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Corresponding Author:	Govert Veldhuijzen Radboudumc Nijmegen, NETHERLANDS
Corresponding Author's Institution:	Radboudumc
Corresponding Author E-Mail:	Govert.Veldhuijzen@radboudumc.nl
Order of Authors:	Govert Veldhuijzen
	Aura A. van Esch
	Michael Klemt-Kropp
	Jochim S. Terhaar sive Droste
	Joost P.H. Drenth
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TITLE:

E-Patient Counseling Trial (E-PACO): Computer Based Education versus Nurse Counseling for Patients to Prepare for Colonoscopy

AUTHORS & AFFILIATIONS:

Govert Veldhuijzen[1], Aura A. van Esch[1], Michael Klemt-Kropp[2], Jochim S. Terhaar sive Droste[3], Joost P.H. Drenth[1]

[1]Department of Gastroenterology and Hepatology, Radboud University Medical Center, Nijmegen, the Netherlands
[2]Department of Gastroenterology and Hepatology, North West Clinics, Alkmaar, the Netherlands
[3]Department of Gastroenterology and Hepatology, Jeroen Bosch Hospital, Den Bosch, the Netherlands

Aura.vanEsch@radboudumc.nl
M.Klemt-Kropp@nwz.nl
j.terhaar@jbz.nl
joostphdrenth@cs.com

CORRESPONDING AUTHOR:

Govert Veldhuijzen
govert.veldhuijzen@radboudumc.nl

KEYWORDS:

Endoscopy, Colonoscopy, e-Health, Patient education, Bowel Preparation, Patient Related Outcome Measures

SUMMARY:

The aim of this trial is to establish the position of online computer-based education as a tool for patient preparation prior to a colonoscopy. Computer based education is compared with the standard of care, nurse counseling, evaluating endoscopic quality measures and patient related outcome measures.

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 counseling 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 counseling 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, audiovisual 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 counseling), both endoscopic quality measures and patient related outcome measures can be evaluated.

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 diarrhea. 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 counseling 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 counseling.

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 counseling 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 counseling. The hypothesis is that CBE is non-inferior to nurse counseling 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 e-health 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 audiovisual 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 (see **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 2**.

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 iProductivity 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 behavior 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 e-Health 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 favor 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 counseling. 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, e-Health 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 1**, 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.

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 anesthetic. 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, centering 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, centering 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, centering 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 millimeters 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 counseling.

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[8]. 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. See also **Table 2**[8].

In this pilot study 385 patients were enrolled. The CAI group contained 188 subjects. The control group receiving nurse counseling had 197 patients. The baseline characteristics were evenly distributed between CAI and nurse counseling. 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. Aar 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 counseling group. As this rating was higher directly after nurse counseling, there is influence of the human factor for personal contact and offering emotional support. Anxiety and information re-call scores showed no statistical difference (see **Table 3**[8]).

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.

Figure 2. Flowchart trial with time points

Table 1. In- and exclusion criteria

Table 2. Bowel preparation scores in our earlier pilot study[8]

Table 3. Secondary outcomes in our earlier pilot study[8]

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

DISCUSSION:

The E-Patient Counseling (E-PACO) trial aims to study the utility, practicality, and patient-perceived usefulness of computer-based education (CBE), in comparison to conventional nurse counseling. 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 counseling)[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 counseling 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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Figure 1.

