the wide span of these efforts has resulted to a myriad of different definitions.[116] The most widely adopted definition of eHealth is: "eHealth is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology".[117]

There is evidence to suggest that eHealth interventions are effective in improving information transfer to patients.[118] Internet based education offers a number of advantages: it can easily visualize information through use of HTML scripts, providing information in a comprehensible and appealing format, it is accessible at any desired moment, and provides the option to remind patients in a timely fashion.[14] Previous studies show that focused e-learning or computer based education paths enables good comprehension and learning and enhances patients satisfaction.[119]

The latest developments in eHealth interventions opens a whole new field with the development of virtual reality (VR) that even allows eHealth to be implemented during an endoscopic procedure. As several studies have examined non-pharmacological interventions to reduce anxiety and pain during endoscopy.[120-123] These studies used a mix of visual or auditory stimuli and found that while true efficacy is not fully established, combined visual and auditory distraction is better in reducing discomfort compared to auditory distraction alone.[121]

VR integrates computer generated visual and auditory signals to recreate an illusionary perception of the actual physical world.[124,125] The distraction that comes with immersive VR induces an analgesic effect and has been used as an adjunct to control pain and anxiety during operative procedures.[126,127] VR technique has become more affordable and better portable, adding to its immersive qualities.[128]

APPROACH OF THESIS

The preceding description of the history of patient education before and during the introduction of endoscopy as a diagnostic and therapeutic tool together with the introduction of the first eHealth strategies in 2013 have resulted in several research questions at the start of this thesis. The main insights gained from literature are presented after each question.

I. What are key elements in designing content of an eHealth patient education intervention?

Important informative elements to prepare for colonoscopy deduced from literature are diet measures, instructions on use of purgatives. Next, practical information such as the route to the department should be incorporated as well as the technical explanation of the procedure and the alternative investigations.[37,41,46] Items requiring patient input are comprehension of risks and complications and the risk assessment for sedative use to gain informed consent.[16,35] A two-way communicating platform could be the nexus between the patient and the endoscopist. State of the art technical audio-visual features should be utilized. To employ computer animation helps to capture

the viewers' attention while adequately informing him/her of objectives for medical procedures.[96,104,107] Written and spoken in comprehensible language in logical order will enable patients to understand the information.[109] Working together with patient panels improves comprehensibility and acceptability of materials.[119]

II. What is the most optimal strategy to deliver patient education to the patient?

As learned from earlier research, the access route to the platform should be as convenient as possible. Earlier studies with downloadable apps or referring to website information reaches only a low percentage of patients.[87] To enable accessibility from every browser, a web based HTML 5 scripted interactive website should be developed. Use of HTML5 code enables the use on desktop, smartphone and tablets. Making the patient open the website and read the information is crucial. An option to achieve this is to implement a visit to this website as a mandatory step into the process of the endoscopy unit invitation, for instance by sending out e-mails or utilizing patient portals. Crucial element in patient participation is the obligation to complete the eHealth intervention before getting their colonoscopy appointment date.

III. What are clinically relevant outcomes for these trials?

Table 1. leads to identification of the key motives that drive this field of science. We could pinpoint three reasons: improving the quality of colonoscopy, optimizing the patient experience and cost control. The quality of bowel preparation in most recent publications was chosen as main outcome measure; most used is the Boston Bowel preparation score, due to the clinical relevance.[96,105,107,110] Several trials added the polyp or ADR to the bowel preparation score. But the value of ADR beyond bowel preparation scores is not evidently clear.[15,99,101] To optimize patient experience, several aspects of patient related outcomes are relevant. Lowering the patient anxiety levels during endoscopy is the most evaluated goal.[56] Furthermore, improving patient satisfaction, often defined as 'willingness to return' is a relevant outcome measure.[129] Physiological measures of stress are seldom used and therefore not implemented in this thesis.[52,66] In literature, the effect of interventions on costs was not often presented.[24] As an important factor in our Dutch health system, we set out to perform this relevant evaluation.

AIM

The goal of this thesis is to establish the position of several eHealth initiatives and validated tools to improve patient care in daily practice of endoscopy.

To achieve this aim, the following objectives were established:

1. To develop an eHealth intervention for patient education prior to endoscopy
2. To implement the eHealth intervention in daily practice, identifying key factors for success
3. To evaluate relevant outcome measures for assessing the effect of eHealth interventions

OUTLINE

In this thesis, I describe a pilot study evaluating the hospital based computer assisted instruction prototype for patient prior to colonoscopy **(chapter 2)**. Next, I provide an overview of the implementation process for the first hospitals using this new technology (**chapter 3)**. The subsequent development of computer based education at home prior to colonoscopy including a video, 3D-animations, text and voce-over, showing every step of the process is outlined in **(chapter 4)** together with the study protocol for a multicenter trial to evaluate this tool. I discuss the main outcomes of this trial in **(chapter 5)**, including the potential cost savings **(chapter 6)**. Our group executed a feasibility study of a practical application of an eHealth intervention during endoscopy with virtual reality glasses **(chapter 7)**. Next, our group examined a validated questionnaire designed to evaluate the effect of eHealth interventions on satisfaction **(chapter 8)**. Finally, I present a general discussion and future perspectives of the thesis **(chapter 9)**.

An overview of the main research questions, study design and measures for all individual chapters is highlighted in table 2.

Table 2. Main research questions and methodology addressed in chapters of this thesis

Chapter	Research question	Study design	Measures
2.	Is hospital based computer assisted instruction (CAI) feasible for patient education prior to colonoscopy in the waiting room of the outpatient's clinic?	Prospective controlled trial	- Bowel preparation scores (BBPS / OBPS) - Comfort scores - Satisfaction scores - 10 item information re-call test
3.	What are the main stumble blocks in implementing computer assisted instruction in real life practice?	Viewpoint paper on experiences in implementation processes	- Implementation data of the CAI in 14 endoscopy suites nationwide
4.	How can CAI be improved into computer based education (CBE) at home using two-way communication?	Multicenter randomised controlled trial – study protocol	- Preparation of trial sites before RCT start
5.	Is CBE non-inferior to nurse counselling prior to colonoscopy in quality of bowel preparation? Does CBE reduce nurse counselling visits / lower patient sickness absence? Does CBE reduce anxiety / improve satisfaction and information recall in patients prior to colonoscopy?	Multicenter randomised controlled trial	- Bowel preparation scores (BBPS) - Sickness absence leave - Anxiety (STAI) - Satisfaction (NPS / WTR) - 10 item information re-call test
6.	Is the use of CBE reducing costs in the endoscopy unit?	Cost minimization analysis	Cost model Out of pocket cost analysis iMTA productivity score
7.	Is the use of VR glasses feasible to relieve pain and discomfort in patients during colonoscopy?	Pilot study	- Anxiety (STAI) - Pain (NRS) - Satisfaction (NPS / WTR)
8.	Is the GESQ questionnaire for measuring patient satisfaction suitable for use in the Dutch population?	Validation study	- Guidelines on questionnaire validation (CONSORT)

CAI: computer assisted instruction. CBE: computer based education. STAI: State-and-Trait Anxiety Inventory. NRS: Numeric Rating Scale. NPS: Net promoter score. WTR: Willingness to return.

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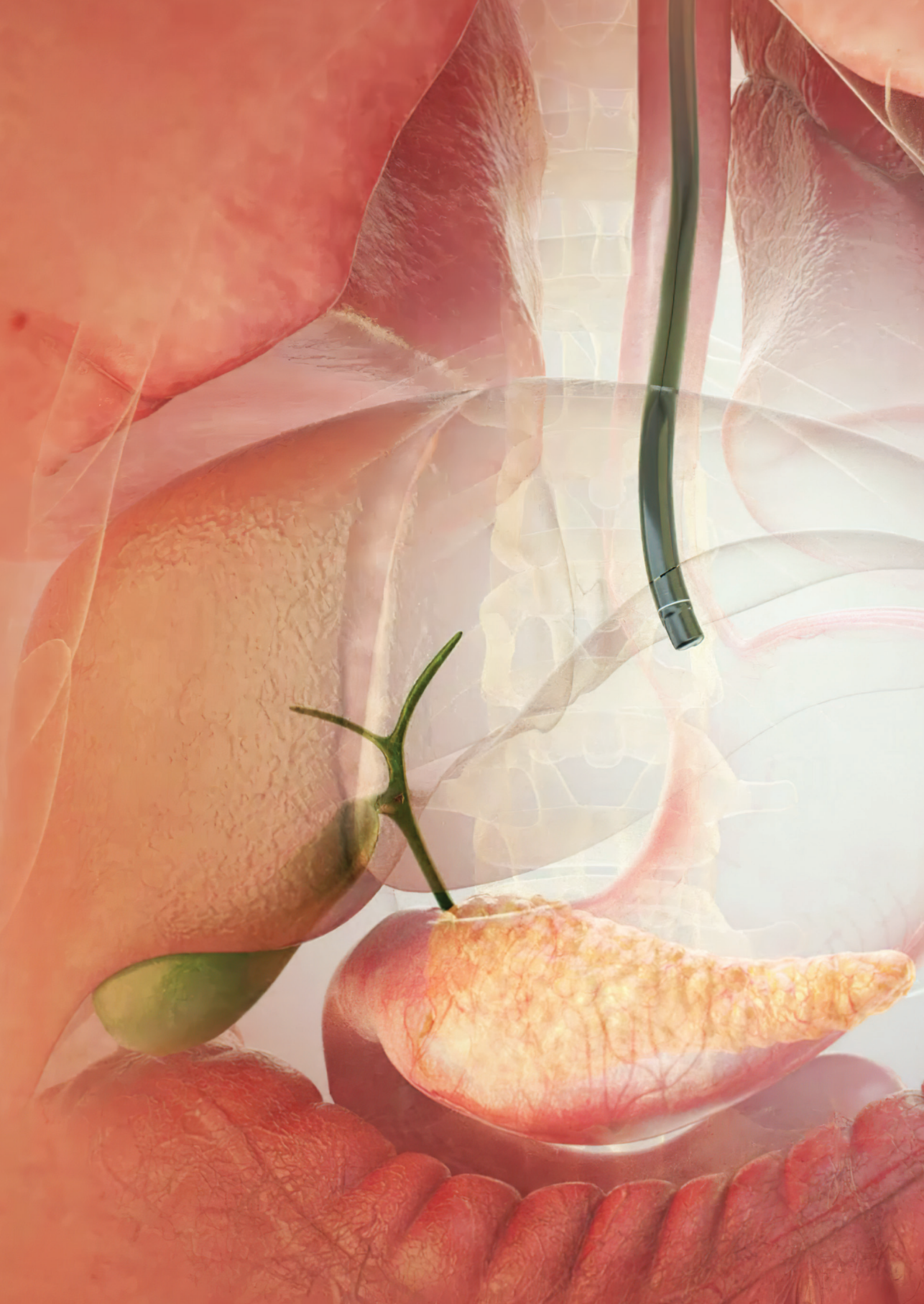

2

Computer-assisted instruction before colonoscopy is as effective as nurse counselling, a clinical pilot trial

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ABSTRACT

BACKGROUND

Better patient education prior to colonoscopy improves adherence to instructions for bowel preparation and leads to cleaner colons. We reasoned that computer assisted instruction (CAI) using video and 3D animations followed by nurse contact maximizes the effectiveness of nurse counselling, increases proportion of clean colons and improves patient experience.

METHODS

Adults referred for colonoscopy in a high volume endoscopy unit in the Netherlands were included. Exclusion criteria were illiteracy in Dutch and audio-visual handicaps. Patients were prospectively divided into two groups, one group received nurse counselling and one group received CAI and a nurse contact before colonoscopy. The main outcome, cleanliness of the colon during examination, was measured with Ottawa Bowel Preparation Scale (OBPS) and Boston Bowel Preparation Scale (BBPS). We assessed patient comfort and anxiety at three different time points.

RESULTS

We included 385 patients: 197 received traditional nurse counselling and 188 received CAI. Overall patient response rates were 99%, 76.4% and 69.9% respectively. Endoscopists scored cleanliness in 60.8%. Comparative analysis of the 39.2% of patients with missing scores showed no significant difference on age, gender or educational level. Baseline characteristics were evenly distributed over the groups. Bowel cleanliness was satisfactory and did not differ amongst groups: nurse vs. CAI group scores in BBPS: (6.54 ±1.69 vs. 6.42 ±1.62); OBPS: (6.07 ±2.53 vs. 5.80 ±2.90) Patient comfort scores were significantly higher (4.29, ± 0.62 vs. 4.42, ± 0.68) in the CAI group shortly before colonoscopy. Anxiety and knowledge scores were similar.

CONCLUSION

CAI is a safe and practical tool to instruct patients before colonoscopy. We recommend the combination of CAI with a short nurse contact for daily practice.

INTRODUCTION

Colonoscopy is the golden standard of diagnosing, surveillance and removal of precancerous lesions like adenoma in the colon which reduces colorectal cancer mortality.[1] The importance herein is well advocated.[2] On the other hand, the prospect of undergoing colonoscopy and the intensive preparation might have a negative effect on patient's comfort and anxiety.[3]

Adequate bowel preparation is crucial, so it is paramount to optimally inform and instruct our patients prior to a colonoscopy.[4] Poorly prepared colons lead to a higher miss-rate of neoplasms,[5] more complications and increase need for repeat examinations with increased costs and cumulative discomfort for patients.[6,7] Therefore, to achieve adequate bowel cleanliness, patients have to adhere to prescribed use of laxative agents and dietary instructions.[8] Patients cleansing scores are influenced by ASA status, co-morbidity, treatment with gut motility modifying drugs. In our study, where these factors were unaffected by the intervention, we did not evaluate these further.

Patient education is obviously of key importance in achieving a well prepared colon. Several educational tools are known to be effective in various degrees; e.g. informative leaflets, cartoons, video and dedicated counselling sessions by a nurse or a physician.[3,9-13] Better education overall establishes higher quality of bowel preparation.[14] In the Netherlands the most common strategy is to provide a nurse counselling session prior to endoscopy.

In recent years, advances in internet technology provide us with novel, web-based education programmes, enabling us to combine the previously mentioned modalities. Computer assisted instruction (CAI), available on desktop and smartphone, helps to raise patient satisfaction about the information provided.[15] Proper implementation, however, is important.[16]

The evidence base that support use of CAI for bowel preparation is lacking. We hypothesise that CAI using video and 3D animations maximizes effectiveness of nurse counselling and therefore improves bowel cleanliness. Furthermore, CAI will positively influence the patient experience.

We conducted a pilot trial assessing the effectiveness of CAI for patient education prior to colonoscopy measuring bowel cleanliness and patient comfort and anxiety.

PATIENTS/MATERIAL AND METHODS

We used a prospective, single center, endoscopist blinded, controlled design to conduct our pilot study.

Patients

Consecutive patients older than 18 years referred for elective colonoscopy were included from March 2013 until November 2013 in a single, large volume endoscopy center (over 4000 colonoscopies/year) in the upper Amsterdam Area in the Netherlands. Exclusion criteria were illiteracy in Dutch and significant audio-visual/mental handicaps. Patients were prescribed the same split dose preparation regime of picosulfate sodium and low fibre dietary advice in the days preceding the colonoscopy.

Study design

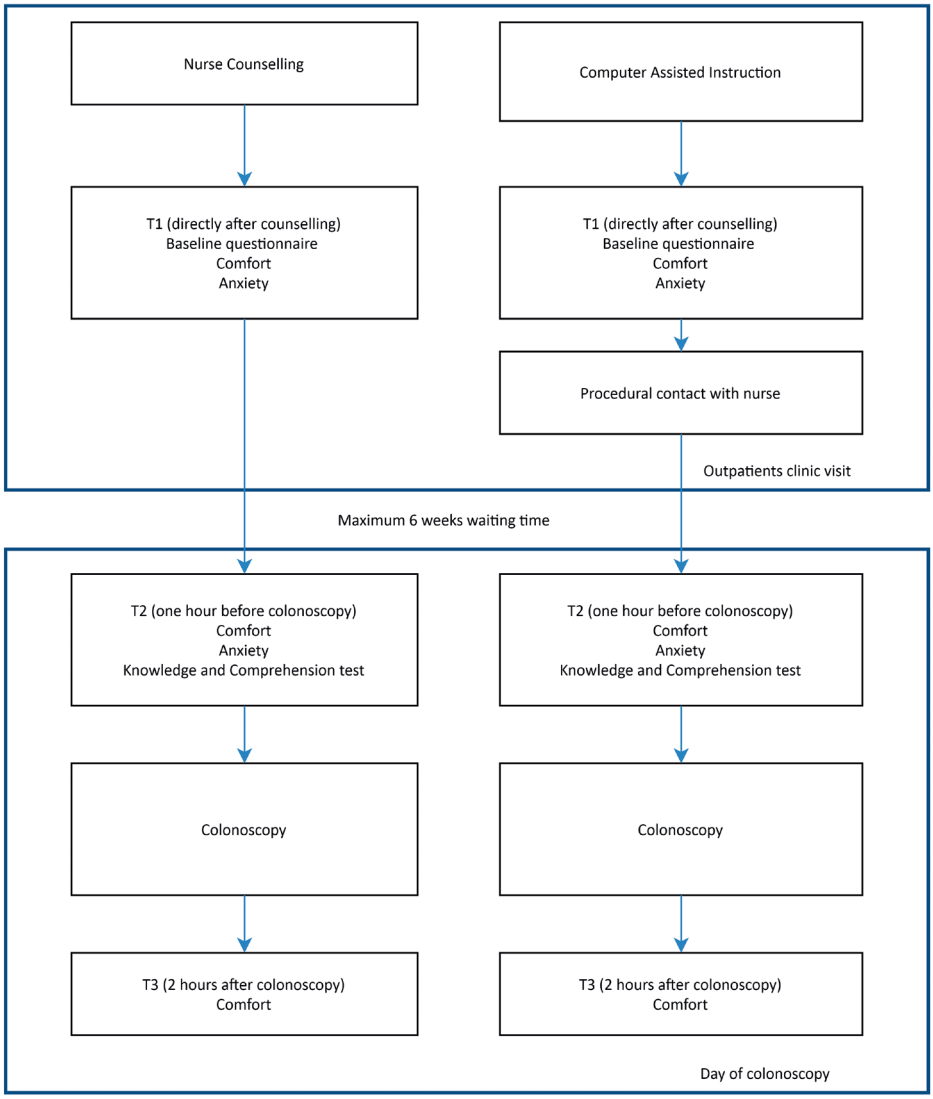
After informed consent was obtained, patients were divided in two groups: the control group received nurse counselling and the intervention group received computer assisted instruction (CAI). We administered three patient questionnaires at three time points. (See the flowchart in figure 1.)

In the first questionnaire, patients reported their baseline characteristics regarding age, gender, educational level, ethnicity, use of drugs, number of recent physician visits and experience in multimedia and internet access. Patients rated comfort ("How do you feel after the received information?") and anxiety ("How anxious are you") on a 5-point Likert scale (T1). Subsequently the CAI group had a contact with a trained endoscopy nurse for practical matters like bridging in anticoagulant therapy, insulin dosage calculation and scheduling of the colonoscopy. In addition, we also provided a unique hyperlink to the CAI with unlimited access. Next, patients were scheduled for colonoscopy, maximum 6 weeks after the counselling session.

After check-in at the endoscopy unit in the hour prior to colonoscopy patients rated comfort and anxiety. Additionally, patient's knowledge and comprehension were tested in a 10-question survey on the provided counselling information (T2). Within two hours post-colonoscopy, patient's comfort was again scored on the 5-point Likert scale (T3).

During colonoscopy, the endoscopist assessed bowel cleanliness with the Boston Bowel Preparation Scale (BBPS); a cumulative score of three bowel segments, ranging from 0-1 "unsatisfactory", 2-3 "poor", 4-5 "fair", 6-7 "good", 8-9 "excellent".[17] To detect subtle differences we applied the Ottawa Bowel Preparation Scale (OBPS). This scale is based on the combination of the cumulative scores of three bowel segments (0 "excellent", 1 "good", 2 "fair", 3 "poor", 4 "inadequate"), with added points for the amount of residual fluid (0 "none", 1 "moderate" and 2 "large").[18]

Figure 1. Flowchart



Computer assisted instruction

We designed an interactive CAI, according to current best practices, such as good accessibility, plain language and a presentation that engaged the user.[19] We presented the information in a stepwise fashion. CAI consists of a web-based platform using video to mimic the patient journey with a voiceover supported by photo's, 3D animation and instructive texts. (figure 2., CAI is available in Dutch via https://trials.medify.eu/cai-colonoscopy) The video was presented in short clips, maximum of 45 seconds, to

maintain the focus of patient. Patient interaction was ascertained by a mandatory mouse-click after each item in the CAI.

All informative elements, especially mandatory for informed consent for colonoscopy (risks, alternatives) were included.

Figure 2. Several screenshots from the computer assisted instruction (the persons in these stills are actors)

Outcomes

The primary outcome was cleanliness of the colon during examination as assessed by the OBPS and the BBPS. The secondary outcomes were patient comfort with the received information, anxiety and knowledge and comprehension.

Statistical analyses

A sample size of 322 provides 80% power, with a two-tailed α of 0.05, to detect an increase in the primary outcome measure (BBPS) from 6.0 in the control group to 6.5 in the experimental group, with a standard deviation of 1.6.

All analyses were performed using SPSS version 20.0 for Windows (SPSS Inc., Chicago, IL, USA). We used descriptive statistics to describe baseline information including frequency count, percentage and mean ±standard deviation. Further analyses included the chi-square test, independent t-test and Mann-Whitney. P-values under 0.05 were regarded statistically significant.

Registration number

The trial was registered in ClinicalTrials.gov with number: NCT02656602

Ethical considerations

The study was approved by the institutional review board of the Medical Center Alkmaar.

RESULTS

Patients

We included 385 patients, 197 in the nurse counselling group and 188 in the CAI group. The baseline characteristics regarding age, gender, educational level and ethnicity were equally distributed among both groups. Mean age was 57 years (range 18-83) in the nurse counselling group versus 59 years (range 18-89) in the CAI group. Educational levels were representative to the general Dutch population.[20] The majority of the participants were of Dutch ethnicity (87%). (Table 1.)

Table 1. Baseline Characteristics

	Nurse counselling	**Computer Assisted Instruction**	**Nurse versus Computer Assisted Instruction (statistical test)**
Gender (n, %) Male Female	97 (49.2) 100 (50.8)	90 (47.9) 98 (52.1)	p = 0.789 (Chi-Square)
Age (mean, range)	57 years, 18-83	59 years, 18-89	p = 0.09619 (t-test)
Ethnicity (n, %) Native Dutch Other	177 (89.8) 20 (10.2)	163 (86.7) 25 (13.3)	P = 0.384 (Chi-Square)
Educational level† (n, %) Low Middle High	59 (29.9) 68 (34.5 70 (35.5)	43 (22.9) 68 (36.2) 77 (41.0)	P = 0.131 (Mann-Whitney)

† Highest completed educational level was split into three levels where 'low' comprised no education through to lower secondary education, 'middle' comprised upper secondary and middle vocational education, and 'high' comprised higher vocational and tertiary education

Both groups were also similar in the number of drugs used and recent physician visits. The use of email was comparably high, over 90% in both groups (90.9% versus 94.1% in the CAI group)

Overall scoring rate of data collection queries at the chosen time points was 99% at T1, 76.4% at T2 and 69.9% at T3. Patients that did not score at T1, T2 or T3 were not included in the time point analysis.

The bowel preparation regime prescribed was picosulfate sodium (99%), in split dose. Two patients received for clinical reasons polyethylene glycol, sodium sulphate, sodium bicarbonate, sodium chloride, potassium chloride.

Primary Outcome

Bowel cleanliness was equal in the two groups with a mean total BBPS scores of 6.54 (± 1.69) in the nurse counselling group and 6.42 (± 1.62) in the CAI group. This is "good" according to the scale.[17]

According to OBPS the nurse counselling group scored 6.07 (± 2.53) and the CAI group 5.80 (± 2.90). Here, the score is "good-fair".[18] (Table 2.) Both scales were scored in 60.8% of all cases. Comparative analysis of the 39.2% of patients with missing scores showed no significant difference on age, gender or educational level.

Table 2. Primary Outcome: Bowel Cleanliness during Colonoscopy

	Nurse counselling (n, % scoring rate)	**Computer Assisted Instruction (n, % scoring rate)**	**Nurse versus Computer Assisted Instruction (Mann-Whitney)**
Ottawa Bowel Preparation Scale (mean, SD)	6.07, ±2.53 (n=115, 58.4%)	5.80, ±2.90 (n=87, 46.3%)	p = 0.418
Boston Bowel Preparation Scale (mean, SD)	6.54, ±1.69 (n=129, 65.5%)	6.42, ±1.62 (n=88, 46.8%)	p = 0.576

Secondary Outcomes

Comfort with the received information

Patient comfort scores directly after counselling (T1) were 4.54±0.56 in the nurse counselling group and 4.17±0.51 in the CAI group ($p < 0.0001$). Patient comfort scores prior to colonoscopy (T2) were significantly higher in the CAI group compared to the nurse counselling group (4.42±0.68 vs 4.29±0.62, $p=0.039$). Patient comfort scores after colonoscopy (T3) were not different between groups. (Table 3.)

Anxiety

We found no significant differences between groups in the 5-point Likert anxiety scores at T1 (total mean 3.04±1.27) and T2 (total mean 2.84±1.30). (Table 3.)

Knowledge and Comprehension

The scores of the 10-question survey was not different among groups (7.31±1.11 vs 7.08±1.17, $p=0.12$). (Table 3.)

Table 3. Secondary Outcomes: Comfort, Anxiety and Knowledge and Comprehension

	Nurse counselling (n, % scoring rate)	**Computer Assisted Instruction (n, % scoring rate)**	**Nurse versus Computer Assisted Instruction (Mann-Whitney)**
Comfort Score after consult/CAI (T1) (1=very low, 5=very high)	Mean 4.54, ± 0.56 (n=193, 98.0%)	Mean 4.17, ± 0.51 (n=188, 100%)	**p = 0.000**
Comfort Score before endoscopy (T2) (1=very low, 5=very high)	Mean 4.29, ± 0.62 (n=162, 82.2%)	Mean 4.42, ± 0.68 (n=124, 66.0%)	**p = 0.039**
Comfort Score after endoscopy (T3) (1=very low, 5=very high)	Mean 4.16, ± 0.93 (n=150, 76.1%)	Mean 4.28, ± 0.84 (n=117, 62.2%)	P = 0.322
Anxiety Score after consult/CAI (T1) (5=very low, 1=very high)	Mean 3.16, ± 1.30 (n=193, 98.0%)	Mean 2.92, ± 1.22 (n=188, 100%)	p = 0.071
Anxiety Score before endoscopy (T2) (5=very low, 1=very high)	Mean 2.80, ± 1.32 (n=162, 82.2%)	Mean 2.90, ± 1.27 (n=124, 66.0%)	p = 0.451
Knowledge and Comprehension 10 item test score before endoscopy	Mean 7.08, ± 1.17 (n=164, 83.2%)	Mean 7.31, ± 1.11 (n=127, 67.6%)	p = 0.112

DISCUSSION

The present study shows that computer assisted instruction (CAI) before colonoscopy results in well prepared colons, comparable to face-to-face nurse counselling. We found that patients who were informed through CAI achieved higher grades of comfort. Interestingly, at baseline this rating is higher in the nurse counselling group, suggesting the influence of the human factor.

Current research on patient education in colonoscopy has been focused on the use of leaflets, video, phone intervention and nurse or physician counselling sessions.[3,9-13] In this era of information technology with internet, social media and open access sources, computers are anchored in the seeking and gathering behaviour by patients for medical instructions as it is fast, easy to use and ubiquitously accessible. The threat is that its information may be experienced as incomprehensible, insufficient and even incorrect. CAI, as provided by the endoscopy unit, has the potential to combine the upsides of the above tools without the drawbacks such as passive learning.[21]

CAI empowers the patient in place, pace and moment of learning, known to have impact on patients satisfaction.[22] In addition, reviewing and sharing online information with relatives is comfortably facilitated. In our trial, some patients viewed the CAI up to six or seven times after providing the secured unique patient hyperlink (data not shown). It is tempting to believe that this contributes to higher grades of comfort before colonoscopy using CAI.

Familiarity with the use of computers, notably by elderly patients, could be of concern. In our cohort, 40% in the CAI group were older than 65 years. We did not find an age dependent effect (data not shown). However, before drawing general conclusions from our results, we need to confirm this in larger studies.

Nurse counselling certainly provides personal contact and offers emotional support. Indeed, we observed higher comfort scores immediately after nurse counselling compared to CAI. On the other hand, limitations of this human factor in transferring information include distraction from the content, nuisances in the interpersonal domain and the non-uniformity when different nurses or physicians are involved.

Limitations

A limitation of the present study is its non-randomized design. This was due to the unavailability of the CAI at the start of patient inclusion. However, this design did not affect the scoring by the endoscopist as he/she was unaware of this information and therefore unaware of assignment over the groups whilst assessing the primary endpoint. The endoscopist scoring rate of 60% is most probably due to the limited administrative time in daily practice. Also, the use of patient reported questionnaires restricts medical data collection as compared to chart review. Therefore, we cannot exclude the possibility of selection bias (such as previous experience with colonoscopy) in assessing secondary endpoints.

We conclude that implementing CAI leads to a properly cleaned colon at colonoscopy, with a positive impact on the patient-experience. Given the above results, this impact may be further augmented when combining the practical side of CAI with the option of a personalized nurse contact. Computer aided representation of the patients' journey through the medical landscape will require constant feedback and further research should include updates of the current CAI.

The use of a larger randomized controlled multicenter trial design with these added elements might also show non-inferiority and cost-effectiveness of such approach. Macro-economic effects of less short absence sick leave might also be interesting.

ACKNOWLEDGEMENTS

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3

Digitaal de patiënt voorbereiden op coloscopie - Ontwikkeling en invoer van een voorlichtingsapplicatie

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SAMENVATTING

Voor een goed verloop van een coloscopie is het essentieel dat patiënten vooraf optimaal van informatie zijn voorzien over de procedure. Patiënten zijn gebaat bij voorlichting over het laxeren, risico's en alternatieven en moeten een 'informed consent' afgeven De endoscopist heeft vooraf patiëntgegevens nodig om een adequate risico-inschatting voor sedativagebruik te maken. De meeste Nederlandse centra hebben een pre-endoscopiespreekuur ingesteld om deze informatie uit te wisselen. Deze werkwijze staat echter onder druk nu het aantal coloscopieën snel toeneemt door de invoering van het bevolkingsonderzoek naar darmkanker.

Om de kwaliteit van de informatievoorziening te verbeteren en logistieke problemen het hoofd te bieden hebben wij de afgelopen jaren gewerkt aan digitale voorlichting. We hebben een applicatie ontwikkeld waarmee de patiënt thuis met 3D-animaties en video wordt voorgelicht en waarmee de actuele gezondheidsinformatie over de patiënt wordt verzameld. Hierdoor krijgen patiënten op een passende en uniforme manier voorlichting en wordt het zorgsysteem ontlast. Dit past in het huidige tijdsperk met nieuwe digitale technologieën in de zorg.

ABSTRACT

Online tool to prepare patient for colonoscopy; development and implementation of a patient-education app

Optimal patient education prior to colonoscopy is essential for an optimal outcome of the procedure. Patients benefit from adequate information regarding laxatives, risks and alternatives, and must provide informed consent. The endoscopist also must have access to patient data in advance of the procedure in order to carry out an adequate risk assessment for the use of sedation. Most centers in the Netherlands usually make use of a pre-endoscopy consultation to exchange this information, but here is now pressure on this practice because the number of colonoscopies is increasing rapidly as a result of the introduction of the national screening programme for colorectal cancer.

We have been working on systems for digital patient information in the past few years, to improve the quality of patient education and to tackle logistical challenges. We have developed an app that the patient can use at home to receive information via 3D animations and video, and that gathers current patient health data. This ensures that patients receive suitable and uniform information and reduces pressure on the health care services. This is also appropriate in the current era of information technologies in the health-care sector.

Om een coloscopie succesvol te laten verlopen is het essentieel dat de patiënt vooraf van goede informatie is voorzien. De meeste Nederlandse ziekenhuizen geven voorlichting tijdens een pre-endoscopiespreekuur. Nu er, mede door het bevolkingsonderzoek naar darmkanker, steeds meer coloscopieën nodig zijn, neemt ook de druk op de endoscopiecentra toe. Een digitale methode om patiënten voor te bereiden kan helpen die druk te verminderen.

Er is een aantal zaken die voorafgaand aan de procedure ter sprake moeten komen. Zo is een belangrijke voorwaarde voor een succesvolle coloscopie dat er zo min mogelijk fecale verontreiniging in de darm aanwezig is. Onvoldoende laxeren verhoogt het risico op een beperkt beoordeelbare coloscopie, waardoor relevante bevindingen zoals poliepen of darmkanker kunnen worden gemist. De coloscopie moet bij onvoldoende laxeren dus herhaald worden.[1]

Daarnaast moet vooraf een risico-inschatting worden gemaakt voor een veilig gebruik van sedatie. Er moet screening plaatsvinden of de patiënt veilig sedatie kan ondergaan en of hierbij aanpassingen nodig zijn. Ook moet nagegaan worden of de patiënt antistolling gebruikt en dient deze medicatie zo nodig te worden aangepast.

Verder moeten patiënten worden ingelicht over de risico's van de procedure en moet informed consent worden verkregen. De regels hiervoor zijn in 2016 bij het in werking gaan van de Wet Kwaliteit, Klachten en Geschillen Zorg verder aangescherpt.[2] Zo moeten mogelijke complicaties gerelateerd aan de coloscopie besproken worden, zoals perforatie, bloeding en het effect van de sedatie, en moet er gewezen worden op alternatieven zoals radiologisch onderzoek. Of dit is besproken wordt vervolgens gedocumenteerd in het patiëntendossier.[3]

Naast deze praktische zaken, is het in de voorbereiding ook van belang in te gaan op de spanning die de patiënt vaak ondervindt bij het vooruitzicht een coloscopie te krijgen. Deze spanning werpt soms een drempel op voor het ondergaan van de coloscopie.[4] Patiënten hebben vaak vragen over hoe de dag van het onderzoek eruitziet, hoe het onderzoek praktisch wordt uitgevoerd en wat het effect van de sedatie is op de beleving. Als patiënten goed worden voorbereid op het onderzoek, kan dit hun angst verminderden.

Om aan al deze punten tegemoet te komen moet de patiënt goede instructies krijgen over het laxeren voorafgaand aan de coloscopie en complete uitleg over de procedure, de risico's en de mogelijke alternatieven. Ook moet de endoscopist actuele medische informatie over de patiënt ontvangen en moet informed consent worden verkregen.

PRE-ENDOSCOPIESPREEKUUR

In Nederland geven endoscopiecentra deze voorlichting meestal tijdens een pre-endoscopiespreekuur. Het is gebleken dat dit de kwaliteit van de coloscopie verhoogd: een goed voorgelichte patiënt houdt zich beter aan dieet- en laxeerinstructies.[5] Uit onderzoek blijkt deze inzet ook kosteneffectief: het vermindert de noodzaak om vanwege een slechte voorbereiding de coloscopie te herhalen.[6] Ook wordt op deze manier het informed consent gestructureerd vastgelegd.

