

Recovery and Return to Work after Gynaecological Surgery

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Recovery and Return to Work after Gynaecological Surgery

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CHAPTER 1

General introduction



Hysterectomy and laparoscopic adnexal surgery are the most frequently performed major gynaecologic surgical procedures carried out throughout the world.¹ They yearly count for 20.000 procedures on benign indication in the Netherlands.² These types of major surgeries may have a considerable postoperative effect on recovery. Increasingly, efforts have been made to accelerate recovery after surgery by introducing minimal invasive surgery and other improvements in the period of immediate postoperative care (i.e. fast-track programs), aiming to reduce morbidity and to accelerate recovery.^{3;4} This development has proven to reduce inpatient stay. However, full recovery and RTW following benign (laparoscopic) gynaecological surgery often takes much longer than expected from a medical perspective.⁵⁻⁷ This may have great consequences for the patient, her surroundings and her work environment. To improve postoperative care and to take full advantage of the potential benefits of minimal invasive surgery, it is of importance to gain insight into the circumstances that determine recovery. How they can be measured and how they may be influenced, in order to improve recovery after surgical procedures.

Recovery after surgery

Although the term postoperative recovery is ill-defined, it is often associated with the duration of hospital stay and the time to return to normal activities of daily living and to work activities. However, the process of convalescence after surgery involves both physical and mental aspects. After a successful recovery the patient is free of postoperative symptoms such as pain and nausea, will feel comfortable and emotionally well and is able to perform normal and work activities again. Consequently, recovery after surgery should not only be measured by day of discharge or the duration of the sick leave period, but also by more subjective recovery outcome measures such as experience of pain or quality of life.⁸ Moreover, it is important to stress that dissimilarities in health care systems, legislative and insurance systems, and reintegration policies between countries have a major influence on the available time to recover and therefore on the time to return to work (RTW).^{9;10}

Postoperative sick leave

The main objective of laparoscopic surgery is to reduce postoperative recovery time by making smaller wounds than with laparotomy. Although procedure costs are higher in many minimal invasive surgeries in comparison to a laparotomic approach, the common conviction is that minimal invasive surgery gains in cost-effectiveness through a reduction of the length of hospital stay and a shorter convalescence period. The reduction of inpatient stay is easily measurable and reduces direct costs. In contrast, sick leave and (subjective) health problems after discharge from the hospital are much more difficult to monitor and influence.

Moreover, sick leave costs are mostly not at the expense of the insurance companies for curative care, but at the expense of employers. Consequently, relatively little attention has been given to the improvement of postoperative care outside the hospital and to decrease the time to RTW.

Several studies however, have reported that time to full recovery and RTW following benign (laparoscopic) gynaecological surgery frequently exceeds what can reasonably be expected from a medical perspective.⁵⁻⁷ These observations are alarming since prolonged absence from work often results in a lack of social structure and meaningful activities^{11;12} and is associated with a reduced probability of eventual RTW, poorer general health and increased risk of mental health problems.^{13;14} As a result, long periods of sick leave may contribute to a reduced quality of life and induce unnecessary, yet substantial, costs for society through lost working hours, physician consultation, and increased use of medication.^{15;16}

Correlates of prolonged sick leave

Little is known about perioperative and work-related factors resulting in delayed RTW in patients who underwent gynaecological surgery. Literature shows that duration of time to RTW was influenced by patients' expectations regarding time to RTW after surgery.¹⁷ Patients with delay in time to RTW after gynaecological surgery have reported pain, anxiety, depression, fatigue and infections as important delaying factors.^{5;17} By contrast, recovery and time to RTW in postoperative gynaecological patients was shorter when they had received limitedly restrictive recommendations at discharge, or when they had been provided with advice on time to RTW.¹⁷⁻¹⁹ This last finding corresponds with studies in general surgical patients that found that well-defined postoperative instructions reduced sick leave by several weeks.²⁰⁻²³

Postoperative care

Detailed recommendations on the resumption of activities after gynaecological surgery are usually not provided by medical specialists as a result of the absence of national or international guidelines on gradual resumption of activities and a lack of knowledge about the physical demands of the patient's job.²⁴⁻²⁶ When recommendations are given, they are not evidence-based but based on tradition and anecdote and show substantial variability between gynaecologists.²⁷⁻²⁹ In the Netherlands, after discharge from the hospital the patient usually has only one post-operative check-up, which traditionally takes place six weeks after surgery. Many patients do not RTW before this check-up, irrespective of surgical technique and the severity of the operation. Moreover, this consultation is focused on examination of the physical condition and not on RTW. Other medical care is fragmented and given only on demand, as a result of which patients often do not know whom to contact for support in case of postoperative complaints. Due to Dutch legislation

patients with paid work, who do not RTW within six weeks after surgery, are obliged to consult their occupational physician. However, as a result of poor communication between the gynaecologists, general practitioners and occupational physicians, often indistinct and conflicting recommendations are given, which are usually not specified per surgical technique.^{28;30-32}

Since frequently no or strongly diverse recommendations are given by health care providers, patients often do not know when to resume which activity, and compliance to advice is low. In addition to fragmented postoperative care, these factors contribute to uncertainties and irrational beliefs of patients and lead to avoidance of the resumption of activities, which may result in a prolonged sick leave and reduced quality of life.^{14;16}

OBJECTIVE

To improve perioperative care and patient outcomes regarding recovery, time to RTW and improved quality of life, patients' needs, (illness) beliefs and preferences regarding perioperative care and resumption of work activities need to be studied. We hypothesize that the RTW expectations of patients can be optimized through multidisciplinary guidelines, and improved perioperative communication between patients and physicians. Furthermore, identification of the most important predictors for prolonged sick leave will provide an opportunity to identify patients with a high risk of prolonged sick leave and anticipate on this by giving them additional care.

The International Classification of Functioning, disability and health (ICF) is used as a theoretical framework for in the improvement of perioperative care and patient outcomes (Figure 1).³³ In this model, recovery and RTW is placed in a bio-psycho-social perspective. Besides a focus on the health condition (i.e. the physical recovery of the surgery), personal factors (e.g. self-efficacy, expectations regarding recovery, coping) and environmental factors (e.g. multidisciplinary convalescence recommendations, communication with health care providers and employer) are also considered as important correlates for recovery and RTW.

To optimize patients' expectations, the development of multidisciplinary convalescence recommendations regarding RTW after gynaecological surgery is chosen as an important starting point. These recommendations can be a tool for gynaecologists, general practitioners and occupational physicians to give unambiguous detailed advice on convalescence to their patients during the postoperative period. These unambiguous recommendations will likely enhance the compliance to advice given by medical specialists and will stimulate the patient to resume activities with increasing gradations of strain, which will presumably bring about a faster recovery.^{19;20;23}

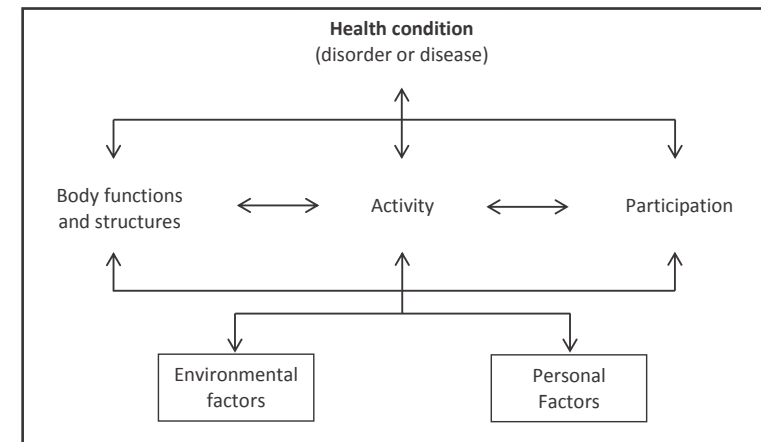


Figure 1. The International Classification of Functioning, disability and health (ICF)

Furthermore, with increased transition of the postoperative recovery process outside the hospital, it is of growing importance for patients to know which care provider to contact for support in case of postoperative complaints.

To improve perioperative communication between patients and physicians, empowerment of patients to actively participate in their consultations with physicians is thought to be very important.^{34;35} Patient empowerment refers to the enhanced ability of patients to actively understand and influence their own health status.³⁶ eHealth interventions seem to be a promising way to empower patients by giving tailor-made education (e.g. detailed recommendations on resumption of (work) activities) and by enhancing interaction between health consumers and professionals.³⁷⁻³⁹ Patients become more actively engaged in their own state of health (e.g. are aware of which complications need additional consultation) and the communication between patient and health care provider becomes more efficient and balanced.⁴⁰⁻⁴² Therefore, a feasible and generally accepted eHealth intervention to empower gynaecological patients during the perioperative period including RTW seems appropriate to reach this aim. To tailor this intervention specifically to the patients' needs, patients need to be intensively involved in the development of this eHealth intervention.

Furthermore, for patient sick-listed more than 10 weeks, integrated care management including a work place intervention will be developed, based on studies in patients sick-listed due to musculoskeletal disorders and distress, where its effectiveness is reported.^{27;28}

To mirror the target group, patients who underwent a hysterectomy (abdominal, vaginal, laparoscopic) or laparoscopic adnexal surgery on benign indication will be chosen for

this research project. These types of surgeries were chosen because they are the most frequently performed major gynaecologic procedures on benign indication with a considerable postoperative effect on recovery.

In summary the aims of this project are:

1. To measure the impact of the level of invasiveness of gynaecological procedures on time to full RTW and to identify the most important socio-demographic, medical, and work-related factors that predict the risk of prolonged sick leave after gynaecological surgery;
2. To identify which activities are in need of recommendations for RTW after laparoscopic adnex surgery and all kinds of hysterectomy (laparoscopic, vaginal, abdominal) on benign indication and to develop evidence- and consensus-based multidisciplinary recommendations for these types of surgery;
3. To develop an eHealth intervention and integrated care management (including a workplace intervention) to empower patients during the perioperative period in recovery and RTW, and to help other relevant stakeholders (e.g. care providers, employers) to support their patient/employee;
4. To evaluate the effectiveness and feasibility (including exploration of facilitators and barriers to future implementation) of the developed eHealth intervention as part of a multidisciplinary care program.

