

Pilot-Studie I: Verontrustende informatie, Psycho-fysiologie en Geheugen.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22694

Source

NTR

Health condition

Doctor-patient communication in oncology bad news consultations.

Sponsors and support

Primary sponsor: Academic Medical Center (AMC),
Amsterdam, The Netherlands

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

Intervention

Outcome measures

Primary outcome

- Psychophysiological responses: our set of physiological measures samples broadly from the electrodermal, cardiovascular system and hormonal system.

Secondary outcome

- Recall of information

- Self reported emotional distress
- Identification with the patient in the video and engagement in the video story.

Study description

Background summary

Background: Cancer patients forget on average 50% of information presented during consultations. When patients forget relevant information, they will experience unnecessary uncertainty, be less likely to act upon advice, follow treatment procedures and make well informed decisions. In bad news consultations patients' recall, their ability to remember and reproduce information, may be reduced due to the emotional distress after hearing the cancer diagnosis. Such distress can lead to psychophysiological responses, resulting in attentional narrowing. This, in turn, decreases recall for additional information, e.g., about treatment or side-effects. It is assumed that oncologists can affect patients' psychophysiological response by allowing space for the expression of patients' emotions or distress during the consultation. Thus, oncologists might improve patients' recall.

Purpose: The research protocol presented covers the PILOT study of the first out of a few proposed successive experimental studies, together making up one research project titled "Recall of information: the role of oncologists' responding to patients' distress and psychophysiological arousal. An experimental study." This research project is among the first to assess the difficult and complex relationships between information about a cancer diagnosis, psychophysiological response, oncologists' responsiveness to emotional distress, and recall. The study presented here, the PILOT of Study I (PILOT- Study I) will focus on the association between the provision of distressing information in an oncology consultation, patients' psychophysiological response and recall. The primary aim of this Pilot study is to identify the most appropriate population base for the recruitment of analogue patients for the large-scale Study I; healthy individuals or cancer patients / survivors?

Primary Research Question PILOT-Study I: To what extent are psychophysiological responses, self-reported emotional distress, recall of information and identification with the video patient influenced by analogue patients being cancer patients / cancer survivors in comparison to healthy individuals?

Plan of investigation: In PILOT-Study I, an experimental, between subjects design will be used, in which two groups of participants (analogue patients) are compared: healthy

individuals (N=20) versus cancer patients/ survivors (N=20). Analogue patients are patients or healthy individuals who watch video vignettes of a simulated consultation while putting themselves in the shoes of the video-patient. All participants will follow study procedures of Study I, involving the continuous assessment of psychophysiological responses of participants while watching a scripted video vignette of an oncologist discussing with a patient both the diagnosis of cancer and additionally the treatment thereof. Recall of information provided in the video consultation will be assessed one day later, using a structured telephone interview.

Relevance for cancer care:

Further research is needed to establish and understand the difficult and complex relationships between patients' emotions, including their psychophysiological response, oncologists' communication and patients' recall of information. Understanding these associations will contribute to theory about the mechanisms by which physician-patient communication leads to better recall. It may guide physician education and training and thus contribute to evidence based patient care. Improving patients' recall is needed as by being well informed, uncertainty can be reduced, the following of treatment procedures improved, control gained and autonomous decision making supported.

Study objective

- In an experimental video-vignette design, we expect cancer patients / survivors (in comparison to healthy individuals) to report better identification with the video patient, to report more emotional distress, to react with a greater psychophysiological response to the provision of emotional distressing information and to display worse recall of information.

- The provision of emotionally distressing information is expected to induce a psychophysiological response in analogue patients compared to baseline.

- We expect a relationship between psychophysiological responses to distressing information and recall of information.

Study design

T0: baseline measures

T1: just after watching the video

T2: one day after watching the video

Intervention

In (PILOT) Study I an experimental design will be used, involving the continuous assessment

of psychophysiological responses of a group of participants (analogue patients) while watching a scripted video vignette of an oncologist discussing with a patient both the diagnosis of cancer (Part 1) and additionally the treatment thereof (Part 2).

An individual psychophysiology baseline (cardiovascular and skin conductance) will be established using a pre-video baseline period and a post-video baseline period. Also, 5 saliva samples will be taken for cortisol analysis. Self-reported distress will be assessed before and after watching the video vignette. A manipulation check will take place after watching the video vignette (e.g. self-reported identification with the video patient, degree of engagement and fidelity of the video).

One day after viewing the video vignette, participants will be approached for a structured telephone interview to assess recall and recognition of information provided in the video consultation.

Contacts

Public

AMC Medical Research

Dep. of Medical Psychology, J3-219

Meibergdreef 9
Leonie Visser
Amsterdam 1105 AZ
The Netherlands
+31 (0) 20 56 68737

Scientific

AMC Medical Research

Dep. of Medical Psychology, J3-219

Meibergdreef 9
Leonie Visser
Amsterdam 1105 AZ
The Netherlands
+31 (0) 20 56 68737

Eligibility criteria

Inclusion criteria

Group 1 (cancer patients / -survivors)

In order to be eligible to participate in Group 1 of this pilot study, a subject must meet all of the following criteria:

- Informed consent;
- Having had cancer or being treated for cancer with a curative intent, with the exception of having (had) esophageal cancer.
- Diagnosed with cancer within a time span of 1 to 5 years ago;

Group 2 (healthy individuals)

In order to be eligible to participate in Group 2 of this pilot study, a subject must meet all of the following criteria:

- Informed consent;
- ‘Healthy’, meaning:
 - Never having had cancer
 - Currently not visiting any medical specialist for another serious medical condition (e.g. COPD, colon diseases, etc.)

Exclusion criteria

Subjects are not eligible if one or more of the following criteria apply:

- Those who suffer from cardiovascular disease and/or hypertension (to prevent interference with psycho-physiological measurements);
- Those who suffer from an endocrine disorder, e.g. diabetes mellitus (to prevent interference with cortisol measures);
- Smoking > 20 cigarettes per week (to prevent interference with cortisol measures);
- No current use of corticosteroid containing medication, including ointments (to prevent interference with cortisol measures);
- Subjects who are not literate in Dutch;
- Subjects who have an uncorrectable hearing or vision problem;

-Age < 18 years

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-12-2013

Enrollment: 40

Type: Anticipated

Ethics review

Positive opinion

Date: 15-11-2013

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	NL4050
NTR-old	NTR4266
Other	KWF / NL44134.018.13 : AMC Medical Research
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A