

# E-Patient Counseling trial

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28342

### Source

NTR

### Brief title

E-PACO

### Health condition

Endoscopy, eHealth, Colonoscopy, Patient Education, Gastroenterology  
Endoscopie, coloscopie, patientvoorlichting, Maag-, Darm-, Leverziekten

## Sponsors and support

**Primary sponsor:** Radboudumc, Jeroen Bosch Ziekenhuis, Medisch Centrum Alkmaar

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

Bowel Cleanliness during colonoscopy

### Secondary outcome

Health Literacy

Anxiety

Comprehension

Cost-Effectiveness

## Study description

### Background summary

#### BACKGROUND

Patient education prior to colonoscopy has become more complex. Current common practice is nurse counselling, which improves adherence to instructions for bowel preparation. This is costly and has disadvantages regarding uniformity and time consumption for both patient and the hospital. We hypothesized that computer based instruction supported by video and 3D animations can replace nurse counselling in most cases, without losing quality of bowel cleanliness during colonoscopy.

#### METHODS/DESIGN

We choose a randomized controlled trial design, endoscopist blinded, to evaluate our primary outcome measure cleanliness of the bowels during colonoscopy. Secondary outcome measures were patient anxiety after instruction and prior to colonoscopy, patient satisfaction and cost effectiveness.

We used head-to-head randomization in three endoscopy units, including different levels (rural, urban, tertiary). Inclusion criteria were adult age and referral for complete colonoscopy. Exclusion criteria were Dutch illiteracy, audiovisual or mental handicaps.

Power calculation was performed, based on a non-inferiory calculation of clinically relevant differences in bowel preparation, using the Boston Bowel Preparation Scale, resulting in 500 patients per group, 1000 patients in total.

#### DISCUSSION

The aim of this trial is to establish the position of online computer based counseling as tool for the education of patients prior to colonoscopy. By choosing a direct comparison with the standard of care, being nurse counseling, both endoscopic quality measures and patient related outcome measures can be evaluated.

### Study objective

Is computer assisted instruction non-inferior to traditional nurse counseling as modality in patient education prior to colonoscopy in bowel cleanliness during endoscopy?

### **Study design**

Measurement after education, prior and after colonoscopy

### **Intervention**

Computer Based Instruction at home

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

Referral for colonoscopy, age > 18 years

### **Exclusion criteria**

Dutch illiteracy, audiovisual and mental handicaps.

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-09-2015
Enrollment:	1000
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	04-09-2015
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL5374
NTR-old	NTR5475
Other	CMO Arnhem-Nijmegen : 2015-1742

## Study results