Gezien de forse groei van het aantal coloscopieën staat de huidige werkwijze echter onder druk. In 2014 zijn 249.900 coloscopieën verricht. Door de introductie van het bevolkingsonderzoek naar darmkanker en de daaruit voortvloeiende surveillance zal dit aantal tot 2020 jaarlijks stijgen met 72.000 endoscopieën.[7]

Ook kleven er in de praktijk verschillende nadelen aan dit spreekuur. Het belast patiënten met een extra polikliniekbezoek en er is extra personele bezetting van endoscopiespreekuren nodig. Bovendien is de manier van voorlichten niet uniform omdat die mondeling wordt gegeven en per persoon en per keer kan verschillen.

Een alternatief voor het pre-endoscopiespreekuur is een digitale methode om de patiënt voor te bereiden. De aandacht voor nieuwe digitale technologieën in de zorg neemt momenteel toe. Zo spreekt het visiedocument *Medisch Specialist 2025* over ‘innovaties die de traditionele vorm van de arts in het ziekenhuis en de patiënt die daar naartoe komt kunnen veranderen’.[8]

Belangrijk voor een succesvolle innovatie is dat het betere zorg voor de patiënt oplevert. Een voordeel van digitale technologie is dat het patiënten de mogelijkheid biedt om laagdrempelig, in de thuissituatie en op het tijdstip dat zij wensen, adequate en passende voorlichting ter beschikking te hebben.[9] Een tweede voordeel is dat de belasting van de zorgverlener kan afnemen doordat het minder tijd en capaciteit kost om gestructureerd actuele medische informatie te verstrekken en te verzamelen.

DIGITALE VOORLICHTING OVER ENDOSCOPIE

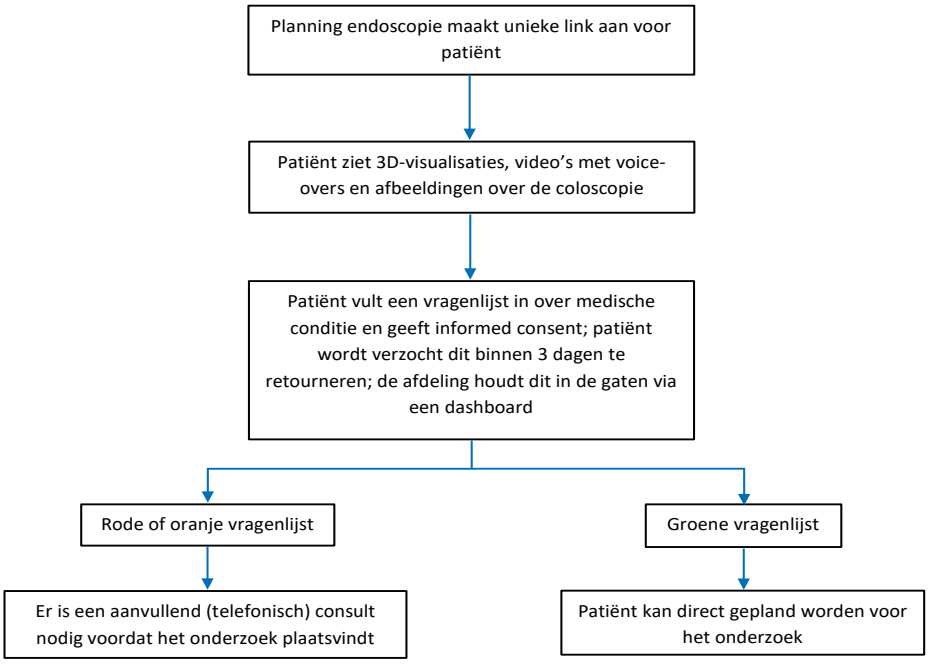
Om de patiënt beter te informeren en de endoscopieafdeling te ontlasten, hebben wij een applicatie ontwikkeld om patiënten voor te lichten over de coloscopie. (Figuur 1.) Met korte filmpjes van de endoscopieafdeling met voice-over, 3D-animaties en ondersteunende tekst, lichten we patiënten digitaal, visueel en interactief voor over de coloscopie. De site informeert de patiënt uitvoerig over de coloscopie, de voorbereiding en de risico’s. Omdat de video’s zijn opgenomen per centrum, raken patiënten zo al vertrouwd met de afdeling. De informatie wordt op een toegankelijke en voor iedereen

gelijke wijze gepresenteerd. Doordat de informatie in meerdere talen beschikbaar is, vormt een taalbarrière ook geen belemmering meer. De patiënt kan de gegevens bovendien meerdere malen terugkijken.

Figuur 1. Screenshots uit de voorlichtingsapplicatie ter voorbereiding op een coloscopie.

Direct na hun verwijzing krijgen patiënten een e-mail met een individuele link die naar de site met de applicatie leidt. Lezers van het *NTvG* kunnen een voorbeeld bekijken via http://ntvg.medify.eu. Als patiënten de voorlichtingsmodule hebben doorlopen vullen ze een gezondheidsvragenlijst in. Deze brengt de relevante voorgeschiedenis in kaart en het gebruik van medicatie, in het bijzonder van antistolling. Aan het einde van de module geeft de patiënt informed consent, die via een beveiligde server verzonden wordt. Deze werkwijze is weergegeven in een stroomdiagram. (Figuur 2.)

Figuur 2. Stroomschema van de werkwijze van de digitale voorlichtingsapplicatie ter voorbereiding op een coloscopie.



De endoscopieafdeling beoordeelt vervolgens deze gegevens en neemt indien nodig vervolgstappen. Dit gebeurt op basis van een lijst waarin alle mogelijke vervolghandelingen via een geautomatiseerd protocol zijn gekoppeld aan de gegevens die de patiënt invulde. Zo kan bijvoorbeeld de trombosedienst worden ingeschakeld. Op deze wijze wordt ook een risico-inschatting voor het gebruik van sedatie gemaakt. Dit gebeurt conform de huidige richtlijn op basis van de ASA-classificatie.[10]

Soms worden patiënten alsnog op het spreekuur beoordeeld of via een telefonisch consult ingelicht. Dit geldt voor patiënten met een mogelijk verhoogd risico door bijvoorbeeld het obstructief slaapapneusyndroom, eerdere problemen bij sedatie of een ASA-classificatie III, of als aanpassing van de antistolling noodzakelijk is. Bij patiënten met veel comorbiditeit (ASA III-IV) is dit persoonlijk contact ook noodzakelijk om voorbereidingen te treffen op de sedatie. Zo nodig kan de behandelaar met deze patiënten ook nogmaals bespreken of de procedure niet te belastend is. Uit onze ervaring blijkt dat aanvullend contact nodig is bij een kwart van de patiënten; de meerderheid rondt het voortraject direct af.

ONDERZOEK

In 2013 is een onderzoek uitgevoerd waarin dit digitale programma werd vergeleken met mondelinge voorlichting. Aan deze pilotstudie deden 385 patiënten mee die voor coloscopie naar een groot perifeer ziekenhuis waren verwezen. De onderzoekers keken onder meer naar hoe schoon de darm was bij de coloscopie. Hieruit bleek dat patiënten die de site bekeken hadden, een goed voorbereid colon hadden bij coloscopie, vergelijkbaar met dat van patiënten die door verpleegkundigen waren voorgelicht.[9]

Patiënten waren ook tevreden over de werkwijze: de applicatie kreeg een waardering van 7,7 uit 10 op de eerste endoscopieafdeling waar deze vorm van voorlichting werd ingezet.[10] De helft van de patiënten keek de informatie meerdere keren terug. Minder dan 5% was niet in bezit van een e-mailadres en gaf de voorkeur aan het pre-endoscopiespreekuur. Voor laaggeletterden zijn de audiovisuele elementen goed te begrijpen; de stichting ABC, belangenbehartiger voor deze patiëntencategorie, heeft in 2015 haar jaarlijkse trofee aan de coloscopie-applicatie uitgereikt na een stemming onder haar leden.

De positieve ervaring leidde ertoe dat ook andere endoscopieafdelingen het digitale voorlichtingsprogramma in gingen zetten. Dankzij subsidie van ZonMw uit de ronde ‘Actieplan eHealth - Leren van implementeren’ is de applicatie operationeel gemaakt in 14 centra. (Tabel 1.) Hierbij is speciale aandacht geweest voor het verkorten van de implementatieduur en het vergemakkelijken van het implementatieproces.

Inmiddels hebben we een gerandomiseerde multicentrische studie opgezet om de opgedane ervaringen met de digitale voorlichting verder te onderzoeken. Hoofduitkomsten zijn de kwaliteit van de darmvoorbereiding en de logistieke effecten, aangevuld met patiëntfactoren als tevredenheid, angst en kennis.

Tabel 1. Overzicht van ziekenhuizen die gebruik maken van een digitale voorlichtingsapplicatie om patiënten voor te bereiden op een coloscopie

Ziekenhuis	**Startdatum**	**Duur implementatie applicatie in maanden**	**Aantal gebruikers mei 2016* - maart 2017**	**Aantal gebruikers per maand †**
Noordwest Ziekenhuisgroep	8-7-2013	9	2063	292
Jeroen Bosch Ziekenhuis	10-3-2014	10	geen data	geen data
OLVG Oost	1-12-2014	8	1388	100
Medisch Spectrum Twente	30-3-2015	5	1843	176
Radboudumc	11-5-2015	7	1259	174
Haga Ziekenhuis	7-7-2015	3	325	45
Isala Ziekenhuis	9-7-2015	2	1755	270
Deventer Ziekenhuis	9-9-2015	2	1743	176
Ziekenhuis Bernhoven	11-9-2015	3	830	88
St. Jansdal	5-10-2015	3	650	52
Tergooi Ziekenhuizen	14-12-2015	3	694	54
Reinier de Graaf groep	01-01-2017	3	408	117
VUmc	01-07-2017	24	36	0
VieCuri Medisch Centrum	15-07-2017	7	950	156
totaal			13944	1700

* Start gestandaardiseerde meting digitale voorlichtingsapplicatie.
† Peilmaand maart 2017

OBSTAKELS IN DE PRAKTIJK

De nieuwe werkwijze heeft zijn uitwerking op administratief, juridisch en financieel gebied, die een obstakel kunnen vormen bij de invoering. Zo is het niet duidelijk hoe de informatie goed kan worden vastgelegd in de verschillende elektronische patiëntendossiers. Mogelijk vormt de beperkte externe toegang van ziekenhuisservers, wat dient om data-lekken te voorkomen, een drempel voor het koppelen van systemen. Dit is op te lossen door de informatie te versturen via een versleutelde e-mailverbinding met het patiënten secretariaat, waar de informatie later in het dossier wordt opgeslagen.

Wat de invoering ook zou kunnen belemmeren is dat het op deze manier vastgelegde informed consent niet voldoende juridische waarde heeft. De juridische afdelingen van de deelnemende ziekenhuizen hebben dit obstakel bekeken. Aangezien in het programma alle informatie wordt gegeven en de patiënt via het vraagformulier actief terugkoppelt of deze informatie is bekeken, is voldaan aan de vereisten voor informed consent.[11] Ook wordt actief gevraagd of patiënt nog aanvullend contact wil met de zorgverlener, om eventuele onduidelijkheden te verhelderen. Behalve dat patiënten informed consent geven direct na de voorlichting, bevestigen zij dit nogmaals tijdens de time-outprocedure, die vlak voor iedere coloscopie plaatsvindt.

Een ander obstakel voor implementatie was de plaats van digitale voorlichting in de financiering van het zorgproduct 'coloscopie'. De beroepsbelangencommissie van de Nederlandse vereniging van mdl-artsen heeft hier in samenspraak met de Federatie Medisch Specialisten een werkbare oplossing voor gevonden, die past binnen het kader van de Nederlandse Zorgautoriteit.

Een belangrijk effect in de praktijk is dat aanzienlijk minder polibezoek nodig is doordat het pre-endoscopieconsult is vervangen. Mogelijk heeft dit ook positieve macro-economische effecten, bijvoorbeeld afname van verzuim op het werk, vermindering van reistijd naar het ziekenhuis en minder gebruik van de ziekenhuisfaciliteiten. De tijd die vrijkomt op de endoscopieafdeling kan bovendien efficiënt worden ingezet voor de patiëntenzorg.

VOORUITZICHTEN

De toename van coloscopiëen die voortvloeit uit het bevolkingsonderzoek naar darmkanker geeft een grote belasting van het pre-endoscopiespreekuur. Volgens de huidige kwaliteitseisen van het bevolkingsonderzoek moet aan de coloscopie een poliklinisch intakegesprek voorafgaan. De inhoud van dit intakegesprek komt grotendeels overeen met die van pre-endoscopiespreekuur en dus ook van de digitale voorlichtingsapplicatie. Daarom is in het Radboudumc te Nijmegen nu ook een gedeelte van dit intakegesprek vervangen door de digitale voorlichting. Hierna komen patiënten pas naar de polikliniek. De consultatietijd is hierdoor van 45 naar 30 min verkort. De ervaring leert dat dit kortere consult bovendien effectiever is, doordat de patiënt een beter geïnformeerde gesprekspartner is geworden.

De endoscopie-afdelingen waar de digitale coloscopievoorlichting is geïmplementeerd werken inmiddels ook volop met voorlichtingsapplicaties voor andere endoscopische verrichtingen. Voorbeelden hiervan zijn applicaties voor de gastroscopie, de percutane endoscopische gastrostomie (PEG)-plaatsing en de endoscopische retrograde cholangiopancreaticografie (ERCP).

Ook worden er binnen andere vakgebieden waarbij patiënten al dan niet invasieve procedures ondergaan, zoals cardiologie en radiologie, momenteel projecten gestart waarbij de patiëntenvoorlichting digitaal wordt ingericht.

CONCLUSIE

Optimale voorlichting voor een coloscopie is van groot belang voor de patiënt en de zorgverlener. Pre-endoscopiespreekuren zijn weliswaar effectief, maar overbelast en medewerkers geven daar niet altijd eenduidige informatie. Patiënten die zich voorbereid hebben met onze nieuwe digitale voorlichting zijn tevreden dankzij de complete informatievoorziening. De voorlichting leidt bovendien tot een adequate voorbereiding van het colon. Daarnaast vermindert het de tijdsbelasting voor de endoscopist doordat de informatieverzameling gestandaardiseerd is.

Bij het invoeren van deze werkwijze hebben we stappen gezet om obstakels te omzeilen, zoals de koppeling met elektronische patiëntendossiers, privacyvraagstukken, het vastleggen van informed consent en declaratie van de kosten binnen de huidige financieringsstructuur. Wij verwachten dat in de toekomst ook andere vakgebieden daarom een dergelijke manier van voorlichten kunnen gaan inzetten en eventuele problemen daarbij kunnen oplossen.

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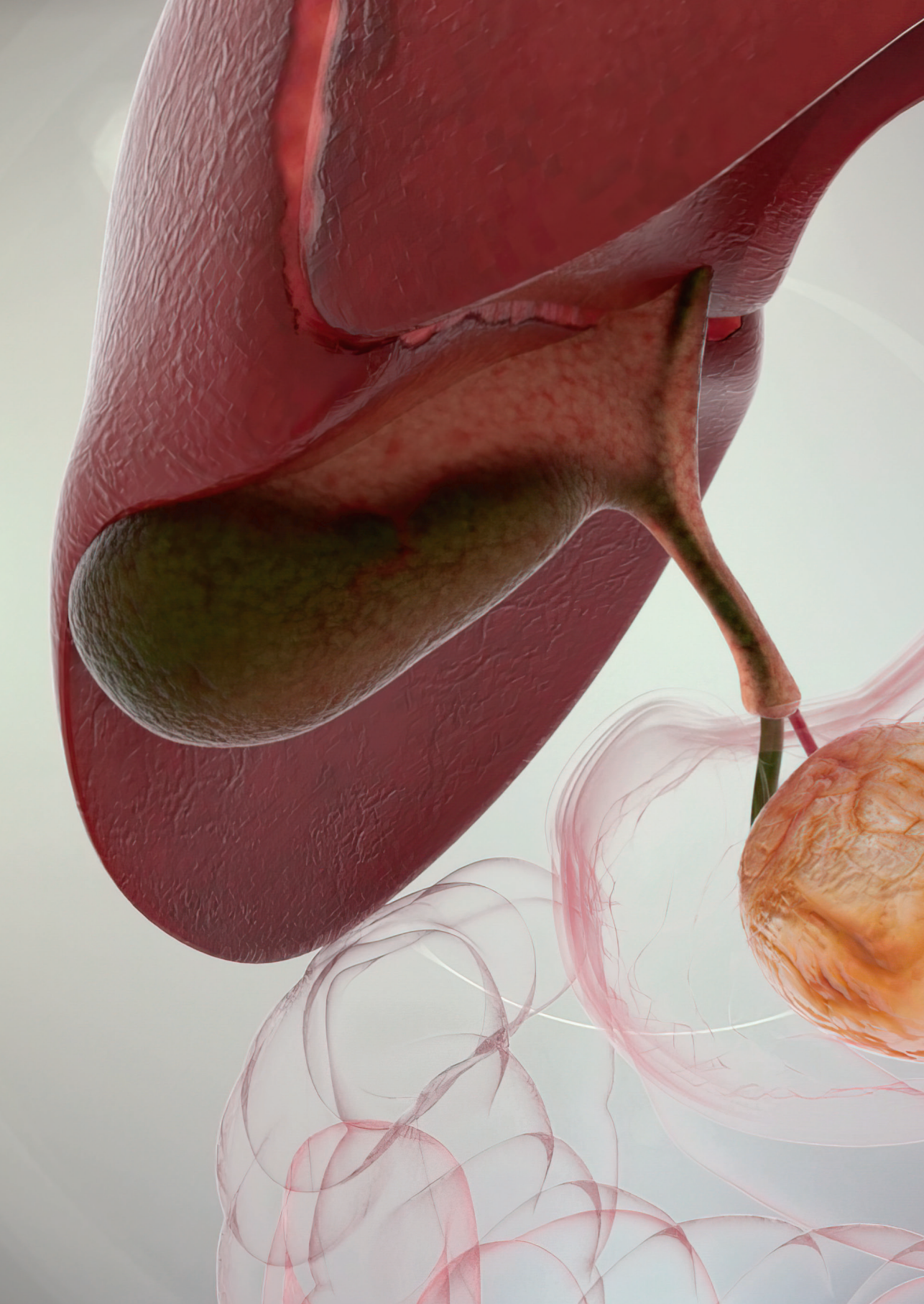

4

E-Patient Counselling trial (E-PACO): computer based education versus nurse counselling for patients to prepare for colonoscopy

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ABSTRACT

Improving patient education focusing on bowel preparation before a colonoscopy leads to cleaner colons. Endoscopy units must obtain informed consent and perform a risk assessment for sedative use prior to a colonoscopy. The current practice in the Netherlands to achieve these goals is nurse counselling in an outpatient setting. This is costly and has disadvantages in terms of uniformity and time consumption for both the patient and the hospital. The hypothesis is that computer-based education with use of video and 3D animations may replace nurse counselling in most cases, without losing quality of bowel cleanliness during colonoscopy.

This multicenter, randomized, endoscopist blinded clinical trial evaluates a primary outcome measure (bowel preparation) during colonoscopy. Secondary outcome measures are sickness absence, patient anxiety after instruction and prior to colonoscopy, patient satisfaction and information re-call. The study will be performed in four endoscopy units of different levels (rural, urban, and tertiary). Inclusion criteria are adult age and referral for complete colonoscopy. Exclusion criteria are Dutch illiteracy, audio-visual handicaps or mental disabilities and no (peers with) internet access.

This trial aims to establish online computer-based education as tool for patient education prior to a colonoscopy. By choosing a direct comparison with the standard of care (nurse counselling), both endoscopic quality measures and patient related outcome measures can be evaluated.

Video Article

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INTRODUCTION

A complete colonoscopy is the procedure for detection of precancerous lesions in the colon.[1] For adequate examination of the colon mucosa, optimal bowel cleanliness is crucial. A poorly prepared colon leads to insufficient adenoma detection rate and therefore the need for repeated procedures. In previous studies, better patient understanding of how to prepare clearly results in a higher quality of bowel preparation.[2] To achieve a clean colon, patients have a restricted diet for 1-2 days and use purgatives to induce diarrhoea. This elicits abdominal discomfort and interrupts daily routine. In view of these barriers, inadequate bowel preparation is not infrequent.[3] Optimal patient compliance to the protocol enhances effective bowel preparation and subsequent efficacy of colonoscopy.

There is appreciable variation in the way information for a colonoscopy is administered to patients[4]. Some patients receive information directly from their health care professional during consultation, or are informed by auxiliary personnel (nurses, technicians, or administrators), while other units provide information through printed leaflets.[5] The effect of any information transfer is compounded by patient dependent factors such as educational level, comprehensive capacities, and cultural aspects. This results in a mixed understanding of the information that can negatively affect compliance to instructions.

A pivotal element in patient preparation is that every patient is thoroughly informed about risks and benefits of the procedure including the bowel preparation steps for colonoscopy. In addition, the routine use of sedative and analgesics requires a risk assessment of the individual patient. Many centers rely on nurse counselling to obtain informed consent before the procedure. This results in patient improved adherence to the instructions for bowel preparation. However, while effective, it is time-consuming for the nurse, repetitive, and results in patient-to-patient variability of information. More importantly, it demands an extra hospital visit for the patient, implicating absence of the patient at work.[6] In summary, it is an economically challenging practice in cost-conscious healthcare environments. Previous studies show that focused e-learning paths enable good comprehension and learning and enhance patients satisfaction.[7] Web-based education is used successfully for increasing knowledge of patients and it has become an accepted mechanism for obtaining informed consent. This has led to the development of tailored instruction programs for bowel preparation that combines the advantages of flexibility in time and environment yet maintains consistency in delivery of information. Previously, the authors developed a tool that allows computer assisted instruction (CAI) for colonoscopy.[8] This tool employs a computer animation that captures the viewers' attention while adequately informing him/her of objectives for colonoscopy. Written in comprehensible language in logical order, the module educates patients on different aspects of colonoscopy. It provides basic anatomical teaching

points and step-by-step instructs the patient how to perform bowel preparation. In our pilot study we showed that CAI for colonoscopy enhanced bowel preparation to the level that is comparable to nurse counselling.

The research group sought to enhance the efficacy of the developed CAI. Its limitation was that it was a unidirectional tool that delivered information but did not allow acquiring patient specific information concerning medical history and medication use. This is an important part of the nurse counselling visit, as it allows a pre-sedation risk assessment when judged by the nurse. Therefore, a dedicated questionnaire was developed, designed to collect data points for structured risk assessment. This questionnaire is completed by the patient at the end of the CAI. This eliminates the need for a face-to-face meeting with a nurse or physician at this point in time. The use of two-way communication (combining CAI with a questionnaire) is practical and provides high quality information to the patient whilst at the same time attending to the need of the endoscopist for information on sedation risks. This combined instruction and acquiring of information is known as computer based education (CBE).[7]

The goal of this trial is to test the utility, practicality, and patient-perceived usefulness of CBE off-center, in comparison to conventional nurse counselling. The hypothesis is that CBE is non-inferior to nurse counselling in achieving high quality of bowel preparation during colonoscopy. This process is independent of time and space and therefore can be viewed in the comfort of the patients' home. Accordingly, the chosen secondary outcomes are patient related outcome measures such as a short leave absence, anxiety, satisfaction and comprehension of information, as these might benefit from delivery through this digital channel. Included process measures are patient activation, health and eHealth literacy to determine which patients benefit most from this tool.

STUDY DESIGN

The trial is set up as an endoscopist blinded multicenter randomized controlled trial design. Inclusion criteria are adult age and a referral for elective complete colonoscopy. Exclusion criteria are illiteracy in Dutch and significant audio-visual handicaps and mental disabilities that preclude delivery of CBE. Also, patients were excluded if there is no internet access or a relative with internet access. (Table 1.) Patients will be recruited by back office staff at the outpatient's clinic in 4 large volume endoscopy centers in the Netherlands. All patients receive a split dose laxative regime based on either polyethylene glycol or sodium picosulfate. After evaluation of in- and exclusion criteria by trained staff, patients are randomized in 1:1 distribution per trial site using a randomization tool (described in the protocol below). Reasons for declining to participate are recorded. The trial flowchart is presented in figure 1.

Figure 1. Flowchart trial with time points

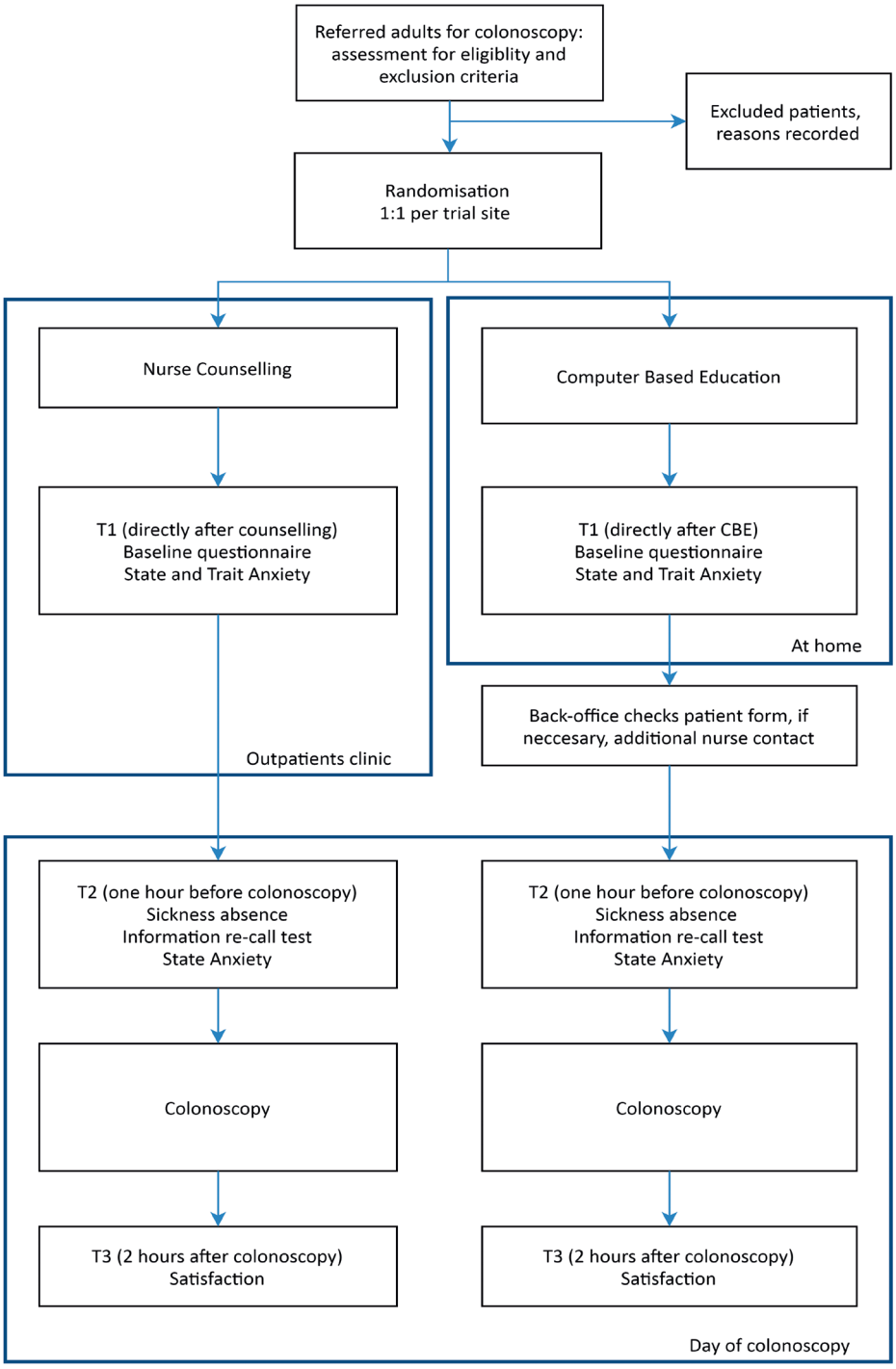


Table 1. In- and exclusion criteria

Inclusion criteria	Exclusion criteria
Adult age	Illiteracy for Dutch
Referral for complete colonoscopy requiring bowel preparation	Audio-visual handicaps
Able to provide informed consent	Mental disabilities
	Unwilling to participate
	No internet access (or relatives with internet access)

OUTCOME MEASURES

The primary outcome measure is the quality of bowel preparation during endoscopy. Endoscopists are trained to score the bowel preparation with the Boston Bowel Preparation Scale (BBPS). The BBPS is a cumulative score of three bowel segments, ranging from 0-1 "unsatisfactory", 2-3 "poor", 4-5 "fair", 6-7 "good", and 8-9 "excellent". Scores of ≥6 are considered adequate.[9,10] As secondary outcomes, the focus is on sickness absence, anxiety, satisfaction and information re-call. Information is also collected on patient activation and health literacy.

The cost minimization effect of the intervention is calculated in two ways. The comparison between groups with regard to endoscopy unit costs will be done using a cost-per-visit analysis. The macroeconomic effect of sickness absence is also evaluated, as patients in the intervention group will need less hospital visits. To do so, several items are assessed: socio-economic status, work status and duration of sickness absence, using an adapted iMTA Productivity Cost Questionnaire.[11]

Patients anticipating invasive medical procedures often experience anxiety that may exceed their coping mechanisms. Anxiety is assessed at T0 and T1 with the State-Trait Anxiety Inventory (STAI).[12] The STAI is a widely used 20-item self-report instrument with scores ranging from 20 (absence of anxiety) to 80 (high anxiety). Patient satisfaction is scored using two different measures. Patient experience impacts future behaviour and therefore "willingness to return" is assessed at T3, ranging from 1 (extremely unwilling to return) to 10 (extremely willing to return). Furthermore, the Net Promoter Score (NPS) is utilized on the question "Would you recommend this endoscopy unit to your peers?". Patient's scores range from 1 (Not at all likely) to 10 (Extremely likely). The NPS will be assessed at T0 and T3 and is calculated as % Promoters (scores 9-10) - % Detractors (scores 1-6).[13] To evaluate patient comprehension of the information in the CBE patients are asked to reproduce elements of the instruction. The patient information re-call is assessed at T1 (before colonoscopy) using a 10-item test, with questions to be answered with "yes" or "no". The effect of patient education in colonoscopy is influenced by the

patient ability to understand medical information. The 14-item Dutch validated Health Literacy Scale is used to assess this item, divided in 3 subscales, at T0.[14] A new 21-item questionnaire is added as a measure for eHealth Literacy.[15] This contains questions regarding the skill and experience of patients in handling medical information online. Patients are confronted with options every day that may have major implications for their health. Effectively managing their choices requires knowledge, skill, and confidence. To this end these elements were mapped at T0 13-item Patient Activation Measure Scale (PAM-13).[16] The current health status of patients is evaluated with the Medical Outcomes Study 36-item health survey (RAND-36) at T0.[17]

STATISTICAL ANALYSIS

To statistically compare both groups on the primary outcome, the relative risk for an inadequately prepared colon, defined as a BBPS <6, is used. In literature, a 90% success rate (for an adequately prepared colon) is common, with a 10% non-inferiority margin as the maximum clinically acceptable difference. The non-inferiority power calculation resulted in 180 patients per group, 360 patients in total. This is required to exclude a difference in favour of the standard group of more than 10%. With a margin of ± 60% loss of patients before completing the protocol, based on earlier research, the target number of patients to approach is set at 1,000. In addition to the non-inferiority analyses, superiority analyses will be conducted to investigate effects on secondary outcome measures.

PROTOCOL

The study is authorized by the ethics review board of the Radboud University Medical Center (#2015-1742). Subsequent approval of the executive boards from each of the participating institutes is obtained (Trial registration: Dutch Trial Registry, NTR 5475).

1. Enrolling patients in the trial/randomization

1.1. Approach all referred patients by general practitioners, surgeons or internal medicine specialists for colonoscopy, to achieve a diverse sample.

1.2. Contact all eligible patients for inclusion by the outpatient's clinic assistant by telephone call or face-to-face contact with the patient in a protocol led manner (described below).

1.2.1. Say the following: Good morning/afternoon, you are speaking to the gastroenterology department of the trial center. You have been referred for colonoscopy, correct? We have to inform you prior to the examination. Do

you have a computer/tablet/smart phone with internet access? (If not, do you have a peer who does?) We have the possibility to give you the information using an internet-based application. This is subject to our scientific research, comparing the novel method to a traditional visit of the outpatient's clinic. If you cooperate in this trial, you will have to answer several questionnaires in the process. We also use information from your patient record. If you agree, we will randomize the method of education; either digital or nurse counselling. If no, reason for declining is noted. Negative answers are categorized in reasons to decline participation. If yes, can I have your e-mail address?

1.3. Randomize patients to the intervention or control group per center after obtaining permission.

NOTE: This is linked to the invitation that is sent out; patients are asked for their e-mail addresses, linked to their patient identification number. The automated HTML script then randomly decides which invitation is being sent (nurse visit or computer-based education). The outcome is visible to the assistant.

1.4. Make sure that the patient reads the automatically sent email with instructions regarding more information on the trial. Here, digital informed consent for trial participation is obtained.

2. Baseline questionnaire

2.1. Subject the patient to the intervention or control group after randomization. Make sure that the patient completes the first questionnaire, containing baseline characteristics, several validated tools such as the RAND-36, PAM-13, eHealth Literacy Scale and the STAI.

3. Intervention arm: patient is prepared with computer-based education

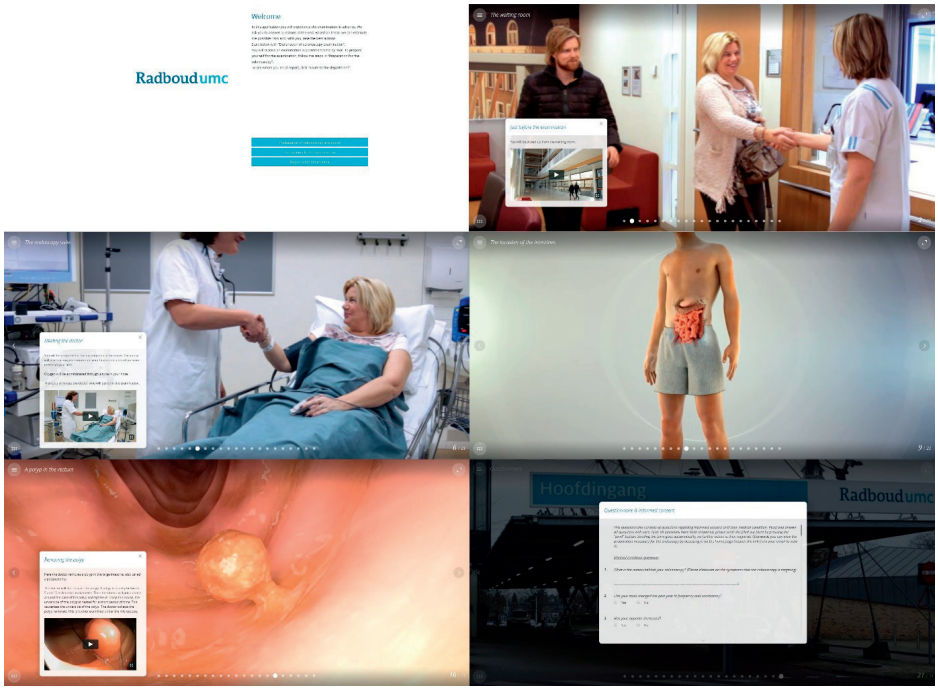
3.1. Make sure that the patient receives the interactive CBE via e-mail.