OUTLINE OF THIS THESIS

Chapter 2 studies the effect of surgical invasiveness on time to RTW after surgery and the most important predictors for prolonged sick leave after gynaecological surgery. Chapter 3 describes the development of postoperative multidisciplinary convalescence recommendations after gynaecological surgery through a modified Delphi method. In chapter 4, the development of the eHealth intervention 'ikherstel.nl' is described, using the Intervention Mapping protocol. Chapter 5 provides an evaluation of the involvement of gynaecological patients in the development of the eHealth intervention. In chapter 6, the design of a RCT to evaluate the feasibility and effectiveness the eHealth intervention as part of a multidisciplinary care program is presented. Chapter 7 describes a process evaluation of the multidisciplinary care program. In chapter 8 the effectiveness of the eHealth intervention on RTW, quality of life and pain intensity after gynaecological surgery is presented. Finally, chapter 9 provides a general discussion with methodological considerations and recommendations for implementation and future research.

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CHAPTER 2

Prediction of time to return to work after gynaecological surgery: a prospective cohort study in the Netherlands

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ABSTRACT

Objective

To measure the impact of the level of invasiveness of gynaecological procedures on time to full return to work (RTW) and to identify the most important preoperative socio-demographic, medical, and work-related factors that predict the risk of prolonged sick leave.

Design

Prospective cohort study.

Setting

Dutch university hospital.

Population

A total of 148 women aged 18-65 years scheduled for gynaecological surgery for benign indications.

Methods

A questionnaire regarding the surgical procedure as well as perioperative and postoperative complications was completed by the attending resident at baseline and 6 weeks after surgery. All other outcome measures were assessed using self-reported questionnaires at baseline and 12 weeks post-surgery. The follow-up period was extended up to 1 year after surgery in women failing to return to work. Surgical procedures were categorized into diagnostic, minor, intermediate and major surgery.

Main outcome measures

Time to RTW and important predictors for prolonged sick leave after surgery.

Results

Median time to RTW was 7 days (interquartile range [IQR] 5-14) for diagnostic surgery, 14 days (IQR 9-28) for minor surgery, 60 days (IQR 28-101) for intermediate surgery, and 69 days (IQR 56-135) for major surgery. Multivariable analysis showed a strongest predictive value of RTW one year after surgery for level of invasiveness of surgery (minor surgery hazard ratio [HR] 0.51, 95% CI 0.32-0.81; intermediate surgery HR 0.20, 95% CI 0.12-0.34; major surgery HR 0.09, 95% CI 0.06-0.16), RTW expectations before surgery (HR 0.55, 95% CI 0.36-0.84), and preoperative functional status (HR 1.09, 95% CI 1.04-1.13). A prediction model regarding the probability of prolonged sick leave at 6 weeks was developed, with a sensitivity of 89% and a specificity of 86%.

Conclusions

RTW often takes a long time, especially after intermediate and major surgery. This study reveals important predictors for prolonged sick leave and provides a prediction model for the risk of sick leave extending 6 weeks after benign gynaecological surgery in the Netherlands.

INTRODUCTION

Return to work (RTW) and full recovery after benign gynaecological surgery often takes a long time, irrespective of the introduction of minimally invasive surgery and other improvements in perioperative care aiming to reduce morbidity and to enhance recovery.¹⁻³ Delays in recovery and time to RTW, reduces quality of life in postoperative women and generates unnecessary yet substantial costs for society through lost working hours, physician consultation and increased use of medication.⁴⁻⁶ Patients with delay in time to RTW after gynaecological surgery reported pain/discomfort, anxiety, depression and infections as important delaying factors.⁷ In contrast, recovery and RTW time was shorter when women received clear uniform recommendations at discharge or when the woman had been provided with a time to RTW advice.^{8,9} However, little is known about preoperative personal and work-related factors as predictors for delayed RTW in women who undergo gynaecological surgery. Knowledge about factors which predict prolonged sick leave provides opportunities to identify high risk patients. These women could receive preventive or therapeutic treatments for the factors that can be influenced, e.g. counseling of RTW expectations and workplace adaptations. Anticipating on important general factors for prolonged sick leave, improvement of perioperative care could be realized for all gynaecological patients.

The first aim of this study was to measure the impact of the level of invasiveness of gynaecological procedures on time to full RTW. The second aim was to identify most important preoperative sociodemographic, medical, and work-related factors that might predict the risk of prolonged sick leave after gynaecological surgery.

METHODS

Study design and participants

This prospective observational cohort study was conducted in the VU University Medical Center in the Netherlands between July 2008 and December 2010. Patients were recruited for participation in the study when scheduled for elective gynaecological surgery on benign indications. Recruitment took place by sending these women an invitation letter on behalf of their gynaecologist, together with an information package consisting of: 1) a patient information letter about the study, 2) a leaflet about participating in scientific research in general, 3) an informed consent form, and 4) a prepaid envelope. By sending back the signed informed consent form to the researchers, the woman indicated that she was interested in participating in the study after which the researcher contacted her to evaluate whether she was eligible to participate in the study. Women aged between 18-65 years undergoing gynaecological surgery (abdominal, vaginal, laparoscopic) on benign indication and employed for at least 8 hours per week (paid or unpaid) including

housewives, were included in the study. Exclusion criteria were: 1) (suspicion of) malignancy; 2) (ectopic) pregnancy; 3) deep infiltrating endometriosis (because of more frequent sick leave before surgery, resulting in other RTW expectations and health status at baseline; 4) acute, ambulatory or only hysteroscopic surgery, 5) working temporarily for an employment agency (because of the increased risk of not completing the follow-up period of one year with the same employment) and 6) not able to understand or complete the questionnaires written in the Dutch language.

Data-collection

For each woman, a questionnaire on type of procedure, perioperative complications and post-operative complications was filled out by the attending resident at baseline and 6 weeks after surgery. All other outcome measures were assessed using self-report questionnaires and were taken at baseline (1 or 2 days before surgery) and 12 weeks after surgery. When a woman had not completed the questionnaire within 1 week after schedule, she received a reminder by email or post. If no response followed, she was reminded by a telephone call. RTW was measured 12 weeks after surgery and if the patient had not RTW fully 12 weeks after surgery, the researchers approached her by telephone at 6, 9 and 12 months after surgery to investigate the time to first full RTW. The follow-up period regarding time to RTW was at maximum one year after surgery, or ended when first full RTW was reached.

Outcome measure

The primary outcome measure in this study is sick leave duration until first full RTW, defined as duration of sick leave in calendar days from the day of surgery until the actual day of full RTW in own work or in other work with equal earnings. Prolonged sick leave was defined as no RTW at 6 weeks after surgery, based on expert recommendations.¹⁰⁻¹²

Potential prognostic factors

Based on a literature search in Pubmed (English, no other limitations) about prognostic factors regarding RTW in a wide variety of surgical patients and clinical experience of the researchers, potential prognostic factors were determined. These factors were divided in five different categories; sociodemographic factors, medical factors, work-related factors, patients' expectations for time to RTW, and health status. Each category consisted of the following factors:

1. Sociodemographic factors:
 - a. Age (years).¹³⁻¹⁵
 - b. Living condition (alone or with family).
 - c. Children or partner in need of care.

2. Medical factors:

- a. Type of surgery: according to the extent of surgery, classification in four groups took place: diagnostic surgery, minor surgery, intermediate surgery, major surgery. Precise assignment per group is presented in table 1 and was based on previous research.²
- b. Major surgical complications: complications during or related to the surgery, defined as enlargement of the wound with more than 8 cm or re-surgery within 6 weeks after initial surgery (major complications).

3. Work-related factors:

- a. Employment: salaried or voluntary (unpaid) and salaried or self-employed.
- b. Physical workload: light to moderate or heavy.^{14;16;17}
- c. Work hours per week: < 20 per week, or 20 hours and more per week.¹⁵
- d. Job satisfaction: (very) unsatisfied or (very) satisfied. This prognostic factor was scored using a numerical visual analogue scale (VAS, range 0-10). Score 0-5 was defined as (very) unsatisfied and 6-10 as (very) satisfied.¹⁸

In the Netherlands, all patients with paid work have rights to claim an occupation sick pay scheme in the Netherlands, so this factor was not considered as a relevant predictor.

4. Patients' expectations for time to RTW after surgery:^{13;16;19-21}

- a. Expectation of the woman regarding time till first full RTW after surgery. Expectations were classified in 'low' and 'normal' expectations, based on detailed multidisciplinary guidelines on time to RTW which were developed by an expert panel of gynaecologists, occupational physicians and general practitioners through a modified Delphi consensus method.¹⁰ Low expectations on time to RTW were defined as longer than 1, 2, 4 and 6 weeks for respectively diagnostic, minor surgery, intermediate surgery and major surgery. A shorter or equal expected time to full RTW was regarded as 'normal'.

5. Health status:²²

- a. Physical and mental health status assessed according to the Short-form health survey (SF-36).^{23;24} Considering the wide range of comorbidities and limited incidence in our relative small population, comorbidities were considered to be most carefully covered by the physical health status of the SF-36.
- b. Functional status measured by a validated Recovery Index (RI) questionnaire.^{2;25} Before surgery, only five questions of this questionnaire are relevant (RI-baseline, see Appendix 1).

