

Board of examiners

Prof. Jacques Van Lankveld

Faculteit Psychologie en Onderwijswetenschappen
Open Universiteit, Nederland

Prof. Frank Buntinx

Academisch Centrum voor Huisartsgeneeskunde
Katholieke Universiteit Leuven

Prof. Wim Van Den Noortgate

Faculteit Psychologie en Pedagogische Wetenschappen
Katholieke Universiteit Leuven

Prof. Filip Cools

Neonatologie UZ Brussel
Vrije Universiteit Brussel

Prof. Hendrik Cammu

Gynaecologie-urologie UZ Brussel
Vrije Universiteit Brussel

Prof. Michel Deneyer, Chair

Pediatrie UZ Brussel
Vrije Universiteit Brussel

Prof. Dirk Devroey, promotor

Vakgroep Huisartsgeneeskunde en Chronische Zorg
Vrije Universiteit Brussel

PhD in Medical Sciences
2015-2016

INVITATION to the Public defence of

Frederik FEYS

To obtain the academic degree of '**DOCTOR IN MEDICAL SCIENCES**'

The Placebo Effect in Sexual Medicine: Methodological Aspects in Randomized Clinical Trials

Tuesday 24 November 2015

Auditorium **1**, 17:00

Faculty of Medicine and Pharmacy, Laarbeeklaan 103, 1090 Brussel

How to reach the campus Jette:

<http://www.vub.ac.be/english/infoabout/campuses>



Vrije Universiteit Brussel

Summary of the dissertation

Medication side-effects can unblind randomized clinical trials (RCTs) that may result in misleading treatment effect estimates. Enhanced intervention blinding of people participating in a study can be achieved by using active placebo's, a placebo that mimics side-effects of the intervention. In the realm of sexual medicine, we found that such blinding-enhanced controlled RCTs for erection pills are absent. We also found a consistent failure to report on study blinding in journal publications. Clearly, the blinding efforts for almost all trials remain unclear. Our study found no conclusive evidence that unblinding leads to underestimating placebo effects or to the overestimation for intervention effects. Secondary analyses provided evidence that prior experience with the intervention substantially lowered placebo scores. It may be that participants with prior experience determine their allocation to placebo more efficiently and consequently engender lower expectancies as to their benefits. After critical appraisal of the blinding status in studies for an ejaculation-delaying pill (dapoxetine), we found no evidence that dapoxetine is more effective than placebo. Dapoxetine comes with harmful effects. We found evidence that participants using dapoxetine have a higher risk of experiencing nausea, headache, dizziness or diarrhoea. One in five participants discontinued dapoxetine. The blinding adequacy of almost all the studies remained unknown. The methodology used in most studies was problematic due to incomplete data reporting, conflict of interests and selective reporting. We conclude that methodological rigour in the conduct and reporting of RCTs is especially imperative for those health conditions that are evaluated subjectively, such as depression, erectile dysfunction, low back pain, and other symptom driven complaints.

Curriculum Vitae

Frederik Feys graduated as a dentist in 1997. He studied medicine for several years and holds a master's degree in family and sexological sciences (2002). Early on, he became fascinated by the placebo effect. Through the use of suggestion he treated very anxious dental patients. Also, he felt the need to overview all available therapies. He would then opt for the best possible treatment. The desire for more efficiency in clinical practice led to the development of software for the dentist, FileDent. He also assisted on a medical decision system, ProMedes, a project of Kluwer Editorial.

In the clinical field he has been working since 12 years as a sex- and couple therapist. He applies the principles of autosuggestion in the form of self-help. He loves knowledge that can flow freely. Therefore he started a blog, gave interviews for radio, newspaper and television. He democratizes knowledge through the use of an open science paradigm. All work with datasets is available to anyone, supporting scientific innovation.

His mission is to further explore how we can openly use the 'vehicle' behind the powerful placebo effect. So that clinicians will be able to incorporate such effects in treatment decisions and patient counselling information. Ultimately improving the health and wellbeing of people.