NOTE: Current best practices are implemented in the design, including the use of plain language, good accessibility and obligatory interaction to engage users.[7] The used CBE is a web-based platform, mimicking the patient journey with specific video guided by voiceover, supported by photos, three-dimensional animation and instructive texts.

3.2. Conduct a dedicated video and photo shoot specific for each separate endoscopy unit in the trial following a uniform script. (Figure 2., the CBE used in one of the trial sites is accessible via https://trials.medify.eu/cbe-colonoscopy). Divide the video in short clips, with a maximum duration of 45 seconds.

Implement a mandatory mouse-click after each item to ascertain interaction in the CBE. Ensure that the tool contains all elements that are obligatory for informed consent such as risks, benefits and alternatives for colonoscopy.

Figure 2. An overview of the computer based education before colonoscopy used in this trial, illustrating all the steps in the patients' journey. The lower right screen depicts the questionnaire for pre-sedation risk assessment and written informed consent.



3.3. Have the patient complete the CBE.

NOTE: The following steps (under tab 3.3) are mandatory for the patient to follow in the CBE.

3.3.1. Click on the link in the email: https://trials.medify.eu/cbe-colonoscopy.

3.3.2. Enter the main menu of the CBE. First, read the pop-up with instructions how to use the CBE.

3.3.3. Click on the tab **Explanation of colonoscopy procedure**.

3.3.4. Read the text on slide (1/21): **How do you prepare for the examination?** After finishing, click **Next**.

3.3.5. Play the video on slide (2/21): **Just before the examination**. The video voiceover will say: "Welcome to the hospital, where the examination of your large intestine will take place. It is important that you are here 30 minutes before the examination is due to start. You check in at the endoscopy center reception and take a seat in the waiting room. A department staff member will pick you up from the waiting room. The telephone number of your contact person is noted to let them know when you can be picked up again." After finishing, click **Next**.

3.3.6. Play the video on slide (3/21): **Preparation for the examination**. The video voiceover will say: "In the preparation room, you will have an intake discussion with a nurse with the help of the COW (computer on wheels). Your name and date of birth are verified, and your medical information checked. You will receive a wrist band with your patient information on it. Then an IV needle is inserted into your arm. The pain killer and, if applicable, the sedative will be administered via this IV needle." After finishing, click **Next**.

3.3.7. Play the video on slide (4/21): **Preparation for the examination**. The video voiceover will say: "The nurse will ask you to take off your trousers/skirt/dress and underwear. You can place your belongings under the bed. You lay down on the bed. You are now ready to be taken to the endoscopy room." After finishing, click **Next**.

3.3.8. Play the video on slide (5/21): **The endoscope**. The video voiceover will say: "The tube with which we will perform the examination is called an endoscope. It is first thoroughly cleaned and kept in a special clean cupboard. The clean endoscope is fed into a box, the cover of which is closed with a cable tie. In accordance with requirements, the endoscope is always checked before the examination starts.". After finishing, click Next.

3.3.9. Play the video on slide (6/21): **Meeting the doctor**. The video voiceover will say: "In connection with the sedative, it is important to monitor your blood pressure, heart rate and the oxygen saturation in your blood. You will have a small clip on your finger and a blood pressure meter on your arm. Then you will meet the gastroenterologist or resident gastroenterologist who will perform the endoscopy." After finishing, click Next.

3.3.10. Play the video on slide (7/21): **Time out procedure**. The video voiceover will say: "Before the procedure actually starts, a time out procedure takes place.

The doctor and nurse will run through a list of control questions with you. You can also ask questions at this time." After finishing, click **Next**.

3.3.11. Play the video on slide (8/21): **Sedative**. The video voiceover will say: "To alleviate the pain, you will receive a pain-relieving medicine, sometimes in combination with a sedative, administered via the IV needle. You will get a bit sleepy, which will help you relax and make the examination easier for you. This is not an anaesthetic. It may cause you to be a bit forgetful for the rest of the day. Due to the medication administered, it is important that you do not drive a vehicle or drink alcohol for twenty four hours after the examination." After finishing, click **Next**.

3.3.12. Read the text on slide (9/21): **Location of the intestines.** After finishing, click **Next**.

3.3.13. Look at the automated 3D animation in the background, centring the intestine. Drag to rotate the 3D image. Read the text on slide (10/21): **Small intestine.** After finishing, click **Next**.

3.3.14. Drag to rotate the 3D image. Read the text on slide (11/21): **Large intestine.** After finishing, click **Next**.

3.3.15. Drag to rotate the 3D image. Read the text on slide (12/21): **Continuation of large intestine examination.** After finishing, click **Next**.

3.3.16. Look at the automated 3D animation in the background, centring the anus. Read the text on slide (13/21): **Alternative examination**. After finishing, click **Next**.

3.3.17. Look at the automated 3D animation in the background, entering the colon. Play the video on slide (14/21): **Air infusion**. The video voiceover will say: "The examination usually takes half an hour. You lie on your left side and the lights are dimmed during the examination. The endoscope is inserted carefully. Then air, or actually carbon dioxide gas, is blown into the intestine. The endoscope is pushed forward to the end of the large intestine. During the withdrawal of the endoscope, the intestinal wall is thoroughly inspected. The doctor may remove small pieces of intestinal tissue or polyps. It may be necessary for you to change your position during the examination. The nurse may occasionally press on your stomach to prevent the endoscope from slipping out of place. In order to ensure that your intestine cramps as little as possible, a medication is often given to relax the intestine. This may cause you to have a dry mouth and your heart may beat faster. After the examination, we place the used

endoscope back in the box and it is covered with a lid before the scope is taken away to disinfection." After finishing, click **Next**.

3.3.18. Read the text on slide (15/21): **Examination technique.** After finishing, click **Next.**

3.3.19. Look at the automated 3D animation in the background, centring a polyp. Play the video on slide (16/21): **Removing the polyp**. The video voiceover will say: *"Here you see the removal of a polyp from the large intestine. This is also called a polypectomy. The doctor will first inspect the polyp. A polyp is usually between 5 and 15 millimetres in diameter. Then the doctor will put a noose around the base of the polyp. This is pulled tight. Using the noose, the base of the polyp is continually heated, which cauterizes the base. The polyp is kept for further examination."* After finishing, click **Next**.

3.3.20. Play the video on slide (17/21): **After the examination**. The video voiceover will say: "After the examination we will take you back to the recovery room. You will be reconnected to the monitoring equipment. The nurse will keep an eye on this and will regularly check on how you are doing. During this period, blood pressure, pain and possible blood loss are monitored. You may have some abdominal pain after the procedure, namely cramping, due to the carbon dioxide gas which was blown into your large intestine during the examination. It is important to release the gas you feel and not to keep it in. When you are awake enough, you will be given something to eat and drink. The IV needle will be removed." After finishing, click **Next**.

3.3.21. Play the video on slide (18/21): **Examination report and follow-up appointment.** The video voiceover will say: "When you have significantly recovered, your companion will be notified that you can be picked up. You can get dressed. When you leave, you will receive a letter from the doctor with the preliminary results of the examination and telephone numbers you can call if you experience any complications after the procedure. The referring physician or a nurse from your surgery will give you the definitive results of the examination and the results of the tissue biopsy." After finishing, click **Next**.

3.3.22. Read the text on slide (19/21): **Have a nice journey.** After finishing, click **Next.**

3.3.23. Read the text on slide (20/21): Risks of the examination**.** After finishing, click **Next.**

3.3.24. Fill out the questionnaire on medical history and medication use on slide (21/21): **Questionnaire & Informed consent**. After finishing, click **Send**.

NOTE: This module serves as a pre-sedation risk assessment. It double-checks the informed consent. After final approval by the patient the information is sent via e-mail to the endoscopy unit.

3.3.25. Click on the tab **Preparation for the colonoscopy** that is now made available. Follow the steps and read all information on the use of the laxatives in the same stepwise fashion.

3.3.26. Click on the tab **Route to the department** for the routing to the endoscopy unit.

3.4. For the trained endoscopic nurse: assess the received information sent by the patient. Use the automated protocol whereby actions are related to the answers provided by the patients.

NOTE: This system automatically labels responses with “green” (no action), “orange” (action might be necessary) and “red” (action is necessary). When in doubt, risk assessment will be performed by a consultant gastroenterologist.

4. Control arm: Patient is visiting the outpatient clinic

4.1. Schedule a visit for the patient at the outpatient clinic for instruction by a trained nurse. Follow the standard operating procedure during counselling.

NOTE: This provides information on how to use the purgatives, dietary instructions, effects of sedation with benzodiazepines and relevant practical matters. Finally, the nurse double-checks signed informed consent and files information on medical history.

5. Day of colonoscopy

5.1. Schedule the patient approximately 2-8 weeks from baseline for the colonoscopy. Ask the patient to complete the questionnaire, containing the 10-item knowledge test, the STAI and measures for patient satisfaction prior to colonoscopy (T1).

5.2. Score the bowel cleanliness during colonoscopy (T2) online and in the endoscopy report; also fill out the several relevant items regarding colonoscopy here (indication, type of sedation and analgesic, ASA classification).

5.3. Ask the patient to complete the post-colonoscopy questionnaire, containing measures for patient satisfaction (T3), just prior to discharge.

REPRESENTATIVE RESULTS

The earlier mentioned pilot study compared nurse instruction to CAI using the same interactive tool as used in this protocol. As the goals of this study were comparable to the outcomes used in this protocol, a short explanation of the results of the pilot are provided here in more detail. (Table 2.)

Table 2. Bowel preparation scores in our earlier pilot study

	Nurse counselling	**Computer Assisted Instruction**	**Nurse versus Computer Assisted Instruction**
	(n, % scoring rate)	**(n, % scoring rate)**	**(Mann-Whitney)**
Ottawa Bowel Preparation Scale (mean, SD)	6.07, ±2.53 (n=115, 58.4%)	5.80, ±2.90 (n=87, 46.3%)	p = 0.418
Boston Bowel Preparation Scale (mean, SD)	6.54, ±1.69 (n=129, 65.5%)	6.42, ±1.62 (n=88, 46.8%)	p = 0.576

In this pilot study 385 patients were enrolled. The CAI group contained 188 subjects. The control group receiving nurse counselling had 197 patients. The baseline characteristics were evenly distributed between CAI and nurse counselling. No significant differences were found comparing groups on bowel preparation scores, using two different scales. In the BBPS analysis nurse vs. CAI group scores were adequate: 6.54 ±1.69 vs. 6.42 ±1.62. In the Ottawa Bowel Preparation Scale, scores were 6.07 ±2.53 vs. 5.80 ±2.90 respectively. On secondary measures, the enquired patient comfort was significantly higher in the CAI group shortly before colonoscopy. A five-point Likert scale was used, ranging from 1 (low) to 5 (high). Results were 4.29, ± 0.62 in the CAI group vs. 4.42, ± 0.68 in the nurse counselling group. As this rating was higher directly after nurse counselling, there is influence of the human factor for personal contact and offering emotional support. Anxiety and information re-call scores showed no statistical difference. (Table 3.)

Supplemental video: An instructive video on how the computer-based education is implemented in the endoscopy unit can be found here: https://vimeo.com/141342029

Table 3. Secondary outcomes in our earlier pilot study

	Nurse counselling (n, % scoring rate)	**Computer Assisted Instruction** (n, % scoring rate)	**Nurse versus Computer Assisted Instruction** (Mann-Whitney)
Comfort Score after consult/CAI (T1) (1=very low, 5=very high)	Mean 4.54, ± 0.56 (n=193, 98.0%)	Mean 4.17, ± 0.51 (n=188, 100%)	p = 0.000
Comfort Score before endoscopy (T2) (1=very low, 5=very high)	Mean 4.29, ± 0.62 (n=162, 82.2%)	Mean 4.42, ± 0.68 (n=124, 66.0%)	p = 0.039
Comfort Score after endoscopy (T3) (1=very low, 5=very high)	Mean 4.16, ± 0.93 (n=150, 76.1%)	Mean 4.28, ± 0.84 (n=117, 62.2%)	P = 0.322
Anxiety Score after consult/CAI (T1) (5=very low, 1=very high)	Mean 3.16, ± 1.30 (n=193, 98.0%)	Mean 2.92, ± 1.22 (n=188, 100%)	p = 0.071
Anxiety Score before endoscopy (T2) (5=very low, 1=very high)	Mean 2.80, ± 1.32 (n = 162, 82.2 %)	Mean 2.90, ± 1.27 (n = 124, 66.0%)	p = 0.451
Knowledge and Comprehension 10 item test score before endoscopy	Mean 7.08, ± 1.17 (n = 164, 83.2 %)	Mean 7.31, ± 1.11 (n = 127, 67.6%)	p = 0.112

DISCUSSION

The E-Patient Counselling (E-PACO) trial aims to study the utility, practicality, and patient-perceived usefulness of computer-based education (CBE), in comparison to conventional nurse counselling. In this manuscript the CBE is demonstrated together with the methodology used to evaluate the hypotheses.

It is established that high quality colonoscopy is the golden standard for prevention of colorectal cancer. Inadequate bowel preparation is related to the missing of neoplasm's and increase need for repeat examinations with increased costs and cumulative discomfort for patients.[18-20] The cleanliness of the colon or bowel preparation is the main quality measure and therefore used as primary outcome measure. Studies that focus on patient education prior to colonoscopy have yield significantly better results in bowel cleanliness for their intervention (cartoons, day-before-colonoscopy reminder calls and nurse counselling).[21-23] However, some of these trials are derived from non-Western populations, so cultural differences might hinder generalizing these findings in Western population.

The pilot study did not find significant differences, so a non-inferiority design is chosen. If this intervention proves to be non-inferior, the operational advantages of counselling at home (reducing personnel and facility costs) still outweigh the investment for endoscopy units. There might be potential gain in the patient related outcome measures like anxiety and satisfaction. For generalization purposes it is of great importance to acquire a large heterogeneous sample that is representative for all patients in a (Western) endoscopy unit. By using four endoscopy units in several Dutch provinces (based in rural, urban and academic hospitals) the aim is to optimize diversity.

Possible influences educating patients are health literacy, educational level and the time between education and the procedure. When the intervention was designed, the perspective from patient panels, nurses and doctors were all incorporated. Lessons learned in other best practices, such as 3D visualization, were implemented. This takes into account the possibility of variation in learning styles between individuals and increases the potential for acquisition and retention of knowledge. The use of voice-over in adjunction to video accommodates patients with low literacy levels. From the elderly user perspective, easily accessible program features are added, such as optionally enlarged fonts and utilizing touch screen. Unlimited access to the information is guaranteed though a re-usable web-based link, so patients are enabled to view their CBE on-demand. Finally, language barriers are easily overcome with the availability in the menu to choose the language.

The double-check of information derived from the questionnaire also reinforces patients to important constructs of information provided earlier. Although guided by logical transitions at first time viewing, user control over the program sequence for repeated learning is allowed. Before the implementation, there was a careful analysis performed to provide a seamless integration of the CBE in the current endoscopy unit process.

A multicenter trial in real life setting has barriers for inclusion. For the clinically gathered questionnaires the usual contact moments were chosen to hand out questionnaires by the endoscopy unit operational staff. Missing questionnaires can be the result. Nevertheless, this trial aims to collect all relevant information at all time points.

Patients are eligible for the trial and can operate the CBE even with very basic computer skills. But in the lowest literacy category, it is not possible to test the hypotheses. As of this, it is important to maintain the possibility of face-to-face patient education in the route towards the endoscopy suite for this group.

As the future will provide more challenges in patient education, more research in this field is important. The method presented is suitable for evaluating the use of CBE in other endoscopic procedures, as well as in other departments.

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DISCLOSURES

The E-PACO trial is an investigator-initiated trial. The authors declare that they have no competing interests.

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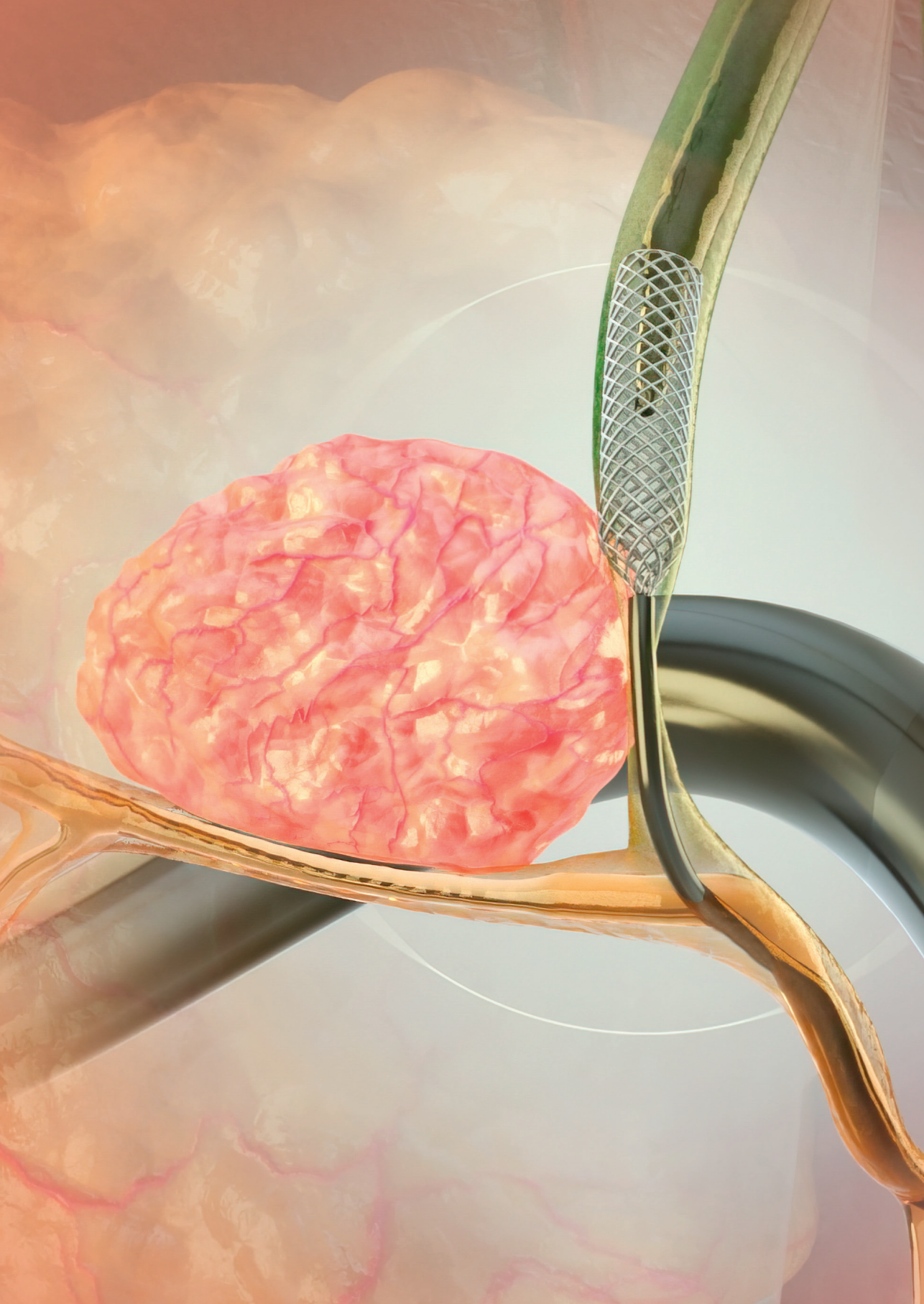

5

Computer based patient education is non-inferior to nurse counselling prior to colonoscopy, a multicenter randomized controlled trial

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ABSTRACT

BACKGROUND AND STUDY AIM

Optimal patient education prior to colonoscopy improves adherence to instructions for bowel preparation and leads to cleaner colons. We developed computer based education (CBE) supported by video and 3D animations. We hypothesized that CBE replaces nurse counselling without losing quality of bowel preparation during colonoscopy.

PATIENTS AND METHODS

We conducted a prospective, multicenter, endoscopist blinded, non-inferiority randomized controlled trial. The primary outcome was adequate bowel preparation, evaluated using the Boston Bowel Preparation Scale (BBPS). Secondary outcome measures were sickness absence due to outpatient clinic visit, patient anxiety / satisfaction scores and information re-call. We included patients in four endoscopy units (rural, urban, and tertiary).

RESULTS

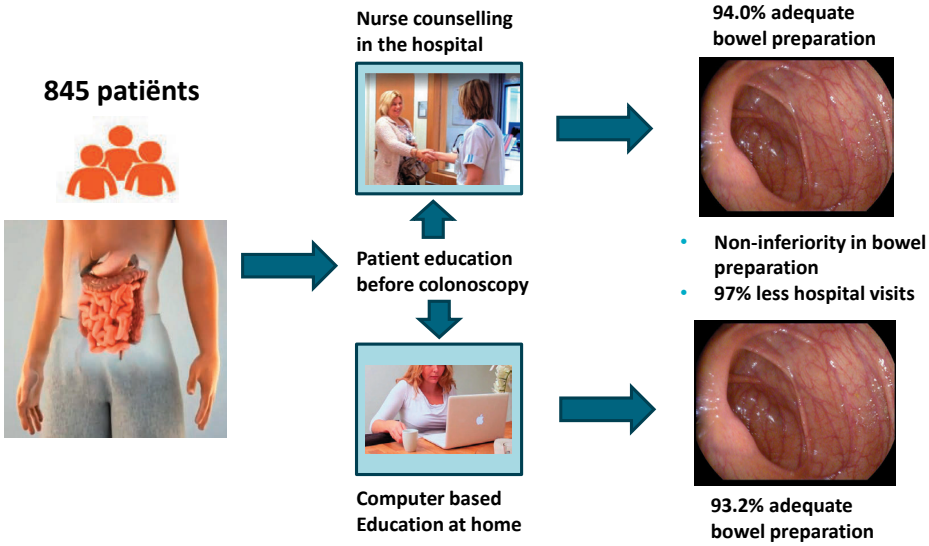
We screened 1035 eligible patients and randomized 845. After evaluation, 684 were included in the intention-to-treat (ITT) group. Subsequently, 497 patients were included in per-protocol (PP) analysis, 217 in nurse counselling and 280 in the CBE group. Baseline characteristics were similarly distributed among groups.

In PP analysis, adequate bowel cleansing was achieved in 93.2 % (261/280) of CBE patients, which was non-inferior to nurse counselled patients (94%, 204/217), with a difference of -0.8% [95% CI [- 5.1; 3.5] %. Non-inferiority was confirmed in the ITT population. Sickness absence was significantly more frequent in nurse counselled patients (28.0% vs 4.8%). In CBE patients, 21.5% needed additional information, resulting in 3.0% extra outpatient visits.

CONCLUSION

CBE is non-inferior to nurse counselling in terms of bowel preparation during colonoscopy, with lower patient sickness leave. CBE may serve as an efficient educational tool informing patients before colonoscopy in routine clinical practice.

GRAPHICAL ABSTRACT



INTRODUCTION

Colonoscopy is the gold standard to detect and remove precancerous colonic lesions, such as adenomas. Colonoscopy, performed under proper conditions, reduces cancer morbidity and mortality.[1] Optimal bowel preparation is a key prerequisite to achieve high adenoma detection rate. Inappropriately cleaned colons result in suboptimal detection of relevant lesions and lead to repeated colonoscopies and shorter surveillance intervals.[2,3]

There are a number of patient related factors associated with poorly prepared colons such as acceptance of the volume of bowel preparation, inability in following instructions, reduced awareness of health behaviour and health illiteracy.[4,5] Several strategies have been used to improve the bowel preparation through optimizing patient education. This can be achieved by use of simple instruction tools.[6] Efforts that involve direct patient contact such as patient navigators or nurses with face-to-face counselling are the most effective.[7] This is also paramount for increasing adherence to colonoscopy screening programs.[8]

Face to face patient counselling is resource-rich and time consuming. The high demand for colonoscopy services, as a result of colorectal screening programs, have surged an interest for more efficient strategies with less personnel while maintaining quality.

There is evidence to suggest that eHealth interventions are effective in improving information transfer to patients.[9] Internet based education offers a number of advantages: it visualizes information in a comprehensible format, it is consistent and accessible at any desired moment, and provides the option to remind patients in a timely fashion.[6]

We have developed a website based platform consisting of 3D animations, video and voiceover text to inform patients on colonoscopy procedure and preparations needed.[10] This programme mimics the patient journey from pre-colonoscopy consultation in the outpatient clinic to discharge after the procedure. A single center observational study compared this platform to nurse counselling. Patients who followed this programme had adequate bowel preparation.[11] Subsequent efforts helped to evolve this programme into an interactive computer based education (CBE). The main improvement consist of the addition of two-way communication to make home-based use feasible, with substitution of all elements of nurse counselling.[12]

The effects of home-based CBE performs in terms of quality of bowel preparation or number of repeated procedures because of inadequately prepared colons are unknown. We hypothesize that CBE as modality for patient education is equally effective to nurse counselling for optimal bowel preparation. We report here on our multicenter

randomized controlled trial with a head to head comparison of traditional nurse counselling versus CBE.

METHODS

Study design and patients

We performed a multicenter prospective endoscopist blinded randomized controlled trial. Patients were recruited from the gastroenterology department at four hospitals in the Netherlands. This included one academic, two urban and one rural based hospital. Patients were recruited and underwent their colonoscopy between September 2015 and December 2017.

We included adults referred for complete colonoscopy requiring bowel preparation who could provide informed consent. Exclusion criteria were patients unwilling to participate, no internet access or relative with internet access, Dutch illiteracy, audio-visual handicaps or mental disabilities. An extensive version of the trial protocol has been published earlier.[10]

Patients were involved in the development of the CBE utilizing focus groups for content feedback. The study group promoted the CBE for the wider public, being nominated in several jury and public award contests. The CBE won the public vote for the yearly award issued by the Dutch low literate patient society in 2015.

Ethics

The study was performed according to the principles of the 1975 Declaration of Helsinki. The CONSORT guidelines were followed for reporting our results. This study was approved by the Institutional Review Board (Medical Research Ethics Committee of the region Arnhem-Nijmegen, number 2015-1765. The trial is registered under the Dutch Trial Registry, NTR 5475. No commercial support was provided for the trial.

Randomization

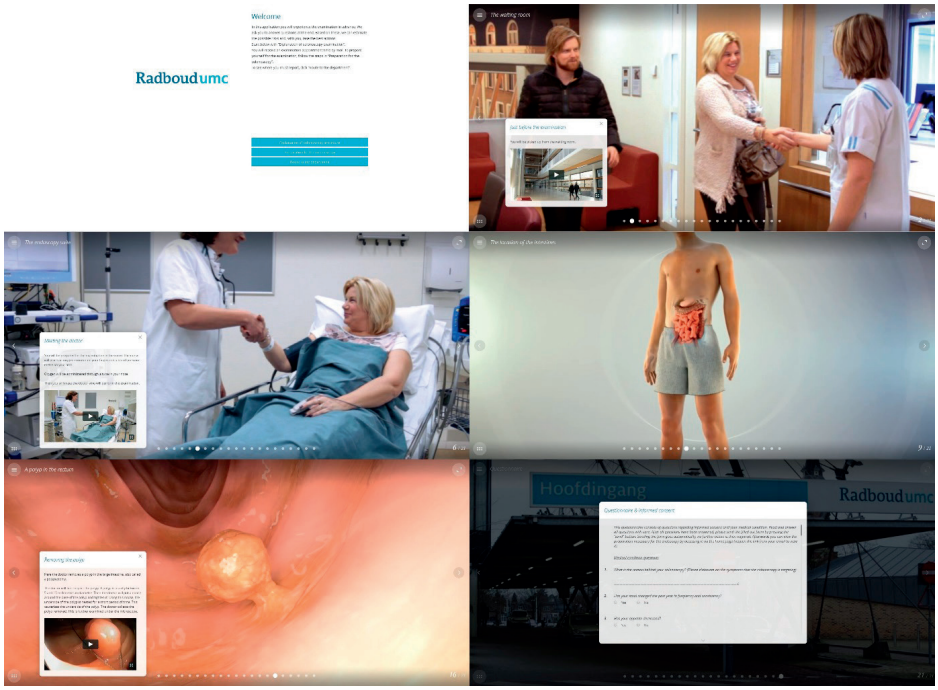
Patients referred for colonoscopy were contacted in person or by telephone call to judge willingness to participate. We employed a structured script to explain goals of the trial. Reasons of patient's unwillingness to participate were recorded. After giving consent to participate, the patient identification number and e-mail address was entered in a secured online tool (Appendix 1s, see Supplementary Material). This tool randomized patients in a 1:1 ratio per trial site and subsequently informed them by automated e-mail on the type of education, being either nurse counselling or CBE. All participating patients provided written informed consent.

Study procedure

After enrolment in the trial, patients were either invited for a nurse counselling session or the CBE. The intervention group received an unique link (known in cybersecurity terms as hash) via e-mail that provided access to the web based platform.[11] In addition to the original software, patients had to complete an online questionnaire on medication use and their medical history. This form was returned via the secured tool to the endoscopy unit. An automated evaluation tool screened for potential risk factors to undergo colonoscopy. If no red flags (for instance, use of anticoagulant or antidiabetic drugs and severe cardiopulmonary condition) were noted, the patient was directly invited for colonoscopy. In other cases, patients were contacted by telephone or scheduled for an additional outpatient visit. This was also recorded.

Each participating hospital's CBE had tailored video's and site specific instructions. The application outlook used video scripts and 3D animations were the same in all four sites. (Figure 1.) The CBE customized to the academic trial site is openly accessible via https://trials.medify.eu/cbe-colonoscopy.

Figure 1. An overview of the computer based education before colonoscopy used in this trial, illustrating all the steps in the patients' journey. The lower right screen depicts the questionnaire for pre-sedation risk assessment and written informed consent. This is adapted from the previously published study protocol, the persons depicted are actors.



The control group was invited by mail to our outpatient clinic for a routine nurse counselling visit. The nurse explained the procedure in full, acquired the relevant information on sedation pre-assessment and handed out a short written leaflet on purgative use.[13] After completing either the CBE of nurse counselling, patients were scheduled for colonoscopy.

Study design

We used patient reported study questionnaires at several time points. (Figure 2.) At the first time point (T1), baseline demographic characteristics, previous experience with colonoscopy, patient satisfaction and validated questionnaires for eHealth literacy and patient productivity were recorded.[14,15] After receiving the patient education (either nurse counselling or CBE), the level of trait and state anxiety was measured.[16]

On the day of colonoscopy, we collected patient information prior to colonoscopy (T2). Laxative use, the information re-call test and patient state anxiety were collected. Here, we also noted information on sickness absence leave.[15] In the CBE group, the need for additional contact moments was scored.

The quality of the bowel preparation during colonoscopy was assessed by the Boston Bowel Preparation Scale (BBPS).[17] Colonoscopy specific data (indication, type of sedation and analgesic, ASA classification) were collected. Finally, prior to discharge (T3) patient satisfaction measures were recorded.[18]

Endoscopy

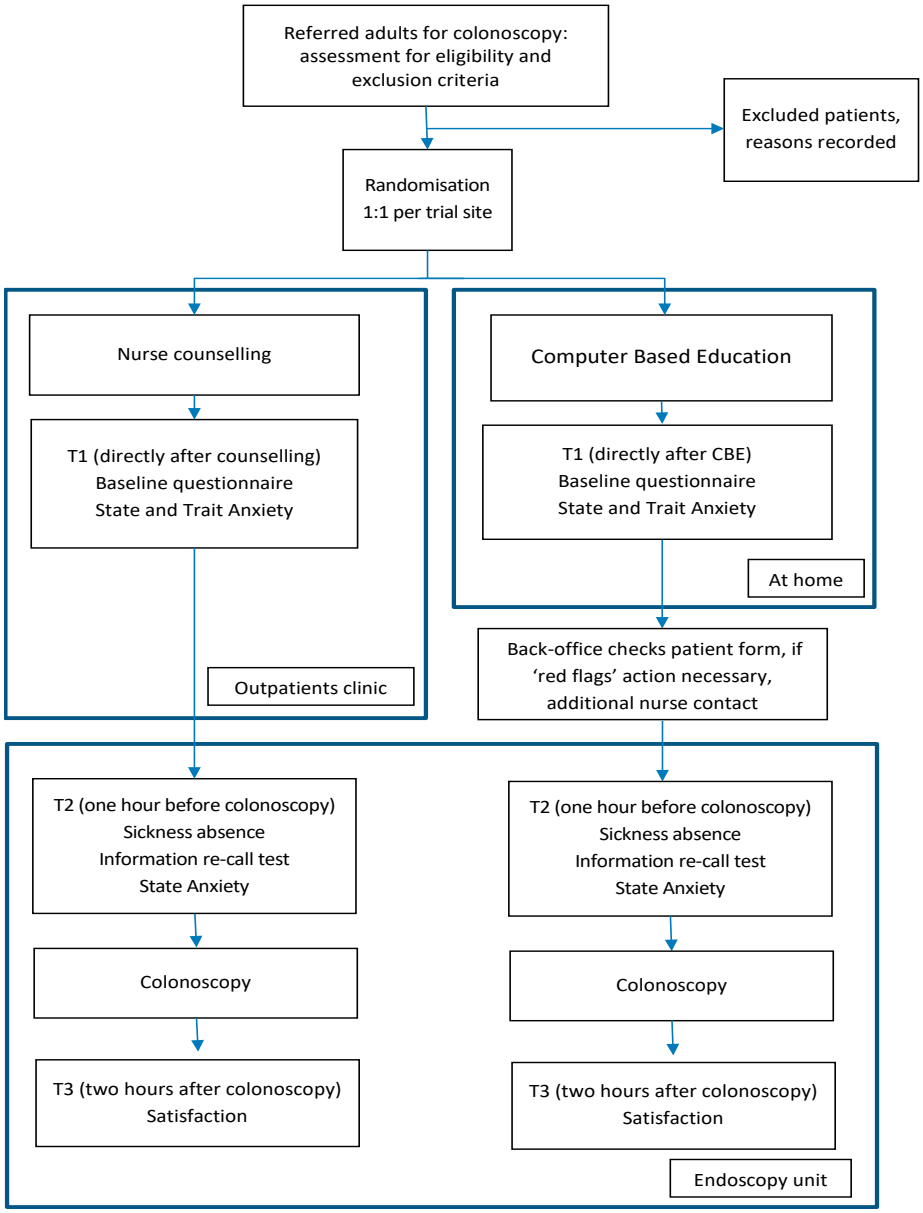
The attending endoscopists were blinded for the type of education patients received. All were familiarized or updated with the use of the BBPS before onset of the trial. The trial sites used either polyethylene glycol or sodium picosulfate-based standard split dose regimes for bowel preparation.[19]

Outcomes

The primary outcome of the trial was quality of bowel preparation as assessed with the BBPS. We recorded the need for repeat examinations due to inadequate BBPS.