Statistical analyses

Data entry was performed using Microsoft Office Access® 2003. All data entries were visually double-checked by two different independent research assistants. Assignment

Table 1. Classification of surgery according to the level of invasiveness**Diagnostic surgery**

Diagnostic laparoscopy

Minor surgery

Laparoscopic

Adnexal surgery

Abdominal cerclage

Vaginal uterine artery occlusion

Intermediate surgery

Laparoscopic

Removal of a cervix (after previous laparoscopic assisted supracervical hysterectomy)

Hysterectomy

Myomectomy

Sacrococcolpopexy

Vaginal prolapse surgery (colporrhaphia, vaginal sacrospinous fixation, Manchester Fothergill)

Vaginal hysterectomy

Major surgery

Laparotomic

Adnexal surgery

Hysterectomy

Myomectomy

of type of surgery took place according to the actually performed treatment. Statistical analyses were performed using SPSS statistical package (SPSS®20) and R. The influence on overall survival (OS) for time to RTW was determined by calculating the Kaplan-Meier estimate and comparisons between curves were performed by the log-rank test. $P < 0.05$ was considered as significant.

Development of prediction model

Stochastic regression imputation was performed to estimate missing scores. Cox proportional hazard models were used to analyze the effect of each potential prognostic factor on RTW over the whole follow-up period, uni and multivariably.²⁶ The cumulative probability of prolonged sick-leave at 6 weeks was chosen as the primary goal to develop the prediction model. To construct the prediction model, the balance between the number of prognostic factors and number of RTW events in the model was considered, which is recommended not to be lower than 10-15 events per factor.²⁷ Therefore only

most relevant predictive factors were added to the Cox proportional hazard model. Subsequently, backward regression was applied and predictors were removed from the model when the p value was >0.05 . To examine whether the outcomes were influenced by the regression imputation, an additional backward regression was applied on the data without regression imputation for the factors with more than 5% missing.

The regression coefficients from this final model were used to obtain the risk of sick leave extending 6 weeks after surgery. This probability was calculated by using the baseline probability of RTW for an individual woman with a follow-up of 6 weeks and the regression coefficients obtained from the Cox model after backward selection.²⁸ The regression coefficients express the effect of the predictors on RTW, while the purpose of the model was to express the risk of prolonged sick leave. Therefore, the sign of the regression coefficients was reversed (e.g. positive became negative). To make our prediction tool suitable for clinical use, each coefficient was divided by the lowest value of a continuous predictor and transformed to a round number of risk scores, reflecting the relative weight in the prediction of prolonged sick leave. The total risk score for each individual woman was determined by multiplying the risk scores by the value of each predictor and summing them up. Next, we divided the women in four equal-sized groups based on these risk scores, ranging from low to high. Risk score intervals were calculated with corresponding 6 weeks predicted probabilities of prolonged sick leave.

We compared the mean predicted probability as estimated by the model of prolonged sick leave of each group to the actual observed probability of the group by the Kaplan-Meier method. These predicted and observed probabilities of prolonged sick leave at 6 weeks, were also plotted to assess calibration (i.e. agreement between predicted and observed probabilities of prolonged sick leave at 6 weeks). To test the discriminative ability of our model, the concordance statistic was determined which is equal to the area under the curve. Explained variation -the amount of variance between individual patients that can be explained by the predictive factors-, was calculated with the Pseudo R^2 technique.²⁹

To adjust our prediction model for the fact that it was developed and tested in the same population, which causes over-optimism of the predictors in the model, bootstrapping techniques were applied (250 bootstrap samples).²⁶ With this technique, a shrinkage factor to adjust the predictors for this over-optimism of its predictive ability, was calculated. Sensitivity, specificity as well as the positive and negative predictive values of this model were calculated for the same cut-off scores used to delineate the risk score categories.

RESULTS

A total of 157 women met the inclusion criteria and were approached to participate in the study, of which 148 were willing to participate and were included in this study. Figure 1 presents the patient flow throughout this trial. Follow-up time ranged from 12 to 52 weeks after surgery.

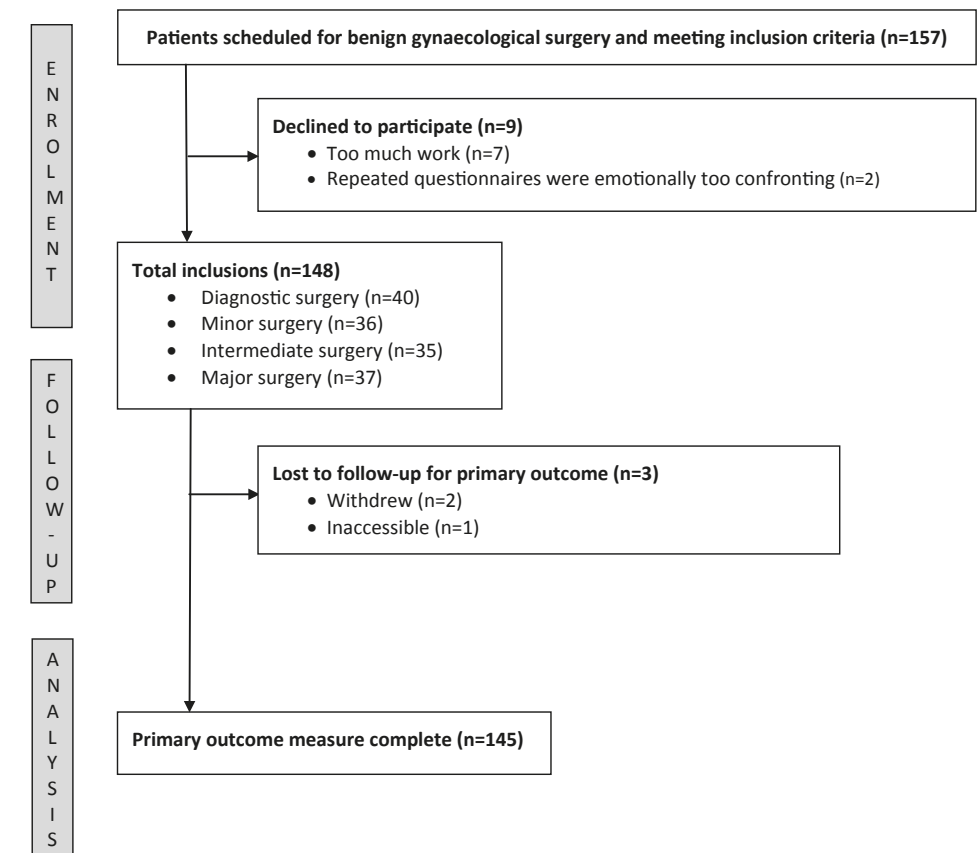


Figure 1. Patient flow

Patient characteristics and loss to follow-up

The questionnaires filled out by the attending resident and the baseline questionnaires filled out by the patients were available for all patients. Table 2 presents the baseline characteristics of participating patients, represented per surgical category and reporting the amount of missing data per characteristic. Data regarding the primary outcome measure, time to full RTW after surgery, were available for 145 (98%) women, and were censored for two patients due to the follow-up period of 1 year.

Table 2. Baseline characteristics and primary outcome measure of participating patients

	Diagnostic surgery (n=40)	Minor surgery (n=36)	Intermediate surgery (n=35)	Major surgery (n=37)	Overall (n=148)	Missing n (%)
Socio-demographic factors						
Age (years) [mean (SD)]	35.5 (4.1)	38.8 (8.3)	46.3 (7.7)	43.3 (7.0)	40.8 (8.0)	0
Medical factors						
Surgical category [n, (%)]	40 (27.0)	36 (24.3)	35 (23.6)	37 (25.0)		0
Surgical complications [n, (%)]	0 (0)	0 (0)	3 (8.6)	3 (8.1)	6 (4.1)	0
Work related factors						
Employment [n, (%)]						0
Salaried	38 (95.0)	32 (88.9)	26 (74.3)	31 (83.8)	127 (85.8)	
Unpaid	2 (5.0)	4 (11.1)	9 (25.7)	6 (16.2)	21 (13.5)	
Physical workload [n, (%)]						2 (1.4)
Light & Moderate	37 (92.5)	31 (86.1)	27 (77.1)	31 (83.8)	126 (85.1)	
Heavy	3 (7.5)	5 (13.9)	7 (20.0)	5 (13.5)	20 (13.5)	
Work hours per week [n, (%)]						6 (4.1)
< 20 hours per week	4 (10.0)	7 (19.4)	6 (17.1)	5 (13.5)	22 (14.9)	
≥20 hours per week	36 (90.0)	28 (77.8)	26 (74.3)	30 (81.1)	120 (81.1)	
Satisfaction with job [n, (%)]						13 (8.8)
(very) unsatisfied	4 (10.0)	2 (5.6)	3 (8.6)	4 (10.8)	13 (8.8)	
(very) satisfied	35 (87.5)	32 (88.9)	27 (77.1)	28 (75.7)	122 (82.4)	

	Diagnostic surgery (n=40)	Minor surgery (n=36)	Intermediate surgery (n=35)	Major surgery (n=37)	Overall (n=148)	Missing n (%)
Women's expectations						
RTW expectation (days) before surgery [n, (%)]						27 (18.2)
Low expectation	3 (7.5)	7 (19.4)	16 (45.7)	8 (21.6)	34 (23.0)	
Normal expectation	34 (85.0)	24 (66.7)	9 (25.7)	20 (54.1)	87 (58.8)	
Health status						
RAND-36 baseline [mean (SD)]						7 (4.7)
Physical health	337 (79.3)	310 (74.6)	252 (80.3)	244 (104.0)	287 (93.8)	
Mental health	318 (73.0)	291 (74.7)	248 (105.0)	233 (97.1)	273 (93.8)	
Recovery index total baseline score (functional status) [mean (SD)]	20 (4.6)	20 (3.8)	18 (4.6)	17 (5.5)	19 (4.9)	4 (2.7)
Full RTW (days) after surgery						
Median (IQR)	7 (5-14)	14 (9-28)	60 (28-101)	69 (56-135)	28 (10-69)	3 (2.0)
Mean (SD)	13.1 (17.2)	21.2 (18.8)	78.4 (72.6)*	103.8 (80.4)*	53.4 (66.7)**	

* One case was censored at 365 days due to end of follow-up period.

