

# Developing an experimental paradigm for assessing the effects of physician-patient communication on patients\* health status

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To test if viewing a medical consultation on video leads to comparable psychological and physiological responses to the communication as being a patient in that consultation.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Therapeutic and nontherapeutic effects (excl toxicity)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31862

### Source

ToetsingOnline

### Brief title

Assessing the effects of physician-patient communication

### Condition

- Therapeutic and nontherapeutic effects (excl toxicity)

### Synonym

pain

### Research involving

Human

### Sponsors and support

**Primary sponsor:** NIVEL

**Source(s) of monetary or material Support:** NWO Spiniza premie aan prof.dr. Jozien

Bensing

## Intervention

**Keyword:** communication, context effect, health, physician-patient relationship

## Outcome measures

### Primary outcome

Main study parameters are the correlations of skin conductance responses, heart rate, positive and negative affect and state anxiety between subjects in a consultation and subjects viewing a consultation.

### Secondary outcome

The correlations of observed physician communication between subjects in a consultation and subjects viewing a consultation.

## Study description

### Background summary

An important issue in measuring the effect of communication is that a clinical consultation is an iterative process of reciprocal interactions constantly influenced by the physician and the patient. This complicates studying the effects of specified communicative behaviors, since patient behavior can not be controlled in the experiments. This can be bypassed by not assessing the effects of communication directly in the patients in the consultation, but instead show a video of a consultation to subjects. This is called the \*analogue patient paradigm\* in which the viewer is the analogue patient. However, it is not clear to which extent the responses to the communication of analogue patients is comparable to the responses of patients actually present in the consultation.

### Study objective

To test if viewing a medical consultation on video leads to comparable psychological and physiological responses to the communication as being a patient in that consultation.

## Study design

A randomized controlled experiment with a mixed between subjects and within subjects design.

## Intervention

There are five groups in which physician communication style is varied in consultations, consequently subjects see their own videos and the videos of other subjects.

## Study burden and risks

Patients have to fill in a questionnaires, take part in a consultation with a physician and talk about menstrual complaints while skin conductance and heart rate are measured, and view videos of these consultations while skin conductance are measured. There are no risks associated with participation. Patients receive no medical treatment.

## Contacts

### Public

NIVEL

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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)

### Inclusion criteria

Female, age over 18, menstruating, experience with menstrual pain.

### Exclusion criteria

Psychiatric disorders, inability to have an unaided conversation in Dutch, serious comorbidity, knowing the physician administering the intervention, being a patient of the general practice where the study is carried out.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	46
Type:	Anticipated

## Ethics review

Not approved  
Date: 22-04-2008  
Application type: First submission  
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	NL22576.041.08
Other	nog niet bekend