The Neurobiological Basis of the Patient-Practitioner Interaction: A PET Proof of Principle Study

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To measure the impact of the two opposite communication styles (warm, empathic and cold, formal) on the neurophysiological changes (endogenous dopamine release) in the human brain using positron emission tomography (PET) neuroimaging. This is an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON37330

Source
ToetsingOnline

Brief title
PET study of the patient-practitioner interaction

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
menstruation pain/period pains

Research involving
Human

Sponsors and support

Primary sponsor: NIVEL
Source(s) of monetary or material Support: Spinoza-premie toegekend aan prof.dr. J.M. Bensing

Intervention

Keyword: communication, dopamine, patient-practioner, PET

Outcome measures

Primary outcome

Main outcome parameter is the change in binding potential of [11C]-raclopride

in the nucleus accumbens (NAC) as an indication of endogenous dopamine release.

Secondary outcome

Secondary outcome parameters are affective (state anxiety, positive and

negative affect states), cognitive (outcome expectations, illness perceptions)

and physiological responses (skin conductance, heart rate).

Study description

Background summary

Recent advances within the field of placebo effect research have demonstrated that the patient-practitioner interaction is an important component in the generation of these multi-facetted neuropsychobiological effects. The neurotransmitters dopamine and opioids have been established as the neural substrates involved affecting the psychological mechanisms of expectancy, reward and motivation, and it is these mechanisms which are inherently involved in patient-practitioner communication. Research has shown that certain aspects of the patient-practitioner communication, such as physician empathy, are important elements of medical care with regard to patient outcomes. A warm, empathic, interaction in which a positive outcome is voiced influences patients* expectancies and outcomes in a positive way; a cold, unempathic interaction in which an uncertain outcome is voiced negatively impacts patients* expectancies and outcomes. These two different communication styles have also been found to have a direct influence on physiological correlates of skin conductance and heart rate. However, the impact of these two communication styles on neurotransmitter release in the brain regions involved with expectancy, reward and motivation has not been explored.

Study objective

To measure the impact of the two opposite communication styles (warm, empathic and cold, formal) on the neurophysiological changes (endogenous dopamine release) in the human brain using positron emission tomography (PET) neuroimaging. This is an extension of our recent findings of affective- and expectancy-oriented communication effects on analogue patients.

Study design

This proof of principle study uses a between subject design. In the recruitment, screening and selection phase, interested participants (N>=36) fill in a battery of psychological tests. On the basis of these, the twelve with the highest interpersonal reactivity index (empathy) rating and menstrual pain experience will be invited to participate in the PET scanning experiment. Each volunteer (N=12) undergoes one PET scan using [11C]-raclopride as radiotracer. During the PET scan, volunteers act as analogue patients and view a one-minute video clip consultation of a general practitioner (N=6 cold, formal communication style; N=6 warm, empathic communication style; random assignment). The volunteers will be instructed to imagine that they are the female patient in the video. On a separate day prior to the PET scan, each subject with be required to undergo an MRI scan to establish brain anatomy coordinates.

Intervention

During a PET scan, participants will watch a video of a physician communicating in an empathic and positive way or watching a video of a physician communicating in an non-empathic way voicing uncertain outcome expectations.

Study burden and risks

In the recruitment, screening and selection section interested participants have to complete questionnaires. There are no risks associated with participation for this. The MRI and PET scans are to be carried out at the Department of Nuclear Medicine & PET research of the VU Medical Center (VUmc). The risks associated with PET scanning are limited, but the subjects will receive tracer doses of radiation, which is estimated at 4 milli-Sievert (mSv) (so less then 10 mSv). Minimal risks are associated with MRI acquisition.

No immediate benefits are to be expected for the individuals participating in this study. No medical treatment is given.

Contacts

Public

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

Women between 18 and 45 years of age, who have experienced sufficient menstrual pain (>=40% of maximum imaginable pain on a VAS intensity of pain scale) within the last six months.
Have regular menstrual cycles
Highest empathic scores from the screening and recruitment process (i.e. in highest tertile)

Exclusion criteria

Inability to have an unaided conversation in Dutch
Any neurological disorder
Claustrophobia
Metal objects in or around the body (braces, pacemaker, metal fragments)
Pregnancy, or possibility that the volunteer could be pregnant
Any earlier exposure to radiation in a study as a healthy volunteer leading to cumulative dose of 10 mSv or more.

Pharmacological treatment with dopamine antagonists
Smokers (exclusion from the PET scan section)

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2012
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	26-04-2012
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
Other	1263
CCMO	NL38364.041.11