** Two cases were censored at 365 days due to end of follow-up period.

Return to work

Figure 2 presents the Kaplan-Meier curves for all four surgical categories. Median times to RTW were 7 days for diagnostic surgery (IQR 5-14), 14 days for minor surgery (IQR 9-28), 60 days for intermediate surgery (IQR 28-101) and 69 days for major surgery (IQR 56-135). The difference between the curves was significant (log rank test: $p < 0.001$). Six weeks after surgery, 87 patients (59%) had returned to work.

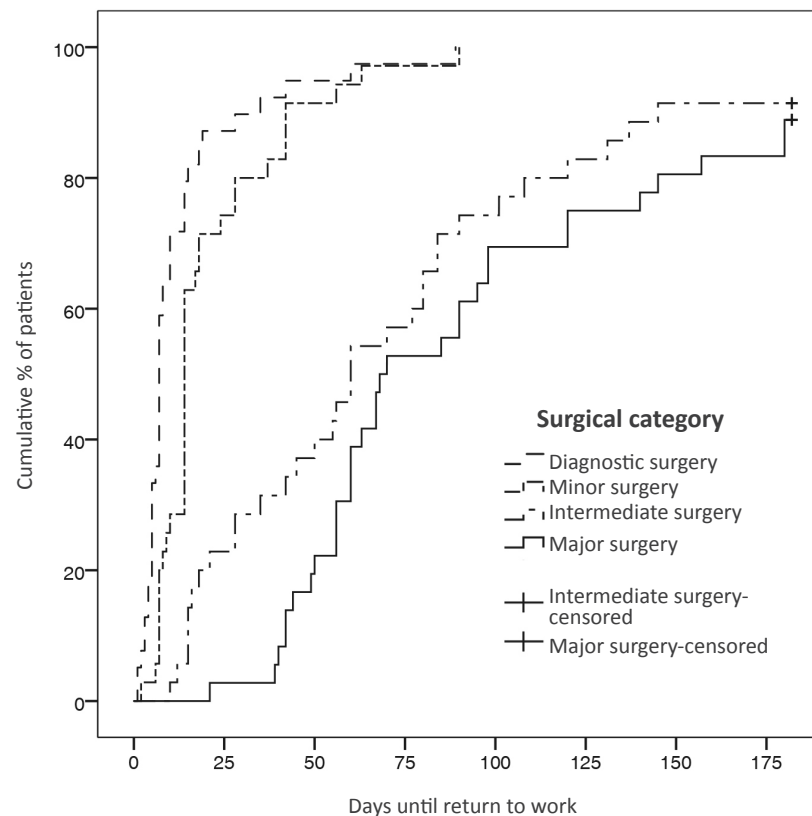


Figure 2. Kaplan-Meier survival curves, presented per type of surgery. Number of days represent days of sick leave after surgery until RTW. In both the intermediate and in the major surgery groups three patients were censored at 182 days because they had not yet RTW.

Prediction model

Table 3 presents the results of the univariable and multivariable Cox regression analysis of the eleven most relevant predictive factors. After applying backward regression analyses, surgical category, RTW expectation (days) before surgery and total baseline score of the RI

were the strongest predictors for RTW 1 year after surgery. The results were not influenced by the regression imputation of the two factors with the highest number of missing (RTW expectation and satisfaction with job). The coefficients from the multivariable analysis are presented after shrinkage. Per predictor, the explained variance and the transformation of the predictor into risk scores of sick leave more than 6 weeks after surgery can be found in Table 3. With these risk scores, the risk of sick leave more than 6 weeks after surgery can be calculated for each individual. This score can vary between -25 and +31. The higher the score, the higher the risk of prolonged sick leave. Each categorical predictor that is not relevant for a particular woman should be multiplied by zero and each predictor that is relevant should be multiplied by one. For the baseline recovery index, the score itself can be used. The weight of all positively scored predictors needs to be added up to form the total risk score (see Appendix 2). For example, a woman who underwent minor surgery, with a normal RTW expectation and with a total score of the baseline recovery index of 18, had a total risk score of $1 \cdot 8$ (minor surgery) + score $0 \cdot 7$ (normal RTW expectation) + $-1 \cdot 18 = -10$. The predicted risk of sick leave extending 6 weeks after surgery for this patient is 16% (Table 4).

Evaluation of the model

In the multivariable analysis, the selected factors for the prediction model --surgical category (47.5%), RTW expectation before surgery (13.9%) and baseline score of the Recovery index (18.4%)-- together explained 57.5% of the variation in RTW, which is good. The area under the curve was 0.67, representing a satisfactory discrimination. Figure 3 presents the calibration plot, which shows that the agreement between predicted and observed probabilities of sick leave at 6 weeks after surgery was good.

The total predicted probability of sick leave at 6 weeks was 38% which reasonably matched the observed risk (Kaplan-Meier estimate) of 41% (see Table 4). For example in this population, a woman with a risk score more than 10, has 80% predicted chance of sick leave more than 6 weeks.

Based on Table 5, a score of ≥ -2 is chosen as threshold value for high risk of prolonged sick leave. Regarding the group of the women with prolonged sick leave, 89% scored ≥ -2 points and was therefore correctly identified (sensitivity) and only 11% of the cases would be missed using this cut-off value. Of the woman with normal sick leave, 86% scored < -2 points and was correctly classified (specificity). In addition, the positive predictive value of the prediction rule at the score level of ≥ -2 is 85%. This means that in this group of high risk patients, additional care for prolonged sick leave is justified in 85% of the cases because they will actually develop prolonged sick leave. The negative predictive value of patients with a risk score < -2 is 89%, indicating that when this threshold is chosen, 89% of these patients will correctly be classified as low risk of prolonged sick-leave.

Table 3. Univariable and multivariable analysis of RTW after 1 year

Predictors	Univariable analysis			Multivariable analysis				
	HR*	95% CI	P-value	HR*	95% CI	P-value	Coefficient**	Risk score***
Socio-demographic factors								
Age (≥ 45 years)	0.73	0.50-1.04	0.08					
Medical factors								
Surgical category								
Diagnostic laparoscopy	0	Reference category					Reference category	
Minor surgery	0.55	0.35-0.86	0.09	0.51	0.32-0.81	<0.01	-0.61	8
Intermediate surgery	0.14	0.08-0.23	<0.01	0.20	0.12-0.34	<0.001	-1.46	20
Major surgery	0.10	0.06-0.17	<0.01	0.09	0.06-0.16	<0.001	-2.14	29
Surgical complications	0.47	0.21-1.07	0.07					
Work-related factors								
Employment (unpaid)	0.58	0.35-0.93	0.02					
Physical workload (heavy)	0.83	0.52-1.33	0.43					
Work hours per week (<20)	0.67	0.43-1.04	0.77					
Satisfaction with job (lvery unsatisfied)	0.65	0.39-1.09	0.10					

Predictors	Univariable analysis			Multivariable analysis				
	HR*	95% CI	P-value	HR*	95% CI	P-value	Coefficient**	Risk score***
Patients expectations								
RTW expectation (days) before surgery (low expectation)	0.45	0.32-0.64	<0.01	0.55	0.36-0.84	<0.01	-0.55	7
Health status at baseline								
Mental health	1.00	1.00-1.01	<0.01					
Physical health	1.01	1.00-1.01	<0.01					
Recovery index total score at baseline	1.11	1.06-1.15	<0.001	1.09	1.04-1.13	<0.001	0.07	-1 x (Baseline score)

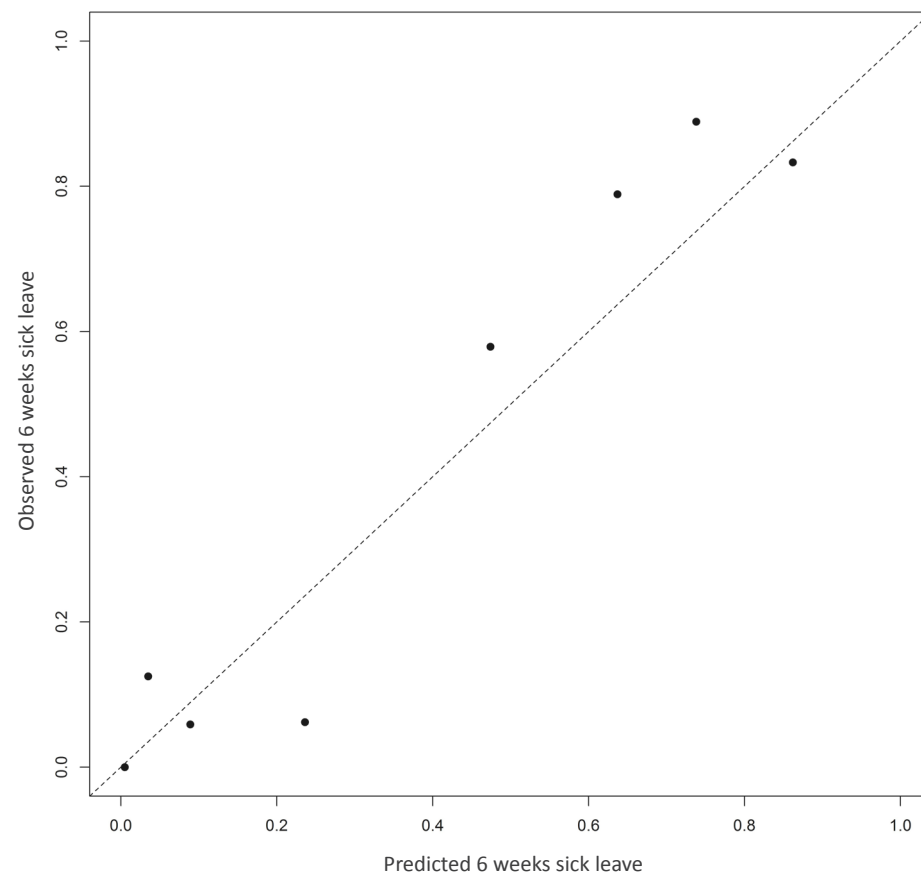
* Hazard ratio (HR) > 1 means a shorter time until RTW and HR < 1 means a longer time until RTW.

