How to effectively tailor website information to older cancer patients' mode preferences : A Randomized Controlled Trial

No registrations found.

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

Summary

ID

NL-OMON26841

Source NTR

Brief title OCA-4

Health condition

Cancer, eHealth, older patients, ageing, patient-provider interaction, communication. Kanker, ouderen, patient-zorgverlener interactie, communicatie.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
 Gastro Intestinal Oncological Centre Amsterdam (GIOCA)
 University of Amsterdam
 Amsterdam
 Source(s) of monetary or material Support: Dutch Cancer Society (KWF kankerbestrijding)

Intervention

Outcome measures

Primary outcome

Distress

Secondary outcome

Communication characteristics during consultation, patients' evaluation of the communication, recall of information, perceived quality of the decision making process and quality of care

Study description

Background summary

Background

Currently, 60% of Dutch patients newly diagnosed with cancer are aged 65 years or older and the number of newly diagnosed cancer patients of this age is rapidly increasing. Due to agerelated problems, these patients are the most at-risk population for poor communication with providers. To increase the likelihood that older cancer patients experience less distress and process information optimally, it is critical to provide information in a variety of ways. Medical information is expected to be better processed by older patients when media sources (in this study a pre-visit website) are combined with interpersonal patient-provider communication. Website information can be provided in various modes, differing in format of information delivery (e.g. text, illustration, video). Furthermore, tailored information, i.e. information that is adapted to the specific mode preferences of an individual, is supposed to have a greater likelihood of reaching and affecting older cancer patients than standardized information.

Purpose

Ultimately, we aim to establish theory- and evidence-based guidance for optimal information provision to older cancer patients. The purpose of this study is to investigate the effects of exposure to a website that is tailored to colorectal cancer patients' mode preferences (offering choices between text only, text with illustrations, video or a combination of these modes) as compared to exposure to a website presenting the information in a fixed manner without offering choices, i.e. either text only, text with illustrations, or video (referred to as 'standardized information'). We particularly focus on differences between older (> 65 year) and younger (< 65 year) patients, taking into account both age and age-related factors. The primary outcome is distress. Secondary outcomes are communication during consultation (immediate endpoints); patients' evaluation of the communication and information recall

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(intermediate endpoints); perceived quality of the decision making process and quality of care (longer term endpoints).

Plan of investigation

The study will be conducted at the multidisciplinary outpatient clinic of the Gastro Intestinal Oncological Centre Amsterdam (GIOCA). A randomized controlled trial (RCT) will be carried out among patients with colorectal cancer (n = 240). Cancer patients will be randomly assigned to receive online information tailored to their mode preferences (experimental group) or similar online information presented as text only, text with illustrations or video (3 control groups) prior to their visit to GIOCA. Patients will be stratified by age (< 65 vs. > 65). Effects of type of website exposure and the mediating role of the secondary outcomes will be assessed by videorecording the consultations with physicians during patients' GIOCA visit and by asking patients to complete questionnaires before their visit to GIOCA (T1), after the first consultation with the physician (T2) and at the end of their visit to GIOCA (T3). After four weeks, patients will be interviewed by telephone (T4). In addition, website usage, website involvement and website satisfaction will be examined.

Study objective

H1: Exposure to a mode tailored website as compared to exposure to a standardized website will have a positive effect on distress before the consultation (H1a), communication characteristics during consultation (H1b), distress directly after the consultation (H1c), communication evaluation (H1d), information recall (H1e), post-visit distress (H1f), perceived quality of the decision making process (H1g) and perceived quality of care (H1h).

H2: Age and age-related differences in ability and motivation moderate the effects of exposure to a mode tailored website on distress before the consultation (H2a), communication characteristics during consultation (H2b), distress directly after the consultation (H2c), communication evaluation (H2d), information recall (H2e), post-visit distress (H2f), perceived quality of the decision making process (H2g) and perceived quality of care (H2h).

H3: The relationship between exposure to a mode tailored website and post-visit distress is mediated by distress before the consultation, communication characteristics during consultation, distress directly after the consultation, communication evaluation and information recall.

H4: The relationship between exposure to a mode tailored website and perceived quality of the decision making process (H4a) resp. perceived quality of care (H4b) is mediated by

distress before the consultation, communication characteristics during consultation, distress directly after the consultation, communication evaluation and information recall.

RQ1: Does exposure to a mode tailored website result in more website usage, more website involvement and higher website satisfaction than exposure to a standardized website with either text only, text with illustrations or video?

RQ2: What are the differences between younger (< 65) and older (> 65) cancer patients in modality choice (only experimental group), website usage, website involvement, website satisfaction (all groups) when exposed to a mode tailored website or a website with text only, text with illustrations or video?

RQ3: What is the effect of gender congruency (i.e. male participants looking at a male patient on the video and female participants looking at female patient) on website satisfaction? (only experimental and video group)

RQ4: What is the implication of modality choice (only experimental group) for the primary and secondary outcomes?

Study design

T1: Questionnaire 1 (before first consultation; including viewing the website);

T2a: Physician consultation (history taking) at the beginning of the day (videotaped);

T2b: Questionnaire 2;

T3a: Physician consultation (diagnosis and treatment plan) at the end of the day (videotaped);

T3b: Questionnaire 3-part 1 (immediately after 'GIOCA-day');

T3c: Questionnaire 3-part 2 (day after 'GIOCA-day' by phone)

T4: Questionnaire 4 (follow-up after 4 weeks by phone)

Intervention

In this randomized controlled trial (RCT), we will investigate the effects of exposure to a website that is tailored to colorectal cancer patients' mode preferences (offering choices

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between text only, text with illustrations, video or a combination of these modes) as compared to exposure to a website presenting the information in a fixed manner without offering choices, i.e. either text only, text with illustrations or video (from now on referred to as 'standardized information').

Contacts

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Eligibility criteria

Inclusion criteria

a) written informed consent; b) referred to the outpatient clinic of the Gastro Intestinal Oncological Centre Amsterdam (GIOCA) of the AMC in Amsterdam for diagnostics on colorectal cancer c) aged 18 years or older; d) sufficient command of the Dutch language; e) no cognitive impairment (e.g. dementia) according to the medical record and f) access to the Internet.

Exclusion criteria

Patient who not fulfill the exclusion criteria are excluded.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-11-2015
Enrollment:	240
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	18-06-2016
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	NL5750
NTR-old	NTR5904
Other	: UVA 2014-6700

Study results