Central mechanisms of ejaculatory dysfunction: a multi-modal fMRI investigation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Interventional

Summary

ID

NL-OMON39680

Source
ToetsingOnline

Brief title
Central mechanisms of ejaculatory dysfunction

Condition

- Sexual dysfunctions, disturbances and gender identity disorders
- Sexual function and fertility disorders

Synonym
ejaculatory dysfunction, premature and delayed ejaculation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: European Society for Sexual Medicine (non-

profit)

Intervention

Keyword: fMRI, premature ejaculation, retarded ejaculation, white matter

Outcome measures

Primary outcome

Main study parameters are changes in brain (so-called BOLD) responses to penis stimulation and pelvic floor contraction, and structural brain information about white matter density (so-called fractional anisotropy, FA) provided by the DTI scans.

Secondary outcome

Secondary study parameters/endpoints: Behavioural and genetic differences between groups and their relation to the measured BOLD response and white matter signal.

Study description

Background summary

Extremes in the duration of the intravaginal ejaculation latency time (IELT) may give rise to subjective complaints of ejaculatory dysfunction, e.g. premature ejaculation (PE) or retarded ejaculation (RE). These problems are prevalent in the male population, and cause considerable distress. Given the well-established link between men*s sexual and general health, and in consideration of the fact that sexual health may be an important contributor to healthy ageing, it would be important to get to the heart of sexual dysfunctions like those that affect ejaculatory/climacteric behaviors.

The brain is the primary suspect in ejaculatory problems as the genitalia seem to function normally in these conditions. Experimental neurobiological investigations in rodent models have focused heavily on subcortical circuitry as the primary mediator of the IELT, but this may only partly be relevant for the human situation where the role of phylogenetically more recently developed

brain structures, like the cerebral cortex, is likely to be important for the control of sexual behavior. Critically, we have highly promising pilot fMRI data suggesting that the integrity of the corticospinal tract close to the genital/pelvic part of the primary sensorymotor cortex may modulate the human IELT. In this project, we will therefore look more closely at the higher brain mechanisms that control the IELT.

Our planned research is very relevant in the field of sexual medicine. Current treatment strategies for ejaculatory dysfunction, like anti-depressants, are suboptimal, and the treatment regime is not always tolerated because of adverse side-effects.

Study objective

The aim of the proposed research is to assess, using multimodal fMRI, both functional (BOLD responses) and structural (white matter) cerebral characteristics of the human IELT. In turn, this could provide specific novel (neocortical) targets in the brain, , through which treatment could be refined. The latter is important as ejaculatory dysfunctions are often treated with anti-depressants, which may have considerable side effects.

Study design

The research we propose is minimally invasive observational research. It consists of two stages:
Stage 1 is a thorough sexual medical assessment/screening, including filling out questionnaires, giving blood and saliva, and an interview with a sexologist.

Stage 2 is an fMRI experiment aimed at uncovering both structural and functional central characteristics of the IELT. In the functional part of the fMRI experiment subjects will receive (non-erotic) penis stimulation and will be asked to contract their pelvic floor muscles. The structural scans will not involve any task. The male subject's female partner will perform the necessary penis stimulations.

Intervention

The intervention entails mild stimulation of the glans penis. Stimulation will occur in a standardized way, and is not aimed to induce feelings of sexual arousal in he subject. Stimulations will be executed by the female partners of the subjects.

Study burden and risks

Most subjects will pay two visits to the UMCG. The first visit, the sexual

medical assessment, will take about one hour. Subjects give a small amount blood, which may be slightly uncomfortable.

The second visit is for the fMRI experiment. 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 an hour). Including questionnaires that should be filled in prior to the experiment, and a post-fMRI psychological task, the total duration of the second visit will amount to approximately two hours.

Female partners only participate in the fMRI experiment, that is, they assist in the fMRI task (penis stimulation).

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

General inclusion criteria (Male Subject: M / Female Partner: F)
• 18 years or older (but not over 65): M+F
• Involved in a sexual relationship for at least six months: M+F
• Signed informed consent: M+F
• Cooperative, able to follow instructions: M+F
• capable of lying still: M
• Normal hand function: F
• Heterosexual: M ;Subject inclusion for phase 2 (fMRI experiment) on basis of sexological assessment
• Men with IELT < 30s & significant subjective complaints (assigned to PE group)
• Men with IELT > 15 min & significant subjective complaints (assigned to RE group)
• Men with IELT 2-6 min & no significant complaints (assigned to Healthy group)
• Free plasma testosterone within normal range (12-26 nmol/l)
• No history of sexual abuse

Exclusion criteria

General exclusion criteria (Male Subject: M / Female Partner: F)
• MRI contraindications (specified for M and F in separate questionnaire)
• outside normal range on personality questionnaire: M+F
• Any psychiatric, somatic or neurological disorders which may affect the Central Nervous System or influence study outcome: M
• Claustrophobia, or difficulty in having head restrained: M
• Poor motor control, or any condition that interferes with precise hand movements: F
• Receiving treatment for ejaculatory complaints: M
• Penile circumcision: M
• Pregnancy or the possibility to be pregnant: F;Criteria leading to exclusion on the day of the fMRI experiment
• When subjects report to have ejaculated in the 24hr prior to the fMRI experiment
• When subjects report recreative drug intake (e.g. cocaine, marihuana, ecstacy) in the last two weeks prior to the fMRI experiment
• When subjects report alcohol intake in the 24hr prior to the fMRI experiment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2012
Enrollment:	164
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-05-2014
Application type:	Amendment
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	NL36439.042.11