** Values are regression coefficients after correction for overoptimism using a shrinkage factor of 0.91.

*** Risk score of prolonged sick leave of more than 6 weeks determined with the regression coefficients after shrinkage.

Table 4. Risk of sick leave 6 weeks after surgery according to risk categories

Risk category	Total risk score	N (%)	RTW at 6 weeks, N (%)	Prolonged sick leave (No RTW at 6 weeks), N (%)	Observed risk of prolonged sick leave (Kaplan-Meier estimate) %	Predicted probability of prolonged sick leave %
1	-25 to -16	41 (28)	38 (93)	3 (7)	5	2
2	-15 to -3	33 (22)	28 (85)	5 (15)	6	16
3	-2 to 9	38 (26)	9 (24)	29 (76)	68	56
4	10 to 31	36 (24)	2 (6)	34 (94)	86	80
Overall	Total	148 (100)	77 (52)	71 (48)	38	41

**Figure 3.** Calibration plot showing the observed (Kaplan-Meier estimate) versus the predicted probability for sick leave 6 weeks after surgery. The dotted line represents the perfect calibration.**Table 5.** Prognostic test characteristics for sick leave 6 weeks after surgery

Cut-off total score	n (%)	Sensitivity [%]	Specificity [%]	Positive predictive value [%]	Negative predictive value [%]
≥ -25	148 (100)	100	0	48	0
≥ -15	107 (70)	96	49	64	93
≥ -2	74 (50)	89	86	85	89
≥ 10	36 (24)	48	97	94	67

DISCUSSION

Main findings

This study showed that RTW after benign gynaecological surgery, especially after intermediate and major surgery, takes a long time (median more than 8 weeks). The level of invasiveness of the surgery, expectation about time of RTW and functional status measured by the baseline score of the RI-questionnaire were identified as strongest predictors for the risk of prolonged sick leave. These three factors together explained 58% of the variation in time to RTW between the women in this study.

Strengths and weaknesses

Few studies have evaluated time to RTW after gynaecological surgery as primary outcome measure. Because of the wide variety of surgeries studied, all surgical levels of invasiveness in benign gynaecological surgery are represented in this study and RTW between various surgical categories may be compared. In addition, this is the first study that developed a prediction model for prolonged sick leave after gynaecological surgery, considering a wide range of sociodemographic, medical, and work-related factors. Relevant predictors were predefined based on a literature search. This prospective cohort study is of high quality owing to only 2% loss to follow-up on the primary outcome measure and in total only 1% of the RTW data are censored due to the follow-up period of 1 year.

A limitation of this study is that it was performed in a university hospital, which may have caused a relatively wide range in days until full RTW due to a high percentage of complex pathology. This may result in a reduced external validity. Another limitation is the fact that the primary outcome might be susceptible to recall bias, because sick leave duration was self-reported by women. Furthermore, in this study the first full day of RTW is taken as outcome measure regarding time to RTW, which does not take into account recurrences of sick leave and therefore is probably an underestimation of work-loss days.³ A limitation, common to all prognostic studies, is the possibility of omitting an important predictor. This study may also be underpowered to detect other predictive factors for RTW. The questions of the RI-baseline questionnaire were selected from the RI-

10/RI-6 questionnaire,^{2,25} based on their appropriateness to be answered before surgery. Therefore, no information is available about the validity and reliability of this selection of five questions. A final limitation is that the generalizability of the prediction model has not yet been evaluated by external validation in another population of gynaecological patients which is necessary before clinical application.³¹ However, this study is currently underway. Furthermore, dissimilarities in health care systems, legislative and insurance systems, reintegration policies, and RTW expectations between countries may decrease the relevance of the prediction model outside the Netherlands.

Interpretation

Time to RTW after surgery

Patients undergoing diagnostic surgery, RTW 1 week sooner than women undergoing minor (laparoscopic) surgery. RTW after minor surgery in our study is about 1 week slower than reported in a Danish, a Korean and a Japanese study of comparable types of surgery.^{9,32,33} A wide range in days until time to RTW was seen in women who received intermediate or major surgery, which is also found in other studies reporting on these types of surgeries.³⁴ Almost all studies outside the Netherlands and UK report an earlier RTW after intermediate and major surgery of at least several weeks,³⁵⁻³⁸ but in other Dutch and English studies the period of sick leave is comparable to our results.^{7,39-41} Part of the explanation for the differences in sickness absence between countries might be the result of dissimilarities in health care system, legislative and insurance system, reintegration policy, and RTW expectations.^{42,43} Patients undergoing major surgery RTW much later than expected, only one had RTW at 6 weeks after surgery, while 6 weeks is generally considered as a normal recovery period for full RTW by gynaecologists.¹⁰⁻¹² An explanation might be an extended recommended sick leave period by occupational physicians, which was about 2 weeks longer than the advice given by gynaecologists for several types of hysterectomies in two Danish and Dutch prospective cohort studies.^{3,44}

Predictive factors of prolonged sick leave and the prediction model

In this study, less invasive surgery was associated with a lower chance of sick leave lasting more than 6 weeks. This result corresponds with several studies that showed a quicker RTW after laparoscopic hysterectomy compared to laparotomic hysterectomy.^{36,45} Another important predictor for prolonged sick leave turned out to be baseline expectations regarding time to RTW after surgery. This is in line with a number of other studies that identified this factor as an important predictor for time to RTW in a wide variety of patients.^{13,16,19-21} The total baseline score of the Recovery index turned out to be a stronger predictor for prolonged sick leave than the RAND-36 mental or physical health. This finding is in line with previous research, which showed that functional status 2 weeks after surgery, was more closely related to prolonged sick leave than the type of surgery.² In contradistinction to other studies, age and work-related factors had little association with

prolonged sick leave in our group of patients.^{13-16,18} However, limited variation of age and work-related factors in this cohort could not be ruled out as explanation for this finding. Surgical complications were not found as a strong predictor of prolonged sick leave either, which may be due to our definition restricted to major complications in order to make sure that only complications affecting time till full RTW were included in this model.

The selected predictors together explained 58% of the variance between individual patients regarding prolonged sick leave. The other 42% of unexplained variance is partly caused by predictors which were not measured in this study or were not strong enough to survive the backward selection process, but a large part of the unexplained variance in sick leave will always remain unexplained due to individual random causes of prolonged sick leave.

Implications for practice

Increased risk of prolonged sick leave with a higher level of surgical invasiveness underlines the importance of minimal invasive surgery regarding a faster RTW. Despite more expensive instrumentation, longer duration of surgery time and higher training costs due to longer learning curves, many minimal access surgeries are cost-effective as a result of both shorter hospitalization and a reduction of sick leave after surgery.⁴⁶ However, as expectation of time to RTW before surgery also appeared an important predictor for prolonged sick leave, it is assumed that even more advantage of minimal invasive surgery regarding a faster RTW could be reached when RTW expectations are optimized. In the present situation, detailed recommendations on resumption of activities are mostly not provided,⁴⁷⁻⁵⁰ show substantial variability when present^{12,51-53} and are often not specified per surgical technique.^{44,53} Several studies have shown that uniform convalescence recommendations regarding return to normal and work activities in a variety of surgical operations reduced sick leave by several weeks.^{4,51,54,55} As a result of this study and considering that RTW expectations seem a relatively easy adaptable factor, it seems advisable to implement guidelines regarding RTW recommendations after gynaecological surgery. The effect of guidelines and tailored recommendations regarding RTW is currently being studied.⁵⁶ The final predictor for prolonged sick leave found in this study, was the RI-baseline score. This questionnaire with only five Likert scale questions requires minimal effort for patients to fill out and could therefore easily be used as supplement to the other two predictors in order to evaluate the risk of prolonged sick leave before surgery.

The practical applicability of the risk scores of the prediction model, depends besides the results of the external validation, on the importance attached to the threshold of 6 weeks of sick leave after surgery. If no RTW at 6 weeks after gynaecological surgery is considered as prolonged sick leave and the cut-off point of the risk score of < -2 is

taken, the negative predictive value is high, thereby preventing treatment in patients with a low risk of prolonged sick leave. It should be noted that there is no consensus of what implies prolonged sick leave and the consequences can be looked at from both psychological and economical perspectives; delayed RTW after surgery reduces quality of life in postoperative women and generates unnecessary yet substantial costs for society.^{4,6} Furthermore, considering the great contribution of the surgical category to the total risk score of prolonged sick leave, it seems reasonable to develop separate prediction models for every surgical category. However this study did not include enough patients to develop prediction models for separate groups of women, but could be used as a basis for new research to develop these models.

CONCLUSION

The results of this study provide an opportunity to identify women with a high risk of prolonged sick leave and to anticipate this by giving them additional care. Furthermore, this study underlines the relevance of woman's expectations for time to RTW, which emphasizes the importance of preoperative counselling and guidelines regarding RTW recommendations after surgery.

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CHAPTER 3

Multidisciplinary convalescence recommendations after gynaecological surgery; a modified Delphi method among experts

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ABSTRACT

Objective

To generate structured detailed uniform convalescence recommendations after gynaecological surgery by a modified Delphi method amongst experts and a representative group of physicians

Design

Modified Delphi study

Setting

Expert physicians recruited by their respective medical boards and employed at different hospitals, doctor's surgeries and health care services

Population or Sample

Twelve experts (five gynaecologists, two general practitioners (GPs), five occupational physicians (OPs)) and a representative sample of 63 medical doctors

Methods

Multidisciplinary detailed recommendations for graded resumption of relevant activities after uncomplicated hysterectomy (laparoscopic supracervical-, total laparoscopic-/laparoscopic assisted-, vaginal- and abdominal hysterectomy) and laparoscopic adnexal surgery were developed. Recommendations were based on a literature review and a modified Delphi procedure among 12 experts, recruited in collaboration with the participating medical boards of gynaecologists, GPs and OPs.

