The role of the brain in the development of vaginistic complaints

Published: 20-07-2009
Last updated: 05-05-2024

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

Summary

ID

NL-OMON33046

Source
ToetsingOnline

Brief title
Disgust and Vaginismus

Condition

- Other condition

Synonym
vaginismus

Health condition

Sexual dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: disgust, fMRI, Sexual Dysfunction, Vaginismus

Outcome measures

Primary outcome

Main study parameters are signal change in bold responses to emotion, in relation to the presented pictures on the four domains (i.e. fear; disgust; coitus and neutral), to the groups (healthy, dysparuenia, vaginismus), and to stimulus domain x group interaction.

Secondary outcome

Behavioural and physiological differences between groups and their relation to the measured BOLD response.

Study description

Background summary

In this project, we will look closely at two distinct areas of interest; disgust and sexual dysfunction (SD), together with the interaction between them. Despite the intuitive connection, this did not necessarily reflect itself in literature. Nevertheless, human sexuality is currently on the forefront of women*s health issues, as SD may have a serious negative impact on relationships and overall emotional well-being across different life stages. If left untreated, SD could cause silent suffering and raw emotional pain. Our principal emotion of interest, disgust, is also a recently growing formulation in its own right after being labeled as the *forgotten emotion of psychiatry* .

Study objective

The aim of the proposed research is to test the hypothesis that the potential role of disgust propensity and/or sensitivity in a group of patients with vaginismus is enhanced compared to dyspareunia and healthy control subjects. This fMRI study, together with rather comprehensive behavioural and physiological measures will be used to investigate implicit and explicit responses. This will direct us, to better locate areas of disgust in the brain. We anticipate that in this study automatic associations (AA) of sexual-disgust could be more accessible providing more information on disgust-induced-defensive-behaviour (DIDB). Utilizing fMRI techniques, the proposed study aims to evaluate the key patterns of brain activation, therefore the neural substrate associated with sexual, fearful, neutral and disgusting stimuli in female subjects with vaginismus, dyspareunia and in a healthy control group.

Study design

In this study a total of 60 subjects will participate, 20 subjects per group. Subjects will be asked to fill in ten questionnaires and a subjective picture rating post fMRI experiment. Whilst lying in the fMRI scanner subjects will be presented with a number of pictures (in a block design) and will have psycho-physiological measures and a visual analogue scale to rate pictures between the blocks of stimuli presented.

Study burden and risks

Subjects will be exposed to a magnetic field of 3 Tesla and rapidly alternating magnet gradients and radio frequency fields. This field strength is used on a routinely basis in fMRI and MRI research. So far, no side effects have been described. On rare occasions, a peripheral nerve (abdomen) is stimulated by the changing magnet gradients. This will cause an itching feeling, but it is not harmful. Therefore, the participating subjects will have minimal to negligible burden due to the nature of the study itself (e.g. staying in the scanner for half an hour). However, subjects will be given comprehensive information about the study, prior signing the informed consent and full freedom to withdraw from the study at any point and for any reason, if they wish to do so. Subjects will be screened whether they are fMRI safe twice; therefore, risks are further minimized. Moreover, they will be offered the option to contact the independent physician for further questions or concerns that they might have generated throughout the study.

The study population shall be composed of two clinical groups, in addition to a control (healthy) group. This study cannot be conducted with a diverse population sample. Our planned research is relevant in the fields of clinical psychopathology and experimental psychotherapy. This study aims at filling in theoretical gaps in the arena of SD and disgust and how these are represented in the brain. To our knowledge, this is the first study of its kind, and it

should offer hands-on applications of the findings in a variety of areas. The findings of this study will aim to aid in the refinement of the current available treatment for females inflicted with vaginismus.

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

FMRI safe
Over 18 years of age
Females

Exclusion criteria

drug abuse
pregnancy
non fMRI safe
Please for a detailed list of the inclusion and exclusion criteria see protocol section c of the dossier

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL27361.042.09