Watching a video of a medical consultation versus participating in a medical consultation: are effects on subjects comparable?

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To test if the *analogue patient paradigm* is a suitable methodology to assess effects of communication on patient outcomes. More specifically we aim to test if watching a video of a simulated consultation on a common medical problem leads to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38144

Source
ToetsingOnline

Brief title
Watching video versus participating in a medical consultation

Condition

- Other condition

Synonym
nvt

Health condition

Het onderzoek heeft geen betrekkinig op een specifieke aandoening. Het onderwerp van de simulatie is menstruatiepijn, maar het onderzoek heeft betrekking op de methodologie.

Research involving
Human

Sponsors and support

Primary sponsor: NIVEL
Source(s) of monetary or material Support: NWO Spinoza premie aan Prof. dr. Jozien Bensing

Intervention

Keyword: analogue patient, communication, health care

Outcome measures

Primary outcome

The study's primary parameters are affective, physiological and cognitive responses measured as state anxiety, psycho-physiological arousal as measured with skin conductance responses and outcome expectations about the 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

Research shows that communication is an important element of medical care with regard to patient outcomes. To assess causal relationships between specified elements in communication and outcomes, strictly controlled experiments are needed. Manipulating communication in real consultations can be ethically unsound, because of burdening patients with research procedures during their care or by exposing patients to unpleasant or possible iatrogenic communication. Furthermore, the interaction between physicians and patients is hard to control, due to its dynamic nature. This complicates studying the effects of specified communicative behaviors. This can be bypassed by not assessing the effects of communication in subjects directly, but by showing a video of a standardized consultation to subjects instead. This is called the *analogue patient paradigm* in which the viewer is the analogue patient. While there is substantive evidence that watching situations (on pictures or in films) evokes the same type of empathic reactions in viewers as participating in those situations, it is not clear if the comparability is large enough to warrant replacing subjects participating in interaction by *analogue subjects* watching a video of that interaction when testing the effects of different types of communication styles. If the validity of the analogue patient methodology proves warranted in healthy subjects, it offers a design with ethical and methodological advantages for researching the effects of medical communication on patient outcomes.

Study objective

To test if the *analogue patient paradigm* is a suitable methodology to assess effects of communication on patient outcomes. More specifically we aim to test if watching a video of a simulated consultation on a common medical problem leads to comparable affective, cogntive and physiological responses in subjects as when they are really participating in this role-played consultation. 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

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 watch randomly one out of the four video consultations. In both phases before and after the video-viewing several psychological and pysiological (phase I only) will be taken.

Study burden and risks

Participants have to fill in a questionnaire at home (half hour) and either role-play a medical consultation and watch this consultation on video (phase I) and subjects (not participating in a role-played interview) will view one out of the four video consultations selected from Phase I (phase II) and fill in some questionnaires (half hour). Throughout Phase I, skin conductance and heart rate are non-invasively measured (three hours). There are no risks associated with participation. Patients receive no medical treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants have to be women with an age between 18 and 45.

Exclusion criteria

Inability to have an unaided conversation in Dutch
Knowing the interviewer who performs the simulated medical consultation
No experience at all with menstrual pain

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2009
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	04-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL24672.041.08