Main Outcome Measures

A multidisciplinary consensus of at least 67% on the relevant detailed convalescence recommendations in relation to hysterectomy and laparoscopic adnexal surgery

Results

Out of initially 65 activities, the expert panel judged 38 activities relevant for convalescence recommendations. Consensus for all activities was achieved after four Delphi rounds and two group discussions. The recommendations were judged by a representative sample of 26 gynaecologists, 19 GPs and 18 OPs as feasible.

Conclusions

Consensus between gynaecologists, GPs and OPs was achieved on all relevant convalescence recommendations, regarding hysterectomy (abdominal, vaginal, and laparoscopic) and laparoscopic adnexal surgery.

INTRODUCTION

Resumption of work activities after gynaecological surgery takes much longer than expected, irrespective of surgical technique and the severity of surgery.¹⁻⁴ There is strong evidence that long periods of sick leave can result in work disability, poorer general health, increased risk of mental health problems and even higher mortality.^{5;6} As a result, long periods of sick leave leads to more physician consultation, medical treatment and higher hospital admission rates.^{6;7} Considering the high costs of sick leave and medical care, prolonged sick leave induces unnecessary yet substantial costs for society.

Well-defined postoperative recommendations have been shown to reduce sick leave by several weeks in comparison to standard care given without any structural convalescence recommendations.^{1;8-13} However, detailed recommendations on resumption of activities are mostly not provided by medical specialists as a result of the lack of recognised guidelines on the gradual resumption of normal activities and a lack of knowledge about the physical demands of the patient's job.¹⁴⁻¹⁷ In addition, because of poor communication between medical doctors,^{18;19} there is substantial variation on the convalescence recommendations given by gynaecologists, general practitioners (GPs) and occupational physicians (OPs).^{2;9;11;20-24} These recommendations are also regularly conflicting^{2;20;21}, are not evidence-based^{2;9;11;20-24} and mostly independent of the type of surgery.^{2;24} Since frequently no or conflicting advice is given, patients do not know when to resume which activity and compliance to advice is low, which may contribute to irrational beliefs and result in delayed recovery, prolonged sick leave and reduced quality of life. This underlines the need generating standardised multidisciplinary pre- and postoperative convalescence recommendations.

Hysterectomy (abdominal (AH), vaginal (VH), total laparoscopic/laparoscopic assisted (TLH/LAVH), laparoscopic supracervical (LSH) is the most frequently performed major surgical procedure for a benign indication in gynaecology. There is a lack of national or international guidelines with respect to resumption of activities after these types of hysterectomies and laparoscopic adnexal surgery. In this study, we aimed to identify which (work related) activities were in need of convalescence recommendations and to formulate these convalescence recommendations in an expert panel of gynaecologists, GPs and OPs.

METHODS

Design of modified Delphi study

A modified Delphi consensus approach was used, guided by a systematic review of the published work on resumption of activities after gynaecological and abdominal general

surgery. The Delphi technique was originally designed as a way to obtain the opinion of experts without necessarily bringing them together face to face.²⁵ For the purpose of this study a modified version of the technique was used, which also involved panel discussions. An overview of the study design is presented in Figure 1. Using repeated anonymous questionnaire rounds and group discussions, the experts were able to give feedback on the previous round in a controlled way to achieve a consensus opinion in a short period of time. For the group discussions, a nominal group technique was used to reach consensus.²⁶ This modified Delphi method has been shown to be an efficient and useful method to bridge gaps in existing evidence of resumption of work activities for specific disorders and to reach a multidisciplinary consensus opinion within a heterogeneous expert group of medical doctors.²⁷ The data were collected between March and September 2009.

Expert panel recruitment

To improve the applicability and future implementation of the recommendations, an expert panel was recruited in collaboration with the participating medical boards of gynaecologists, OPs and GPs. As the different health care providers each have their own focus during the postoperative recovery period, an equal distribution between gynaecologists and OPs was aimed for. In addition, GPs were part of the expert panel because of their experience with the whole recovery period. This resulted in a panel of twelve experts: five gynaecologists, five OPs and two GPs. They were all members of their medical boards, had sufficient experience with patients who underwent gynaecological surgical interventions in their own daily practice and reported to have no potential conflict of interest.

Literature review

A systematic review of the current literature in 24 available and relevant national and international databases (such as Pubmed, Embase, Cochrane library and the American Medical Disability Advisor) from 1993 to 2008 was performed by a medical information specialist and the primary investigator. Searches were carried out for convalescence recommendations and time to return to work (RTW) and normal activities (RNA) after gynaecological and abdominal surgery on benign indications. Eligibility of the papers was assessed by three researchers (JAH, JRA and AVN), taking in consideration study design, population, size and RTW/RNA as primary outcome measures. A summary of this review was sent to all panel members to be used when completing the first Delphi questionnaire.

Case definition and draft case description

A draft case description was developed by the researchers for each surgical intervention (laparoscopic adnexal surgery and the four surgical approaches of hysterectomy: AH, VH, TLH/LAVH, LSH). In these case descriptions, an uncomplicated surgical procedure in otherwise healthy patients without any other major problems (i.e. no comorbidity,

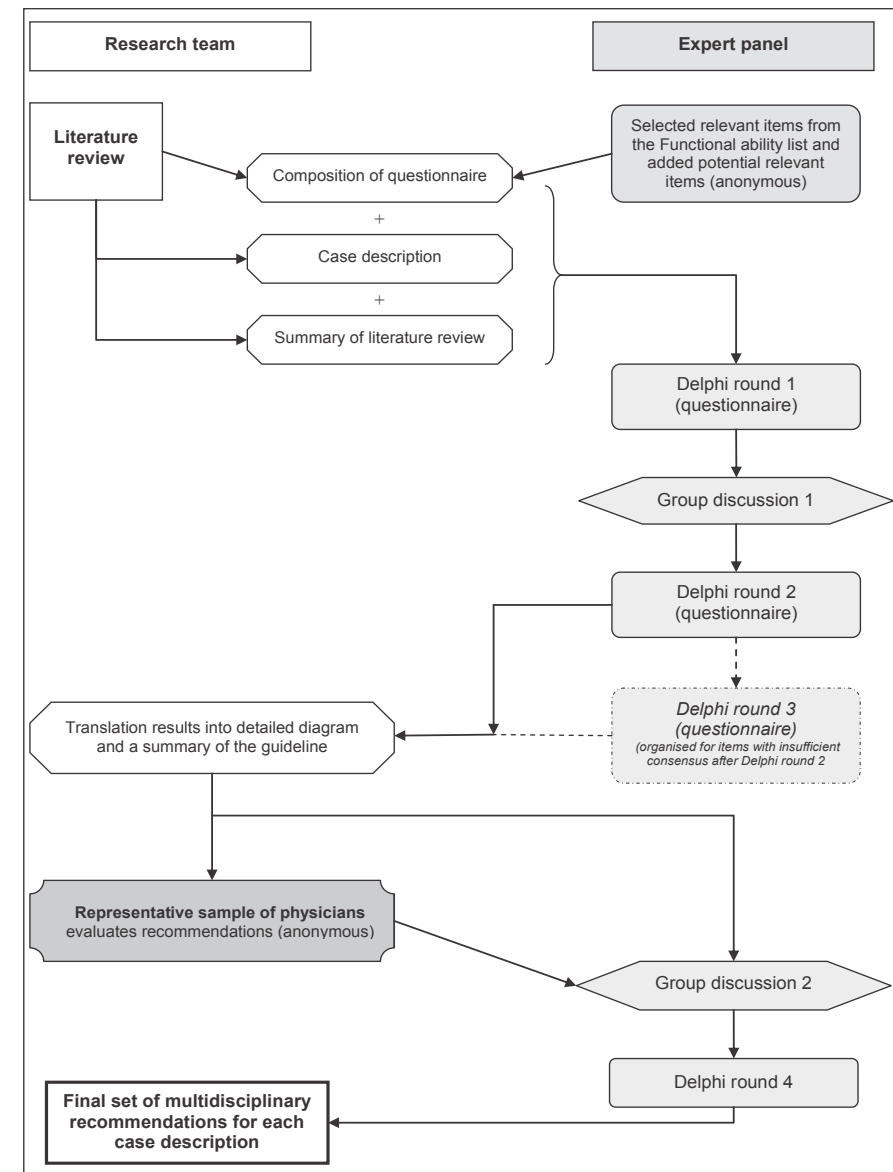


Figure 1. Study design; the step-wise modified Delphi method used in this study to reach a multidisciplinary consensus on convalescence recommendations.

psychosocial problems or obstacles other than medical for recovery or resumption of work) was portrayed. During the study, the case descriptions served as reference points for the panel members.

Development of a list with relevant convalescence recommendations

The Functional Ability List (FAL) was used to develop convalescence recommendations.²⁸

The FAL has a legal status to assess functional abilities in the Netherlands, and is used by OPs and insurance physicians (IPs) to assess and advise patients about functional abilities in their work. It distinguishes 59 different physical and psychosocial activities such as lifting, focusing attention, kneeling, etc. To improve the efficiency of the study procedure, in the initial part of the first Delphi round the panel members were asked which items of the FAL list were considered relevant for developing a multidisciplinary guideline and whether they recommended additional activities to be added to the list. Based on these results the first questionnaire was composed and sent to the panel.

