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

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- 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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22694

Bron
NTR

Aandoening

Doctor-patient communication in oncology bad news consultations.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC),
Amsterdam, The Netherlands
Overige ondersteuning: Dutch Cancer Society (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

T0: baseline measures

T1: just after watching the video

T2: one day after watching the video

Onderzoeksproduct en/of interventie

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 taking 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4050
NTR-old	NTR4266
Ander register	KWF / NL44134.018.13 : AMC Medical Research
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A