The therapeutic effects of physicians' communication style on patients' outcomes.

No registrations found.

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

Summary

ID

NL-OMON23778

Source
NTR

Health condition

This study does not relate to a specific health condition. The subject of the simulation is menstrual pain, but the research relates to the methodology. To assess the effect of different types of communication, healthy women acting as analogue patients are included and randomly assiged to one of the four scripted video-taped consultations.

Sponsors and support

Primary sponsor: Prof. dr. J.M. Bensing
PO Box 1568,
3500 BN Utrecht, The Netherlands.
E: j.bensing@nivel.nl
T: +31 30 2729666
Source(s) of monetary or material Support: This project was funded by the Spinoza Prize awarded to Prof. dr. J. M. Bensing, PhD by the Dutch Research Counsel (NWO). The NWO was not involved in the research process.

Intervention

Outcome measures

Primary outcome

The study's primary parameters are affective, physiological (phase I only) and cognitive responses measured as state anxiety, and outcome expectations about the simulated illness in the interview. The study endpoint is the concordance of these measures between 1) subjects participating in the interview and subjects re-viewing their own interview and 2) between subjects participating in an interview and other participants (not participating in any interview) viewing interviews of others.

Secondary outcome

Secondary study parameters are heart rate, positive and negative affect and illness perceptions about the simulated
illness in the interview. Demographic variables, health status, trust in healthcare, communication preferences and
empathic ability will be measured as control variables.

Study description

Background summary

Communication between provider and patient is an essential element of medical care with regard to patient outcomes. To assess causal relationship between specified elements in providers' communication and patient outcomes, controlled experiments are needed. One method is to use analogue patients, in which lay people are asked to watch a video consultation and identify with the video patient. However, the validity should yet be established. This study aims to assess whether the 'analogue patient paradigm' is a valid methodology to assess the specific effects of providers' communication on patient outcomes. Therefore, a two-phase partly observational, partly experimental study with a mixed within- and between subjects design will be conducted. In phase I, 30 healthy subjects will participate in a role-played interaction with an interviewer to simulate a medical consultation and subsequently watch their own conversation on video. In phase II, four videos from Phase I will be selected which differ in physician's communication style (showing affect and raising expectations). In a 2x2 experimental design, 320 subjects will watch randomly one out of the four video consultations. In both phases before and after the video-viewing several psychological and physiological (phase I only) will be taken.

Study objective

The overall goal of this study is to test if the analogue patient paradigm is a valid method to assess the effects of physician-patient communication. More specifically, in Phase I, we aim

to test if viewing a role-played interview about a common medical problem on video leads to comparable psychological and physiological responses as participating in this role-played consultation. If this is indeed the case, it provides support for testing the effects of different communication styles in medical interaction in a rigorous experimental design where the actual interaction process can be replaced by a video of interaction. The objective of Phase II is to test whether this so-called ‘analogue patient paradigm’ is a reliable and valid method to test the effects of different types of communication on subjects’ outcome measures.

Study design

Participants have to fill in a questionnaire at home aimed to assess their background characteristics. Before the experiment (Timepoint 0), background characteristics are assessed and participants' affective and cognitive responses are measured (resp. using the PANAS and STAI-state, and the IPQ-R). Then participants are randomly allocated to one of the four video consultations. After having seen the video (Timepoint I) participants again complete the PANAS, STAI-S and IPQ-R, and also the QUOTE-COM and CARE to asses communication preferences.

Intervention

A two-phase partly observational, partly experimental study with a mixed within- and between subjects design. In
phase I, 30 healthy subjects will participate in a role-played interaction with an interviewer to simulate a medical
consultation and subsequently watch their own conversation on video. In phase II, four videos from Phase I will be
slected which differ in physician's communication style (showing affect and raising expectations). In a 2x2 experimental design, 320 subjects will randomly watch one out of the four video consultations. In both phases before and after the video-viewing several psychological and physiological (phase I only) will be taken.

Contacts

Public
PO Box 1568
M. Osch, van
Utrecht 3500 BN
The Netherlands
+31 (0)30 2729632
Scientific
PO Box 1568
M. Osch, van
Utrecht 3500 BN
The Netherlands

+31 (0)30 2729632

Eligibility criteria

Inclusion criteria

1. Being a women between 18-45 years with sufficient command of Dutch language;

2. Experience with period pain (at least once in the last six months).

Exclusion criteria

1. Not in the range between 18-45 years;

2. Inability to have an unaided Dutch conversation;

3. No experience with period pain.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	320
Type:	Actual

Ethics review

Positive opinion

Date:	25-03-2013
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	NL3758
NTR-old	NTR3922
Other	METC UU : 08-292/O
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A