Description of the structural consensus method

First three Delphi questionnaire rounds and group meeting

In the first round, the functional ability of each activity (FAL item) was scored by each panel member separately for each case description on a timeline (i.e. 2 days, 4 days, etc.), including a score of the (un)certainty of their decision on a ten-point Likert scale ranging from one ('very uncertain') to ten ('very certain'). Figure 2 shows an example of the activity 'carrying & lifting'. The relevance of all FAL items was scored additionally. On a scale from one ('not relevant') to ten ('very relevant'), the experts were asked to rate to what extent every activity was in need of developing convalescence recommendations. The relevance of FAL-items with a median score below seven were discussed by the expert panel during the first group meeting in order to determine whether the item should be included in the study. All other items with a median score of seven or higher were included without further discussion.

In the second round, the median values and range of the relevance scores, ability scores and certainty of each decision obtained in the first Delphi round, were calculated for each item. These (anonymous) results were presented graphically in a group meeting and were discussed with the expert panel, providing the opportunity to explore which items approached consensus from the ability scores, and which items had wide variance in the opinions of panel members. After an item was discussed, the panel members were asked to rate the ability scores again (anonymously), based on the group discussion and their own opinion. They had to rate the abilities with a score based on their maximum certainty, taking in consideration that the most restrictive ability score had to be chosen in case of uncertainty.

TLH/LAVH	T0	T1:	+2 dy	+4 dy	1 wk	2 wk	3 wk	4 wk	6 wk	8 wk	10 wk	12 wk	4 m	6 m	8 m	10 m	12 m
Ability score																	
Certainty of decision (0-10)																	

Ability score

0. Normal, can carry roughly 15 kg (toddler)
1. Slightly limited, can carry roughly 10 kg (infant)
2. Limited, can carry roughly 5 kg (bag of potatoes)
3. Very limited, can lift roughly 1 kg (litre container of milk)

Time schedule:

T0: period prior to surgery
 T1: day of surgery
 2 dy: second day after surgery, etc.
 1 wk: first week after surgery, etc.
 4 m: fourth month, etc.

Time points of measurement

Figure 2. Example of the item carrying & lifting of the functional ability list

If consensus was not reached on all relevant activities regarding all surgical procedures after the first two rounds, a third Delphi questionnaire round would be organized. In this round, the activities for which consensus was not reached during the second questionnaire round would be sent to the panel members again. Taking in consideration the median score of round two, they would have to rate the functional ability score once more.

Evaluation of the feasibility of recommendations by a representative sample of physicians

The results of the last Delphi round (round two or three) were translated into detailed diagrams and a summary of the guideline with draft recommendations for the postoperative resumption of (work) activities. This draft was sent to a representative sample of physicians (gynaecologists, GPs and OPs) derived from the professional organizations that were represented by the panel members (The Dutch Society of Obstetrics and Gynaecology (NVOG), The Dutch College of General Practitioners (NHG), the Dutch Association of Occupational Physicians (NVAB)), taking into account their geographical distribution in the Netherlands. They judged the presented results on their feasibility in practice and whether they had objections against the consensus opinion. If they had objections, they were encouraged to explain their objections and to propose other recommendations.

Final expert panel meeting and fourth Delphi round

The results of the last Delphi questionnaire round and the judgment of the representative sample of physicians were presented and discussed at the second group meeting. The procedure of round two was again used to develop a final set of multidisciplinary recommendations, differentiated by disorder, surgical technique and time after surgery.

Consensus rules

To identify consensus, and to determine which activities had to be selected to be scored again in the next questionnaire round because of a lack of consensus, a set of consensus rules was used, defined differently for dichotomous and non-dichotomous items. Consensus for dichotomous items was reached when mean consensus over all time points was at least 75% and consensus per individual time point was higher than 50%. For items with three or more grades of ability, consensus was reached when mean consensus over all time points was at least 67% and consensus per time point exceeded 50%. All items and time points had to be rated by at least nine panel members.

RESULTS

Literature review

The literature search resulted in 2979 papers. All titles or abstracts were reviewed and cross references of relevant papers were checked, resulting in 81 potentially relevant papers and four clinical guidelines about recovery time until full RTW. After assessing eligibility of these papers and guidelines, a selection of seven full papers^{1;11;20;21;29-31}, four clinical guidelines³²⁻³⁵ and 32 articles^{1;4;30;36-65} summarized in tables by the authors, were sent to all panel members.

Number of Delphi rounds and response rate

Four questionnaire rounds and two group discussions were required to meet the objectives of the study. The response rate for round one was 92% (11/12 experts) and in rounds two, three and four 100% of the experts responded. All the experts completed the entire study.

Preliminary list of relevant convalescence recommendations

During the initial part of Delphi round one, the expert panel judged that 38 out of the initial 59 items of the FAL list and four additional activities (taking a bath, jumping, vacuum cleaning and sexual intercourse) should be included in the convalescence recommendations. The results of the first-round questionnaire were based on these 42 items, which are represented in Table 1.

Consensus course

First Delphi questionnaire round

After the first Delphi questionnaire round, for each item the consensus per time unit and the mean consensus was calculated. Consensus was not reached for any of the 42 items regarding all surgical procedures. In Table 1, the consensus flow for TLH/LAVH is represented.

Table 1. Consensus course for TLH/LAVH

Category	Item	Number of gradations	Round 1 Consensus (%)	Round 2 Consensus (%)	Round 3 Consensus (%)	Round 4 Consensus (%)
Personal functioning	Focusing attention	3	63	77	c	c
	Dividing attention	3	67	84	c	c
	Memory	3	59	68	c	c
	Insight into own abilities	3	65	70	c	c
	Action tempo	2	70	90	c	c
Social functioning	Transportation	2	81	97	c	c
					c	c
Adjusting to environment	Vibrations	2	79	87	c	c
Dynamic movements	Reaching	3	57	100**	100	c
	Frequent reaching	4	54	73*	96	c
	Bending	3	71	93	c	c
	Frequent bending	4	60	83	c	c
	Rotation	2	82	91	c	c
	Pushing or pulling	3	64	84	c	c
	Lifting or carrying	4	56	67*	88	c
	Frequent light lifting	4	52	69*	88	c
	Frequent heavy lifting	2	83	94	c	c
	Sustained walking	4	55	66*	85	c
	Walking per day	4	55	88	c	97***
	Climbing stairs	4	56	76	c	c
	Climbing	4	62	83	c	c
Kneeling or squatting	2	83	96	c	c	
Static postures	Prolonged sitting	4	57	72	c	c
	Sitting per day	4	58	75	c	c
	Prolonged standing	4	55	77	c	c
	Standing per day	4	54	79	c	c
	Prolonged kneeling or squatting	2	87	90	c	c

Table 1. Continued

Category	Item	Number of gradations	Round 1 Consensus (%)	Round 2 Consensus (%)	Round 3 Consensus (%)	Round 4 Consensus (%)
Static postures	Prolonged bending	2	78	93	c	c
	Working above shoulders	2	73	87	c	c
	Changing posture	2	67	76**	100	c
Working hours	Hours per day	5	63	75*	94	c
	Hours per week	5	63	84	c	100***
	Shift work	3	62	86**	100	c
Other activities (not-work related)	Taking a bath	2	72	89	c	c
	Sexual intercourse	2	85	97	c	c
	Jumping	2	79	95	c	c
	Vacuum cleaning	2	73	91	c	c
	Riding a bicycle ^a	2	-	83	c	c
	Driving a car ^a	2	-	78	c	c

This table presents the mean consensus per activity per Delphi round for TLH/LAVH. When consensus is reached after round two (see Methods), the activity was excluded from the next Delphi round and presented in this table as 'c' (consensus).^a Additional item after first Delphi round. ^c Consensus achieved.

* Mean consensus reached, but contains time point with consensus lower than 50%.

** Mean consensus reached, but contains time point that is rated by less than nine panel members.

*** Adjustment of ability score during fourth Delphi round.

For clarification of items and ability gradations, see Appendix 3.

First group meeting and Delphi questionnaire rounds two and three

During the first group meeting, the results of the first questionnaire round were discussed and differences in opinion between the panel members were explored. The median relevance score of six FAL-items (effective action, independent action, handling emotional problems of others, expression of personal feelings, dealing with conflicts, protective measures), was scored below seven by the panel members in the first Delphi round. For those items, the expert panel discussed whether they should still be part of the convalescence recommendations. All six items were judged to be irrelevant by the vast majority of panel members (effective action 12/12, independent action 12/12, handling emotional problems of others 11/12, expression of personal feelings 12/12, dealing with conflicts 12/12, protective measures 9/12) and thus excluded from the next Delphi questionnaire round. After the group discussion, two additional items (riding a

bicycle and driving a car) were judged by a majority of votes to be relevant for developing convalescence recommendations and were added to the list of items for the next Delphi questionnaire round. The list of items that was used in the next Delphi questionnaire round consisted of 38 activities.

During the second Delphi questionnaire round, consensus was reached for 16 of the 38 items. The items for which consensus was not reached were then sent to the panel members for a third Delphi questionnaire round. After the third round, consensus was reached for 36 activities regarding all surgical procedures.

Evaluation of the feasibility of recommendations by a representative sample of physicians

For all five procedures, the consensus of the first three Delphi rounds was judged by 26 gynaecologists, 19 GPs and 18 OPs. Major revisions were not requested and only minor revisions were proposed.

Second group discussion and Delphi round four

The two activities whereby consensus was not reached in questionnaire round three (walking per day and standing per day) were taken to the fourth Delphi round, where consensus was also reached for these activities. Based on the proposed minor revisions by the representative sample of physicians and contradictions in ability score regarding some activities/surgical procedures, an adjustment of the ability score was made for 14 different activities during Delphi round four. Table 1 shows for which activities an adaptation was made for laparoscopic hysterectomy ('walking per day' and 'working hours per week'). After round four, consensus for all 38 activities was reached.

