# The use of Virtual Reality for Patient Diversion during colonoscopy feasability study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

# **Summary**

### ID

NL-OMON25837

Source NTR

Brief title VR-PADI

#### **Health condition**

colonoscopy, anxiety, pain, distraction, virtual reality, feasibility coloscopie, angst, pijn, afleiding, virtual reality, haalbaarheid colonoscopy, anxiety, pain, distraction, virtual reality, feasibility coloscopie, angst, pijn, afleiding, virtual reality, haalbaarheid

### **Sponsors and support**

**Primary sponsor:** Radboud University Medical Centre **Source(s) of monetary or material Support:** fund = initiator = sponsor

### Intervention

#### **Outcome measures**

#### **Primary outcome**

Feasibility of the use of virtual reality glasses during current default colonoscopic procedures including sedation.

(patient wear virtual reality glasses whole procedure, communication with patient is not restricted, effect on combining sedation and VR)

#### Secondary outcome

- Are patients satisfied according to the type of colonoscopy? (with or without VR glasses)

- Are patients wearing VR glasses less anxious after colonoscopy compared to patients who did not wear VR glasses?

- Is the pain score of patients wearing VR glasses lower compared to the pain score of patients who did not wear VR glasses?

- Is there less need to apply additional sedation when VR is used?

# **Study description**

### **Background summary**

Colonoscopy is a highly invasive examination performed for: 1) screening, diagnosis, and sometimes treatment of colorectal cancer; 2) evaluating inflammatory bowel disease; and 3) detecting other structural lesions in the colon. In 2014, 242,900 colonoscopic procedures were performed in the Netherlands [1], and these numbers increase by the year. Due to the invasive nature of the examination, patients may experience pain and discomfort during colonoscopy [2]. Unpleasant experience with colonoscopy may cause anxiety of experiencing the same amount of unpleasantness during prospective colonoscopy, causing patients to refuse colonoscopy [3]. Sedative medication is used to relieve pain and discomfort during the procedure. Although sedative medication has positive effects on pain and discomfort, it may cause adverse effects [4].

Several studies were performed to reduce pain and discomfort during endoscopy [5-11]. These studies were focused on visual [6, 8, 11], auditory [5, 7, 11], acupunctural [10], and slow-wave photic [9] distraction, and show promising results. Lembo et al. suggested that combined visual and auditory distraction has a higher effect on reducing abdominal discomfort during flexible sigmoidoscopies compared to auditory distraction alone [11].

A technique which uses a combination of visual and auditory distraction and which is suggested to have an analgesic and relaxing effect is virtual reality (VR) [12, 13]. VR allows the user to participate in a simulated environment. The field of burn wound therapy has been the primary interest in implementing VR, since wound debridement in patients with burn wounds is a painful intervention. Several studies have shown the potential of VR in pediatric and adult burn wound patients [14-16]. In addition, a study of Furman et al. VR distraction

was used to relieve pain and unpleasantness in patients receiving dental treatment [17]. This study showed that a higher patient satisfaction was reached by procedures using VR distraction compared to procedures using auditory distraction or without any distraction at all.

Research has been performed towards the functional mechanism of action of VR in the brain. Hoffman et al. investigated the effects of VR distraction on pain related brain activity using fMRI [13]. The results show that VR distraction has positive effects on pain related brain activity in five regions associated with pain sensation, when VR is used as an additional analgesia. The results of the study of Hoffman et al. are promising for implementing VR distraction into other medical procedures, e.g. colonoscopy, to relieve procedural pain and discomfort.

Although studies have been performed to reduce pain and discomfort during endoscopic procedures. To the best of our knowledge, no studies have been performed to reduce pain and discomfort during colonoscopy using VR. Therefore, in our study we wanted to investigate the feasibility of using VR distraction during colonoscopy to reduce pain and anxiety.

### Study objective

Patients who undergo colonoscopy are subject to discomfort related to the procedure; is it feasable to enhance patient comfort with Virtual Reality glasses worn during colonoscopy?

### Study design

Questionnaires are filled out at:

Inclusion (at home)

Pre colonoscopy (in the hospital)

During colonoscopy (by the researcher)

Post colonoscopy (in the hospital)

#### Intervention

Patients wear a set of virtual reality glasses showing 360 degrees nature video's during colonoscopy

# Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

-Aged above 18

-Indication of colonscopy

### **Exclusion criteria**

-Visual and/or auditory impaired

-Dementia

-Limited Dutch language skills

-Diagnosed with balance disorders or epilepsy

# Study design

### Design

Study type:

Interventional

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Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	18-10-2016
Enrollment:	24
Туре:	Anticipated

# **Ethics review**

Positive opinion	
Date:	11-10-2016
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 NL5583 NTR-old NTR6175 Other Commissie Mensgebonden Onderzoek Nijmegen-Arnhem : 2016-2750

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# **Study results**

### Summary results

N/a