# 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**

#### **Public**

**NIVEL** 

Otterstraat 118-124 Utrecht 3513 CR NL **Scientific** 

NIVEL

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## **Trial sites**

## **Listed location countries**

**Netherlands** 

## **Eligibility criteria**

#### Age

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

4 - Watching a video of a medical consultation versus participating in a medical con ... 3-05-2025

## 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