Secondary outcome measures were patient related outcome measures, including sickness absence leave, anxiety levels after instruction and prior to colonoscopy, satisfaction and information re-call.

Figure 2. Flowchart Timepoints



Questionnaires

At baseline, T1, we included a validated questionnaire on health literacy (Dutch validated Health Literacy Scale).[14] Anxiety levels were assessed at T1 using the State-Trait Anxiety

Inventory (STAI). This commonly used 20-item self-report instrument provides scores ranging from 20 (absence of anxiety) to 80 (high anxiety) combining both State (dynamic, at one particular moment) and Trait (static, based on character) anxiety levels.[15]

Patients reported sickness absence leave at T2, with the adapted iMTA Productivity Cost Questionnaire to evaluate the macroeconomic effect. (Appendix 2s.)[16] Information re-call was tested at T2 using the same 10-item information re-call test used in our prior pilot study.[11]

For patient satisfaction, two measures were recorded at T3. First, the patients were asked about their willingness to return to the endoscopy unit. This is commonly used in the context of patient satisfaction in endoscopy.[20] Next, the Net Promoter Score (NPS) is utilized on the question "Would you recommend this endoscopy unit to your peers?". Patient's scores range from 1 (Not at all likely) to 10 (Extremely likely). The NPS is calculated as % Promoters (scores 9-10) - % Detractors (scores 1-6).[18]

Statistical analysis

Data was analysed on an intention-to-treat and per-protocol basis. Presentation of the data included the means, medians and standard deviations for quantitative data. The point estimates are presented with 95% confidence intervals (CI)." In case of categorical data, counts and frequencies were used.

We used the relative risk of an inadequately prepared colon to compare both groups. In comparable bowel preparation studies, 90% success rate (for an adequately prepared colon) is commonly used, with a 10% non-inferiority margin as the maximum clinically acceptable difference.[19,21]

The non-inferiority power calculation resulted in 180 patients per group, 360 patients in total. With a margin of ± 60% attrition of patients before completing the protocol, based on earlier research, the target number of patients to approach was set at 1,000 to acquire the adequate per-protocol sample.

Comparisons between groups were assessed using bi-variate analyses. In addition to the non-inferiority analyses in the intention-to-treat and per-protocol population, superiority analyses (Chi-Square, t-test, ANCOVA) were conducted to investigate effects on secondary outcome measures. Possible differences between the groups concerning secondary outcomes were assessed using two-sided testing. P-values <0.05 were considered statistically significant for the secondary outcomes and no correction for multiple testing was performed as these analyses were considered exploratory.

RESULTS

From September 2015 to December 2017 a total of 1035 patients were assessed for eligibility. Of those, 190 patients declined to participate for several reasons. (Figure 2.) A total of 845 patients underwent randomization in four hospitals. After randomization, 161 patients were excluded from further analysis for the following five reasons: missing data (n=35), premature withdrawal from the trial (n=34), not receiving a scheduled colonoscopy (n=5) an incomplete colonoscopy due to pain / stenosis (n=41) or absence of BBPS score (n=46).

This resulted in 684 patients who were included in the ITT analysis population. In these patients, the age and gender were not significantly different amongst groups.

A total of 497 patients were entered for the PP analysis. A total of 217 patients received nurse counselling while 280 patients were assigned to CBE. (See study flow chart, figure 3.) All patients included in the analysis had 100% adherence to nurse counselling and to the complete CBE.

Of these 497 patients, 100% completed the baseline study forms at T1, with lower response rates on pre-colonoscopy (55.6%) at T2 and post-colonoscopy (47.3%) forms at T3. Baseline characteristics were not significantly different with respect to age, gender, educational level and ethnicity. Prior experience with colonoscopy was comparable in both groups, with 46.8% in the nurse group and 51.5% in the CBE group. (Table 1.)

Figure 3. Flowchart trial

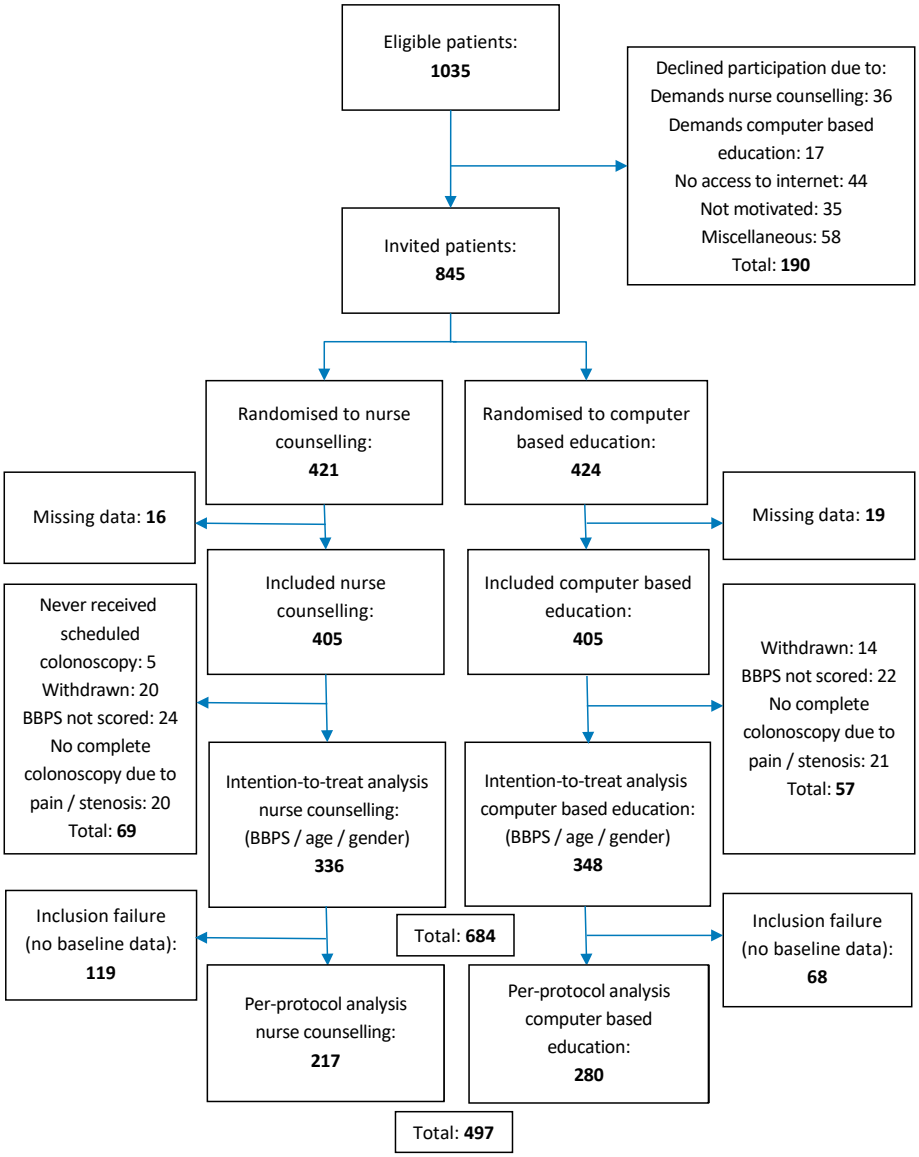


Table 1. Baseline Characteristics

Per-protocol population	Nurse counselling	Computer Based Education	Nurse versus Computer Based Education (statistical test)
Gender n (%) Male Female	106 (48.8) 111 (51.2)	129 (46.1) 151 (53.9)	p = 0.539 (Chi-Square)
Age (mean, SD)	56 years, 14.5	56 years, 14.5	p = 0.797 (t-test)
Ethnicity n (%) Native Dutch Other	194 (89.4) 22 (10.1)	242 (86.4) 30 (10.7)	p = 0.764 (Chi-Square)
Educational level† n (%) Low Middle High	27 (12.4) 121 (55.8) 69 (31.8)	41 (14.6) 154 (55.0) 85 (30.4)	p = 0.980 (Chi-Square)
Prior experience with colonoscopy n (%)	101 (46.8)	140 (51.5)	p = 0.301 (Chi-Square)

† Highest completed educational level was split into three levels where 'low' comprised no education through to lower secondary education, 'middle' comprised upper secondary and middle vocational education, and 'high' comprised higher vocational and tertiary education

Primary endpoint

BBPS scores were collected for all 684 patients. In the ITT and PP population, mean BBPS scores in both groups exceeded the threshold of 6 considered adequate. In the PP population, the mean BBPS in the nurse counselling group was 8.00 (95% CI 7.78; 8.21), comparable to that of the CBE group at 7.81 (95% CI 7.62; 8.00), p=0.207.

We subsequently calculated the risk to obtain an adequate BBPS (> 6). In the ITT population the CBE group, 93.4% of patients, reached an adequate BBPS score, compared to 95.8% assigned to the nurse counselling group. The 95% confidence interval of the relative risk difference (–2.4%) was –5.8% to 0.9%, which was within the prespecified non-inferiority margin of 10%.

In the PP population the CBE group, 93.2% of patients reached an adequate BBPS score, compared to 94.0% assigned to the nurse counselling group. The 95% confidence interval of the relative risk difference (–0.8%) was –5.1% to 3.5%, which was within the prespecified non-inferiority margin of 10%. Thus, our findings showed that CBE is not inferior to nurse counselling in both the ITT and PP population (i.e., that the null hypothesis was rejected).

The difference of -2.4%, 95% CI [–5.8; 0.9]% and -0.8%, 95% CI [- 5.1; 3.5]% in formal testing for superiority showed no statistical difference between groups in both the ITT and PP population. The number of repeat colonoscopies due to inadequate bowel preparation was not significantly different amongst groups in both the ITT and PP population, being 4 (0.6%) in nurse counselling versus 7 (1.0%) in CBE in the ITT group and 3 (0.6%) in nurse counselling versus 6 (1.2%) in CBE in the PP group. (Table 2.)

Table 2. Primary Outcome: Bowel Preparation during Colonoscopy

Per-protocol population	**Nurse counselling (n, % scoring rate)**	**Computer Based Education (n, % scoring rate)**	**Nurse versus Computer Based Education (statistical test)**
Rate of adequate bowel preparation n (%) (BBPS 6 or higher)	204 (94.0)	261 (93.2)	Superiority p = 0.720 (Chi-square) Non-inferiority: delta -0.8%, 95% CI [- 5.1; 3.5] (within margin)
Boston Bowel Preparation Scale (mean, 95% confidence interval)	7.995, 95% CI [7.78; 8.21]	7.811, 95% CI [7.62; 8.00]	p = 0.207 (t-test)
Decision to repeat colonoscopy due to inadequate bowel preparation n (%)	3 (1.4)	6 (2.1)	p = 0.528 (Chi-Square)

Subsegmental BBPS scores in the right, transverse and left colon were equally distributed amongst groups. In the excellent BBPS scores of 8 and higher no significant differences were observed amongst groups (73.3% in nurse counselling, versus 69.3% in CBE, p = 0.331). (See appendix tables 1s. and 2s.)

Secondary end points

Sickness absence leave

Sickness absence leave was significantly lower in the CBE group, 28.0% in the nurse counselling group, and 4.8% in the CBE group, p < 0.001. (Table 3.)

Table 3. Secondary Outcomes: Short Absence leave, anxiety, satisfaction and information re-call

	Nurse counselling	**Computer Based Education**	**Nurse versus Computer Based Education (statistical test)**
Need for Sickness Absence Leave (n, %) [number of respondents (%)]	35 (28.0) [125 (57.3)] (n, % scoring rate)	7 (4.8) [145 (51.8)] (n, % scoring rate)	p < 0.001 (Chi-Square)
Anxiety (STAI, score range from 20 [no anxiety] -80 [high anxiety])			
Trait Anxiety Mean (SD)	53.42 (5.26) (n=202, 93.1)	53.20 (4.83) (n=212, 75.7)	p = 0.522 (independent sample t-test)
State Anxiety after patient education Mean (SD)	55.3 (5.45) (n=203, 93.5)	54.43(5.82) (n=218, 77.9)	p = 0.101 (independent sample t-test)
State Anxiety pre-colonoscopy Mean (SD)	58.23 (5.74) (n=118, 54.4)	57.79 (5.29) (n=144, 51.4)	p = 0.654 (independent sample t-test)
Rise in State Anxiety after education and prior to colonoscopy Mean (SD)	3.09 (6.98) (n=111, 51.2)	2.83 (7.90) (n=124, 44.3)	p = 0.437 (ANCOVA)
Patient satisfaction			
NET promoter score (%promoters minus %detractors)	+40.9% (n=110, 50.7)	+46.3% (n=121, 43.2)	p = 0.45 (independent sample t-test)
Willingness to return (on a scale from 1-10) Mean (SD)	8.13 (1.35) (n=110, 50.7)	8.51 (1.70) (n=121, 43.2)	p = 0.059 (independent sample t-test)
Information re-call test (10 basic item test score before endoscopy, score 1-10) Mean (SD)	7.18 (1.17) (n=125, 57.6)	7.24 (1.06) (n=144, 51.4)	p = 0.702 (independent sample t-test)

Anxiety

Anxiety scores were completed in 235 patients in total, 111 in the nurse counselling and 124 in the CBE group at baseline and sequentially before colonoscopy using the STAI. The baseline trait and state anxiety scores were equally distributed in both groups: 53.42 (5.26) in nurse counselling versus 53.20, (4.83) in CBE. This was also the case in state anxiety prior to colonoscopy. Comparing both groups, we noted an expected rise in anxiety scores between the moment of education and just before colonoscopy. The small difference in the rise of scores, indicating a possible benefit of either modality, was not significant amongst groups: 3.09 (6.98) versus 2.83 (7.90), p=0.437. (Table 3.)

Satisfaction
Patient satisfaction (defined as willingness to return) scores on the education before colonoscopy, were high but not statistically different between both groups. The nurse counselling group scored a mean of 8.13 (1.35) out of 10, whereas the CBE group scored an 8.55 (1.30), p=0.059. Second, the NET-promoter scores recorded were +40.9% versus +46.3% respectively, which is also not significant amongst groups (p=0.45). (Table 3.)

Information re-call
Information re-call was tested using a 10-item questionnaire. There was no significant difference between groups, with 7.18 (1.17) in the nurse counselling group, versus 7.24 (1.06) in the CBE group. (Table 3.)

Endoscopy
When asked whether patients required additional information prior to the colonoscopy in the CBE group, 78.5% of the patients reported negative and were directly scheduled after CBE. In 21.5% of the cases, there was an extra contact moment, 18.5% by telephone call, 3.0% at the outpatient clinic. A total of 70 endoscopists were involved in the trial.

DISCUSSION

This multicenter randomized controlled trial, evaluated computer based education as an educational tool for patient counselling prior to colonoscopy. We found in our intention-to-treat as well as per protocol analysis that CBE is non inferior to nurse counselling in terms of bowel preparation. At the same time, CBE reduced 79% of patient visits to the outpatient clinic compared to conventional nurse counselling. An added value of CBE is the lower proportion of patients who report sickness absence leave prior to endoscopy. CBE, with two-way communication in place, functions therefore as a time and resource effective nexus between patients and the endoscopy unit.

We also investigated psychological parameters such as stress or anxiety that may accompany (preparation for) a colonoscopy but found that there was no difference in trait (or 'character') anxiety scores between groups. Similarly, the state (or "moment") anxiety scores, both after education and prior to colonoscopy, were comparable between the groups both after receiving education and just prior to colonoscopy, as were the anxiety levels before colonoscopy. Finally, CBE shows high scores for patient satisfaction and information re-call at levels similar to those after nurse counselling. (Appendix 3s.)

There have been several comparable studies that have used various means of electronic communication. One study enriched patient communication by sending

a series of 15 text messages to patients and found that they to achieving better colonoscopy preparation.[22] In addition, digital send instructions increase appointment adherence with less same-day cancellations.[23] Trials utilizing smartphone apps showed improved bowel preparation.[24-26] An important difference with these studies using text messages via SMS of smartphone app is that our approach aimed achieve patient engagement through the use of visual 3D animation as a teaching tool to provide better insight and actual visualisation of the procedure. Also, web based solutions like ours have the benefit over smart phone apps that it is ubiquitously available on all devices (e.g. desktop computer, tablet of smartphone) without the need for users to download it first. More importantly, the fact that our CBE platform may substitute nurse counselling, common practise in several health care services, is a novel element and relevant to policy makers.[27]

Earlier, authors hypothesized that there is a "ceiling effect" of 90% adequate bowel preparation score for educational interventions that influence these scores in any endoscopy unit.[28] As a result, these interventions will be beneficial in underperforming units with scores well below the 85% benchmark advised by the U.S. Multi-Society Task Force on Colorectal Cancer Screening.[29] In several recent (non-Western) studies demonstrating improved bowel cleanliness by smart phone intervention, baseline scores in the control group were often below this point (77.2%-73.6%).[25,30] By contrast, in our four trial units (already performing well above 90% adequate bowel preparation in controls) the ceiling effect might have prevented to detect meaningful superiority differences. We therefore adopted the non-inferiority design, novel to this type of research.

Initiatives in other fields utilizing the same functionality of CBE have shown that it can reduce the number of outpatient visits. For example, use of CBE improves patient self-management in inflammatory bowel disease, diabetes, asthma, and chronic obstructive pulmonary disorder.[31,32]

We realize that CBE is not suitable for every patient. The patient with low (eHealth) literacy are less likely to benefit. In our trial, 3.0% of patients paid an extra visit to the hospital despite CBE. CBE should therefore be positioned as an adjunct to nurse counselling in vulnerable patient groups, as they might need an alternative access for relevant health care information.

The implication of our finding is that CBE may save valuable time for the nurses and free up resources. With the growing future need for colonoscopies due to the national colorectal cancer screening programme and subsequent surveillance colonoscopies, and the current problems in recruiting nursing staff in Dutch hospitals, this is very relevant.[33,34]

Our randomized clinical trial comes with strengths and limitations. Summarizing strengths, our trial was conducted with a large, real life sample of patients. The non-inferiority hypothesis and power allows robust statements on CBE efficacy. We tested this CBE in a real-world setting, with patients with patients having a variety of indications (Appendix Table 3s), both with and without previous experience of colonoscopy. Also, we used three different types of endoscopy units, with a variety of different practices (Appendix tables 4s and 5s), so the results are well generalizable to daily practice. In the catchment area of our endoscopy centers, CBE can be used in up to 94% of patients undergoing colonoscopy.[11]

On the other hand, our trial comes with limitations. There was a significant number of dropouts after randomization due to inclusion failures. However, this did not result in an unequal distribution regarding baseline characteristics among the arms in both the ITT and PP population, limiting the risk of selection bias. Due to the use of patient reported questionnaires we do not have 100% data collection at all time points, although the trial protocol called for that. While this did not affect our main outcome, it might have affected assessment of secondary outcomes such as anxiety and satisfaction. Satisfaction was measured several hours after administration of sedatives. Sedatives may cause a euphoric effect after administration and result in higher overall scores. However, type of sedative use was distributed equally (data not shown) over the groups, precluding bias. We did not collect complete medical histories of our patients, including previous abdominal surgery, or risk factors for poor bowel preparation such as diabetes mellitus, constipation, or use of motility influencing drugs. We surmise that the effect of these risk factors on the bowel preparation efficacy in our trial is limited in view of the small difference in BBPS scores. We did not collect data on adenoma detection rate (ADR) as this was outside the remit of this clinical trial. From literature, the robust correlation between adequate BBPS and ADR suggest that BBPS is a good technical proxy parameter.[35]

CONCLUSION

In this trial we have established non-inferiority for computer based education compared to nurse counselling prior to colonoscopy in bowel preparation. This finding paves the way for further upscaling of CBE in endoscopy units to prepare their patients more effectively before colonoscopy. A patient prepared with CBE reduces the need for outpatient clinic capacity, leading to less absenteeism at work, high satisfaction scores and good re-collection of information.

STATEMENTS

GV carries out the trial, conceived the study, organized the design and coordination of the study and drafted the first version of this manuscript. MK, JT, BvB and AvE participated in the design and coordination of this study. JD supervised GV and participated in its design and coordination. All authors read and approved the final manuscript.

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An abstract of this study has been presented at the Dutch Association for Gastroenterology Spring conference 2019, in Veldhoven, the Netherlands, the European Society of Gastrointestinal Endoscopy conference 2019 in Prague, Czech Republic and the Digestive Disease Week 2019 in San Diego, USA.

COMPETING INTERESTS

The E-PACO trial is an investigator-initiated trial. The authors declare that they have no competing interests.

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SUPPLEMENTARY MATERIAL CHAPTER 5

In the following pages supplemental data is provided, as referred to in chapter 5.

Appendix 1s. Data stewardship statement

The company behind the software is ISO27001 and NEN7510 compliant and has declared all the controls from ISO27002 as applicable. ISO27001 is an international standard for information security, while NEN7510 is a Dutch standard for healthcare, based on ISO27799 "Health informatics — Information security management in health using ISO/IEC 27002". This contains for example encryption of information at rest and in transit, access management and so on.

As also required by the General Data Protection Regulation, patient information (and backups) are encrypted and access is logged and restricted to authorized users. Patient information is stored on EU servers. We are not allowed to divulge the precise strength of the encryption algorithms for security reasons.

Appendix 2s. iMTA Productivity Cost Questionnaire

In this trial, the iMTA Productivity Cost Questionnaire is used to evaluate the macroeconomic effect. For further explanation and to download the iMTA Productivity Cost Questionnaire and guiding manual, visit the iMTA website: https://www.imta.nl/questionnaires

Website based information:

iMTA has developed several questionnaires over the past 25 years. These questionnaires are available for use by others to improve standardization in measurement in health economic evaluation.

Productivity losses

The impact of disease on the ability of a person to perform work should be part of an economic evaluation when a societal perspective is applied. iMTA is highly experienced in methods for measuring and valuing productivity losses. During the past years several questionnaires were developed for measuring productivity losses and several scientific papers were written on this topic including the valuation of productivity losses. These questionnaires contributed to the development of the iMTA Productivity Cost Questionnaire (iPCQ), bundling all relevant parts of the previously mentioned questionnaires into a short generic measurement instrument. Additionally, we developed a manual containing information on the modular structure of the iPCQ and its scoring- and valuation methods that are used for the cost calculations. The iPCQ is a generic questionnaire and is applicable to national and international studies. Currently, 16 translations are available, among which Dutch, English, German, Spanish and French. See below for a full list of translations. For the measurement of productivity losses, we recommend applying the iPCQ.

Appendix 3s. Patient satisfaction with computer based education

In the trial additional information was gathered besides the presented data in the manuscript with regard to the patient experience in the computer based education group.
To this end, patients were asked the following questions directly after completion of the computer based education platform.

Patients were presented the question “If you were asked to give an evaluation of the computer based education, ranging from 1 (very bad) until 10 (very good), what would that be?”. We used a 10 point scale; 203 patients scored this item, with a mean score of 7.62 (SD 1.44).

Statistics
If you were asked to give an evaluation of the computer based education, ranging from 1 (very bad) until 10 (very good), what would that be?

N	Valid	203
	Missing	294
Mean		7.62
Std. Deviation		1.448

If you were asked to give an evaluation of the computer based education, ranging from 1 (very bad) until 10 (very good), what would that be?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	1	0.2	0.5	0.5
	2	1	0.2	0.5	1.0
	3	4	0.8	2.0	3.0
	4	2	0.4	1.0	3.9
	5	5	1.0	2.5	6.4
	6	15	3.0	7.4	13.8
	7	49	9.9	24.1	37.9
	8	80	16.1	39.4	77.3
	9	34	6.8	16.7	94.1
	10	12	2.4	5.9	100.0
	Total	203	40.8	100.0	
Missing	System	294	59.2		
Total		497	100.0		

Patients were also “Would you recommend computer based education to a relative before undergoing colonoscopy?”, again using a 10 point scale. Again 203 patients scored this item, with a mean score of 7.69 (SD 1.55).

Subsequently patients who scored 1-6 (31 patients) and 9-10 (59 patients) were asked to motivate their low or high scores with qualitative input. Responses in the low score group that were related to the CBE can be categorized into “technical remarks” and “accessibility for elderly”. Responses in the high score group can be categorized into “high clarity of explanation”, “good use of video and visualization”, “easy online accessibility”, “no need for hospital visit” and “time and space independent”. (data not shown)

Statistics

Would you recommend computer based education to a relative before undergoing colonoscopy? Please express your answer on a scale ranging from 1-10, where 1 is absolutely not and 10 is most certainly.

N	Valid	203
	Missing	294
Mean		7.69
Std. Deviation		1.546

Would you recommend computer based education to a relative before undergoing colonoscopy? Please express your answer on a scale ranging from 1-10, where 1 is absolutely not and 10 is most certainly.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	1	0.2	0.5	0.5
	2	2	0.4	1.0	1.5
	3	2	0.4	1.0	2.5
	4	1	0.2	0.5	3.0
	5	8	1.6	3.9	6.9
	6	17	3.4	8.4	15.3
	7	49	9.9	24.1	39.4
	8	69	13.9	34.0	73.4
	9	30	6.0	14.8	88.2
	10	24	4.8	11.8	100.0
	Total	203	40.8	100.0	
Missing	System	294	59.2		
Total		497	100.0		

Table 1s. Boston Bowel Preparation scores
Subsegmental scores right colon (RC), transverse colon (TC) and left colon (LC).

Group Statistics

	Type of education	N	Mean	Std. Deviation	Std. Error Mean
RC	Nurse counselling	217	2.55	0.712	0.048
	CBE	280	2.48	0.693	0.041
TC	Nurse counselling	217	2.68	0.614	0.042
	CBE	280	2.64	0.594	0.035
LC	Nurse counselling	217	2.76	0.523	0.035
	CBE	280	2.69	0.569	0.034
Total BBPS	Nurse counselling	217	8.00	1.580	0.107
	CBE	280	7.81	1.641	0.098

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
RC	EV assumed	0.178	0.673	1.117	495	0.265	0.071	0.063	-0.054	0.195
	EV not assumed			1.113	458.110	0.266	0.071	0.064	-0.054	0.196
TC	EV assumed	0.260	0.611	0.634	495	0.526	0.035	0.054	-0.073	0.142
	EV not assumed			0.632	456.716	0.528	0.035	0.055	-0.073	0.142
LC	EV assumed	7.090	0.008	1.595	495	0.111	0.079	0.050	-0.018	0.177
	EV not assumed			1.613	480.916	0.107	0.079	0.049	-0.017	0.176
Total BBPS	EV assumed	1.173	0.279	1.265	495	0.207	0.185	0.146	-0.102	0.472
	EV not assumed			1.271	472.465	0.204	0.185	0.145	-0.101	0.470

Table 2s. Excellent (≥8) BBPS scores

Type of patient education * excellent BBPS (≥8) Crosstabulation					
			Excellent BBPS (≥8)		
			<8	≥ 8	Total
Nurse	Nurse counselling	Count	58	159	217
		% within Type of patient education	26.7%	73.3%	100.0%
	Computer based education	Count	86	194	280
		% within Type of patient education	30.7%	69.3%	100.0%
Total		Count	144	353	497
		% within Type of patient education	29.0%	71.0%	100.0%

Chi-Square Tests					
	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	0.944[a]	1	0.331		
Continuity Correction[b]	0.760	1	0.383		
Likelihood Ratio	0.948	1	0.330		
Fisher's Exact Test				0.370	0.192
Linear-by-Linear Association	0.942	1	0.332		
N of Valid Cases	497				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 62.87.

b. Computed only for a 2x2 table

Table 3s. Indication for colonoscopy
From the endoscopy reports data was collected on the indication for colonoscopy. This was subsequently categorized according to the indication groups commonly used.

Indication for colonoscopy * Type of education Crosstabulation

			Type of education		
			CBE	Nurse	Total
Indication for colonoscopy	Suspected inflammatory bowel disease	Count	18	11	29
		% within Indication for colonoscopy	62.1%	37.9%	100.0%
	Symptoms (anaemia, rectal bleeding, weight loss, etc)	Count	177	126	303
		% within Indication for colonoscopy	58.4%	41.6%	100.0%
	Surveillance	Count	50	46	96
		% within Indication for colonoscopy	52.1%	47.9%	100.0%
	Family history	Count	21	19	40
		% within Indication for colonoscopy	52.5%	47.5%	100.0%
	Other	Count	9	14	23
		% within Indication for colonoscopy	39.1%	60.9%	100.0%
	Positive faeces occult blood test	Count	5	1	6
		% within Indication for colonoscopy	83.3%	16.7%	100.0%
Total		Count	280	217	497
		% within Indication for colonoscopy	56.3%	43.7%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	6.411[a]	5	0.268
Likelihood Ratio	6.598	5	0.252
N of Valid Cases	497		

a. 2 cells (16.7%) have expected count less than 5. The minimum expected count is 2.62.

Note: In the trial population, patients were not included who were referred for colonoscopy after a positive faeces occult blood test via the Dutch national colon cancer screening programme. This was due to regulatory reasons with regard to clinical research in these patients. Therefore, the number of primary screening colonoscopies and referrals with positive occult blood tests are very low in our population.

Table 4s. Laxative regimes (1)
In the trial, 3/4 trial sites used Polyethylene glycol, 1 trial site used sodium picosulfate. Patients reported the used regime on the day of colonoscopy. In total, 269 patients (54.1%) responded. Comparing the different groups (nurse counselling and CBE), no significant difference was found in the used regimes (see tables below). Cross tabulation on the type of laxative used and an adequate bowel preparation showed no significant difference amongst groups.

Type of laxative * Type of education Crosstabulation

			Type of education		
			CBE	Nurse	Total
Type of laxative	Sodium Picosulfate	Count	63	46	109
		% within Type of laxative	57.8%	42.2%	100.0%
	Polyethylene glycol	Count	80	79	159
		% within Type of laxative	50.3%	49.7%	100.0%
	Phosphoral	Count	0	1	1
		% within Type of laxative	0.0%	100.0%	100.0%
Total		Count	143	126	269
		% within Type of laxative	53.2%	46.8%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.594[a]	2	0.273
Likelihood Ratio	2.980	2	0.225
N of Valid Cases	269		

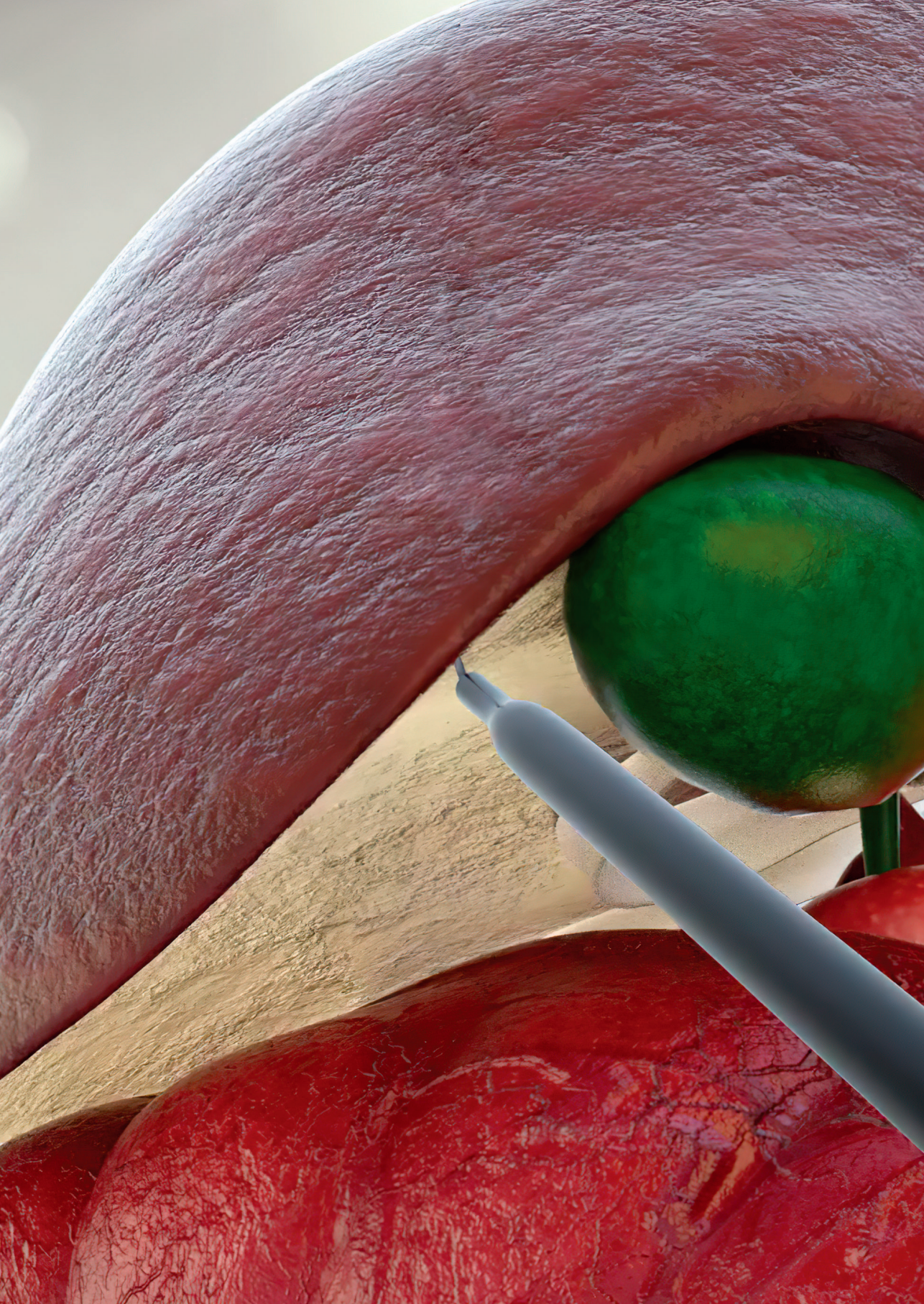
a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is .47.

Table 5s. Laxative regimes (2)

Type of laxative * BBPS adequate (>6) Crosstabulation					
			BBPS adequate (>6)		
			Inadequate	**Adequate**	**Total**
Type of laxative	Sodium Picosulfate	Count	9	100	109
		% within Type of laxative	8.3%	91.7%	100.0%
	Polyethylene glycol	Count	9	150	159
		% within Type of laxative	5.7%	94.3%	100.0%
	Phosphoral	Count	0	1	1
		% within Type of laxative	0.0%	100.0%	100.0%
Total		Count	18	251	269
		% within Type of laxative	6.7%	93.3%	100.0%

Chi-Square Tests			
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	0.770[a]	2	0.680
Likelihood Ratio	0.823	2	0.663
Linear-by-Linear Association	0.753	1	0.386
N of Valid Cases	269		

a. 2 cells (33.3%) have expected count less than 5. The minimum expected count is 0.07.



6

Computer based education to prepare patients for colonoscopy is reducing operational costs of endoscopy units, with lower patient and societal expense

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Submitted

ABSTRACT

AIM

We developed computer-based education (CBE) to improve bowel preparation for colonoscopy and using a randomised clinical trial we found that CBE is non-inferior compared to nurse counselling using adequate bowel preparation as outcome measure (93.2% versus 94%). We set out to calculate the cost minimization effects of CBE.

METHODS

We performed cost minimization calculation using a cost model for three patient routes (nurse counselling, CBE alone and both). This model includes wages of staff, CBE implementation and license costs. We calculated per visit costs of both strategies using the Institute for Medical Technology Assessment (iMTA) costing tool and the reported average travel distance for colonoscopy in the Netherlands in both scenarios. The iMTA Productivity questionnaire was used for adapted cost friction. For statistical analysis, we performed bootstrap to compare results and to calculate 95% confidence limits.

RESULTS

The adaptation of the cost model after process evaluation resulted in 33 relevant parameters for cost calculation. Input on all parameters was retrieved in the four trial units. This resulted in varying costs for the three patient routes per trial site: nurse counselling €18,30 - €28,42, CBE alone €4,04 - €8,86 and CBE with additional counselling €7,01 - €19,78. Data in the CBE group was imputed (135 to 280 patients). The endoscopy unit paid on average €8,36 (CI €7,83-€8,84) per patient in the CBE group. In the nurse counselling group, this was significantly higher, €22,56 (CI €22,00–€23,12). The average patient out of pocket costs were €5,80 for a nurse visit. With mandatory visits in 100% and 3% of the cases, the total cost made by all patients were €1260,09 in nurse counselling versus €46,45 in the CBE group. In total 271 patients (125 nurse counselling, 146 CBE group) completed the iMTA questionnaire. In the nurse group, 54 (43.2%) patients reported absence from either paid or unpaid work of needing replacement for unpaid work, versus 29 (19.8%) in the CBE group (p=0.007). The e calculated productivity loss was significantly higher in the nurse counselling group: €35,84 (95% CI: € 26,79 -€48,41) versus CBE: €13,89 (95% CI: €7,64 – €18,84).

CONCLUSION

CBE reduces costs for endoscopy units, patients and society.

INTRODUCTION

The diagnostic accuracy of colonoscopy is reliant on the quality of bowel preparation, which is linked to the patient's compliance with the preparation instructions. Optimizing patient education prior to colonoscopy improves adherence to these instructions and leads to cleaner colons.[1-3] In recent decades, nurses from endoscopy units were tasked with patient education and obtaining informed consent. Better prepared patients have increased the efficiency of the endoscopy unit as proper education reduces the rate of examination failures.[4,5] It is reasonable to expect that by improving patient understanding, compliance, and readiness to consent, patient education programs improve quality of care. Patient education has numerous other benefits, such as increased patient satisfaction, cooperation, and decreased anxiety.[2] However, this comes at a considerable investment to endoscopy units as education programs drain endoscopy nurses who otherwise would facilitate primary endoscopy services.

The costs of patient education for the endoscopy department are dependent on the modality of patient education used. Patient navigators e.g. nurse counselling is an effective but very expensive type of patient education programs. As employment of nurses is an important cost-driver, employers are seeking for alternative services that deliver comparable patients education quality, but at lower cost. In literature however, the plethora of publications on improved patient education programs only seldomly evaluate the associated costs.[6-11]

In most health care environments the standard-of care for endoscopic patient education consists of face-to-face nurse counselling visits at the outpatients clinic.[12] Several stakeholders are still requesting face-to-face contacts. For instance, the Dutch nationwide colorectal screening program, accounting for approximately one quarter of all colonoscopies in the Netherlands, demands such a pre-colonoscopy outpatients clinic visit.[13-15]

These visits have several cost-elements specific for the healthcare provider: providing outpatients consulting rooms, (auxiliary) staff for handling appointments and most costly the wages of the nurse who offers the consultation. This has spurred eHealth initiatives that use computer based education (CBE).[12]

Not only hospital costs are important to full economic evaluation of any healthcare intervention. The importance of mandatory out of pocket costs for patients is well known by clinicians as a barrier for undergoing treatments.[16] The main contributing factor in patient education before colonoscopy are travel costs for outpatient clinic visits. Third, there is the societal perspective. An important burden of disease to society is the loss of productivity.[17] Patients (or 'clients' in case of screening colonoscopies) have to report short absence leave which creates considerable loss of productivity.[18]

We developed an eHealth platform that serves as a nexus between patients and endoscopy units. CBE replaces a physical outpatient visit as patients are educated supported by video and 3D animations, health information of the patient is acquired and informed consent documented (' e-consent') and a pre-sedation risk assessment is being performed.[19] Behind the scenes, auxiliary staff can manage patient flows more effectively, with a reduction of 21% of outpatient visits[20] A randomized clinical trial found that CBE is non-inferior to nurse counselling in terms of bowel preparation.[20] To investigate all costs involved with patient education prior to endoscopy, we interrogated data from the development phase of the CBE.[19].

We set out with two questions central to a comprehensive (endoscopy unit, patient and society) economic evaluation of CBE: 1. costs of the current practice of nurse counselling and 2. the cost reduction achieved by CBE.

METHODS

We designed the following strategy to assess costs and cost derived benefits associated with CBE and describe the methodology used to calculate the reduction in operational costs of the endoscopy unit as our primary outcome.

An alternative approach based on the institute for Medical Technology Assessment (iMTA) questionnaire data was used to calculate costs related to the secondary outcomes such as patient expenses and societal costs. All costs presented in this article are in euros indexed at the price level of 2016, as most data was collected in this period.

Endoscopy unit operational costs

We combined the data from two prospective observational studies to answer our research questions on endoscopy unit costs.[20,21] The first study is a multicenter randomized controlled trial with four trial sites: two urban, one academic and one rural based department.

In this study we compared bowel preparation quality between nurse counselled patients versus patients in the CBE group; the study demonstrated non-inferiority for the CBE on this outcome.[20] The strategy to compare costs based on a non-inferiority study is to perform a cost minimization calculation.[22]

In this trial 497 patients fulfilled the per-protocol requirements. Of these patients, 217 received the nurse counselling group while 280 were CBE instructed. In the CBE group, 135/280 patients filled out a questionnaire prior to colonoscopy, containing questions regarding the patient education route followed in the CBE algorithm. Of this

group, 21.5% required additional information, 18.5% could be counselled via telephone alone. But the remaining 3.0% of patients reported an extra outpatient clinic visit. From the endoscopy unit cost perspective, we defined three patient's education routes: nurse counselling, CBE alone and CBE with additional action (telephone or visit). The additional action group is combined as the key additional cost driver (nurse wage) is comparable.

To compare both groups (217 in nurse counselling versus 280 patients in the CBE group) we had to resolve the missing data in the CBE group. We decided to impute missing data on the patient route after CBE, as we assumed the missing values occurred at random without selective dropout, precluding selection bias. The proportion of patients in each route was used to randomly assign the missing 145 patients to each of the routes. For more detail, we performed this imputation stratified on trial site level. This resulted in complete data on 280 patients in the CBE group.

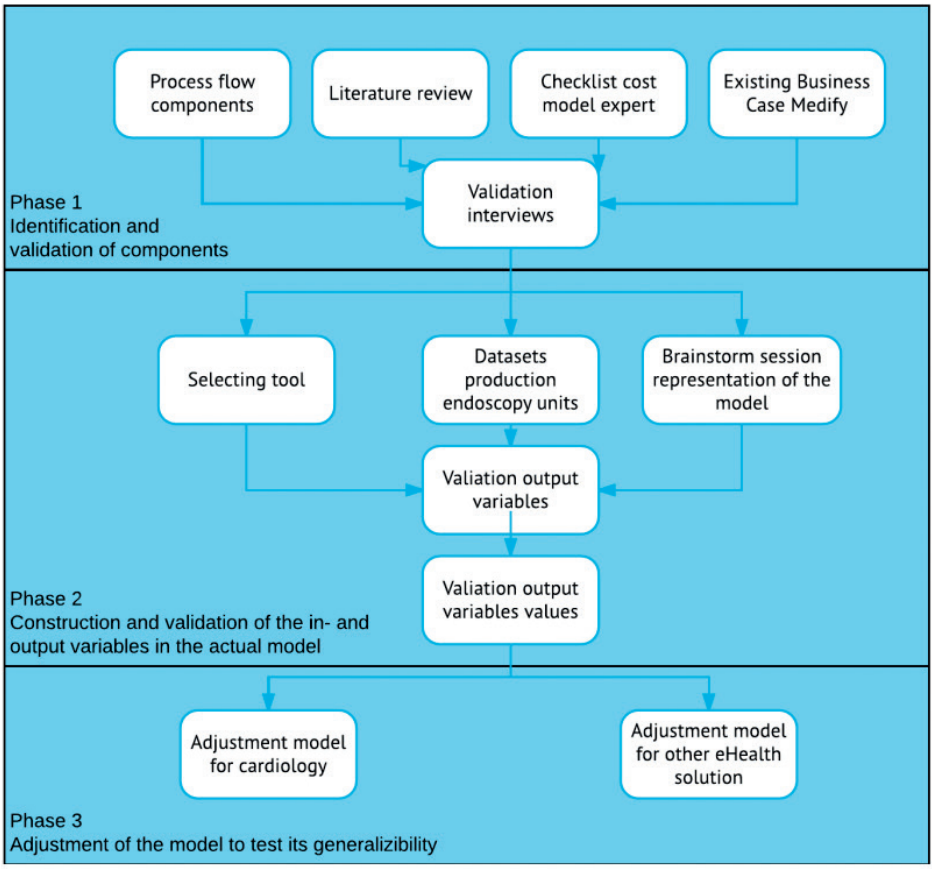
The second study described a cost model which was developed to evaluate the costs effected by CBE implementation.[21] We included all relevant components of the work process to afford better insight in costs and savings for hospital management.

Development of standardized cost model

For the development of the cost model, we use a mixed-methods approach. We reviewed the business case of CBE provided by the supplier of the CBE software. We mapped the patient flow in several endoscopy units where the CBE was already implemented. We identified and validated key components of the cost model through literature research and qualitative interviews with financial experts (e.g. hospital department managers) in the field.

The following phase consisted of the construction the final model. An overview of this process is depicted in figure 1., reprinted with permission.[21]

Figure 1. Applied method for construction and validation of the original cost model (reprint with permission)



The model was built in Excel with addition of Microsoft Visual Basic for Applications. Input variables required by the model are categorized as salaries, production numbers, process steps and actors and time spent on process steps. Based on controller input, key performance indicators (KPIs) for conversion, cost savings and time spent were established.

We adapted this cost model by excluding the KPI's. We added the implementation and license costs to the calculation. As most endoscopy units have contractual license agreements for a 5 year period, the implementation costs (such as customizing the CBE with locally shot video material, change management and process integration) were amortized accordingly. In this way, we could establish true costs for three patient routes (nurse counselling, CBE alone and CBE with additional counselling).

Obviously, the costs of these elements of the model varied between the trial sites in the original multicenter RCT. We therefore made robust assumptions for these different costs (regarding the pay rate of auxiliary staff) based on the experiences of the research team of the original trial. Finally, we used data with regard to the proportions of patients in each trial site from the earlier performed multicenter randomized controlled trial to enrich this model.

Secondary outcomes

Next to the costs made by the endoscopy units, we were interested in effects for patients and the society.

Patients

For patient costs, we calculated the cost of nurse counselling visit. We hypothesized that the main cost drivers in this category would be travel costs. To calculate this, we used iMTA costing tool to establish the cost per kilometre and average hospital parking fees.[23] Travel distances were not recorded on patient level as it was outside the remit of the original trial. Therefore, we used travel data provided by the Dutch national colorectal cancer screening program monitor. Their 2017 report included average travel distance from patients homes to their endoscopy unit (calculation based on ZIP code).[24]

The total amount that all patients in the original trial have spent will be calculated from these cost components. In the nurse counselling group, this includes all patients (100%), in the CBE group we included patients that required additional nurse counselling visit (3%) after CBE.

Society

To assess the burden of patient education prior to colonoscopy on society, we assumed that the main societal costs were due to lost productivity of our patients. The average age of patients undergoing colonoscopies in the earlier trials was between 56 and 59 years.[20,25] Therefore still most patients were considered to take active part in the workforce. To establish the costs of productivity loss we used the friction cost method derived from the completed iMTA Productivity questionnaire.[26]

To calculate the costs the following inputs were used: work status (employed, unemployed), the number of hours absent from work, absent from unpaid work or hours someone else had to absent from work (for instance to babysit) to allow the patient to get educated prior to endoscopy. For these three categories, the average hourly wages for male, females and unpaid work were provided by the iMTA costing tool.[23]

Statistics

Presentation of the data will include the means, medians, standard deviations and ranges for quantitative data. In case of categorical data, counts and frequencies are used. For estimating the mean and 95% CI for endoscopy unit and productivity loss costs in the CBE group, we performed bootstrapping after data imputation.

RESULTS

Endoscopy unit operational costs

On the basis of our original trial we calculated that 209 patients received CBE alone (74.6%) versus 71 patients receiving CBE with additional action (25.4%).[20] Stratification on trial site level explains the small difference with the patient reported data (CBE alone 78.5%, CBE with additional action 21.5%).

The adaptation of the cost model after process evaluation resulted in 33 relevant parameters for cost calculation. Input for all parameters was retrieved from the four trial units. (See supplementary materials tables 1s. and 2s.) This resulted in varying costs per trial for the three patient routes per trial site: nurse counselling €18.30 - €28,42, CBE alone €4,04 - €8.86 and CBE with additional counselling €7,01 - €19,78. (Table 1.)

Table 1. Average costs for patient education routes per trial site

	1. Urban Costs in euro (n, %)	**2. Academic Costs in euro (n, %)**	**3. Urban Costs in euro (n, %)**	**4. Rural Costs in euro (n, %)**
Nurse counselling (n = 217)	€ 19,20 (67, 38.5%)	€ 28,42 (72, 42.6%)	€ 21,46 (43, 48.3%)	€ 18,30 (35, 51.5%)
CBE alone (n = 209)	€ 5,05 (89, 51.1%)	€ 8,86 (66, 39.1%)	€ 5,88 (23, 25.8%)	€ 4,04 (31, 45.6%)
CBE with additional counselling (n = 71)	€ 9,25 (15, 8.6%)	€ 19,78 (31, 18.3%)	€ 12,18 (23, 25.8%)	€ 7,01 (2, 2.9%)
Total, n (% of 497 patients)	171 (34.4 %)	169 (34.0 %)	89 (17.9 %)	68 (13.7 %)

The academic trial site noted the highest costs to educate patients. The rural based trial site had the lowest cost per patient. Main drivers of the differences in costs between trial sites were time spend by staff and the staff wages (see supplementary materials). The pay rate variation amongst trial sites was explained by the average age and level of experience of staff members. The calculated costs per trial site were used to perform total cost minimization calculation: this allowed comparison of average cost of the CBE versus average cost of nurse counselling for all 497 patients.

To educate a single patient using CBE, the endoscopy unit paid on average €8.36 (95% CI: €7.83-€8.84) per patient. Nurse counselling resulted in significantly higher costs: €22.56 (95% CI: €22.00–€23.12). Significance was confirmed as bootstrapping did not show overlap of the presented confidence intervals.

Patients

The cost per kilometre, based on the iTMA costing tool, was €0.19 and average hospital parking fees were €3.03.[23] Travel distance was on average 14.5 kilometres.[24] Therefore, the total expenses for a patient to obtain nurse counselling was €5,80. With mandatory visits in 100% and 3% of the cases, the total cost made by all patients was €1260,09 for nurse counselling versus €46.45 for CBE. Corrected costs for sample size in both groups (217 versus 280 patients, correctional factor 1.29) are € 1625,93 in nurse counselling versus €46.45 in the CBE group. Patient education via CBE results in a 97.1% reduction of patient expenditure.

Society - Productivity loss

In total 271 patients (125 nurse, 146 CBE group) completed the iMTA questionnaire. (Table 2.) Important factor in this questionnaire is distribution of gender, as males are attributed higher wages. This was equally distributed in both groups.

Table 2. Results of 271 patients filling out the IMTA questionnaire

	Nurse counselling N =125	**Computer based education N = 146**	**p value (statistical test)**
Male, n (%)	58 (46,4%)	67 (45,9%)	p = 0.2 (Chi-Square)
Productivity loss reported, n (%)	54 (43.2%)	29 (19.8%)	**P = 0.007 (Chi Square)**
Paid work	28 (22.4%)	6 (4.1%)	
Unpaid work	1 (0.8%)	1 (0.7%)	
Replaced unpaid work	25 (20%)	22 (15.1%)	
Average hours absent, mean (SD)	3.43 (SD 1,98)	3.83 (SD 2,74)	P = 0.49 (independent t-test)
Total productivity loss (95% CI)	€35,84 (€ 26,79 -€48,41)	€13,89 (€7,64 – €18,84)	

Productivity loss was defined by absence from either 1. paid or 2. unpaid work or 3. needing replacement for unpaid work. Patients who were counselled by nurses reported productivity loss in 54 (43.2%), while this was 29 (19.8%) for patients who received CBE (p=0.007). Main cause for this relevant difference was the category of patients reporting absence of paid work, 28 (22.4%) in the nurse counselling group versus only 6 (4.1%) in the CBE group. The mean number of hours reported was not significantly different.

The calculated productivity loss was significantly higher in the nurse counselling group: €35,84 (95% CI: € 26,79 -€48,41) versus CBE: €13,89 (95% CI: €7,64 – €18,84).

DISCUSSION

CBE creates a significant cost reducing effect for endoscopy units. This was mainly caused by the reduced need of the main cost drivers nursing staff wages and time spend per patient.

The costs of patient education were the highest in the academic trial site and lowest in the rural units. One explanation is that the academic site has a more complex caseload of patients, resulting in more time needed for nurses to safeguard the endoscopy workflow.[27]

We found that only 3.0% of CBE patients needed a pre-colonoscopy visit which resulted in a 97% drop of patient expenditure on travel costs.

From a societal standpoint the introduction of CBE significantly reduces patient productivity loss calculated with the cost-friction method.[26] The main cause of this reduction is the absence of paid work (22.4% versus 4.1%) in contrast to absence of unpaid work or needing replacement for unpaid work. This is most probably due to the ubiquitous availability of the CBE, which allows patient education to be easily transferred outside of office hours.

The annual number of colonoscopies is rising and moving from nurse counselling to CBE will have a major impact on a macro-economic scale. The data presented here assumes 100% CBE utilization to educate patients. But implementing CBE in the endoscopy department is not as easy as buying new office furniture. Implementation demands investments and change management. The basic motive to design the original cost model was to have an instrument that could show the substitution of costs in an endoscopy unit.[21] As it turned out, the original business case provided by the sales department of the software developer was too optimistic about the cost reducing effects. Main shortcoming of the business model was not considering the effect of transition of tasks amongst staff. Nursing time saved by CBE resulted in more back office workload.

This study showed the importance of fully implementing the CBE in an endoscopy department for every patient that is invited for endoscopy. Parallel tracks with old fashioned letters via mail increased the workload of primarily auxiliary staff, that is already faced with more back office work due to the CBE. The used model was applied to prospectively monitor the actual cost in four endoscopy units during the

implementation process of the CBE in 2016. (Table 3.) Full implementation is crucial to achieve the maximal costs reduction.

Table 3. Conversion rates and cost savings of patients educated via CBE platform in the first year of implementation (published earlier, reprint with permission)

Rates per year	Target	Actual 2016-2017
Conversion		
Hospital A	60%	35%
Hospital B	80%	40%
Hospital C	80%	27%
Hospital D	80%	50%
Cost savings		
Hospital A	€4958,67	€-2652,60
Hospital B	€49.916.54	€12.860 (FORECAST)
Hospital C	€53.814,96	-€27.024 (FORECAST)
Hospital D	€62.115,60	€31.065,94

Strengths and limitations

A major strength of this article includes the refined basis of all calculations made. The high detailed cost model allows for robust statements on cost minimization effects. The triangular view (endoscopist, patient and society) gives a complete insight when it comes to the economic evaluation of the CBE. Moreover, our CBE is one of few enhanced patient education modalities to produce data on the cost saving effect. A limitation might be that nurse counselling visits prior to endoscopy appears to be quite specific for the Dutch endoscopy unit. Although this has led to the successful implementation in 26 units across the Netherlands, generalizability of the measured cost reducing effects to other countries might be hampered. As with all cost evaluation studies, there is to some extend the risk of assumption bias. The use of extrapolated data in this study is also a limitation.

CONCLUSION

Computer based education shows a cost reducing effect for endoscopy units and lowers expenses made by patients and society. This study fuels the evidence base of the benefits of this eHealth intervention.

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SUPPLEMENTARY MATERIAL CHAPTER 6

In the following pages supplemental data is provided, as referred to in chapter 6.

Overview all input and output parameters for the four trial sites.

Table 1s. Input parameters in cost model

Baseline parameters	**Trial site 1 (urban)**	**Trial site 2 (academic)**	**Trial site 3 (urban)**	**Trial site 4 (rural)**
Number of colonoscopies per annum	7000	3500	5000	4000
Average monthly income for auxiliary staff (wages based on average years of experience)	€ 2.529,00	€ 2.655,00	€ 2.343,00	€ 2.163,00
Calculated salary costs per minute*	€ 0,35	€ 0,37	€ 0,32	€ 0,30
Average monthly income for endoscopy nurses (wages based on average years of experience)	€ 3.052,00	€ 3.179,00	€ 3.052,00	€ 2.719,00
Calculated salary costs per minute*	€ 0,42	€ 0,44	€ 0,42	€ 0,37
Average monthly income for gastroenterologists (wages based on average years of experience)	€ 8.513,00	€ 8.101,00	€ 7.280,00	€ 7.688,00
Calculated salary costs per minute*	€ 1,05	€ 1,00	€ 0,90	€ 0,95
*Calculated salary costs per minute assumes 36 hours of work per week. Including social taxes, pension withholds, 8% holiday pay and 8.3% fixed year-end bonus.				

Table 1s. Continued.

Workflow input parameters nurse counselling	**Trial site 1 (urban)**	**Trial site 2 (academic)**	**Trial site 3 (urban)**	**Trial site 4 (rural)**
How were patients invited?	By mail	By mail	By mail	By mail
Mailing costs (print / postage) *	€ 4,00	€ 4,00	€ 4,00	€ 4,00
Who sent out the mail?	Auxiliary staff	Auxiliary staff	Auxiliary staff	Auxiliary staff
How much time did the mailing process take (in minutes per patient)? #	2	5	3	3
Calculated salary costs for mailing process	€ 4,70	€ 5,83	€ 4,97	€ 4,89
How much time did the nurse counselling session take (in minutes per patient)?	20	35	25	20
Who performed the nurse counselling session?	Endoscopy nurse, supervised by gastro-enterologist	Endoscopy nurse, supervised by gastro-enterologist	Endoscopy nurse, supervised by gastro-enterologist	Endoscopy nurse, supervised by gastro-enterologist
Calculated salary costs for nurse counselling session	€ 10,51	€ 18,60	€ 12,50	€ 9,40
* Source: Zorgvisie				
# Including 0.13 euro telephone costs per minute				
Workflow input parameters computer based education				
What percentage of colonoscopy referrals came from general practitioners?	35%	0%	25%	40%
Does the general practitioner already inform patients about computer based education?	No	No	No	No
What percentage of colonoscopy referrals came from other specialists (internal medicine/surgery)?	20%	40%	30%	25%
Does the other specialists already inform patients about computer based education?				
Does the other specialist already inform patients about computer based education?	No	Yes	No	No

Table 1s. Continued.

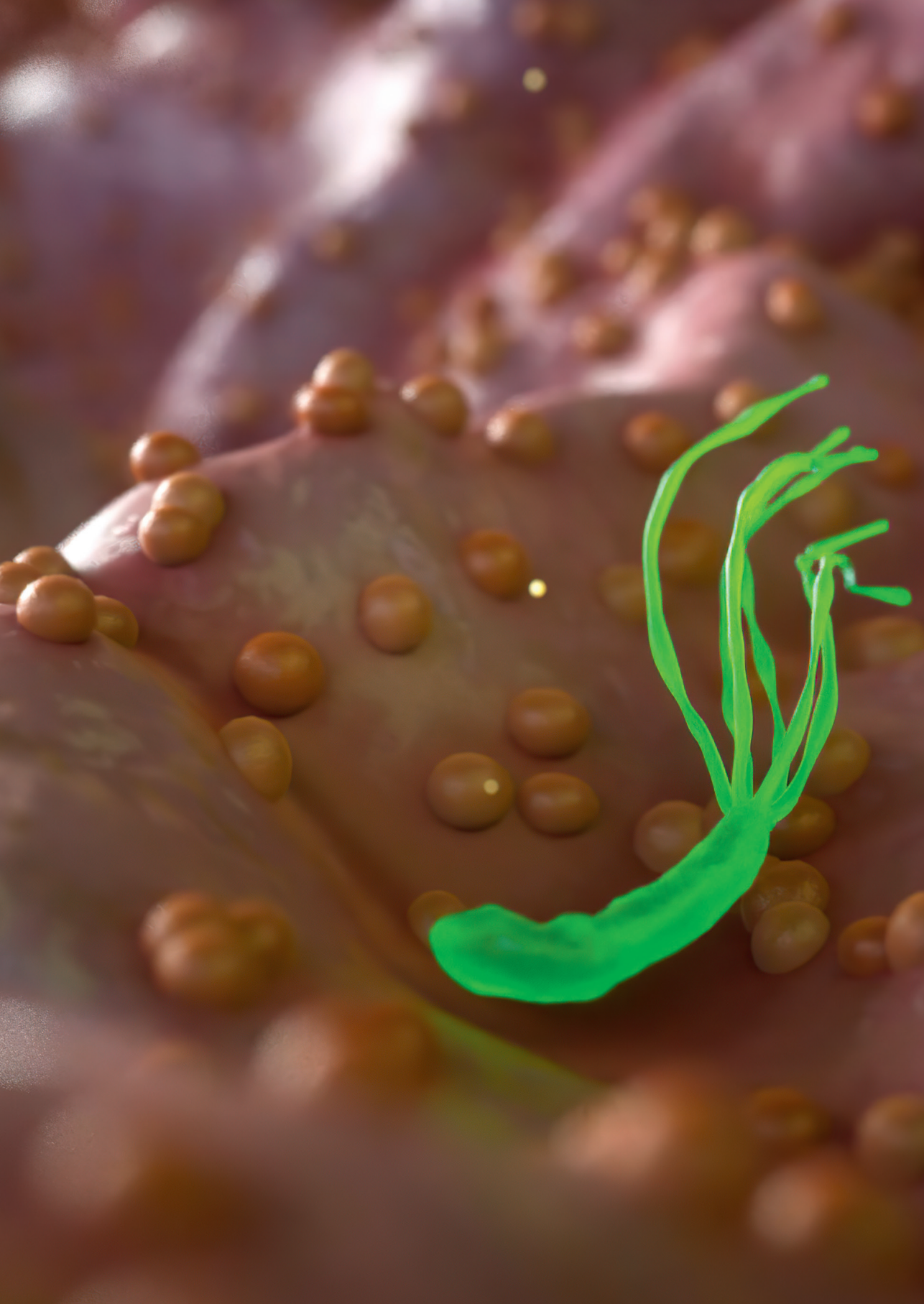
Workflow input parameters computer based education	**Trial site 1 (urban)**	**Trial site 2 (academic)**	**Trial site 3 (urban)**	**Trial site 4 (rural)**
What percentage of colonoscopy referrals came from gastroenterologists?	45%	60%	45%	35%
Invitational process computer based education				
Number of patients with known e-mail address in patient file	20%	20%	20%	20%
Who will call patients to gather the e-mail address?	Auxiliary staff	Auxiliary staff	Auxiliary staff	Auxiliary staff
How much time did the calling process take (in minutes per patient)?	10	15	12	8
Monitoring of computer based education intakes				
Who monitors the computer based education intakes and calls patients when no response is returned?	Auxiliary staff	Auxiliary staff	Endoscopy nurse	Auxiliary staff
How much time did the monitoring process take (in minutes per patient)?	4	5	4	5
Estimated percentage of patients requiring an extra telephone call after no response	15%	30%	15%	5%
Administrative work computer based education				
Who manages the patient information forms returning from the computer based education tool?	Auxiliary staff	Auxiliary staff	Auxiliary staff	Auxiliary staff
How much time did the administrative process take (in minutes per patient)?	2	3	2	1
Additional nurse counselling session (either via telephone or in the outpatient's clinic)				
Actual percentage of patients requiring additional counselling	14%	32%	50%	6%

Table 1s. Continued.

Administrative work computer based education	**Trial site 1 (urban)**	**Trial site 2 (academic)**	**Trial site 3 (urban)**	**Trial site 4 (rural)**
How much time did the nurse counselling session take (in minutes per patient)?	10	25	15	10
Who performed the additional nurse counselling session?	Endoscopy nurse	Endoscopy nurse	Endoscopy nurse	Auxiliary staff
Computer based education software costs				
Initial development and implementation costs (including shooting video)	€ 7.000,00	€ 7.000,00	€ 7.000,00	€ 7.000,00
License costs*	€ 3.276,00	€ 4.680,00	€ 4.212,00	€ 3.744,00
Number of license years	5	5	5	5
License costs per annum	€ 1.400,00	€ 1.400,00	€ 1.400,00	€ 1.400,00
Calculated license and implementation costs per patients undergoing colonoscopy	€ 0,67	€ 1,74	€ 1,12	€ 1,29
*based on number of gastroenterologists per trial site				

Table 2s. Output parameters in cost model

	Trial site 1 (urban)	**Trial site 2 (academic)**	**Trial site 3 (urban)**	**Trial site 4 (rural)**
Nurse counselling costs per patient	€ 19,20	€ 28,42	€ 21,46	€ 18,30
Computer based education alone costs per patient	€ 5,05	€ 8,86	€ 5,88	€ 4,04
Computer based education with additional nurse counselling session costs per patient	€ 9,25	€ 19,78	€ 12,18	€ 7,01



7

Virtual reality distraction for patients to relieve pain and discomfort during colonoscopy

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ABSTRACT

BACKGROUND

Colonoscopy is an invasive procedure which may cause pain and discomfort to the patient. The routine use of sedation, whilst effective, is expensive and requires logistical planning. Virtual reality (VR) offers immersive, three-dimensional experiences that distracts the attention and might provide comfort to the patient. We performed a pilot study to investigate the feasibility of VR distraction during colonoscopy.

METHODS

Adults referred for colonoscopy were considered for inclusion and divided over two groups: with and without VR glasses. Main outcome was patient acceptance of wearing VR glasses during colonoscopy without compromising the technical success of the procedure. Secondary outcomes were patient comfort, pain and anxiety before, during and after the procedure, using validated patient questionnaires. Patients' comments were collected through a qualitative interview.

RESULTS

We included 19 patients, 10 were offered VR glasses. All patients accepted VR glasses without prolonging procedural time. No disadvantages of the VR glasses were reported in terms of communication or changing of position of the patient. We found that patient comfort, pain, anxiety and satisfaction in relation to the procedure were similar in both groups. Patients described a pleasant distracting effect using VR glasses.

CONCLUSION

VR glasses during colonoscopy are accepted by patients and do not compromise endoscopic technical success. Patients reported VR experience as pleasant and distracting.

INTRODUCTION

The use of colonoscopy as a diagnostic and therapeutic tool is likely to rise. This is mainly caused by the implementation and expansion of colorectal cancer screening projects, targeting ever younger patients.[1] Endoscopic procedures are associated with embarrassment, pain and discomfort.[2] This proves an important barrier to undergo colonoscopy and may subsequently curtail the willingness of patients to be subjected to repeat surveillance colonoscopies.[3,4]

Indeed, a relevant proportion of the patients (18-29%) experience anxiety due to concerns related to preparation for, execution of, and anticipation of the result of colonoscopy.[5] Sedatives to relieve anxiety is the method of choice used in order to mitigate discomfort patients experience during colonoscopy.[6] However, drug induced sedation comes with adverse effects related to suppression of pulmonary and circulatory function.[7,8] There is a higher post-procedural risk of pneumonia in elderly patients.[9] Deep sedation even puts patients at an increased risk for the procedural related complication of perforation.[10] Also, the monitoring of patients during and after sedation is both logistically demanding and costly.[11]

Therefore, several studies have examined non-pharmacological interventions to reduce anxiety and pain during endoscopy[12-18]. These studies used a mix of visual[13,15,18,19] or auditory stimuli[12,14,18] and found that while true efficacy is not fully established, combined visual and auditory distraction is better in reducing discomfort compared to auditory distraction alone[18].

Virtual reality (VR) integrates computer generated visual and auditory signals to recreate an illusionary perception of the actual physical world.[20,21]. The distraction that comes with immersive VR induces an analgesic effect and has been used as an adjunct to control pain and anxiety during operative procedures.[22,23]. VR technique has become more affordable and better portable, adding to its immersive qualities.[24]

VR reduces pain during burn wound debridement[25-27], and discomfort during dental procedures[28].

A questionnaire study found that up to 25% patients are willing to undergo colonoscopy with VR glasses instead of sedation. Key patient motive is the reduction of sedative use which allows patients to drive their cars home themselves afterwards.[29]

But still unknown is the patient acceptance (e.g. feasibility) of performing colonoscopy on patients actually wearing VR glasses. Wearing VR glasses could potentially be disadvantageous to the colonoscopy procedure, as it could obstruct communication with patients. Conversely, the procedure itself might compromise the VR effect, as

positional changes of the patient are sometimes necessary. Therefore, we set out on this pilot study to investigate the use of VR distraction during colonoscopy. The primary aim was to assess the patient acceptance of wearing VR glasses whilst undergoing colonoscopy. We were also interested whether VR reduces discomfort, pain, anxiety and satisfaction in patients compared to the standard practice.

METHODS

This experiment was designed as a pilot study to evaluate patient acceptance and practical feasibility. A control group was designed to allow evaluation of procedural and patient related outcomes. The sample size was set at 12 subjects per group. This computation was based on a rule of thumb for pilot studies.[30]

Ethical permission from the Radboudumc Ethics Committee was obtained prior to commencement of the study (number 2016-2750). The trial was registered with the Dutch trial Registry (NTR6175).

Patients

We screened patients who were already scheduled for outpatient colonoscopy. The inclusion criteria of the study were adult age and any elective indication of colonoscopy. The exclusion criteria of the study were visual and/or auditory impairments, dementia, limited Dutch language skills, and a diagnosis of balance disorders or epilepsy.

After evaluation of above criteria, informed consent was obtained from all participants and participants of the study were allocated to the VR (intervention) or non-VR (control) group. The allocation was based on the day the colonoscopy was planned. Participants were informed in which group they were allocated on the day of the procedure.

Intervention

The hardware we used to generate VR distraction was the Samsung® Gear VR (Consumer Edition - SM-R322, combined with Galaxy S7). This is an inexpensive ($172) of-the-shelf wide field-of-view 3-dimensional virtual reality headset that projects video and rendered graphics into 2 independent lenses. The current model is the size of a small pair of ski goggles, with a combined weight of 470 g, and is positioned on the head with elastic straps. The video content which was visualized on the VR hardware contained several short clips (with a total length of 19 minutes and 59 seconds) of moving 360-degree cameras featuring tropical islands and forests in the Caribbean (supported by VR firm Visyon, Eindhoven, The Netherlands). The VR content was without audio, to allow optimal communication with the patient. The authors considered the chosen VR content to be of a relaxing and not overly thrilling character, generating an adequate level of distraction for all participants.