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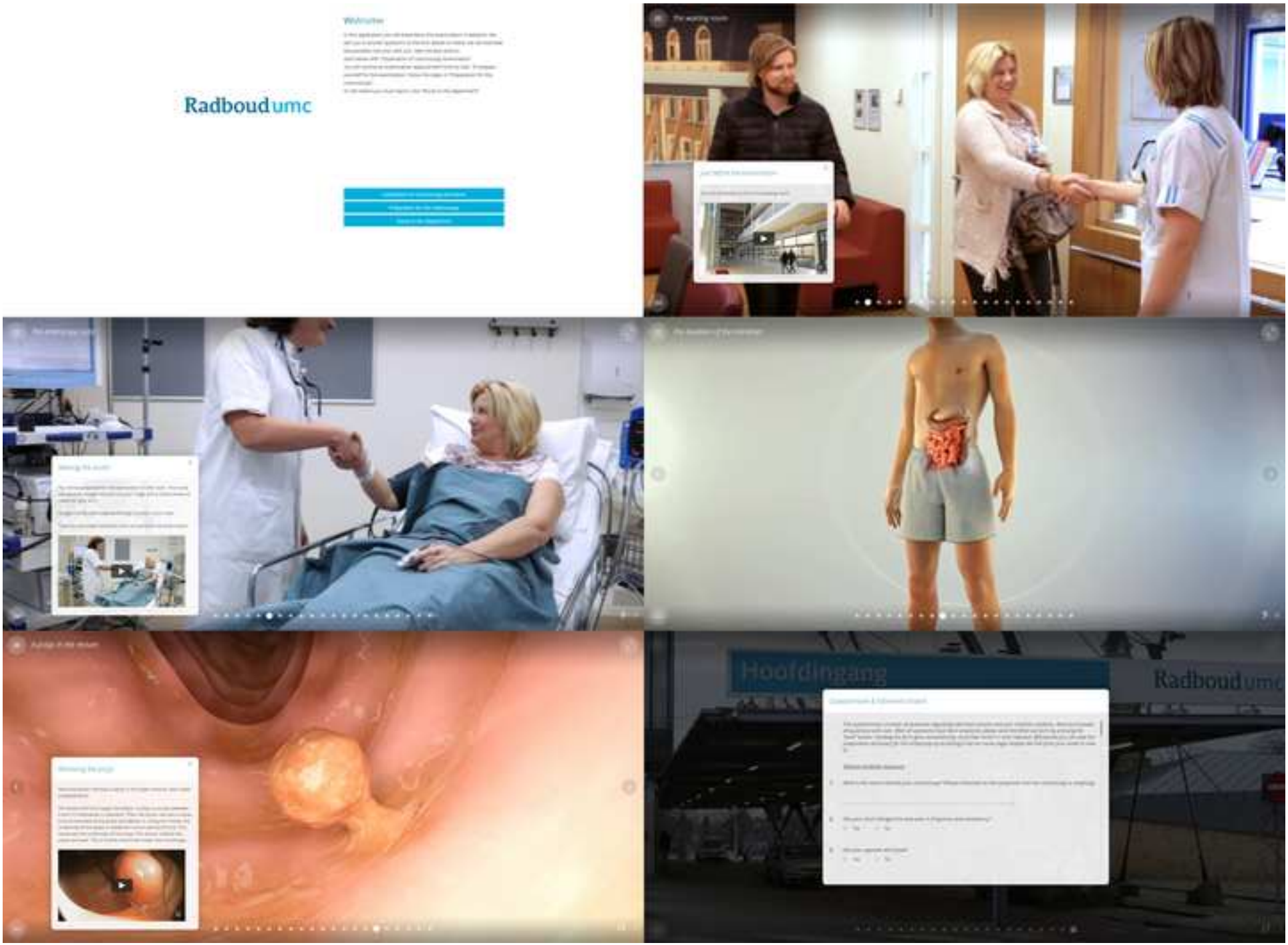

Figure 2. (PDF)

