SUBSTITUTION OF USUAL PERIOPERATIVE CARE BY E-HEALTH & ICT; a cost-effectiveness analysis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON53164

Source
ToetsingOnline

Brief title
I recover 3

Condition

- Lifestyle issues
- Obstetric and gynaecological therapeutic procedures

Synonym
herstel na operaties, Perioperative care

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Convalescence, Cost-effectiveness, E-health, Perioperative care

Outcome measures

Primary outcome

1.Quality-of-life (Rand 36 or EQ-5D)

2.Return-to-normal activities including work (RNA/RTW) according to WHO

definition of social participation (ICF, 40)

Secondary outcome

- Return to physical activities

- Return to work

- Length of recovery

- Empowerment

- Pain intensity

- Patients satisfaction

- Protocol adherence

- Quality improvement

Study description

Background summary

In the last decade the number of surgeries increased with 30% in the Netherlands (1.3 M/year in 2009). To reduce costs, in-hospital perioperative care is increasingly reduced due to one day hospitalisations (>50%) and transferred to primary care. Guidance & monitoring on recovery and resumption of (work)activities are mostly not provided in secondary and primary care. The increase of surgeries leads to rising hospital care costs, increasing with more than 33% between 2000-2009[1] In addition,

studies showed that due to the poor quality of usual perioperative care, return-to-normal-activities/work after surgery is hampered, leading to high productivity loss costs .

Our placebo controlled RCT showed that webportal significantly improved quality-of-life, return-to-(work)activities (9 days difference), pain intensity, and patient satisfaction compared to placebo. We hypothesize based on these results that the webportal substituting usual postoperative care can reduce 68ME/yr healthcare costs & 1355ME/yr productivity loss.

Study objective

This study proposal hypothesizes that huge health efficiency gains can be achieved by substitution and improvement of usual peri operative care by Ehealth and ICT. The main research question is: Is perioperative E-health & ICT costeffective compared to usual perioperative care?

Study design

Randomized controlled trial; 661 patients with abdominal surgery in 11 participating hospitals;
A cost-effectiveness, cost-utility analysis & budget impact analyses of the intervention will be performed from a societal & healthcare level.

Intervention

Patients in the intervention group will receive a special perioperative care program. This care program consists of:

1. E-health intervention (webportal and accelerometer)
1.1 Personalized convalescence plan
The most important tool of the webportal is the possibility to generate a tailored convalescence plan, including advice about resumption of (work) activities. Using a modified delphi method, specific convalescence recommendations are developed for the above mentioned types of abdominal surgery.It aims to improve recovery, return to normal activities/work and quality of life. The convalescence plan is approved electronically by the surgeon who performed to surgery on the first post-operative day, resulting in a definitive convalescence plan.
1.2 Feedback on recovery
a. Recovery monitor and report
This is a tool to identify recovery problems and to give patients feedback on their recovery progress. Inventory of the resumption of activities takes place

at several moments after surgery and is graphically displayed in a recovery report allowing to track progress. In case patients fall behind, an alerting system advises them to contact a specific health care professional, depending on the underlying problem. It also aims to improve monitoring & transition of postoperative care: After the patient has given consent, the webportal can be accessed to all involved healthcare providers in secondary and primary care to monitor patient*s recovery and to improve transition of secondary to primary care.

b. Accelerometer

The accelerometer will be used as an aid for patients and their physician to monitor and give feedback on recovery. Patients have to wear the accelerometer from the seventh day before surgery until a few weeks after surgery. In a separate pilot study we will determine the time period that patients have to wear the accelerometer after surgery. In the seven-day period before surgery, the accelerometer will be blinded in both groups (intervention and control group). After surgery the display will be visible in the intervention group, but remains blinded in the control group. Preoperative activity is defined as the average activity score of the 7 days before surgery. Postoperative activity will be expressed each day as a percentage of the preoperative value.

1.3 E-consult

In case patients fall behind, an alerting system advises them to contact a specific health care professional by e-mail (e-consultation).

In case of a successful convalescence period, patients are offered the opportunity for e-consultation. This aims to substitute standard postoperative consultation in outpatient clinics to reduce costs and workload and to meet patient preferences of care during out of office hours. This will only be available for patients in subgroup 1.

2. Interventions at cluster level

2.1 Guidelines with convalescence recommendations

Guidelines (developed in the above mentioned modified Delphi method) will be distributed among clinical staff of the 11 participating hospitals in order to stimulate evidence-based discharge instructions. All health professionals involved in clinical care, receive a pocket card on which these recommendations are summarized for quick reference. Residents involved in discharge communication are instructed to explain the convalescence recommendations to their patients before discharge. Giving structural discharge instructions based on evidence-based guidelines aims to prevent feelings of uncertainty, irrational beliefs and postoperative fear among patients, which may hamper recovery.

2.2 Early postoperative check in the outpatient department

Following an open procedure patients will get an appointment for a postoperative consultation in the outpatient clinic, four weeks after surgery. After a laparoscopic procedure this appointment will take place two weeks after surgery. As described before, patients will be offered an e-consultation, in case of a uncomplicated postoperative recovery period (only for patients in

subgroup 1).

Study burden and risks

The webportal www.ikherstel.nl is an ICT and e health intervention. It aims to improve recovery by personalized perioperative recovery recommendations. In the event of severe complications, the gynecologist can choose not to approve the convalescence plan and patients then receive a message that the convalescence plan is not valid anymore and that they should follow up with the specific instructions given at discharge. With consent of the patient, the approved convalescence plan is also disclosed to the general practitioner and/or occupational physician of the patient. An accelerometer will be used as an objective outcome measure to monitor recovery.

In subgroup 1, data will be collected in both groups (intervetion and control group) by means of self-reported electronic questionnaires before surgery and 2 weeks (T1), 6 weeks (T2), 12 weeks (T3) and 26 weeks (T4) after surgery.
In subgroup 2, data will be collected before surgery and 2 week (T1), 4 weeks (T2), 6 weeks (T3), 12 weeks (T4), 26 weeks (T5), 40 weeks (T6) and 52 weeks (T7).

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients aged from 18 to 70 years old who are on the waiting list for a laparoscopic cholecystectomy, an open or laparoscopic colectomy, an open or laparoscopic appendectomy, open or laparoscopic inguinal hernia surgery, an abdominal or laparoscopic hysterectomy or laparoscopic adnexal surgery. Due to differences in surgical procedures we identify two subgroups in the study population:
Subgroup 1: Patients who are on the waiting list for a laparoscopic cholecystectomy, an open or laparoscopic appendectomy, open or laparoscopic inguinal hernia surgery or laparoscopic adnexal surgery.
Subgroup 2: Patients who are on the waiting list for an open or laparoscopic colectomy, or an abdominal or laparoscopic hysterectomy.

Exclusion criteria

• Surgery without a curative intention or with additional radio- or chemotherapy
• Colectomy because of crohn*s disease or ulcerative colitis
• Deep infiltrating endometriosis
• Perforated appendicitis
• Adnexal surgery because of pelvic inflammatory disease/ tubal ovarian abces
• Combination of surgery with other surgical procedures
• Concomitant health problems affecting daily activities
• Severe comorbidity which might complicate the postoperative course
• Patients who are unable to understand the information belonging the research
• Insufficient understanding or ability to fill in (Dutch) questionnaires

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	08-08-2015
Enrollment:	685
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL49248.029.14