Study design

At T1, all participants filled out a baseline form on a tablet with items on demography, prior experience undergoing colonoscopy, prior VR experience and a validated general health questionnaire (RAND-36).[31] At the day of the colonoscopy, T2, all patients received a second form that included validated questionnaires on anxiety (STAI) and pain (NRS), approximately 15 minutes before the colonoscopy.[32,33] The patients in the intervention group also tested the VR glasses before colonoscopy. See figure 1.

Figure 1. Samsung® Gear VR shown on a patient preparing before and during colonoscopy (with permission)

During colonoscopy, T3, one researcher (NK) observed the patient's well-being and positioning together with several procedural aspects e.g., time to cecum intubation and time of total procedure. All patients received conscious sedation with (Midazolam and/or Alfentanil) according to the standard of care, the dose was increased at physician discretion. After colonoscopy the patient completed a set of questionnaires at T4, including anxiety (STAI), pain (NRS), Net promoter score and willingness to return questions. A short qualitative interview was held with the patients of the intervention group to explore their experiences with VR glasses.

Measures

Primary outcome

The main outcome is patient acceptance of wearing VR glasses during the procedure. This includes adequate positioning of the VR glasses during the entire procedure, even during patient repositioning. In addition, we recorded cecal intubation rate, cecum and total procedure time as well as administered sedatives and analgesics.

Secondary outcomes

Patient comfort

Patient comfort was measured using a five point Gloucester Comfort scale: 1, comfortable and 5, severe discomfort.[34]

Patient pain
An eleven point Numeric Rating Scale (NRS) was used to measure pain of the patient before and during the procedure: 0, no pain and 10, highest imaginable pain.[32]

Patient anxiety
The State Trait Anxiety Inventory (STAI) was used to measure the anxiety of the patient before and after the procedure. The 20-item STAI is widely used with scores ranging from 20 (absence of anxiety) to 80 (high anxiety).[33]

Patient satisfaction
The general health of the participants was measured using the RAND 36 questionnaire[31]. Net Promoter Score (NPS)[35] and an eleven point scale of willingness to return: 0, no willing at all and 10, definitely willing, were used to measure participant satisfaction with the procedure.

Statistical Analysis
Statistical analysis was performed using SPSS version 22 (International Business Machines Corporation, Armonk, New York, United States). Mann Whitney U-tests were used to test whether the median scores for, i.e., age, pain, dose of medication, duration of the procedure, anxiety, satisfaction, NPS, and willingness to return, of the VR (intervention) and non-VR (control) group were comparable to each other. Fisher's Exact tests were used to test categorical data. A P-value of 0.05 or less was considered statistically significant.

RESULTS

In total 24 patients entered the trial. (Figure 2.) Patients were recruited at the endoscopy outpatient clinic. There were 55 eligible patients scheduled for colonoscopy within a 4 week timeframe and we invited 38 consecutive patients. A total of 24 accepted our invitation. and Informed consent was obtained from all patients. After allocation, two patients in the VR (intervention) group and three patients in the non-VR (control) group were excluded (three patients cancelled the scheduled appointment, one was admitted to the hospital and in one patient there was a technical problem with the endoscopy equipment). As a result, 19 patients were entered the final analysis, 10 in the VR group and 9 in the non-VR group. All patients in the intervention group accepted the VR glasses during the whole procedure. In all patients no adverse events of VR distraction in combination with medication were observed. One endoscopist performed all procedures (FV) except one in the VR group (BvH). FV had > 5 years of experience, BvH >3 years.

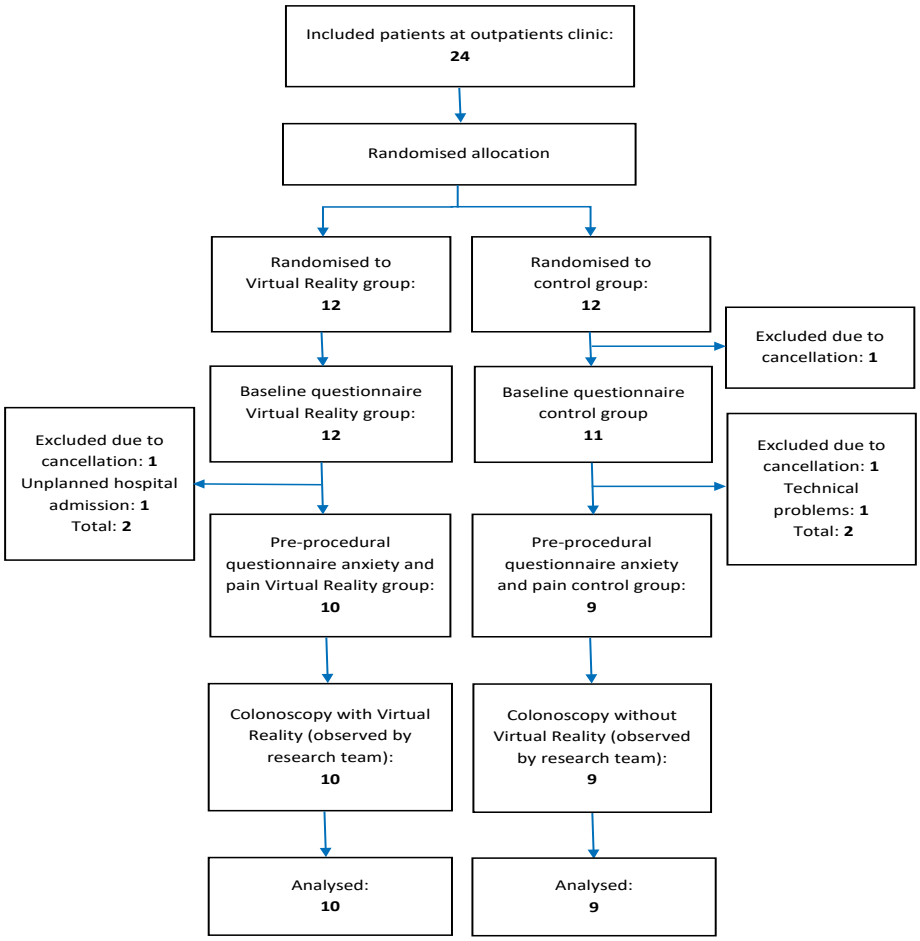
Baseline characteristics

No significant differences were observed in the baseline characteristics of the two groups, i.e., gender (55.6 % women in the control group, versus 60% women in the intervention group), age (median, 64, versus 65 years), level of education, RAND-36, previous colonoscopy, and prior experience with VR. (Table 1.)

Procedure characteristics

There were no differences in procedural characteristics. The time to reach the cecum (median 10.48 minutes in the control group, versus 6.83 minutes in the intervention group), time to complete procedure (median 21.20 minutes in the control group, versus 22.60 minutes in the intervention group), and completed colonoscopies (100% in the control group, versus 90% in the intervention group) were well comparable in both groups. (Table 2.)

Figure 2. Study Flowchart



Similarly, both groups were comparable in terms of initial intravenous bolus of sedatives and analgesics, i.e., dose of Midazolam (median, 2.5 mg in both groups), dose of Alfentanil (median, 0.25 mg in both groups).

Table 1. Baseline characteristics

	Control (non VR) (n=9)	**Intervention (VR) (n=10)**	**P value**
Age (years)*	64 [47.5;67.5]	65 [62;67]	0.414†
Gender (male: female)	4:5	4:6	1.000‡
RAND-36			
Physical functioning*	90 [70;100]	82.5 [72.5;95]	0.549†
Role limitations due to physical health*	87.5 [68.75;100]	68.75 [50;84.38]	0.156†
Role limitations due to emotional problems*	100 [53.13;81.25]	83.33 [47.92;100]	0.133†
Energy/ fatigue*	75 [72.5;90]	59.38 [48.44;81.25]	0.497†
Emotional well-being*	85 [75;100]	75 [50;81.25]	0.113†
Social functioning*	100 [73.47;94.9]	81.25 [62.5;100]	0.113†
Pain*	89.79 [73.47;67.5]	72.45 [67.35;100]	0.497†
General health*	55 [35;67.5]	57.5 [52.5;66.25]	0.497†
Health change*	50 [25;62.5]	37.5 [25;50]	0.549†
Number of previous colonoscopies*	2.5 [1.75;5]	2 [1.25;3.75]	0.515†
Level of education			0.733#
Primary school	0 (0)	0 (0)	
Lower vocational education	0 (0)	10 (1)	
Lower general secondary school	0 (0)	0 (0)	
Intermediate general secondary school	11.1 (1)	10 (1)	
Intermediate vocational education	22.2 (2)	20 (2)	
Upper general secondary school	22.2 (2)	10 (1)	
Higher vocational education	33.3 (3)	50 (5)	
University	11.1 (1)	0 (0)	
Prior experience with VR (yes) % (n)	22.2 (2)	30 (3)	1.000‡

*Variables are denoted as median [inter quartile range]. † Mann-Whitney U test. ‡ Fisher's Exact test. # Chi-square test.

Patient pain, comfort and anxiety

The results of the pain scores, patient comfort scores and anxiety scores are summarized in table 3. Median pain score before (0 in both groups) and during (3 in both groups) the procedure was similar in both groups. The Gloucester Comfort scale did not reveal significant differences in patient comfort between the two groups (4 patients (44%) in

the control group were rated comfortable, versus 4 patients (40%) in the intervention group). No significant difference was observed between the median anxiety score prior to the procedure (49 in the control group, versus 48.5 in the intervention group). The median baseline anxiety score (trait) was similar in the intervention group compared to the control group (29 in the control group, versus 35 in the intervention group). The median anxiety score increased after the procedure (50 and 50).

Table 2. Procedure characteristics

	Control (non VR) (n=9)	**Intervention (VR) (n=10)**	**P value**
Dose Midazolam, in mg*	2.5 [2.5;3] min 2; max 3.75	2.5 [2.38;3] min 2.5; max 3	0.842†
Dose Alfentanil, in mg*	0.25 [0.25;0.50] min 0.25; max 0.50	0.25 [0.25;0.5] min 0.25; max 0.50	0.278†
Completed colonoscopies % (n)	100 (9)	90 (9)	1.000‡
Patient acceptance of VR glasses % (n)	n/a	100 (10)	n/a
Time to reach the cecum, in minutes*	10.48 [8.65;13.80] min 6.10; max 19.00	6.83 [5.75;10.77] min 2.66; max 11.92	0.094†
Time to complete procedure, in minutes*	21.20 [19.72;35.15] min 19.18; max 44.07	22.60 [16.25;25.45] min 9.95; max 26.43	0.340†

*Variables are denoted as median [inter quartile range], as are minimum and maximum. †Mann-Whitney U test. ‡ Fisher's Exact test.

Table 3. Pain, patient comfort and anxiety results

	Control (non VR) (n=9)	**Intervention (VR) (n=10)**	**P value**
Pain score (pre procedure) *	0 [0;3]	0 [0;1.75]	0.968†
Pain score (during procedure) *	3 [1;4]	3 [1.5;5.5]	0.661†
Gloucester comfort scale % (n)			0.699#
Comfortable	44.4 (4)	40 (4)	
Minimal	44.4 (4)	30 (3)	
Mild	11.1 (1)	20 (2)	
Moderate	0 (0)	0 (0)	
Severe	0 (0)	10 (1)	
STATE (Pre procedure) *	49 [48;50]	48.5 [45.75;50.25]	0.497†
TRAIT*	29 [21;36.5]	35 [28;41.5]	0.156†
STATE (Post procedure) *	50 [48;52.5]	50 [47.75;51.25]	0.549†

*Variables are denoted as median [inter quartile range]. † Mann-Whitney U test. ‡ Fisher's Exact test. # Chi-square test.

Patient satisfaction

No differences were observed between the two groups for the patient satisfaction. All patients scored high satisfaction rates in the used scales (median score was of 9 out of 10 in both groups). The results of patient satisfaction were summarized in table 4.

Table 4. Satisfaction results

	Control (non VR) (n=9)	Intervention (VR) (n=10)	P value
Patient satisfaction*	9 [8;10]	9 [6.5;10]	0.905†
NPS*	9 [8;10]	9 [7.75;10]	0.905†
Willingness to return*	9 [7.5;10]	9 [6.75;10]	0.720†

*Variables are denoted as median [inter quartile range]. † Mann-Whitney U test.

Qualitative comments

The majority (9/10) rated use of VR glasses as positive. Four patients indicated that they preferred to select the VR content themselves. Two patients complained of the quality of the movie and 1 patient indicated that the resolution of the VR movie was too low. The physician who performed the colonoscopy was able to communicate with all patients in the intervention group and did not experience any limitations of use of VR.

DISCUSSION

Our pilot study shows that it feasible to use VR distraction during colonoscopy as we observed complete patient acceptance of the device during all procedures. Procedural time was not prolonged as a result of our intervention.

Comfort, pain, anxiety or patient satisfaction was not affected by VR, but patients reported a positive distracting effect of the VR glasses.

This pilot study indicates that there are no obstacles to investigate VR glasses further in a larger sample of patients. Important to the design of subsequent trials from the endoscopist perspective is that the use of VR glasses did not interfere with the completion colonoscopy.

Various studies found that visual and/or auditory distraction during endoscopic procedures reduces pain and improves satisfaction as a result of during endoscopic procedures.[13,15,18] In this pilot we were not able to identify these advantages for VR. This accords with two trials that used VR in burn wound victims and the authors point

towards a better customized VR system instead of the used off-the-shelf VR sets to resolve this issue.[36,37]

Indeed, patients reported that the effect of the VR distraction was less immersive probably because of the content showed. Other studies found that content is relevant to the level of distraction[12,15]. Low pixel resolution of the VR content influenced the experience of at least one participant and previous studies showed that low resolution videos reduce the quality of experience.[38]

The literature on VR for patients in endoscopy is scarce. A retrospective study of 190 patients found that VR allowed unsedated transnasal gastroscopy in children and young adults. In this study VR assisted transnasal gastroscopy was safe and cost-effective for staging of eosinophilic esophagitis.[39] The argument has been made that VR allows avoiding sedation for colonoscopy which fuels patients' experience.[40] Therefore it is probable that in selected patients VR during colonoscopy will be the preferred option.[29]

Strengths and limitations

Our study was performed in a real life setting and selected a representative sample of patient which adds to the external validity of the study. By using Samsung Gear VR to provide distraction, we have chosen a widely available and relatively inexpensive VR device, enhancing the generalizability of the study.

Our study also comes with limitations. First, the small sample size does not allow robust statements on clinically relevant endpoints like reducing anxiety or pain or improving patient satisfaction. Also, recent literature points out that our sample size computation carries the risk of overestimation of the required sample size when designing a main trial to confirm our results.[41] Secondly, the physicians who performed the procedure were not blinded, because the patients in the control group did not wear VR glasses. Although we did not observe a difference in administration of drugs in the control group and intervention group, this could have affected the choice and dose of sedatives. The ideal set-up is a direct comparison of sedation vs VR, instead of VR combined with sedation as done in our pilot.

We used patient reported measures for pain and comfort after patients were recovering from sedative administration. The post amnesia effect of midazolam might have had some effect, but the Gloucester scale rated by the nursing staff revealed no differences between groups.

Because of the low costs of the VR device, VR distraction may easily be deployed in colonoscopy. There are several technical shortcomings such as low resolution,

orientation, and content, which may improve the distractive effect ensuring an enhanced patient comfort and satisfaction.

To achieve a maximal immersive effect, VR content must be developed which provides specific targeted distraction for colonoscopy, e.g., relaxing colors, relaxing music, and properly selected visualizations.

CONCLUSION

In summary, patients accept VR distraction undergoing colonoscopy, without compromising technical success of the procedure. Future studies are justified to evaluate the possible substitution of sedation with VR. Patients reported VR experience as pleasant and distracting, facilitating patient recruitment for these trials.

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GV and NK carried out the trial, conceived the study, organized the design and coordination of the study and drafted the first version of this manuscript. AvE participated in the design and coordination of this study. JD supervised GV, RvW supervised NK, both participated in trial design and coordination. All authors read and approved the final manuscript.

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8

The gastrointestinal endoscopy satisfaction questionnaire captures patient satisfaction as a key quality indicator of gastrointestinal endoscopy

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ABSTRACT

BACKGROUND

Patient satisfaction is a crucial indicator of gastrointestinal endoscopy quality. The gastrointestinal endoscopy satisfaction questionnaire (GESQ) was recently validated for assessment of patient satisfaction undergoing endoscopy in English-speaking countries with good internal and face validity. We translated and validated the GESQ in the Netherlands.

METHODS

The original GESQ was translated in Dutch according to the World Health Organisation (WHO) linguistic validation guidelines. First, internal validation of the Dutch GESQ (D-GESQ) was established by application of the think-aloud method and subsequent expert panel analysis. Next, the D-GESQ was embedded in the computer-based education (CBE) program in our unit, with a 30-day interval after endoscopy. Adult patients, who were informed via CBE and had undergone endoscopy, were included. Exclusion criteria were conscious sedation, limited Dutch language skills, no e-mail address available, dementia and visual impairment. For statistical analysis, several psychometric analyses of the questionnaire were performed to identify the underlying dimensions and assessed the questionnaire for reliability and validity.

RESULTS

In total, 227 of 1065 patients completed the D-GESQ, a response rate of 21.3%. Men comprised 52.6% (N=129) of patients. Mean age was 62.7 ±11.54 years. In total 180 patients (79.3%) had previously undergone endoscopy, with 157 (87.2%) of them two or more times. The exploratory factor analysis showed that the 21 questions could best be clustered into five clusters instead of four in the original GESQ. The D-GESQ had an overall Cronbach α of 0.88, confirming the high internal validity of the tool.

CONCLUSION

The Dutch version of the GESQ showed high internal validity and practicality. We recommend the D-GESQ for routine use in daily clinical practice to improve quality of patient care in daily endoscopic practice.

INTRODUCTION

Endoscopy is the most effective strategy for the diagnosis of gastrointestinal diseases, especially oesophageal, gastric and colorectal cancer.[1] Of these, colorectal cancer leads to high morbidity and mortality, with an estimated 1.8 million diagnoses and 862,000 deaths in 2018 worldwide.[2,3] During colonoscopy, precancerous lesions can be detected and removed, thereby reducing the incidence of colorectal cancer. With adequate surveillance, this risk is further reduced. As a result, colonoscopy-based screening programs have been implemented in many countries in recent years.[4]

There are several technical outcome measures of colonoscopy such as adenoma detection rate and quality of bowel preparation. Patient measures, such as comfort and satisfaction have also been recognised as increasingly important outcomes. Therefore, the European Society of Gastrointestinal Endoscopy (ESGE) has stated that patient satisfaction is one of the most important outcome measures of endoscopy.[6] This information should be gathered routinely, so it could subsequently improve service quality.

Patient satisfaction represents the evaluation by patients of the performance of the health care provider. Patients' experiences and perceptions have become a central focus in health care delivery.[8] It can serve as an ultimate endpoint to health care quality, because good patient satisfaction is associated with decreased utilization of medical services, improved compliance and better prognosis.[9,10]

To assess patient satisfaction of endoscopic procedures the gastrointestinal endoscopy satisfaction questionnaire (GESQ) was recently developed in the United Kingdom. This questionnaire tool, available in the English language, has shown good internal and construct validity.[11]

To allow the use of the GESQ in the Dutch language area we adapted it in a manner useful for clinicians and health care practitioners while maintaining the meaning and intent of the original items. The idea was to develop a valid and reliable Dutch quantitative instrument to measure patients' cognitive and emotional response after endoscopy.

To this end, we translated and validated the GESQ in a Dutch endoscopic population, according to the guidelines of the World Health Organization (WHO).[12]

METHODS

The English version of the GESQ was used with permission of the authors.[11] The translation of this questionnaire was performed using backward and forward translation.[12,13] The questions were first translated into Dutch by a Dutch native speaker. We strived to provide a translation which most closely resembles the original instrument. The result of the translation was discussed with the expert panel. This panel was composed by four members of our research team (AvE, CR, GV, MdJ). As a result, some minor adjustments were made.

Then the questionnaire was translated backwards into English by a different translator, being an English native speaker. Next, the original questionnaire was compared with the backward translation in another expert panel meeting. Finally, the 1.0 version of D-GESQ was fine-tuned based on the outcomes of this session.

Patients who had undergone upper endoscopy or colonoscopy were recruited from the outpatient's clinic of the Radboudumc, Nijmegen The Netherlands, for the internal validation process.

A member of the research team asked patients to complete the 1.0 version of the questionnaire. We applied the think-aloud method, meaning that while performing a task, patients verbalize whatever crossed their minds.[14]

Based on the data coming from the original development of the GESQ we estimated that 20 patients would be sufficient to obtain data saturation. The data saturation point is classified as the point at which the possibility of collecting new additional information has been reached.[15] Main goal of the think-aloud method was to evaluate whether each question was interpreted correctly. General comments were also collected. The aim was to create a questionnaire which was clear to all patients and that covered all aspects of patient satisfaction. The results of these conversations were analysed, and questions were rewritten where necessary, resulting in a 2.0 version.

The 2.0 version of the questionnaire in Dutch (see Supplementary Material) was embedded in the online computer based education (CBE) platform used in our endoscopy unit.[16] This platform acts as a nexus between the endoscopy department and the patient throughout the scheduling and patient education process prior to endoscopy.[17] The D-GESQ was timed to be sent out automatically, 30 days after patients had been subjected to upper endoscopy or colonoscopy. This interval was chosen because it allows additional patient reported evaluation of adverse events. The 30 day period is the chosen interval in the quality measure for colonoscopies performed in the Dutch colorectal cancer screening programme.[4] There were no reminders sent by email.

Patients

Patients were included if they were older than 18 years, had undergone either upper endoscopy or colonoscopy and had received CBE about the endoscopic procedure through our electronic platform prior to the procedure date.

Exclusion criteria were use of propofol sedation as this leads to underreporting of procedural pain, limited Dutch language skills, no e-mail address available, dementia and visual impairment. This was ascertained as these patients did not use the CBE platform route. Informed consent for study participation was obtained from all patients by following the hyperlink in the e-mail that allows entering the questionnaire.

A number of baseline demographic items were collected prior to the D-GESQ. These included age, gender, ethnicity, educational level and working status. Prior experience with endoscopic procedures was recorded.

We distinguished 3 educational levels based on completed education, with 'low' comprising no education up until lower secondary education, 'middle' comprising upper secondary and middle vocational education, and 'high' comprising higher vocational and tertiary education.

Statistical analyses

Baseline characteristics were analysed using an independent 2-sample t test to compare continuous variables. For comparing non-parametrical variables, the Kruskal Wallis test was used. Continuous data were noted as mean and standard deviation, categorical data as numbers and percentages.

Power calculation required a minimum of 210 included patients, as for each question the required sample size consists of 10 patients to be able to perform a confirmatory factor analysis (CFA).[18] The confirmatory factor analysis was performed to evaluate if our data fit with the predefined factor model made by the original authors.[11,18] The model of the confirmatory factor analysis was based on multiple cut-off values for a good fit. Acceptable criteria for these fits were an Adjusted Goodness of Fit (AGFI) >0.90, Tucker Lewis Index (TLI) >0.95, Comparative Fit Index (CFI) >0.90, Root Mean Square Error of Approximation (RMSEA) <0.08 and a Standardized Root Mean Square Residual (SRMR) <0.08.[19]

Before we performed the CFA, the Bartlett test of sphericity and the Kaiser-Mayer-Olkin (KMO) were used to test whether the data were suitable for factor analysis. To verify if our data could be clustered into the same four factors, the exploratory factor analysis (EFA) was performed using principal component analysis with varimax rotation.[20] Factors were extracted if the factor loading was ≤0.4, because those questions do not contribute to any factor. The internal consistency was determined by calculating the Cronbach's

alpha and item-total correlations for verifying the reliability. A Cronbach's Alpha between 0.7-0.95 was accepted for internal consistency. The item-total correlations were allowed to vary between 0.2-0.8, with <0.2 meaning there is not enough relation and >0.8 meaning there is too much relation, and therefore not providing additional information. A p-value < 0.05 was accepted as statistically significant. SPSS 25.0 and R Studio 3.4.4 were used to perform the statistical analyses.

All answers were scored according to the Likert scale. One point for the most positive answer and 5 points for the least positive answer. The same applied for binary (1 or 5) and three-point Likert scales. The D-GESQ total score was calculated by the following formula: (Score – lowest possible score) / score range x 100. This results in a range from 1 (very unsatisfied) to 100 (very satisfied).

This study followed the principles of the Declaration of Helsinki[21] and was in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO). Ethics approval was obtained from the METC Arnhem-Nijmegen, number 2016-3020. The trial was registered in the Dutch Trial Register (NTR), number 26875.[22]

RESULTS

Think-aloud method

The data saturation point was reached after completing the questionnaire by 17 patients. Based on data received by performing the think-aloud procedure, two questions were corrected. Question 3 had an inadequate number of answer options; 89% of the patients answered plenty and none of them answered the last option "no". During the think-aloud procedure patients reported that they missed the option sufficient, so this option was added. Question 17 was rewritten. We replaced "your questions" into "any questions", because patients suggested that if they had questions, they would be answered by the given explanation, but in most cases, they did not have any questions.

Main study

From January 2018 until July 2019, we sent the 2.0 version of the D-GESQ to 1065 patients who were informed via the CBE platform. In total, 227 of 1065 patients completed the final questionnaire and were included in the study, resulting in a response rate of 21.3%. Baseline characteristics of these patients are summarized in table 1.

Table 1. Baseline characteristics

Variables	Total patients (N=227)
Sex, n (%)	
Male	129 (52.6%)
Female	98 (43.2%)
Age, years (mean ±SD)	62.70 ± 11.54
Underwent endoscopy before, n (%)	
Yes	180 (79.3%)
No	47 (20.7%)
Number of endoscopies before, n (%)	
1	23 (12.8%)
2	51 (28.3%)
3	33 (18.3%)
4	17 (9.4%)
5	10(5.6%)
>5	46(25.6%)
Last endoscopy, n (%)	
1-3 months ago	106 (46.7%)
4-6 months ago	7 (3.1%)
6-12 months ago	12 (5.3%)
1-4 years ago	37 (16.3%)
>5 years ago	18 (7.9%)
Level of education†, n (%)	
Low	40 (17.6%)
Middle	94 (41.4%)
High	93 (41.0%)
Daily life, n (%)	
Student	1 (0.4%)
Paid employment	59 (26.0%)
Self-employed	19 (8.4%)
Househusband/housewife	15 (6.6%)
Unemployed	3 (1.3%)
Disabled	18 (7.9%)
Retired	112 (49.3%)
Ethnicity, n (%)	
Dutch	221 (97.4%)
Indonesia/former Dutch East Indies	3 (1.3%)
German	1 (0,4%)
Other	2 (0.9%)

† Highest completed educational level was split into three levels where 'low' comprised no education through to lower secondary education, 'middle' comprised upper secondary and middle vocational education, and 'high' comprised higher vocational and tertiary education

Table 2. Factor loadings of the exploratory factor analysis

Question number	Content of question	Skills and satisfaction	Information before endoscopy	Pain and discomfort	Information after endoscopy	Hospital
1	Information before endoscopy was easy to understand		0.84			
2	Information before endoscopy was useful		0.82			
3	Opportunity to ask questions about endoscopy		0.41			
4	Given explanation was easy to understand		0.82			
5	Given explanation was useful in answering questions		0.75			
6	Communication skills of endoscopist	0.79				
7	Technical skills of endoscopist	0.76				
8	Communication skills of other staff	0.66				
9	Discomfort during endoscopy			0.72		
10	Pain during endoscopy			0.71		
11	Discomfort after endoscopy			0.85		
12	Pain after endoscopy			0.82		
13	Opportunity to ask about findings				0.77	
14	Amount of explanation				0.77	

Table 2. Continued.

Question number	Content of question	Skills and satisfaction	Information before endoscopy	Pain and discomfort	Information after endoscopy	Hospital
15	Findings explained by endoscopist					0.63
16	Given explanation was easy to understand				0.56	
17	Given explanation was useful				0.71	
18	Comfort of recovery area					0.56
19	Overall satisfaction	0.55				
20	Endoscopy in future by same endoscopist	0.73				
21	Overall reputation of the hospital					0.65
Eigen-value		6.69	2.64	1.70	1.39	1.22

In total, 52.6% were men (N=129). The mean age was 62.7 ±11.54 years. Of all patients, 79.3% had a history of an endoscopic procedure. In this group, 157 (87.2%) had undergone endoscopy two or more times. Most of the patients (41.4%) had secondary education as the highest education level. These levels of education are representative of the general Dutch population.[23] Almost half of the patients (49.3%) were retired. The age and gender of the respondents to the D-GESQ matches with a study from our unit on an independent cohort that was referred for elective colonoscopy.[24]

Validation of the D-GESQ

All 227 included patients answered each question, so there was no missing data. The confirmatory factor analysis (CFA) showed the following results: GFI 0.718 (not acceptable), RMSEA 0.110 (not acceptable), SRMR 0.085 (acceptable), and the TLI was 0.751 (not acceptable).

According to these results, we concluded that our data did not fit with the four-factor model of the original article, so a four factor model was not acceptable for the D-GESQ. The KMO and the Bartlett's Test of Sphericity for measuring the sampling adequacy and homoscedasticity, respectively, showed that the KMO measure was 0.832 and the

Bartlett's Test of Sphericity was significant (X^2 = 2240.289, p<0.001), implying that our data were suitable for exploratory factor analysis.

The subsequent exploratory factor analysis showed that questions could best be clustered into five clusters.[25] Compared to the original version of the GESQ, we created a new category: Skills and hospital were divided into skills and satisfaction. Hospital became a different cluster.[11] Three clusters remained the same: information before endoscopy, pain and discomfort during or after endoscopy and information after endoscopy. These titles were given to the clusters of questions after analysing which common content each cluster contained. The factor loadings are shown in table 2. The factor loadings represent the correlation between the question and the subcategory to which it belongs. An eigenvalue of >1 explains 64.9% of the total variance, both before and after rotation.

Internal validity

To determine the internal consistency reliability, we analysed the Cronbach α for each subcategory. These results are shown in table 3. including the item component correlation. The overall Cronbach α of the D-GESQ was 0.88. The Cronbach alpha for the subcategories ranged between 0.449 and 0.868. Information before endoscopy had a value of 0.848, skills and satisfaction were 0.868, pain or discomfort 0.831, information after endoscopy 0.724 and hospital 0.449. So, there was a high internal consistency, with an acceptable corrected item-total correlation, except for the corrected item-total correlation of the component hospital.

Patient satisfaction

Patient satisfaction scores were calculated; the overall mean satisfaction score was high (79.6 ±10.7 out of 100 maximum). Table 4. lists baseline characteristics that may have affected patient satisfaction. Patients who underwent endoscopy previously were more satisfied than patients who did not (p = 0.015). When patients had a history of ≤2 endoscopy procedures, they were more satisfied compared to patients who underwent <2 endoscopies (p = 0.019).

Table 3. Internal consistency of the D-GESQ

Component	Question number	Corrected item-total correlation	Cronbach α
Information before endoscopy	1	0.612	0.848
	2	0.749	
	3	0.479	
	4	0.763	
	5	0.698	
Skills and satisfaction	6	0.697	0.868
	7	0.755	
	8	0.579	
	19	0.642	
	20	0.800	
Pain or discomfort during or after endoscopy	9	0.687	0.831
	10	0.659	
	11	0.680	
	12	0.625	
Information after endoscopy	13	0.524	0.724
	14	0.542	
	16	0.553	
	17	0.677	
Hospital	15	0.158	0.449
	18	0.296	
	21	0.384	

Disabled patients had significantly lower satisfaction scores (P=0.034). Sex, age, level of education and timing of the last previous endoscopy did not influence the satisfaction.

Table 4. Factors influencing satisfaction score

Factor	Satisfaction score (mean, SD)	p-value (statistical test)
Sex	80.4 ± 10.5	0.818
Male	78.6 ± 11.1	(independent t-test)
Female		
Age	78.3 ± 10.5	0.846
≤65	80.8 ± 10.9	(independent t-test)
>65		
Education	78.3 ± 10.4	0.568
Low educated	79.7 ± 10.2	(Kruskal Wallis)
Secondary education	80.2 ± 11.4	
Well educated		

Table 4. Continued.

Factor	Satisfaction score (mean, SD)	p-value (statistical test)
Experience of previous endoscopy Yes No	80.2 ± 9.8 77.2 ± 13.6	0.015* (independent t-test)
Number of endoscopies before ≤2 >2	79.3 ± 9.8 81.0 ± 9.7	0.019* (independent t-test)
Daily life Student Paid employment Self-employed Househusband/housewife Unemployed Disabled Retired	95.2 ± 0.0 80.5 ± 9.6 79.6 ± 9.3 74.2 ± 12.9 76.2 ± 5.4 73.2 ± 10.8 80.8 ± 10.9	0.034* (Kruskal Wallis)
Last endoscopy 1-3 months ago 4-6 months ago 6-12 months ago 1-4 years ago >5 years ago	80.9 ± 9.9 79.8 ± 10.8 76.3 ± 9.4 79.9 ± 10.3 79.7 ± 8.6	0.520 (Kruskal Wallis)

DISCUSSION

In this study, we systematically translated and validated the original GESQ into the Dutch language. Our study demonstrates that the D-GESQ is a valid instrument for quantitative assessment of satisfaction in patients undergoing upper endoscopy and/or colonoscopy in the Netherlands.

This is supported by a high level of internal consistency (Cronbach alpha 0.839) with homogenous clustering represented by high numbers of corrected item-component correlation, except the component hospital. The high construct validity is supported by the EFA. The principal component analysis of the EFA demonstrated a clustering into five components (information before endoscopy, pain and discomfort, skills and satisfaction, information after endoscopy and hospital).

We found that the initial CFA in our population did not match with the model fit described in the original study. Therefore, our definitive D-GESQ questionnaire is now categorized in five domains while still containing 21 questions. These five domains

measure components of satisfaction that could help identifying specific targets for improvement for a given endoscopy department.

Patients undergoing endoscopy under propofol sedation were included in the original study and in the Korean validation study of the original questionnaire (the K-GESQ), whilst this was an exclusion criterion in our study.[26] We did so because many questions could not be answered reliably after propofol sedation (for example item pain during endoscopy). Interestingly, in a study in 1104 patients in Romania (R-GESQ), that used the GESQ to compare propofol sedation versus unsedated endoscopy, this effect became visible as patients with propofol scored significantly lower procedural pain (5.2 versus 14.1%).[27] In addition, propofol sedation induces euphoria in nearly half of the patients undergoing elective endoscopy which might affect the quality of the answers.[28] Both K-GESQ and R-GESQ has been validated in populations that were younger and contained a higher proportion of females compared to our sample.

Our results show that patients with prior experience in undergoing endoscopic procedures, especially exceeding more than two prior endoscopies, reported higher levels of satisfaction. Disabled patients scored lower levels of satisfaction which is also known from previous studies.[29,30]

Strengths and limitations

In our study, the rate of missing data was 0%. This is exceptionally low compared with a maximum missing rate of 50% for some items in the original article and 1.4% in the K-GESQ.

Our study has some limitations. The development of a reliable questionnaire depends on the patient sample that participates and how the questions are interpreted by them. To eliminate bias, we utilized the think-aloud method. The challenge when translating a questionnaire is that it must be adapted in a culturally relevant and comprehensible form while maintaining the intention and meaning of the original questions.[31] By performing the translation and validation according to the WHO guidelines[13], we ensured optimal comparability between the original GESQ from the UK[11] and this Dutch translation.