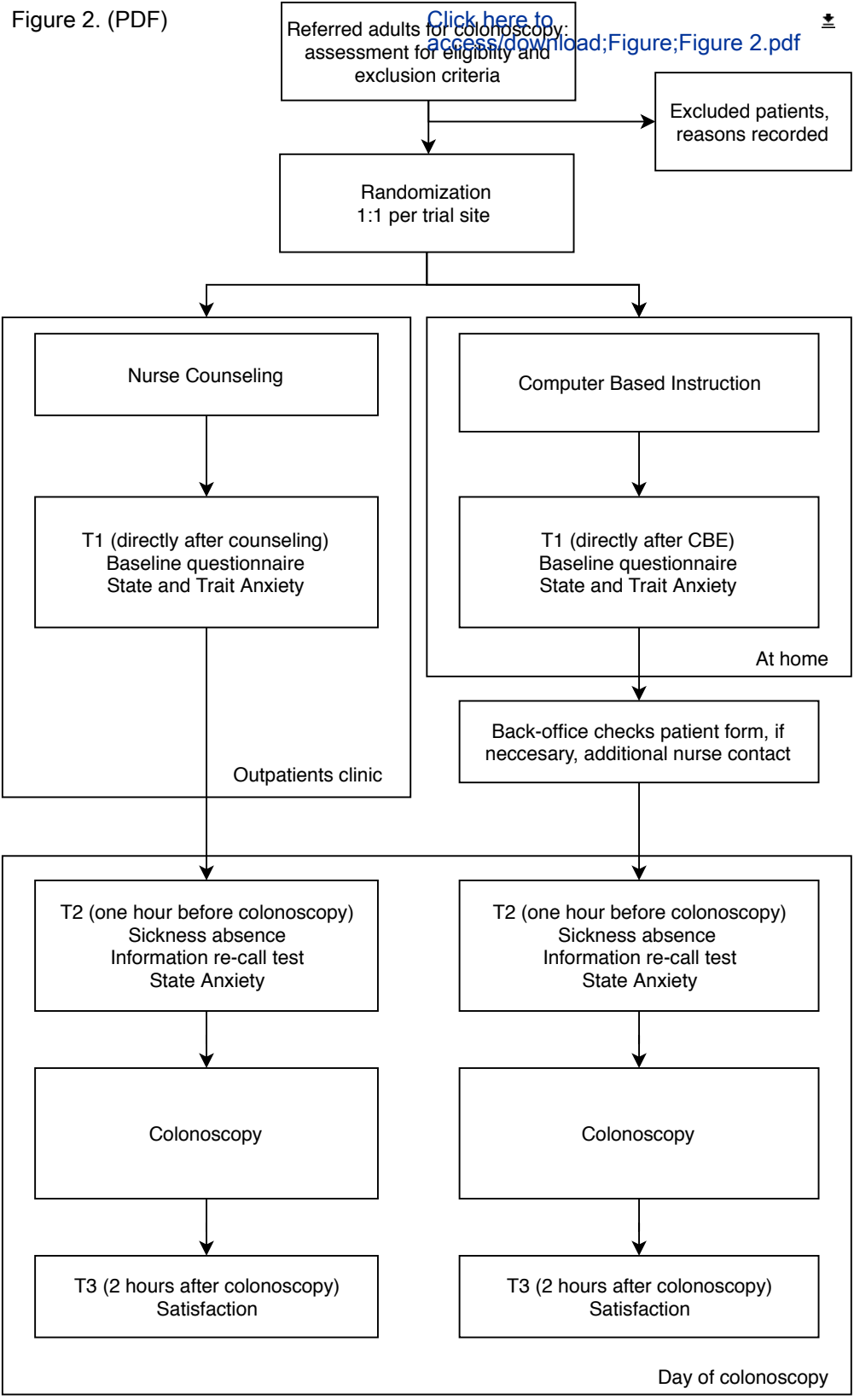

Figure 2. (SVG)


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Table 1.

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

Table 2.

	Nurse counseling (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**

Table 3. Click here to access/download;Table;Table3.xlsx

	Nurse counseling (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**

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
Computer Based Education	Medify BV	n/a	Computer Based Education tool for patient instruction prior to colonoscopy
Computer / tablet	Any		A computer or tablet should be used to complete the e-learning and fill out the questionnaires
Medify Content Management System	Medify BV	n/a	A content management system to process the e-learning content

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Title of Article: E-Patient Counselling Trial (E-PACO) – Study protocol: Computer Based Patient Education versus Nurse counselling for patients to prepare for colonoscopy

Author(s): Govert Veldhuijzen[1], Aura A. van Esch[1], Michael Klemt-Kropp[2], Jochim S. Terhaar sive Droste[3], Joost P.H. Drenth[1]

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CORRESPONDING AUTHOR

Name:	Govert Veldhuijzen
Department:	Department of Gastroenterology and Hepatology
Institution:	Radboud University Medical Centre, Nijmegen, The Netherlands
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Final rebuttal document "E-Patient Counseling Trial (E-PACO) – Study protocol: Computer based education versus nurse counseling for patients to prepare for colonoscopy"

Dear editor,

Thank you again for improving our manuscript. Please find enclosed the revised manuscript. Changes in the manuscript are highlighted in red. Below you will find our point-by-point reply to the comments from the editors.

We hope our replies will be satisfactory so that our manuscript will meet the threshold for publication.

Thank you for your consideration.

Yours sincerely, on behalf of all co-authors,

With regard,
Govert Veldhuijzen, MD

Editorial comments:

1. Please revise the protocol to ensure that the written protocol text lines up with the actions performed in the videos that are played. There are some mismatches between what the written text states and what is actually in the video: https://trials.medify.eu/cbe-colonoscopy
We conscientiously updated the protocol section to align the text in the manuscript protocol section exactly to the information in the CBE and the video voiceovers. As we made sure all the text is exactly the same, an additional supplemental file is not added.

2. It is unclear what you mean the voiceover. If this is meant as the video narration, please move this suggested narration to a supplemental file.
The term voiceover is used to describe the video voiceovers of the video clips in the CBE. For clarification, the word video is added when the word voiceover is used. This is not the same as the JoVe video narration. On several slides of the CBE, without the videos with voiceover embedded in the CBE, there is room to let the Jove video narration to be spoken.

3. Please highlight up to 2.75 pages of protocol text for inclusion in the video. I have made suggested highlighting. Please revise if necessary.
We agree with the highlighted section you added; we only added point 3.3.25 & 3.3.26.

The focus of the protocol is the section "explanation of colonoscopy procedure". As the other sections are designed in similar fashion, this part of the protocol might be briefly addressed.

We like to suggest to utilize the use of "Screen Recorded Video" for the highlighted section. This will show the full extent of the CBE, without losing details of the 3D animation that might occur in case of filming a person clicking on a computer screen through the CBE slides.

4. Additional comments are in the attached manuscript.
We addressed all comments in the manuscript (adding a comment after the comment by the editor).