Virtual Reality as pain relief during colonoscopies - Psychological factors related with the effect of Virtual Reality during colonoscopies

Published: 21-07-2015
Last updated: 19-04-2024

Primary objective: to investigate which independent variables (gender, age, abdominal pain during previous month, previous abdominal surgery, fear, locus of control, coping and focused attention) were related to the patients which are able to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42393

Source
ToetsingOnline

Brief title
Psychological factors related with the effect of Virtual Reality

Condition

- Gastrointestinal conditions NEC

Synonym
Pain, Satisfaction

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colonoscopy, Pain, Psychological factors, Virtual Reality

Outcome measures

Primary outcome

a) the percentage of patients that is able to undergo colonoscopy with VR and without sedation up to the moment that the scoop reach the coecum, b) the identification of independent variables related to this percentage.

Secondary outcome

a) the score for the overall pain level, b) the score for the pain level at the most painful moment, c) the score for the overall patients satisfaction level, d) the score for the overall doctors satisfaction level, e) the identification of independent variables related to the overall pain level and f) the identification of independent variables related to the overall patients satisfaction level.

Study description

Background summary

The final aim of using VR during colonoscopies, is to make unsedated colonoscopies more comfortable, to benefit the advantages of unsedated colonoscopies and to enlarge the amount of unsedated colonoscopies. Following the ongoing questionnaire (MEC 2013-42) and the finished pilot (RTPO-893), the current study will investigate which patients will benefit most from the effect of VR during colonoscopies.

Study objective

Primary objective: to investigate which independent variables (gender, age,

abdominal pain during previous month, previous abdominal surgery, fear, locus of control, coping and focused attention) were related to the patients which are able to undergo coloscopie with VR and without sedation up to the moment that the scoop reach the coecum.
Secundary objective: to investigate the level of pain and satisfaction and which independent variables were related with the level of pain and satisfaction.

Study design

Based on the inclusion and exclusion criteria, the gastroenterologist selects the patients who are eligible for participation in this study. All participants undergo the same procedure. Data is gathered by questionnaires, attention task and observation.

Study burden and risks

Because no sedation is used, there are no side effects related to the use of sedation. Thereby the recovery time is shorter, daily activities can be resumed earlier and patients can participate in traffic independently. Also costs for healthcare are lower because no sedation is used.
In addition to a certain time investment, the risico exists that the pain relief is insufficiënt by using VR and undergoing colonoscopy is (too) painful. Therefore, the possibility exists to ask for sedation during colonoscopy.

Contacts

Public
Martini Ziekenhuis

Van Swietenplein 1 Van Swietenplein 1
Groningen 9728NT
NL
Scientific
Martini Ziekenhuis

Van Swietenplein 1 Van Swietenplein 1
Groningen 9728NT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 years and older
Scheduled for colonoscopy
Mentally competent
Dutch speaking, reading and writing
Approval of attending physician

Exclusion criteria

Severe comorbidity
Pregnant
Colonic stenosis
Physical limitations

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2015
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL53709.099.15