

# Optimizing perioperative care for gynaecological patients.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21213

### Source

NTR

### Health condition

- hysterectomy
- laparoscopic adnexal surgery

## Sponsors and support

**Primary sponsor:** VU University Medical Center

EMGO Institute

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

1. Return to work (RTW);
2. Recovery Specific Quality of Life (RS-QoL).

### Secondary outcome

1. Cost-effectiveness;
2. Patient satisfaction.

## Study description

### Background summary

Resumption of work activities after gynaecological surgeries takes much longer than expected, irrespective of surgical technique and level of invasiveness. Considering the high costs of sick leave and the adverse consequences of sick leave for employees in combination with the high number of gynaecological procedures performed annually in the Netherlands, prolonged sickleave induce unnecessary high costs for the society.

In this study we will study the (cost)effectiveness of a transmural, perioperative care program for gynaecological patients.

### Study objective

Compared to usual care, a new perioperative care program will improved recovery and accelerated resumption of (work)activities. Resumption of work contributes significantly to QOL and will prevent disability due to general and mental health problems and associated financial deprivation. Moreover, the program will reduce direct and indirect costs for the Dutch society.

### Study design

1. Baseline;
2. 2 weeks;
3. 6 weeks;
4. 12 weeks;
5. 6 months;
6. 12 months.

### Intervention

Control group: Usual care.

Intervention group: Multidisciplinary peri-operative care program including an interactive weblog and additional workplace intervention in case of delayed recovery. The interactive weblog provides patient-tailored detailed instructions on the resumption of (work)activities. These

recommendations are based on consensus achieved among gynaecologists, GPs, OPs and GPs using a structural consensus method, including a systematic review. The weblog additionally provides tools to improve self-empowerment and to improve the communication between patients, care-providers and employers, preventing conflicting recommendations. Patients'

recovery can be closely monitored by the weblog, allowing the application of a very successful workplace (participative ergonomics) intervention to improve patients' recovery and reduce sick-leave.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

1. Female;
2. Age between 18-65 years;
3. Employed (>8 hours/week);
4. Scheduled for a hysterectomy or laparoscopic adnexal surgery in one of the

participating hospitals.

## Exclusion criteria

1. Malignancy;
2. (Ectopic) pregnancy;
3. Deep infiltrating endometriosis;
4. Concomitant surgical procedures or major health problems affecting daily activities;
5. Sick listed for more than 6 months;
6. Dealing with a lawsuit to their employer;
7. Not able to understand or complete the questionnaires;
8. No Internet access.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	280
Type:	Anticipated

## Ethics review

Positive opinion

Date: 10-06-2011

Application type: First submission

## 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
NTR-new	NL2793
NTR-old	NTR2933
Other	ZonMW : 171102015
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A