# Validation of the Dutch version of the International Index of Erectile Function (IIEF) in patients with erectile dysfunction and controls

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The present study is designed to validate the Dutch IIEF. The psychometric properties of the Dutch version of the IIEF will be investigated.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Sexual function and fertility disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON38309

**Source**
ToetsingOnline

**Brief title**
IIEFVALIDATION

### Condition

- Sexual function and fertility disorders

**Synonym**
Erectile dysfunction, Impotence

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** erectile dysfunction, IIEF, questionnaire, validation

## Outcome measures

### Primary outcome

The present study is a validation study. The primary outcome of this study is validation of the Dutch IIEF. The psychometric properties of the Dutch version of the IIEF will be investigated.

### Secondary outcome

A secundary outcome is better validation of studymaterial en medical information thanks to a proven validated questionnaire. This validation study will help to get more certainty about accuracy of data collected during studies with the Dutch IIEF-15.

# Study description

### Background summary

Erectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. Erectile dysfunction is a fairly common disorder with a great impact on several aspects of quality of life. In the Netherlands the prevalence of erectile dysfunction lies between 10 and 27% in men of all ages. Prevalence of ED rises with age. As a result of the aging baby-boom population, prevalence of ED in western countries will rise. It is estimated that in 2025 worldwide around 322 million men will have ED to some extent. Treatment with PDE5-inhibitors is available for ED and widely used.
ED can be a result of other conditions such as cardiovascular disease, hypertension, hyperlipidaemia, diabetes mellitus and depression. Therefore ED can be a possible marker for this conditions, which makes it important to diagnose ED. ED can be diagnosed with different diagnostic instruments, the simplest is with self-report questionnaires. The International Index of Erectile Function (IIEF) is a 15-item self-administered questionnaire developed by Rosen et al. as a brief and reliable measure of erectile function. The 15

items differentiate five domains of male sexual function (erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction).
The IIEF was developed for use by clinicians and researchers.
Different studies are done to validate the IIEF in Portuguese, Urdu, Malay and German. It is remarkable that despite the fact that the IIEF is broadly used both in clinical and research settings in the Netherlands, different versions of the Dutch IIEF circulate. Moreover, a Dutch version was never validated. Therefore this validation study will be performed. The present study is designed to investigate the psychometric properties of the Dutch version of the IIEF-15.

**Study objective**

The present study is designed to validate the Dutch IIEF. The psychometric properties of the Dutch version of the IIEF will be investigated.

**Study design**

We will perform an anonymous, case-control study. Patients with ED will be recruited in the outpatient clinic of the department of urology of the LUMC. Men coming with ED for explanation of a Nocturnal Penile Tumescence test (NPT) will receive a questionnaire as part of the normal protocol to fill in during this visit. At the end of this visit they will receive a second questionnaire, which is an additional action, necessary for this study to measure test-retest repeatability. Participants will be asked to fill in this second questionnaire 3 weeks after their visit and return it by mail in the distributed freepost return envelope.
To constitute a control group, the male partners of sexually active women consulting a urologist in our clinic will be asked to participate in the study and will receive the patient information form. The urologist will provide the questionnaire with an identification code.

**Study burden and risks**

Participants will fill in the questionnaire (IIEF-15) twice. This is a 15-item self-administered questionnaire developed as a brief and reliable measure of erectile function. This questionnaire contains questions about sexuality, an intimate subject. The burden associated with participation however will be low because participants voluntere to participate in the study. There are no risks associated with participation.

# 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

Criteria for inclusion are:
- heterosexual men
- at least one attempt of sexual intercourse over the last 4 weeks
- speak and understand the Dutch language.

## Exclusion criteria

Criteria for exclusion are:
- Use PDE5 inhibitors
- Men under 18 years of age
- Not able to speak and understand the Dutch language

- No sexual activity over the last 4 weeks
- Not heterosexual

# Study design

## Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-04-2015 |
| Enrollment: | 80 |
| Type: | Actual |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 12-03-2014 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 | NL46878.058.13 |