

E-Patient Counseling trial

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28342

Bron

NTR

Verkorte titel

E-PACO

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc, Jeroen Bosch Ziekenhuis, Medisch Centrum Alkmaar

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Bowel Cleanliness during colonoscopy

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Measurement after education, prior and after colonoscopy

Onderzoeksproduct en/of interventie

Computer Based Instruction at home

Contactpersonen

Publiek

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The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Referral for colonoscopy, age > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Dutch illiteracy, audiovisual and mental handicaps.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	15-09-2015
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten