Informing Patients about Symptom Distress

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON22417

Source

NTR

Brief title

INSTRUCT

Health condition

Patient-caregiver communication, information structuring, tailoring, empathy, hematology, malignant lymphoma, experimental video-vignettes

Sponsors and support

Primary sponsor: Department of Medical Psychology Academic Medical Center | University of Amsterdam

Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

Primary outcome of the study is participants' recall (active memory and recognition) of medical information.

Secondary outcome

Secondary outcomes include: satisfaction with the information received, physician trust, and expected symptom distress.

Study description

Background summary

Treatment-related symptoms cause patients suffering from cancer significant distress. This impairs patients' everyday functioning, sometimes even leading them to discontinue their treatment. Providing patients with information that is congruent with their needs can help them to prepare for treatment, increase their adherence, reduce their distress, and ultimately promote their recovery. Adequate information provision thus forms a crucial component of optimal cancer care. Yet, while it has been consistently shown that patients indeed value information about symptoms highly, their information needs are often not met. Hence, improving oncologists' information-giving skills is imperative. While much has been written about the importance of information provision to ensure better health outcomes, the exact pathways underlying this process remain largely unclear. To advance oncologists' information-giving skills, it must thus first be determined what optimal provision of information in fact entails.

The aim of the overall project, therefore, is twofold. First, through a series of experimental studies, the essential components of oncologists' – and, more specifically, hematologists' – adequate information provision are explored. Doing so, particular attention is paid to the ways in which doctors provide structure and tailor information to the patient's needs. Moreover, the role of doctors' display of empathy is investigated. The effects on patients' recall of information, information satisfaction, and perceived distress are of prime interest. Second, on the basis of the experimental findings, this project ultimately seeks to practically contribute to the improvement of oncologists' information-giving competence by designing and evaluating different prototypes of innovative training modules (e.g., mobile apps, elearning programs, and serious games). This is done in close collaboration with a panel of hematologists, to ensure their learning needs are met. Led by a team of psychologists, health communication researchers, education specialists, and doctors, this project thereby combines insights from medical practice with a solid, theory-driven approach to ultimately contribute to the reduction of patients' treatment-related symptom distress.

Study objective

- 1a. Providing information about expected symptom distress due to chemotherapy in a structured manner improves patients' information recall, satisfaction, and trust in the physician.
- 1b. Communicating information about expected symptom distress due to chemotherapy in an

emphatic manner improves patients' information recall, satisfaction, and trust in the physician.

1c. The hypothesized effect in 1a is strengthened when the physician communicates information about expected symptom distress due to chemotherapy in an emphatic manner (cf. 1b).

- 2a. Tailoring information about expected symptom distress due to chemotherapy to the patient's preferences improves patients' information recall, satisfaction, and trust in the physician.
- 2b. The hypothesized effect in 2a is strengthened when the physician communicates information about expected symptom distress due to chemotherapy in an emphatic manner (cf. 1b).

Study design

Participants will be asked to complete a short series of questions before the intervention (Q0) as well as after having viewed the video (Q1). Q0, video viewing, and Q1 have to be completed in one sitting.

Intervention

This experimental study consists of twelve experimental conditions, including two main streams: 4 conditions pertaining to H1 (information structuring) and 8 conditions belonging to H2 (information tailoring). Each participant is randomly assigned to one of the twelve conditions. The intervention consists of a role-played video-vignette of a consultation between a hematologist and a patient. Upon having seen the video, participants are asked to complete a series of questions concerning their perceptions, knowledge, and thoughts about the video.

In the first experimental stream, participants receive a video in which information structuring is varied (high/low) and crossed with physician empathy (high/low) in a 2x2 factorial design.

In the second experimental stream patient information preferences (high/low) are combined with information tailoring (preferences met/unmet) and subsequently crossed with physician empathy in a 2x2x2 design.

Contacts

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Eligibility criteria

Inclusion criteria

- 1. Age 18 or older;
- 2. Dutch speaking;
- 3. Having a stable internet connection

Exclusion criteria

- 1. Age under 18
- 2. Non-Dutch speaking
- 3. Internet connection problems

4. Reading/comprehension issues

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 17-10-2016

Enrollment: 420

Type: Anticipated

Ethics review

Positive opinion

Date: 03-11-2016

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 NL6022 NTR-old NTR6153

Other KWF AMCUVA 2014-6777 : AMR CJ451014

Study results

Summary results

N/A