

# Evaluation of information needs regarding sexuality after stoma surgery: a cross sectional study in patients and their partners

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON47779

### Source

ToetsingOnline

### Brief title

SPIIN: Stoma patients intimacy information needs

### Condition

- Sexual function and fertility disorders

### Synonym

ostomy, Stoma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Urologie

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Information needs, Relationship, Sexual health, Stoma

## Outcome measures

### Primary outcome

- To obtain an insight in the needs and perspectives of patients with a stoma on sexual health care provided by care providers.

### Secondary outcome

- To determine patients\* point of view on which care provider should be accountable for providing sexual healthcare
- To determine patients\* point of view on type and timing of sexual health care
- To collect information on partner\* perspective and opinions on sexual health care provided by care providers.
- To collect information on the influence of having a stoma, sexual dysfunction, and treatment on relationships
- To collect information on partners\* potential caregiving concerns and productivity loss

## Study description

### Background summary

Patients who underwent stoma surgery, for any reason, often experience difficulties with intimacy and sexuality. At the same time, intimacy and sexuality remain difficult subject to discuss by health care providers. Little is known on the current format of sexual and intimacy care for stoma patients and their partners. It isn't clear if stoma patients and, if applicable, their partners receive enough information about the possible changes. To deliver

optimal care, patients\* need and perspective on health care regarding sexuality and intimacy are needed. In addition, little is known about the impact of stoma surgery on the relationship between patient and partner and how these factors impact partner' wellbeing.

## **Study objective**

The aim of our study will be to evaluate the perspective of patients with a stoma on sexual and intimacy health care currently provided by care providers. Furthermore, we will identify patients\* wishes and views upon this important part of oncology health care and the impact of a stoma and SD (sexual dysfunction) on relationships. Partners will be included as they suffer from the effects of a stoma on patients\* wellbeing and sexuality as well.

## **Study design**

Data for this cross-sectional survey will be collected among patients who underwent stoma surgery in the past 6 - 24months at Leiden University Medical Center and Haaglanden Medical Center. Two different questionnaires will be used; one evaluating patients\* perspective and one evaluating the perspective of the partners. Structure and design of these questionnaires were derived from questionnaires used in previous studies performed by our research institute. These questionnaires were designed to evaluate sexual health care and impact of disease, sexual dysfunction, and treatment on relationships. Data will be processed and analysed anonymously.

## **Study burden and risks**

Patients will receive an information letter by post, explaining the objectives of the study. An informed consent form will be added with this letter. Participation can be considerate at home, without any haste. If consent is provided, a questionnaire will be send to the respondents. It concerns a patient (and partner) survey with sensitive questions

## **Contacts**

### **Public**

Selecteer

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### **Scientific**

Selecteer

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- Patients who underwent stoma surgery in the past 6 \* 24 months at LUMC and HMC
- Partners, if applicable, of patients who underwent stoma surgery in the past 6 \* 24 months at LUMC and HMC
- Age older than 18 years
- Patients and/or partners must consent in order to be included in the study
- Ability to understand a questionnaire in Dutch

### **Exclusion criteria**

- Patients who are mentally incompetent to give informed consent
- Age under 18
- Patients who passed away
- Patients who moved abroad

## **Study design**

## Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 28-09-2017

Enrollment: 400

Type: Actual

## Ethics review

Approved WMO

Date: 17-07-2017

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 15-02-2018

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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	NL61663.058.17