To be able to also screen for early to mid-term complications after endoscopy, we e-mailed the D-GESQ 30 days after endoscopy. The survey response rate was much lower in our study then in the original study, 21.3% compared to 86.2%. In the original study, patients had to mail their completed questionnaire in a prepaid envelope. Earlier research has shown that patients were more satisfied when surveys could be completed on site compared to sending by post or email.[32] We sent an automated hyperlink by e-mail instead of a paper version by mail in the original study. We strived to lower the threshold to start and complete the questionnaire so that selection bias would be

reduced. But although the most cost effective option, e-mail does not yield the best response rate, in comparison with mail or telephone.[33]

The response rate would have been higher when a patient filled out the questionnaire on the hospital bed, chosen to do in both the K-GESQ and R-GESQ studies. Benzodiazepines however causes an euphoric state on the day after endoscopy, which could lead to overestimation of satisfaction.[32]. Another limitation is recall bias when patients complete the questionnaire after 30 days. Unfortunately, the appropriate timing for questionnaires after endoscopy has not been determined.[34] In our opinion, some recall bias is acceptable as the chosen timing gives a better reliability compared to completing the questionnaire under sedation. We decided that by sending the e-mail 30 days after endoscopy, a homogenous response time was achieved. Reminding e-mails were not sent out, because that could have affected the homogeneity of the response time. The wide variation in response time in the original study might well have affected the results.[26]

In conclusion**,** our study describes the validation process of the GESQ in Dutch. The D-GESQ was found to have high internal and construct validity. We recommend the D-GESQ for routine use in daily clinical practice to continuously improve the quality of patient care in the endoscopy unit.

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The D-GESQ trial is an investigator-initiated trial.

Authors' contributions

MdJ carries out the trial. MdJ and GV conceived the study, organized the design and coordination of the study and drafted the first version of this manuscript. AvE and CR participated in the design and coordination of this study. PS supervised the final manuscript. All authors read and approved the final manuscript.

Authors' information

The authors declare that they have no competing interests

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SUPPLEMENTARY MATERIAL CHAPTER 8

D-GESQ questionnaire (in Dutch)

Gastro-intestinale endoscopie tevredenheidsvragenlijst

Dank voor uw deelname aan ons onderzoek naar patiënttevredenheid.

Hieronder volgen een aantal vragen over uw achtergrond en eerdere ervaringen met een darmonderzoek, om tenslotte te eindigen met de vragen over uw ervaring met het endoscopiecentrum.

De volgende vijf vragen gaan over de periode voorafgaand aan uw endoscopie-onderzoek. De eerste twee vragen gaan specifiek over de informatie die u voorafgaand aan uw endoscopie-onderzoek heeft ontvangen (papier of digitaal).

1. Hoe gemakkelijk was de toegezonden informatie te begrijpen?

   Zeer makkelijk **Makkelijk** **Redelijk** **Moeilijk** **Zeer moeilijk**

2. Was de toegezonden informatie bruikbaar in het beantwoorden van uw vragen?

   Zeer bruikbaar **Bruikbaar** **Redelijk bruikbaar** **Niet echt bruikbaar** **Onbruikbaar**

3. Hoeveel gelegenheid had u om vragen te stellen over het endoscopie-onderzoek?

   Ruimschoots **Voldoende** **Een beetje** **Geen**

4. Hoe gemakkelijk was deze uitleg te begrijpen?

   Zeer makkelijk **Makkelijk** **Redelijk** **Moeilijk** **Zeer moeilijk**

5. Was de gegeven uitleg bruikbaar in het beantwoorden van uw vragen?

   Zeer bruikbaar **Bruikbaar** **Redelijk bruikbaar** **Niet echt bruikbaar** **Onbruikbaar**

De volgende vijf vragen gaan over het moment dat het endoscopie-onderzoek werd uitgevoerd.

6. Wat vond u van de communicatieve vaardigheden (beleefd, respectvol, inlevend en vriendelijk) van de persoon die de endoscopie uitvoerde?

   Zeer slecht **Slecht** **Redelijk** **Goed** **Zeer goed**

7. Wat vond u van technische vaardigheden (daadkrachtig, voorzichtig en vaardig) van de persoon die de endoscopie uitvoerde?

   Zeer slecht **Slecht** **Redelijk** **Goed** **Zeer goed**

8. Wat vond u van de communicatieve vaardigheden (beleefd, respectvol, inlevend en vriendelijk) van de andere medewerkers op de endoscopie-afdeling?

Zeer slecht **Slecht** **Redelijk** **Goed** **Zeer goed**

9. Hoeveel ongemak heeft u ervaren tijdens het endoscopie-onderzoek?

Zeer veel **Veel** **Gemiddeld** **Weinig** **Geen**

10. Hoeveel pijn heeft u ervaren tijdens het endoscopie-onderzoek?

Zeer veel **Veel** **Gemiddeld** **Weinig** **Geen**

De volgende 11 vragen gaan over de periode na het endoscopie-onderzoek.

11. Hoeveel ongemak heeft u ervaren na het endoscopie-onderzoek?

Zeer veel **Veel** **Gemiddeld** **Weinig** **Geen**

12. Hoeveel pijn heeft u ervaren na het endoscopie-onderzoek?

Zeer veel **Veel** **Gemiddeld** **Weinig** **Geen**

13. Hoeveel gelegenheid had u om te vragen naar de bevindingen?

Ruimschoots **Een beetje** **Geen**

14. Wat vond u van de hoeveelheid uitleg die gegeven werd over de bevindingen?

Te veel **Voldoende** **Niet genoeg**

Als u geen uitleg heeft gekregen, gaat u verder bij vraag 18.

15. Heeft de persoon die de endoscopie heeft uitgevoerd, u zelf de bevindingen verteld?

Ja **Nee**

16. Hoe gemakkelijk was de uitleg te begrijpen?

Zeer makkelijk **Makkelijk** **Redelijk** **Moeilijk** **Zeer moeilijk**

17. Was de gegeven uitleg bruikbaar in het beantwoorden van eventuele vragen?

Zeer bruikbaar **Bruikbaar** **Redelijk bruikbaar** **Niet echt bruikbaar** **Onbruikbaar**

18. Hoe comfortabel was uw verblijf in de uitslaapkamer/nazorgruimte?

Zeer slecht **Slecht** **Redelijk** **Goed** **Zeer goed**

19. Wat is uw algehele tevredenheid over uw endoscopie-onderzoek?

Zeer tevreden **Tevreden** **Matig tevreden** **Ontevreden** **Zeer ontevreden**

20. Stel, u moet in de toekomst nog een keer een endoscopie ondergaan, hoe tevreden zal u dan zijn als deze door dezelfde persoon wordt uitgevoerd?

Zeer tevreden **Tevreden** **Matig tevreden** **Ontevreden** **Zeer ontevreden**

21. Wat is uw algehele beeld over het ziekenhuis?

Zeer slecht **Slecht** **Redelijk** **Goed** **Zeer goed**

9

Discussion and future perspectives

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SCOPE OF THE THESIS

This thesis focused on the concept of eHealth in clinical medicine. In this thesis, I described the inception, development and implementation of an eHealth intervention targeting patient education before endoscopy. In the first chapters I presented the testing phase of the prototype, organizational and medicolegal effects and the subsequent development into web based education at home.[1-3] In the following chapters, I discussed the results of the multicenter study that evaluated this intervention and showed that this intervention comes with potential savings.[4] Next, I presented a proof of concept study during endoscopy on a different eHealth intervention. Finally, our group investigated a tool to improve measurements to evaluate satisfaction of new eHealth interventions in endoscopy.

MAIN FOCUS

1. To develop an eHealth intervention for patient education prior to endoscopy
2. To implement the eHealth intervention in daily practice, identifying key factors for success
3. To evaluate relevant outcome measures for assessing the effect of eHealth interventions

SUMMARIZING MAIN FINDINGS

Development of computer based education

In **chapter 2** our group conducted a pilot study on computer assisted instruction (CAI) in the hospital followed by a short nurse contact versus nurse counselling alone. The main outcome, cleanliness of the colon during examination, was measured with both the Ottawa Bowel Preparation Scale (OBPS) and Boston Bowel Preparation Scale (BBPS). We assessed patient comfort and anxiety at three different time points. In total we included 385 patients: 197 received traditional nurse counselling and 188 received CAI. Overall patient response rates were 99%, 76.4% and 69.9% respectively. Endoscopists scored cleanliness in 60.8%, leaving 39.2% of the patients with missing scores. Comparative analysis of the missing scores showed no significant difference on age, gender or educational level. In the analysed group of 60.8% baseline characteristics were evenly distributed over the groups. Bowel cleanliness was satisfactory and did not differ amongst groups: nurse vs. CAI group scores in BBPS: (6.54 ±1.69 vs. 6.42 ±1.62); OBPS: (6.07 ±2.53 vs. 5.80 ±2.90) Patient comfort scores were significantly higher (4.29, ± 0.62 vs. 4.42, ± 0.68) in the CAI group shortly before colonoscopy. Anxiety and knowledge scores were similar. We concluded that CAI is a safe and practical tool to instruct patients in the hospital before colonoscopy. At that time, we recommended the combination of CAI in the hospital followed by a short nurse contact for daily practice.

Motivated to improve the scalability of the hospital based computer assisted instruction, our group published a viewpoint paper. In this **chapter 3** we started out with the consensus view that optimal patient education prior to colonoscopy is essential to safeguard the quality of the procedure.

As concluded, patients benefit from adequate information regarding laxatives, risks and alternatives. Furthermore, from a medicolegal standpoint, informed consent has to be obtained.[5] Also the endoscopist needs access to patient data prior to the procedure in order to carry out an adequate risk assessment for the use of sedation. This posed challenges in data safety management and communication with the hospital electronic health records.

Most endoscopy units in the Netherlands integrated a pre-endoscopy consultation in their clinical care pathways to obtain this mandatory information. This practise has several benefits to maintain quality. But the number of colonoscopies was increasing rapidly as a result of the introduction of the Dutch national screening program for colorectal cancer. Consequently, nurse counselling had become increasingly resource intensive. This was a key driver for innovation of this process.

A newly developed web based platform would have to resolve the identified important implementation obstacles. With our developed CAI we seized the opportunity to develop an expanded system that could substitute this hospital based practice and tackle logistical challenges. We explained our proposed new algorithm to educate patients before endoscopy.

Chapter 4 described the subsequent development from hospital sited computer assisted instruction – with one-way communication - into computer based education (CBE) at home that allows two-way communication. We outlined the hypothesis of a study protocol to establish the effect on quality of bowel preparation. This multicenter, randomized, endoscopist blinded clinical trial protocol evaluated the primary outcome bowel preparation during colonoscopy. The secondary outcome measures were sickness absence, patient anxiety after instruction and prior to colonoscopy, patient satisfaction and information re-call. We also evaluated patient consumption of additional consultation time (by phone or visit) in the CBE group. We therefore included validated questionnaires for eHealth literacy, health-related quality of life and patient activation measure, as well as a patient reported productivity tool. Patient were recruited in four endoscopy units of different levels (rural, urban, and tertiary). The inclusion criteria were adult age and referral for complete colonoscopy. Exclusion criteria were Dutch illiteracy, audio-visual handicaps or mental disabilities and no (peers with) internet access. The intention was to evaluate online computer-based education as tool for patient education prior to a colonoscopy. By choosing a direct comparison

with the standard of care (nurse counselling), both endoscopic quality measures and patient related outcome measures were valuated.

Evaluation of computer based education

In **chapter 5** we report on our prospective, multicenter, endoscopist blinded, non-inferiority randomized controlled trial. The primary outcome was successful bowel preparation, using the Boston Bowel Preparation Scale (BBPS). Secondary outcome measures were sickness absence due to outpatient's clinic visit, patient anxiety and satisfaction scores and information re-call. The study was performed in four endoscopy units of different levels (rural, urban, and academic).

We screened 1035 eligible patients and randomized 845. After evaluation, 684 were included in the intention-to-treat (ITT) group. Subsequently, 497 patients were included in per-protocol (PP) analysis, 217 in nurse counselling and 280 in the CBE group. Baseline characteristics were similarly distributed among groups. In PP analysis, adequate bowel cleansing was achieved in 93.2 % (261/280) of CBE patients, which was non-inferior to nurse counselled patients (94%, 204/217), with a difference of -0.8% [95% CI [- 5.1; 3.5]%. Non-inferiority was confirmed in the ITT population. Sickness absence was significantly more frequent in nurse counselled patients (28.0% vs 4.8%). In CBE patients, 21.5% needed additional information, resulting in 3.0% extra outpatient visits.

Therefore, we concluded that CBE is non-inferior to nurse counselling in terms of bowel preparation during colonoscopy, with lower patient sickness leave. The CBE platform reduced outpatient visits. Therefore, the recommendation was made that CBE may serve as an efficient educational tool informing patients before colonoscopy in routine clinical practice.

With every improvement or change in clinical care pathways cost issues must be evaluated. This is pivotal for endoscopy units who are deciding on their pre-procedural counselling strategy. We analysed the current cost of nurse counselling and which cost savings could be attributed to CBE in **chapter 6**. As CBE replaces a nurse counselling visit it might have several cost minimization effects; we evaluated this primarily from the perspective of the endoscopy unit. We also included both the patient and the societal viewpoint by calculating patients' travel costs and productivity loss.

To evaluate endoscopy unit expenditure, we developed a cost model to establish the associated costs for three patient routes before colonoscopy (nurse counselling, CBE alone and with additional counselling). This model comprised wages of auxiliary staff, CBE implementation and license costs and other factors derived from process flow review. We applied this model to perform cost minimization calculation of the CBE versus the nurse counselling strategy based on extrapolated data from our earlier trial.

For patient costs, we calculated per visit cost of both strategies using the institute for Medical Technology Assessment (iMTA) costing tool and the reported average travel distance for colonoscopy in the Netherlands in all three scenarios. Finally, to assess societal costs, we used the adapted cost friction iMTA Productivity questionnaire. We performed bootstrap to compare results.

The development of the cost model after process evaluation resulted in 33 relevant parameters. Input on all parameters was retrieved in the four trial units. This resulted in varying costs for the three patient routes per trial site: nurse counselling €18.30 - €28,42, CBE alone €4,04 - €8.86 and CBE with additional counselling €7,01 - €19,78. The difference in costs amongst trial sites was mainly explained by the length of consultation time and use of more expensive personnel.

With extrapolated data (135 to 280 patients) in the CBE group the endoscopy unit paid on average €8.36 (CI €7.83-€8.84) per patient. In the nurse counselling group, this was significantly higher, €22.56 (CI €22.00–€23.12).

The average patient out of pocket costs were €5,80 for a nurse visit. With mandatory visits in 100% and 3% of the cases, the total cost made by all patients were €1260.09 in nurse counselling versus €46.45 in the CBE group.

In total 271 patients (125 nurse, 146 CBE group) filled out the iMTA questionnaire. Gender was similar distributed in both groups. In the nurse group, 54 (43.2%) patients reported absence from either paid or unpaid work of needing replacement for unpaid work, versus 29 (19.8%) in the CBE group (p=0.007). The mean number of hours reported was not significantly different, but the calculated productivity loss was significantly higher in the nurse counselling group: €35,84 (95% CI: € 26,79 -€48,41) versus CBE: €13,89 (95% CI: €7,64 – €18,84).

Computer based education showed a cost reducing effect for endoscopy units and lowers expenses made by patients and society. This study fuelled the evidence base of the benefits of this eHealth intervention. Full implementation of this modality will free up valuable health care resources.

eHealth application during endoscopy

To evaluate the impact of eHealth solutions during colonoscopy we performed a proof of concept pilot study on virtual reality (VR) glasses in **chapter 7**. Main goal was establishing the feasibility of this intervention during colonoscopy. If VR would not compromise the technical success of colonoscopy, this could pave the way for future trials to evaluate if this device could serve as a potential substitution of sedative and analgesic drugs. We included adults referred for colonoscopy and divided them in two groups: with and without VR glasses. Main outcome was patient acceptance of wearing

VR glasses during colonoscopy without compromising the technical success of the procedure. Secondary outcomes were patient comfort, pain and anxiety before, during and after the procedure, using validated patient questionnaires. Patients' comments were collected through a qualitative interview. We included 19 patients, of which 10 used VR glasses. All patients accepted VR glasses without lengthening procedural time. No disadvantages of the VR glasses were reported in terms of communication or changing of position of the patient. We found that patient comfort, pain, anxiety and satisfaction in relation to the procedure were similar in both groups. Patients described a pleasant distracting effect using VR glasses.

We concluded therefore that VR glasses during colonoscopy were well accepted by patients and did not compromise endoscopic technical success. Future studies are justified to evaluate the possible substitution of sedation with VR. Patients reported that the VR experience was pleasant and distracting, facilitating recruitment for these trials.

Developing tools for evaluating eHealth applications in endoscopy

In this thesis, we used several outcome measurement tools provided by earlier research. However, for some patient outcome measures, there was no standard available. In case of patient satisfaction, there was a validated English tool - the gastrointestinal endoscopy satisfaction questionnaire (GESQ) - described in literature.[6]

For use in clinical practice as well as future trials, we set out to see if this tool could be validated in Dutch. In **chapter 8** we described this validation process for the GESQ that assessed patient satisfaction in endoscopy. The original GESQ was translated in Dutch according to the World Health Organization (WHO) linguistic validation guidelines. First, internal validation of the Dutch GESQ (D-GESQ) was established by application of the think-aloud method and subsequent expert panel analysis. Next, the D-GESQ was embedded in the CBE platform in our unit, with a 30-day interval after endoscopy. Adult patients, who were informed via CBE and had undergone endoscopy, were included. Exclusion criteria were conscious sedation, limited Dutch language skills, no e-mail address available, dementia and visual impairment. For statistical analysis, several psychometric analyses of the questionnaire were performed to identify the underlying dimensions and assessed the questionnaire for reliability and validity. In total, 227 of 1065 patients completed the D-GESQ, yielding a response rate of 21.3%. Men comprised 52.6% (N=129) of patients. Mean age was 62.7 ±11.54 years. In total 180 patients (79.3%) had previously undergone endoscopy, with 157 (87.2%) of them twice or more. The exploratory factor analysis showed that the 21 questions could best be clustered into five clusters instead of four in the original GESQ. The D-GESQ had an overall Cronbach α of 0.88, confirming the high internal validity of the tool. We concluded that the Dutch version of the GESQ showed high internal validity and

practicality. We therefore recommended the D-GESQ for routine use in daily clinical practice to improve quality of patient care in daily endoscopic practice.

Strengths and limitations

In this thesis, we embarked on a trajectory to establish our objectives. The decisions we made in the design of our trials resulted in several strengths, but undoubtedly also several limitations. These will be discussed here for each chapter.

In **chapter 2**, we stated that computer assisted instruction (CAI) empowers the patient in place, pace and moment of learning, and is known to have impact on patients satisfaction.[7] The main limitation of the CAI pilot study was its non-randomized design. This was due to the unavailability of the CAI at the start of patient inclusion in March 2013. The first patients in the CAI group were included in July 2013. However, this design did not affect the score by the participating endoscopists as he/she was unaware of this information and therefore unaware of assignment over the groups whilst assessing the primary endpoint. The endoscopist scoring rate of 60% was unforeseen low, introducing some selection bias in this study. Forgetting to score this item was probably due to the endoscopist' busy daily practice. Also, the use of patient reported questionnaires restricts medical data collection as compared to chart review. Therefore, we cannot exclude the possibility of some selection bias (such as previous experience with colonoscopy) in assessing secondary endpoints. Familiarity with the use of computers, notably by elderly patients, could have been of concern. In our cohort, 40% in the CAI group were older than 65 years. However, we did not find an age dependent effect (data not shown). Before drawing general conclusions from our results, we needed to confirm our findings in a randomized study instead of this pre – after implementation design. As we demonstrated a small difference in effect on our primary outcome of bowel preparation quality, this subsequent trial should be adequately powered to test a non-inferiority hypothesis.

We published our experiences with implementation of CAI outside of the first participating hospitals in **chapter 3**. The strength of this position paper was that we were able to share the problems we encountered in this phase of the thesis.

But the format of a position paper posed the main limitation, as we did not use a systematic approach of the presented literature. Our position paper therefore lacked explicit criteria for article selection without evaluation of selected articles for validity.

The evolution of the CAI into a computer based education (CBE) and the CBE process implantation showed that in the period 2013-2017 several important obstacles were overthrown. We demonstrated the way to safely manage patient data and privacy via the CBE platform. Also, we showed how to deal with the legal value of online reported

informed consent. And we provided insight in managing the financial basis. Thus, we reported on all these crucial items that hampered the scalability of our platform. Important issue still partly present today is establishing a safe communication between the hospital electronic health records and the CBE platform. In place, this could eliminate the nuisance of simple data transferal work currently performed by auxiliary staff.

In **chapter 4**, we described the technical development of the algorithm behind the CBE platform and propose a study protocol to evaluate this new patient education system.

Main strength of this article was publishing it in a video journal. This allowed us to optimally visualize the CBE platform in a stepwise fashion. The presented study protocol strength was the large sample size chosen, to support non-inferiority statements. Also, the extensive collection of data on secondary outcomes proved insightful. Limitations were that we had chosen the usual contact moments to hand out the clinically collected questionnaires by the endoscopy unit operational staff. Missing questionnaires might be the result. Nevertheless, this protocol aimed to collect all relevant information at all time points. The majority of patients would be eligible for the trial and could operate the CBE even with very basic computer skills. But in the lowest literacy category, it could be problematic to test the hypotheses. As of this, we included the possibility of face-to-face patient education in the route towards the endoscopy suite for this group.

We reported the results of the trial in **chapter 5**. Summarizing strengths, our trial was conducted with a large, real life sample of patients. The non-inferiority hypothesis based on both intention-to-treat en per-protocol analysis of the data and power allows robust statements on CBE efficacy. As we tested the CBE in a real-world setting using three different types of endoscopy units, the results are well generalizable to daily practice. On the other hand, this trial comes with limitations. There was a significant number of dropouts after randomisation due to inclusion failures. However, this did not result in an unequal distribution regarding baseline characteristics among the arms in both the ITT and PP population, limiting the risk of selection bias. Due to the use of patient reported questionnaires we do not have 100% data collection at all time points, although the trial protocol called for that. While this did not affect our main outcome bowel preparation (100% data collected), the lower response rate might have affected assessment of secondary outcomes such as anxiety and satisfaction. We did not collect complete medical histories of our patients, including risk factors for poor bowel preparation such as diabetes mellitus, constipation, or use of motility influencing drugs. We surmise that the effect of these risk factors on the bowel preparation efficacy in our trial is limited in view of the small difference in BBPS scores. We did not collect data on adenoma detection rate (ADR) as this was outside the remit of this clinical trial. From literature, the robust correlation between adequate BBPS and ADR suggest that BBPS is a good technical proxy parameter.[8]

In **chapter 6** we presented the cost effect analysis of implementation of CBE in the endoscopy unit. The strength of this article is the triangular approach that illustrated the effect on costs for endoscopy units, patients and society. While the main readership most probably would be most interested in the effect on costs for the endoscopy unit, the other costs might be more important for your patient and health care policy makers. Another strength was the developed highly detailed cost model including 38 parameters that are affected by CBE implementation. This allows for accurate cost-effect statements. The main limitation of this study was the low response rate (54.5%) of the patient reported data. To be able to evaluate the cost effect for the complete group, we had to extrapolate data, with the risk of assumption bias. Also, other elements of our analysis might have introduced some assumption bias, such as using of average travel distance instead of collecting this data.

Strengths of the VR glasses pilot study reported on in **chapter 7** were the novel application of this device in endoscopy and the focus on patient acceptance. Important to the design of subsequent trials from the endoscopist perspective is that the use of VR glasses did not interfere with the colonoscopy. The VR glasses study was performed in a real life setting which adds to the external validity of the study. By using Samsung Gear VR to provide distraction, we have chosen a widely available and relatively inexpensive VR device, enhancing the generalizability of the study. This study also comes with limitations. First, the small sample size does not allow robust statements on clinically relevant endpoints like reducing anxiety or pain. As various studies found that visual and/or auditory distraction during endoscopic procedures reduced pain and improved satisfaction we were not able to identify these advantages for VR in this pilot.[9-11]

The ideal set-up would be a direct comparison of sedation and analgesics versus VR, instead of VR combined with sedation as done in our pilot. Interestingly, one patient declined the offered sedatives in the VR group (data not shown), maintained excellent comfort[1] and satisfaction scores (9/10).

The literature on VR for patients in endoscopy is scarce. A retrospective study of 190 patients found that VR allowed unsedated trans nasal gastroscopy in children and young adults. In this study VR assisted trans nasal gastroscopy was safe and cost-effective for staging of eosinophilic esophagitis.[12] The argument has been made that VR allows avoiding sedation for colonoscopy which fuels patients' experience.[13] Therefore it is probable that in selected patients VR during colonoscopy will be the preferred option.[14]

Strengths of **chapter 8** where we report on the validation of the D-GESQ were the strict adherence to WHO guidelines for translating and validating and how we utilized the think-aloud method to ensure face validity.[15] This leads to a tool that has a culturally relevant and comprehensible form while maintaining the intention and meaning of the original questions.[16]

A main limitation was the much lower survey response rate in our study then in the original study, 21.3% compared to 86.2%. This might have been influenced by e-mailing the D-GESQ 30 days after endoscopy, although this time window enables to screen for early to mid-term complications after endoscopy. This might have caused some recall bias. The response rate would have been higher when a patient would have filled out the questionnaire on the hospital bed. Benzodiazepines however causes an euphoric state on the day after endoscopy, which could lead to overestimation of satisfaction.[17] Unfortunately, the appropriate timing for questionnaires after endoscopy has not been determined.[18] We strived to lower the threshold to start and complete the questionnaire so that selection bias would be reduced. But although the most cost effective option, e-mail does not yield the best response rate, in comparison with mail or telephone.[19]

We summarized the main findings, implications and limitations of the research in this thesis below in table 1.

CAI: computer assisted instruction. CBE: computer based education. STAI: State-and-Trait Anxiety Inventory. NRS: Numeric Rating Scale. NPS: Net promoter score. WTR: Willingness to return.

Table 1. Main findings, implications and limitations of this thesis

Chapter	Main findings	Implications	Limitations
2.	Computer assisted instruction (CAI) before colonoscopy is feasible and yields adequate bowel preparation scores when used as patient education prior to colonoscopy at the outpatient's clinic	Use of 3D visualization and video prior to colonoscopy, in an in-hospital setting, is a useful adjunct to nurse counselling	Non-randomised protocol 60% reporting on main outcome
3.	After rudimentary experiences, the CAI is suitable for implementation outside the first trial site Serval important implementation obstacles are identified	More patients can benefit from this type of education Obstacles for scalability are identified and mostly removed	Narrative report Non systematic approach to literature
4.	With an algorithm embedded in software, the CAI can be upgraded to a CBE for more effective use from both patient and hospital perspective	CBE at home has the potential to substitute a nurse counselling visit with several advantages	Only applicable in eHealth literate patients (e.g. with e-mail address) Requires investment from endoscopy units

Table 1. Continued.

Chapter	Main findings	Implications	Limitations
5.	CBE is non-inferior in bowel preparation quality to nurse counselling CBE reduces outpatients' visits CBE does not affect anxiety, satisfaction or information re-call of patients	CBE is an efficient educational tool informing patients before colonoscopy at home and can be applied in routine clinical practice.	Use of patient reported data No positive effect on anxiety or other secondary outcomes
6.	From patient, hospital and societal view, CBE reduces costs	Full implementation of this modality will free up valuable health care resources	No real world data
7.	The use of (Virtual Reality) VR glasses feasible to relieve pain and discomfort in patients during colonoscopy	Future studies are justified to evaluate the possible substitution of sedation with VR. Patients reported that the VR experience was pleasant and distracting, facilitating recruitment for these trials.	Small pilot study No reduction of pain or increase in satisfaction established due to sample size
8.	D-GESQ has high validity for measuring patient satisfaction	D-GESQ can be used for routine use in daily clinical practice to improve quality of patient care in daily endoscopic practice	Low response rate 21.8% Single center validation

REFLECTION

In this PhD thesis, I served as a nexus between software entrepreneurs, endoscopy units and patients. I found that matching expectations between these partners is crucial to succeed in this endeavour. In the more personal domain, it proved paramount to match expectations in the years that my clinical training as an endoscopist and gastroenterologist went hand in hand with deadlines for manuscripts, running and finalizing the multicenter randomized controlled trial and guiding the students contributing to this thesis.

One could conclude that the inspiration for writing this thesis was the concept of business provided interventions that I tried to evaluate following the rigor of evidence based medicine. The most challenging task I experienced as a PhD candidate was recruiting the trial sites and subsequently implementing both the CBE platform as well as managing the distribution of questionnaires in daily practice. Fortunately, I could

always get the technical support from the software development team, for which I am very grateful to this day.

The most interesting struggle for any research performed in collaboration with business partners, either pharmaceutical companies, medical devices companies or eHealth start-ups, is how to preserve scientific integrity. As I had no competing interest in this company, and the fact that they never interfered with my conclusions, presentations or scientific publications, safeguarded this important point.

I learned valuable lessons on how the development of business models, the sales driven scale up of eHealth and the continuous efforts to help departments implement this new working algorithm is all crucial to successful and fast paced expansion of the CBE.

The more standard route of evidence based medicine with proof of concept studies, subsequent RCT's and systematic reviews, leading to the updates of guidelines most certainly would have been the longer route. On a more philosophical note, I wonder if eHealth interventions at all are suitable for this approach, as the pace of development is faster than current evidence based science can deliver.

In planning the path that lead to this thesis, I learned several important lessons. Main lesson: a PhD candidate does not invent everything by himself. To produce relevant documentation for trials, ethical committee paperwork, statistical backgrounds and the publication of the first articles any PhD candidate benefits from regular meetings; failing to structure this properly in the earlier stages has created lag time.

FUTURE PERSPECTIVES

As the current 2020 global COVID-19 crisis and subsequent lock down of society evidently shows, there is a growing demand for eHealth solutions that allow patients and health care providers to communicate without visiting the hospital.[20] On-demand eHealth can allow physicians and patients to communicate ubiquitously, 24/7, with the use of their smartphones or webcam-enabled computers.

In the field of cloud based solutions, comparable to our computer based education, new interesting solutions are being developed, especially in the United States.[21]

Guidance on multiple levels should be in place to ensure high quality of new eHealth products that enter the hospital. A major role for setting quality standards is there for scientific committees and professional societies. Hospital directory boards should be up to speed with the eHealth developments and actively engage in discussions with their staff which elements in patient pathways allow substitution of face-to-face care into eHealth solutions.

Insurance companies should provide well-funded innovation platforms to expedite eHealth best practises. Regulatory governmental agencies should set a target to hospital based health care providers, as this already proved successful in the financing of mental healthcare in the Netherlands.

I therefore propose the following agenda for further augmentation of eHealth in patient education in the hospital setting:

1. Setting a goal or % of hospital health care that is providing via eHealth (or blended solutions)
2. Define current practices in the hospital arena that benefits from substitution by eHealth
3. Provide relevant data in the fields of patient education (real-time, big data, RCT)
4. Allow several software developers to enter this market and compete to achieve lower costs
5. Keep eHealth active on the agenda of scientific

GENERAL CONCLUSION

Endoscopists should always strive to optimally prepare their patients before endoscopic procedures. This beholds careful selection of patients that truly will benefit from an endoscopy.[22]

In this thesis, we have provided a set of outcome measures derived from extensive literature search that helps to identify factors that help the endoscopist to improve patient education.

The concept of eHealth as the ultimate solution to the (often administrative) problems of health care today has been often challenged or even criticized. In close cooperation with eHealth entrepreneurs, we were able to develop a practical eHealth application in the field of endoscopy with good performance on endoscopy quality, patient reported measures and reducing costs. As a result, over 25 hospitals in the Netherlands today benefit from of this platform. (Figure 1.)

Figure 1. Hospitals currently using the CBE platform in and outside of the Netherlands. In orange, the participating trial site of the E-PACO trial (logos on the right)

But this success comes with several obligations. To continuously improve the CBE platform, our group has relied on external business partners. The upside is up-to-date knowledge of software solutions. But we as health care providers need to be aware that these partners have financial motives. These are crucial to keep their business and products viable on the market, but this sometimes collides with providing the most optimal product for all hospitals at all times. Nonetheless, we definitely owe to them that implementation was performed at this very high pace.

In this thesis we also present the first positive experience of implementing eHealth during colonoscopy using virtual reality. The final project, validation of the GESQ in Dutch, helps endoscopy units in the Netherlands to measure this patient reported outcome in the future.

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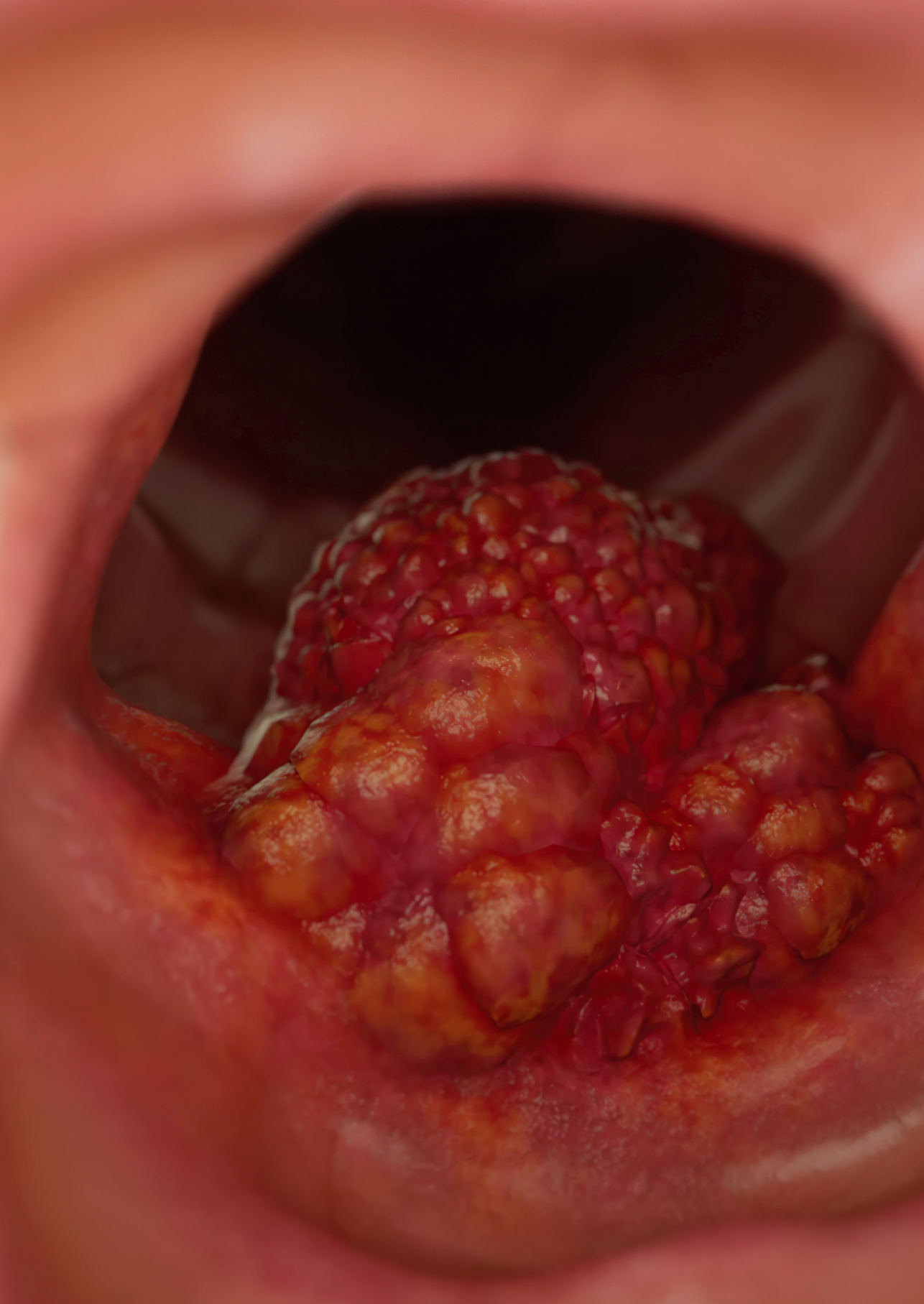

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Nederlandse samenvatting

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In de jaren zestig en zeventig van de vorige eeuw ontwikkelde de flexibele endoscopie zich explosief. Daarmee kwam een nieuw diagnostisch instrument beschikbaar dat bruikbaar is voor het diagnosticeren van maag- en darmaandoeningen, in het bijzonder (potentieel) kwaadaardige afwijkingen in de slokdarm, maag- en dikke darm. Endoscopie is niet alleen een diagnostisch maar ook een therapeutisch instrument, omdat endoscopische verwijdering van poliepen kanker voorkomt. Met name de endoscopie van de dikke darm, colonoscopie genoemd, heeft zich ontwikkeld als de techniek bij uitstek om deze neoplastische letsels op te sporen en te verwijderen. Aangezien een relevant aantal van deze letsels, zoals adenomen, (potentieel) kwaadaardig kunnen zijn, is duidelijk gebleken dat hierdoor de sterfte aan dikke darmkanker vermindert. Dit heeft wereldwijd geleid tot de invoering van grootschalige screening van darmkanker wat brede steun geniet van zowel de bevolking als de beleidsmakers.

Aan de diagnostische nauwkeurigheid en therapeutische veiligheid van de colonoscopie zijn een aantal voorwaarden verbonden. Belangrijk is de kwaliteit van de beoordeling door de endoscopist die de colonoscopie uitvoert. Die wordt bepaald door het aantal gevonden adenomen per procedure, de adenoom detectie graad (ADR). Bij kwalitatief goed uitgevoerde colonoscopieën wordt in één op de vier colonoscopieën door de arts een adenoom gevonden.

Om een hoge ADR te bereiken is een optimale darmvoorbereiding één van de belangrijkste vereisten. Daarnaast is het belangrijk de endoscopisten adequaat te trainen, voldoende tijd te nemen voor inspectie tijdens het terugtrekken van de endoscoop en de procedure optimaal te plannen. Onvoldoende gereinigde darmen leiden ertoe dat minder relevante afwijkingen worden ontdekt. Hierdoor moeten colonoscopieën eerder herhaald worden. Een schone dikke darm tijdens de colonoscopie vermindert dus de kans op morbiditeit en mortaliteit van darmkanker.

Er zijn een aantal factoren die ermee samenhangen dat patiënten zich slecht voorbereiden op een colonoscopie, zoals onvolledig inname van laxeermiddelen, leeftijd, geslacht en co-morbiditeit. Belangrijke redenen dat patiënten de inname van laxeermiddelen niet voltooien, zijn het onvermogen om instructies op te volgen, door bijvoorbeeld een verminderd inzicht in gezondheid of analfabetisme. Daarom is het van het grootste belang om patiënten voorafgaand aan een colonoscopie op maat te informeren en te instrueren. Er zijn diverse strategieën onderzocht om de instructie van de patiënt te optimaliseren en daarmee de darmreinheid te verbeteren; deze worden hieronder nader beschreven.

Zodra een patiënt is verwezen voor een colonoscopie dient er een volledige voorlichting plaats te vinden, met bijzondere aandacht voor het opvolgen van de laxeerinstructies. Een ander cruciaal element vóór de endoscopie is dat elke patiënt grondig wordt geïnformeerd over de aard, de risico's en de voordelen van, alsmede de alternatieven

voor de procedure (het concept van geïnformeerde toestemming ofwel informed consent). De patiënt moet voldoende tijd krijgen om de informatie te overdenken en vragen te stellen. Het is de verantwoordelijkheid van de endoscopist om dit met de patiënt te bespreken en voor elke procedure te documenteren.

Vanwege het invasieve karakter van een colonoscopie kan een patiënt schaamte, angst voor pijn en ongemak voelen. Het aanbieden van slaapmiddelen verdient de voorkeur om angst en ongemak die patiënten ervaren tijdens een colonoscopie te verminderen. Naast het geven van optimale voorlichting aan de patiënt en het verkrijgen van informed consent, dient de arts voorafgaand aan dit routinematige gebruik van slaapmiddelen en pijnstillers een individuele risicobeoordeling met betrekking tot de patiënt te maken. Voordat een patiënt een endoscopie kan ondergaan moet dus het nodige voorbereid worden.

Het effect van elke informatieoverdracht wordt medebepaald door factoren als opleidingsniveau, inzicht in gezondheid en culturele achtergrond van de patiënt. Te weinig aandacht daarvoor kan ertoe leiden dat de patiënt de informatie onvoldoende begrijpt en de instructies onvoldoende opvolgt. Veel ziekenhuizen vertrouwen op persoonlijke begeleiding door verpleegkundigen of artsen om dit te voorkomen en informed consent te verkrijgen voorafgaand aan de procedure. Dit leidt tot een betere naleving van de instructies voor de darmvoorbereiding. Hoewel deze praktijk dus effectief is, is het voor de hulpverlener tijdrovend en repetitief, wat ertoe kan leiden dat informatie die aan de patiënten wordt verstrekt varieert. Het vereist bovendien een extra ziekenhuisbezoek voor de patiënt, wat gepaard gaat met extra reiskosten en het opnemen van verlof. Het leidt dus tot extra kosten voor de endoscopie afdeling (bijvoorbeeld het loon van de verpleegkundige), de patiënt (reiskosten) en de maatschappij (verlof van het werk).

Het doel van dit proefschrift is derhalve om verschillende eHealth-initiatieven en gevalideerde instrumenten te onderzoeken die de patiëntenzorg in de dagelijkse praktijk van de endoscopieafdeling kunnen verbeteren.

Om dit doel te bereiken zijn de volgende doelstellingen bepaald:

1. Het ontwikkelen van een eHealth-interventie die patiënten digitale voorlichting geeft voorafgaand aan de endoscopie
2. Deze eHealth-interventie in de dagelijkse praktijk te implementeren, waarbij de belangrijkste factoren voor succes worden geïdentificeerd
3. Evaluatie van relevante (patiënt gerelateerde) uitkomstmaatregelen voor de beoordeling van deze eHealth-interventie

Hieronder beschrijven we de verschillende onderdelen van het proefschrift waarin deze vragen aan bod zijn gekomen.

Ontwikkeling van digitale voorlichting thuis

In **hoofdstuk 2** beschrijven we een pilotstudie waarin digitale voorlichting op een beeldscherm in de wachtkamer gevolgd door een kort administratief gesprek met een verpleegkundige wordt vergeleken met verpleegkundige voorlichting alleen. De mate van schoonheid van de dikke darm tijdens het onderzoek, werd gemeten met zowel de "Ottawa Bowel Preparation Scale" (OBPS) als de "Boston Bowel Preparation Scale" (BBPS). We beoordeelden het comfort en de angst van de patiënt op drie verschillende tijdstippen. In totaal hebben we 385 patiënten geïncludeerd: 197 kregen traditionele verpleegkundige begeleiding en 188 kregen digitale voorlichting. De totale respons van de patiënten was respectievelijk 99%, 76,4% en 69,9%. Endoscopisten scoorden in 60,8% van de gevallen de mate van schoonheid van de darm. Vergelijkende analyse van de 39,2% van de patiënten met ontbrekende scores liet geen significant verschil zien op leeftijd, geslacht of opleidingsniveau. De basiskenmerken waren gelijkmatig verdeeld over de groepen. De darmreinheid was naar tevredenheid en verschilde niet tussen de groepen: de scores van de verpleegkundige vs. digitale voorlichting groep bij BBPS: (6,54 ±1,69 vs. 6,42 ±1,62); OBPS: (6,07 ±2,53 vs. 5,80 ±2,90) Het comfort van de patiënt was significant hoger (4,29, ± 0,62 vs. 4,42, ± 0,68) in de digitale voorlichting groep kort voor colonoscopie. Angst en kennisscores waren vergelijkbaar. We concludeerden dat digitale voorlichting in de wachtkamer een veilig en praktisch hulpmiddel is om patiënten voor colonoscopie te instrueren. We hebben destijds dan ook de combinatie van digitale voorlichting in de wachtkamer met een kort verpleegkundig contact aanbevolen voor de dagelijkse praktijk.

Gemotiveerd om het gebruik van digitale voorlichting in het ziekenhuis te verbeteren, hebben we een opiniestuk gepubliceerd. In dit opiniestuk (**hoofdstuk 3)** zijn we uitgegaan van het standpunt dat een optimale patiëntenvoorlichting voorafgaand aan de colonoscopie essentieel is voor een optimaal resultaat van de procedure. Dit was het startpunt voor ons onderzoek.

Zoals eerder geconcludeerd, hebben patiënten baat bij adequate informatie over laxeermiddelen, risico's en alternatieven. Vanuit een juridisch oogpunt moeten zij informed consent geven. De endoscopist moet voorafgaand aan de procedure toegang hebben tot de gegevens van de patiënt om een adequate risico-evaluatie voor het gebruik van sedatie uitvoeren. Dit levert uitdagingen op ten aanzien van veilig datamanagement en de communicatie tussen het platform van de digitale voorlichting en de elektronische patiëntendossiers.

De meeste centra in Nederland hebben een pre-endoscopie spreekuur in hun klinische zorgpaden geïntegreerd om deze informatie te verkrijgen. Dit consult levert voordelen op voor kwaliteitsbewaking. Het aantal colonoscopieën is echter snel toegenomen als gevolg van de invoering van het nationale bevolkingsonderzoek voor darmkanker. Als gevolg hiervan was de begeleiding van patiënten door verpleegkundigen steeds

tijdrovender geworden. Dit was tevens een belangrijke drijfveer voor innovatie van dit proces.

Een nieuw online platform zou de kwaliteit kunnen verbeteren en tijd kunnen besparen. Met de eerder ontwikkelde digitale voorlichting in de wachtkamer als basis hebben we de kans aangegrepen om dit platform te ontwikkelen en zodoende de logistieke uitdagingen het hoofd te bieden. We presenteerden ons voorgestelde algoritme om de digitale voorlichting te integreren in de dagelijkse endoscopiepraktijk.

Hoofdstuk 4 beschrijft de verdere ontwikkeling van digitale voorlichting in de wachtkamer – met eenzijdige informatieoverdracht - naar digitale voorlichting thuis met de mogelijkheid tot interactieve communicatie. In dit hoofdstuk schetsen we het onderzoeksprotocol dat het effect van digitale thuisvoorlichting op de kwaliteit van de darmvoorbereiding moet vaststellen.

Deze multicenter gerandomiseerde, endoscopisch geblindeerde, klinische studie is ontworpen met als de primaire uitkomstmaat darmvoorbereiding tijdens colonoscopie. De gekozen secundaire uitkomstmaten waren ziekteverzuim, de angst van de patiënt na de instructie en voorafgaand aan de colonoscopie, de patiënttevredenheid en de mate waarin de patiënt de informatie onthoudt. We hebben ook getracht om de consumptie van extra consultatietijd te meten (per telefoon of bezoek) in de digitale voorlichtingsgroep. Daarom hebben we gevalideerde vragenlijsten voor onder andere “geletterdheid in eHealth”, “kwaliteit van leven in relatie tot gezondheid” en “mate van actieve patiënten rol” opgenomen. Ook hebben we een meetinstrument naar arbeidsproductiviteit ingebouwd, welke door de patiënt wordt gerapporteerd. De patiënt werd gerekruteerd in vier endoscopische eenheden van verschillende niveaus (landelijk, stedelijk en tertiair). De gekozen criteria voor deelname waren volwassen leeftijd en verwijzing voor volledige colonoscopie. Criteria voor uitsluiting waren Nederlands analfabetisme, audiovisuele handicaps of verstandelijke beperkingen en tenslotte het niet hebben van toegang tot internet, ook niet via mantelzorgers.

Evaluatie van digitale thuisvoorlichting

In **hoofdstuk 5** bespreken we de resultaten van onze prospectieve gerandomiseerde multicenter studie naar digitale thuisvoorlichting versus verpleegkundige voorlichting. De primaire uitkomstmaat was succesvolle darmvoorbereiding, geëvalueerd met de “Boston Bowel Preparation Scale” (BBPS). Secundaire uitkomstmaten waren ziekteverzuim als gevolg van polikliniekbezoek, angst en tevredenheidsscores van de patiënt en het onthouden van informatie. Het onderzoek werd uitgevoerd op vier endoscopie afdelingen in verschillende ziekenhuizen (landelijk, stedelijk en academisch gesitueerd). We hebben 1035 patiënten gescreend op geschiktheid en 845 patiënten gerandomiseerd. Na evaluatie van de gegevens werden 684 patiënten in de intention-to-treat (ITT) populatie opgenomen. Vervolgens werden 497 patiënten opgenomen in

de per-protocol (PP) populatie; 217 kregen verpleegkundige voorlichting en 280 digitale voorlichting thuis. De basiskenmerken bleken gelijkmatig verdeeld over de groepen. In de PP-populatie werd succesvolle darmreiniging bereikt in 93,2 % (261/280) van de digitaal voorlichting thuis groep, wat niet inferieur was aan de verpleegkundige voorlichting groep met 94% (204/217). Het verschil was -0,8% [95% betrouwbaarheidsinterval (CI) -5,1 - 3,5]. In de ITT-populatie werden deze bevindingen bevestigd. Ziekteverzuim kwam significant vaker voor in de verpleegkundige voorlichtingsgroep (28,0% versus 4,8%). In de digitale voorlichtingsgroep had 21,5% van de patiënten extra informatie nodig, wat resulteerde in 3,0% extra polikliniekbezoeken. Daarom concluderen we dat digitale voorlichting thuis niet onderdoet voor verpleegkundige voorlichting op het gebied van darmvoorbereiding tijdens colonoscopie. Deze werkwijze levert wel minder ziekteverlof op voor de patiënt. Na de succesvolle transformatie van digitale voorlichting in de wachtkamer naar thuis concluderen we dan ook dat dit platform minder poliklinische bezoeken aan de patiënten heeft opgeleverd. Daarom wordt de aanbeveling gedaan dat digitale thuisvoorlichting kan dienen als een efficiënt educatief hulpmiddel om patiënten voor colonoscopie te informeren in de reguliere klinische praktijk.

Bij elke discussie over verandering in de zorg nemen kosten een centrale rol in. Betaalbaarheid is cruciaal voor endoscopieafdelingen die besluiten om hun pre-procedurele voorlichting te veranderen. Daarom hebben we in **hoofdstuk 6** geanalyseerd welke kosten (en kostenbesparingen) aan digitale thuisvoorlichting kunnen worden toegerekend. Aangezien de digitale thuisvoorlichting in de plaats komt van een verpleegkundig voorlichtingsgesprek, kan dit een aantal kosten verminderende effecten hebben; we hebben dit voornamelijk vanuit het perspectief van endoscopieafdeling geëvalueerd. Bovendien is er vanuit het patiënt en het maatschappelijk perspectief gekeken naar invoering van digitale thuisvoorlichting, door te kijken naar effecten op productiviteitsverlies en de reiskosten van patiënten.

Om de kosten voor de endoscopie-afdeling te evalueren, hebben we een kostenmodel ontwikkeld. In dit model streefden we ernaar om de werkelijke kosten vast te stellen voor de drie gebruikelijke vormen van patiëntenvoorlichting: verpleegkundige voorlichting in het ziekenhuis, alleen digitale thuisvoorlichting en digitale thuisvoorlichting aangevuld met extra (telefonische) begeleiding. Dit model omvat de salarissen van het secretariaat en endoscopie verpleegkundigen, de implementatie en licentiekosten van de digitale thuisvoorlichting en andere kostenfactoren die zijn geïnventariseerd in een grondige procesanalyse. Met behulp van dit model voerden we een kosten minimalisatie berekening uit van de digitale thuisvoorlichting versus verpleegkundige voorlichting op basis van geëxtrapoleerde gegevens uit onze eerdere studie.

Voor de patiëntkosten hebben we de kosten per bezoek van beide strategieën berekend met behulp van de kostentool die door het instituut voor Medische Technologie Beoordeling (iMTB) is ontwikkeld en de gerapporteerde gemiddelde reisafstand

voor colonoscopie in Nederland in de eerdergenoemde scenario's. Tot slot, om de maatschappelijke kosten in te schatten, gebruikten we een aangepaste iMTB vragenlijst voor beoordeling van productiviteitsverlies. We hebben de statistische methode van bootstrapping uitgevoerd om de resultaten te kunnen vergelijken.

Uit de procesevaluatie kwamen 33 relevante parameters naar voren. Bij elk van de vier endoscopieafdelingen in de studie zijn de gegevens verzameld van alle parameters. De kosten van de drie alternatieve vormen van patiëntenvoorlichting bleken verschillend tussen de vier afdelingen. Ook waren er wisselende kosten voor de drie alternatieven per afdeling: verpleegkundige begeleiding € 18,30 - € 28,42, alleen digitale thuisvoorlichting € 4,04 - € 8,86 en digitale thuisvoorlichting thuis met extra begeleiding € 7,01 - € 19,78. De belangrijkste verklaring voor de opgetreden verschillen in kosten tussen de vier afdelingen bleek de inzet van duurder personeel en een langere duur van het voorlichtingsgesprek.

Na extrapoleren van de gegevens (van 135 naar 280 patiënten) in de digitale thuisvoorlichting groep bleken de kosten voor de endoscopie-afdeling van voorlichting per colonoscopie gemiddeld €8,36 (CI €7,83 - €8,84) per patiënt. In de groep van de verpleegkundige voorlichting was dit significant hoger, €22,56 (CI €22,00- €23,12).

De gemiddelde reiskosten die door de patiënt worden gemaakt voor bezoeken van de polikliniek voor verpleegkundige voorlichting bedroegen € 5,80. Aangezien 100% van de patiënten in de verpleegkundige en slechts 3% in de digitale thuisvoorlichting groep naar het ziekenhuis moesten komen, bleken de totale kosten die in de eerste groep gemaakt werden €1260,09 tegenover slechts €46,45 in de digitaal voorgelichte groep.

In totaal hebben 271 patiënten (125 in de verpleegkundige, 146 in de digitale thuisvoorlichting groep) de iMTB-vragenlijst ingevuld. Het geslacht was in beide groepen gelijk verdeeld. In de verpleegkundige groep meldden 54 (43,2%) patiënten (43,2%) afwezigheid van betaald, onbetaald werk of noodzaak tot vervanging voor onbetaald werk, tegenover 29 (19,8%) in de digitale thuisvoorlichting groep (p=0,007). Het gemiddelde aantal gemelde afwezige uren was niet significant verschillend, maar het berekende productiviteitsverlies was wel significant hoger in de verpleegkundige voorlichtingsgroep: €35,84 (95% CI: € 26,79 -€48,41) versus €13,89 (95% CI: €7,64 – €18,84) bij digitale thuisvoorlichting.

Digitale thuisvoorlichting laat dus een reductie van kosten zien voor endoscopie-afdelingen en verlaagt de kosten die patiënten en de samenleving moeten maken. Deze studie onderbouwt de stelling dat deze vorm van eHealth werkt. Volledige implementatie van deze aanpak kan waardevolle middelen in de gezondheidszorg vrijmaken.

eHealth tijdens endoscopie

Om de impact van ook andere eHealth-oplossingen, nu *tijdens* colonoscopie te evalueren, hebben we een in **hoofdstuk 7** beschreven pilotstudie gedaan naar het gebruik van virtual reality brillen. Het hoofddoel was de haalbaarheid van deze interventie vast te stellen gedurende een colonoscopie. Indien succesvol, zou deze pilot de weg kunnen vrijmaken voor toekomstige studies om te onderzoeken of gebruik van dit apparaat kan dienen als een mogelijke vervanging van slaapmiddelen gedurende colonoscopie. We rekruteerden volwassenen die voor colonoscopie werden doorverwezen en verdeelden deze over twee groepen: met en zonder VR-bril. De belangrijkste uitkomstmaat was dat de patiënt het dragen van een VR-bril tijdens de colonoscopie accepteerde zonder dat dit het technische succes van de procedure in het gedrang bracht. Secundaire resultaten waren het comfort, de pijn en de angst van de patiënt voor, tijdens en na de procedure, met behulp van gevalideerde vragenlijsten voor de patiënt. De opmerkingen van de patiënten werden verzameld door middel van een kwalitatief interview. We hebben 19 patiënten geïncludeerd, waarvan 10 patiënten een VR-bril kregen aangeboden. Alle deze patiënten accepteerden een VR-bril zonder dat de proceduretijd verlengd werd. Er zijn geen nadelen van de VR-bril geobserveerd in het kader van communicatie of het uitvoeren positieverandering van de patiënt tijdens de colonoscopie. We ontdekten dat het comfort, de pijn, de angst en de tevredenheid van de patiënt met betrekking tot de procedure in beide groepen gelijk waren. In een kort vraaggesprek na afloop beschreven patiënten dat de VR-bril een aangenaam afleidend effect heeft.

We concludeerden daarom dat de VR-bril tijdens colonoscopie goed geaccepteerd werd door de patiënten en geen afbreuk deed aan het succesvol uitvoeren van de colonoscopie. Hiermee is de weg vrij voor toekomstige studies met als opzet het vervangen van sedativa door de VR-bril. Aangezien patiënten bovendien aangaven dat VR-ervaring prettig was, zal dit de werving van proefpersonen voor deze studies vergemakkelijken.

Ontwikkelen van tools voor de evaluatie van eHealth-toepassingen in endoscopie

In dit proefschrift hebben we gebruik gemaakt van een aantal eerder ontwikkelende en gevalideerde vragenlijsten voor het meten van emoties en vaardigheden van patiënten. Voor sommige uitkomstmaten in relatie tot de patiëntbeleving was er echter geen standaard beschikbaar. In het geval van patiënttevredenheid was er wel een gevalideerde Engelstalige vragenlijst beschreven in de literatuur.

Voor gebruik in de klinische praktijk en voor toekomstige studies hebben we onderzocht of dit instrument in het Nederlands vertaald en gevalideerd kon worden. In **hoofdstuk 8** hebben we dit validatieproces beschreven voor de gastro-intestinale endoscopie-tevredenheidsvragenlijst (GESQ) die de patiënttevredenheid na afloop

van een endoscopie beoordeelt. De oorspronkelijke GESQ is in het Nederlands vertaald volgens de richtlijnen van de Wereldgezondheidsorganisatie (WHO). Eerst is de interne validatie van de Nederlandse GESQ (Dutch-GESQ of D-GESQ) tot stand gekomen door toepassing van de think-aloud methode en de daaropvolgende analyse door het panel van deskundigen. Vervolgens werd de D-GESQ ingebed in het CBE-platform van onze endoscopieafdeling, met een interval van 30 dagen na endoscopie. Volwassen patiënten, die via de CBE werden geïnformeerd en een endoscopie hadden ondergaan, werden opgenomen. Uitsluitingscriteria waren bewuste sedatie, beperkte Nederlandse taalvaardigheid, geen e-mailadres beschikbaar, dementie en visuele beperking. Voor statistische analyse zijn verschillende psychometrische analyses van de vragenlijst uitgevoerd om de onderliggende dimensies te identificeren en de vragenlijst te beoordelen op betrouwbaarheid en validiteit. In totaal hebben 227 van de 1065 patiënten de D-GESQ ingevuld, wat een respons van 21,3% oplevert. 52,6% (N=129) bestond uit mannen. De gemiddelde leeftijd van de proefpersonen was 62,7 ±11,54 jaar. In totaal hadden 180 patiënten (79,3%) eerder een endoscopie ondergaan, waarvan 157 (87,2%) twee of meer keren. De verkennende factoranalyse toonde aan dat de 21 vragen het best konden worden geclusterd in vijf clusters in plaats van vier in de oorspronkelijke GESQ. De totale D-GESQ had een Cronbach α van 0,88, wat de hoge interne validiteit van het instrument bevestigt. We concludeerden dat de Nederlandse versie van de GESQ een hoge interne validiteit en bruikbaarheid vertoonde. Daarom bevelen we de D-GESQ aan voor routinematig gebruik in de dagelijkse klinische praktijk om de kwaliteit van de patiëntenzorg in de dagelijkse endoscopische praktijk te verbeteren.

Conclusie

Endoscopie-afdelingen moeten er altijd naar streven om hun patiënten optimaal voor te bereiden op een endoscopie. Dit heeft direct gevolgen voor de kwaliteit van zorg bij deze ingreep.

In dit proefschrift hebben we een reeks uitkomstmaten opgenomen die zijn gebaseerd op uitgebreid literatuuronderzoek om factoren te identificeren die de endoscopist helpen om de voorlichting van patiënten te verbeteren.

Het concept van eHealth als de ultieme oplossing voor de huidige problemen in de gezondheidszorg is vaak bekritiseerd. Maar door nauwe samenwerking met inspirerende eHealth-ondernemers zijn we erin geslaagd een praktische eHealth-toepassing te ontwikkelen en te implementeren met goede prestaties op het gebied van endoscopische kwaliteit, door patiënten gerapporteerde uitkomstmaten en kostenreductie. Hierdoor profiteren op dit moment meer dan 25 ziekenhuizen in Nederland van dit platform.

Maar dit succes gaat hand in hand met de verplichting deze technologie door te blijven ontwikkelen. Om het digitale thuisvoorlichtingsplatform voortdurend te verbeteren,

doen we in dit geval een beroep op externe ICT-leveranciers. Deze partners hebben financiële motieven, cruciaal om hun bedrijf en producten levensvatbaar te houden op de markt, die soms botsen met het leveren van het meest optimale product voor alle ziekenhuizen op elk moment. Desalniettemin hebben we het aan hen te danken dat de digitale thuisvoorlichting in Nederland in een zeer hoog tempo is ingevoerd.

Tevens hebben we de eerste positieve ervaringen opgedaan met eHealth tijdens coloscopie door inzet van virtual reality. Tenslotte hebben we een vragenlijst naar tevredenheid van patiënten gevalideerd voor het Nederlands taalgebied. Dit helpt Nederlandse endoscopieafdelingen om patiënttevredenheid te meten in de toekomst.

A

Appendices

I. DATA STEWARDSHIP STATEMENT

Research data management must abide to the highest standards of safety, to avoid data leaks. This safeguards scientific integrity, supports reuse of data and allows safekeeping of valuable datasets.

All research data that is presented in this thesis has been obtained at the department of Gastroenterology and Hepatology, North West Hospital group Alkmaar, the Netherlands, the department of Gastroenterology and Hepatology, Radboudumc academic hospital, Nijmegen, the Netherlands, the department of Gastroenterology and Hepatology, Jeroen Bosch Hospital, Den Bosch, the Netherlands and the department of Gastroenterology and Hepatology, Bernhoven Hospital, Uden, the Netherlands. In chapter 3, the data on educated patients is presented on endoscopy unit level based on the dashboard from Medify (software developer). For chapter 6, input in the cost model included interviews in the Reinier de Graaff hospital in Delft, the Netherlands and the Medisch Spectrum Twente in Enschede, the Netherlands. This data is archived according to Findable, Accessible, Interoperable and Reusable (FAIR) principles.[1]

Primary data were mostly captured via online questionnaire websites SurveyMonkey and ZohoSurvey, accessible by password by members of the research group. This was subsequently exported into secondary data sets in Microsoft Excel or IBM SPSS Statistics. After finalization of each trial, the data was safely migrated to a local server in the department of Gastroenterology and Hepatology in the Radboudumc hospital. This server is support by the ICT department of the Radboudumc, with daily backups.

The studies in this thesis including humans were all performed according to the principles of the declaration of Helsinki and Dutch 'good clinical practice' guidelines.[2] The author of this thesis was trained in April 2013 in 'good clinical practice' before patients were included in the first trial described in chapter 2.

All studies had approval of the Medical Ethical Committee Boards in Alkmaar and Arnhem-Nijmegen. All study protocols were reviewed by these boards and found to be not subsidiary to the Dutch legislation regarding patient based research (Wet Mensgebonden Onderzoek – WMO).

All patients provided written informed consent via the online patient questionnaires for the trials in chapter 2., 5., 6., 7. and 8. This novel method was designed with the additional approval by the Medical Ethical Committee Boards Arnhem-Nijmegen. All study protocols involving patients were registered at the clinical trial registries of Clinical Trials (clinicaltrials.gov) and the Dutch Trial register (ntr.nl). All data generated is included in the published articles and additional files are available upon request from the corresponding author.

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   **both authors contributed equally*

III. LIST OF PRESENTATIONS

1. Abstract presentation: “Endoscopic management of large colorectal polyps: safety and effectiveness aspects in a real-life cohort.” - Dutch Association for Gastroenterology Fall conference October 2011, Veldhoven, The Netherlands
2. Poster presentation: “Respiratory Rescue Support by Extracorporeal Membrane Oxygenation - Mobile Off-Center Experience With a Novel Jugular Dual Lumen Approach” – Dutch Association of Intensive Care Winter conference February 2012, Ede, The Netherlands
3. Abstract presentation: “Computer Assisted Instruction before colonoscopy is as effective as nurse counselling, a controlled trial” - Dutch Association for Gastroenterology Spring conference 2014, Veldhoven, The Netherlands
4. Poster presentation: “Computer Assisted Instruction before colonoscopy is as effective as nurse counselling, a controlled trial” - Digestive Disease Week May 2014, Chicago, United States of America
5. Invited expert presentation: “Is computer assisted instruction before colonoscopy the future?” - Association of Dutch endoscopy nurses - Dutch Association for Gastroenterology Spring conference 2015, Veldhoven, the Netherlands
6. Poster presentation: “Computer Assisted Instruction before colonoscopy is as effective as nurse counselling, a controlled trial” - United European Gastroenterology Week October 2015, Barcelona, Spain
7. Abstract presentation: “Feasibility of the use of virtual reality glasses to relieve pain and discomfort in patients during colonoscopy” - Dutch Association for Gastroenterology Spring conference March 2017, Veldhoven, the Netherlands
8. Invited expert lecture: “eHealth integrated in the endoscopy unit” – Annual Dutch Association for Gastroenterologists Symposium June 2018, Amsterdam, The Netherlands
9. Presentation Endoscopy Video Symposium: “How to improve your Cecal Intubation rate” – Dutch Association for Gastroenterology Fall conference October 2018, Veldhoven, The Netherlands
10. Abstract presentation: “e-Patient Counselling trial (E-PACO): Computer Based Patient Education is non-inferior to nurse counselling prior to colonoscopy, a multicenter randomized controlled trial” - Dutch Association for Gastroenterology Spring conference March 2019, Veldhoven, the Netherlands
11. Abstract presentation: “e-Patient Counselling trial (E-PACO): Computer Based Patient Education is non-inferior to nurse counselling prior to colonoscopy, a multicenter randomized controlled trial” - The European Society of Gastrointestinal Endoscopy conference 2019 in Prague, Czech Republic
12. Poster presentation: “e-Patient Counselling trial (E-PACO): Computer Based Patient Education is non-inferior to nurse counselling prior to colonoscopy, a multicenter randomized controlled trial” - Digestive Disease Week May 2019, San Diego, United States of America

IV. LIST OF AWARDS / GRANTS

1. Student Award Dutch Association for Gastroenterology Spring fall 2011.
   Abstract: “Endoscopic management of large colorectal polyps: safety and effectiveness aspects in a real-life cohort.”

2. Innovation prize North West Hospital Group 2013
   Title entry: “Computer assisted instruction prior to colonoscopy”

3. Innovation prize Jeroen Bosch Hospital 2014
   Title entry: “Computer assisted instruction prior to colonoscopy”

4. Grant ZonMW Actieplan eHealth – “Leren van implementeren” - €50.000
   Title: “Promoting the implementation of computer based education prior to colonoscopy”

5. ABC Trofee 2015
   Title entry: “Promoting access to patient education prior to colonoscopy in health illiterate patients”

6. Finalist, 2nd place Achmea Quality Award 2015
   Title: “Promoting the implementation of computer based education prior to colonoscopy”

7. Nominee Research Prize - Training and Research Region East Netherlands 2015
   Title: “E-Patient Counselling Working Group to promote computer based education prior to colonoscopy”

8. Nominee Value Based Health Care Award 2016
   Title: “Promoting the implementation of computer based education prior to colonoscopy”

V. CURRICULUM VITAE

Govert Veldhuijzen was born on Tuesday the 5th of February 1985 in Dordrecht. After graduating from the Johan de Witt Gymnasium in Dordrecht in 2003, he started his academic career at the University College Maastricht, a faculty of the Maastricht University.

In 2004 he started studying Medicine at Maastricht University. During this study he served several clinical rotations abroad: Obstetrics and Gynaecology at Makerere University in Kampala, Uganda in 2009, Internal Medicine at the Vrije Universiteit Brussel in Brussels in 2009, Belgium and Obstetrics and Gynaecology at the University of Pretoria, in Pretoria, South-Africa. He graduated in October 2011. He wrote his master thesis at the department of Gastroenterology and Hepatology of the Maastricht University Medical Center+ titled: "Endoscopic management of large colorectal polyps: safety and effectiveness aspects in a real-life cohort".

His first clinical work as junior medical doctor started in December 2011 as a resident Intensive Care at the Medical Center Alkmaar in Alkmaar, where in February 2013 he started working on the first clinical research of this thesis under supervision of dr. Michael Klemt-Kropp, gastroenterologist. In January 2014 he started his training in Gastroenterology and Hepatology by working at the Internal Medicine department at the Jeroen Bosch Hospital in Den Bosch under supervision of dr. Watske Smit, nephrologist.

In March 2015, after winning a ZonMW grant, he started as formal PhD candidate under supervision of professor dr. Joost Drenth and dr. Aura van Esch, gastroenterologists at the Radboudumc Nijmegen.

In June 2016 he started his training in Gastroenterology and Hepatology at the Jeroen Bosch Hospital under supervision of dr. Bob Scheffer, gastroenterologist. Since May 2018 his training continued at the Radboud University Medical Center Nijmegen, under the supervision of dr. Mariëtte van Kouwen, gastroenterologist. In November 2020 he obtained his license as a consultant in gastroenterology and hepatology, with a subspeciality in advanced endoscopy. From January 2021 he works as a gastroenterologist and advanced endoscopist at the Gelre Hospitals in Apeldoorn, the Netherlands.

Govert Veldhuijzen is living in Utrecht, the Netherlands. He is married with Judith Groeneweg. Together they have a baby daughter: Vivian.