Final convalescence recommendations and case descriptions

For each case description (hysterectomy (AH, VH, TLH, LSH) and laparoscopic adnexal surgery), a final set of convalescence recommendations was formulated, based on the consensus findings of Delphi round four and an analysis of the comments of the representative sample of physicians.

Figure 3 presents a detailed diagram of the recommendations for TLH/LAVH and Figure 4 shows an example of how the recommendations may be summarized for guidelines.

Category	Item*	Number of ability gradations*																			
			T0	T1	2 dy	4 dy	1 wk	2 wk	3 wk	4 wk	6 wk										
Personal functioning	Focusing attention	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Dividing attention	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Memory	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Insight into own abilities	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Action tempo	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Social functioning	Transportation	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Adj. to environment	Vibrations	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Dynamic movements	Reaching	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Frequent reaching	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Bending	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Frequent bending	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Rotation	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Pushing or pulling	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Lifting or carrying	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Frequent light lifting	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Frequent heavy lifting	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Sustained walking	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Walking per day	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Climbing stairs	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Climbing	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Kneeling or squatting	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Static postures	Prolonged sitting	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Sitting per day	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Prolonged standing	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Standing per day	4	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Prolonged kneeling or squatting	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Prolonged bending	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Working above shoulders	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Changing posture	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	
Working hours	Hours per day	5	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Hours per week	5	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Shift work	3	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Other activities (not-work related)	Taking a bath	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Sexual intercourse	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Jumping	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Vacuum cleaning	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Riding a bicycle	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Driving a car	2	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Time schedule		T0	T1	2 dy	4 dy	1 wk	2 wk	3 wk	4 wk	6 wk											

*For clarification of items and ability gradations, see appendix 3.

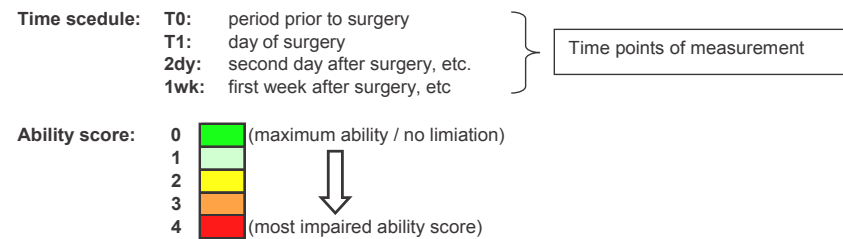


Figure 3. Detailed convalescence recommendations after fourth Delphi round for TLH/LAVH

	Examples	Considered medically possible from (days/weeks after day of surgery)				
		Lapsc Adn	LSH	TLH	VH	AH
Light activities	<ul style="list-style-type: none"> lifting or carrying 5kg 2 hours sustained sitting 30 minutes sustained standing & walking 	2dy	1 wk	1 wk	2 wk	2 wk
Moderate activities	<ul style="list-style-type: none"> lifting or carrying 10kg pushing or pulling 15kg riding a bicycle vacuum cleaning 	1 wk	2 wk	2 wk	3 wk	3-4 wk
Heavy activities	<ul style="list-style-type: none"> lifting or carrying 15kg standing & walking during entire working day 	2 wk	3 wk	3 wk	4 wk	6 wk
Resumption of (average) job	<ul style="list-style-type: none"> +/- 8 hrs a day +/- 40 hrs a week 	2 wk	3 wk	3-4 wk	4 wk	6 wk

Abbreviations: Lapsc Adn: Laparoscopic adnexal surgery
 LSH: Laparoscopic supracervical hysterectomy
 TLH / LAVH: Total laparoscopic hysterectomy / Laparoscopic assisted hysterectomy
 VH: Vaginal hysterectomy
 AH: Abdominal hysterectomy

Time schedule: dy: day(s)
 wk: week(s)

Figure 4. Summary of the final set of multidisciplinary convalescence recommendations

DISCUSSION

Main findings

In this study, the modified Delphi method proved to be an efficient and useful method to bridge gaps in opinions between gynaecologists, GPs and OPs, and to achieve a consensus opinion between the stakeholders in a relatively short period of time. After four questionnaire rounds and two group meetings, consensus was reached for all relevant recommendations. Based on the consensus findings, detailed convalescence recommendations for resumption of activities after hysterectomy (AH, VH, LH) and laparoscopic adnexal surgery have been formulated.

Comparison with other studies

The literature review revealed no comparable studies that developed or evaluated detailed convalescence recommendations after hysterectomy or laparoscopic adnexal surgery. In clinical practice, recommendations are mainly based on traditions and personal opinions.

Previous studies of advice on return to work include an UK guideline of the Department for Work and Pensions (DWP),³² and clinical guidelines of the American Medical Disability Advisor (MDA).³³⁻³⁵ The DWP guideline claim to report evidence-based recovery times and

recommend a postoperative recovery time to full activity (including work) of three weeks after laparoscopic-assisted-hysterectomy and 7 weeks after abdominal hysterectomy, regardless the nature or physical taxation of the job. This is comparable to the 4 and 6 weeks recommended by our expert panel for full return to a physically demanding job. The guidelines of the MDA report consensus-based advice for a minimum, optimum and maximum length of disability for uncomplicated cases, itemized for the demands of the job.⁶⁶ In relation to laparoscopic adnexal surgery, LH, VH and AH, the MDA recommends an optimum length of disability of 1, 4, 4 and 6 weeks for sedentary work and 3, 10, 10 and 12 weeks for a very physically demanding job, respectively. When we compare these results with the developed recommendations in this Delphi study, it is striking that for all types of hysterectomy and job classifications, at least 2-6 weeks less sickness leave is advised in our guidelines. The most plausible explanation for this substantial difference in recommendations in postoperative recovery is that the two guidelines were developed for different purposes. Our guideline is developed as an aid for the gradual resumption of activities and reintegration, whereas the MDA disability guideline tables represent important points in time at which, if full recovery has not occurred, additional evaluation should take place and is designed to determine the duration of sickness benefit.

Another distinguishing feature of the results of our study compared to the previously mentioned guidelines is the level of specification of the recommendations. The DWP guidelines and MDA only report the recovery time until full return to work, whereas the results of our Delphi study provide detailed advice of different types of graded activities from the day of surgery until a full return to work.

Strengths and limitations

A primary strength of the present study lies in the use of the modified Delphi method, in which the participants had all relevant and available literature at their disposal, were allowed to maintain anonymity during the questionnaire rounds which prevents peer pressure, and had the opportunity to revise their opinion during the group discussions. The questionnaire rounds prevented domination by any particular individual who might otherwise be overly influential in a group decision. Furthermore, representatives from the stakeholder groups of gynaecologists, OPs and GPs were involved, which can improve the practical applicability of the research findings,⁶⁷ and leads to guidelines that are endorsed by all stakeholders. A third strength is the heterogeneous expert panel, with the different health care providers each having their own focus during the postoperative recovery period, which provided a wide range of opinions for the formulation of the convalescence recommendations.⁶⁸

Furthermore, all experts completed the entire study, which underlines the agreement of the experts with the design and content of the study and the generalisability of the

consensus results.⁶⁹⁻⁷¹ Lastly, the evaluation of the feasibility of the recommendations by a large sample of geographically dispersed physicians, allowed an examination of different points of view and prevented recommendations that go against general clinical practice.⁷²

The main limitation of this study was the use of the functional ability list, which was originally developed for detailed assessment of functional ability by OPs and IPs in the Netherlands. Conversely, in our study we used this instrument for judgment of different gradations of strain in the recovery process after a medical intervention. By using the FAL, the gradations of strain were judged in great detail. In combination with the variation of recovery time per patient, determining to which extent a patient could be strained at a given time was a challenging task for the experts. However, at this moment it is the most suitable instrument available for this kind of study and the experts did reach a consensus opinion for all activities and gradations of strain. A second limitation is that the convalescence recommendations are based on opinions of a single group of Dutch experts and cannot be taken to be reflective of all Dutch experts.⁷³ Nevertheless, the evaluation of the recommendations by a representative sample of physicians indicates that the results are representative for the stakeholders. It needs to be noted that the convalescence recommendations are mere point-estimations of an average recovery time with a natural range, not taking into account other (non)medical factors that might influence the postoperative recovery time. If complications or co-morbidities are present, the physician will have to determine whether the recovery period will need to be extended. Since this was an exclusively Dutch study, external validity has to be examined for the results to be applicable internationally. Finally, it is possible that the expert panel has inadvertently overlooked an important convalescence recommendation. However, such a risk is minimal since the panel members were a heterogeneous sample of experts, they had elaborate opportunity to provide suggestions for relevant activities and all available knowledge about convalescence recommendations provided by the literature review was used.

Interpretation of the results and policy implications

The recommendations can be interpreted as an average functional recovery time for a healthy woman between 18 and 65 years old, not taking into account other (non) medical factors that might influence the postoperative recovery time. The convalescence recommendations are rooted in expert-based knowledge and are point-estimations of an average recovery time with a natural range. Therefore, the judgment of the specialist has to be applied in case of complications or in the presence of comorbidities.

The recommendations are meant to be a tool for gynaecologists, GPs and OPs to assist them in giving unambiguous detailed convalescence recommendations to their patients during the perioperative period. By doing so, patients will be better informed about when it is thought to be medically safe to resume daily and work activities after gynaecological

surgery, and it will give them the possibility to arrange (workplace) adaptations if necessary. Prospective cohort studies exploring sick leave after general surgical procedures show that return to work is mainly influenced by the expectations of the patient and their supervisors, rather than physical factors or the type of surgery.^{1,8-10} Therefore, it is assumed that detailed convalescence recommendations will especially help to exploit the potential advantages of minimal invasive surgical procedures to accelerate recovery. Furthermore, the unambiguous recommendations developed in this study will likely enhance the compliance to advice given by medical specialists and stimulate the patient to resume activities with increasing gradations of strain, which will presumably bring about a quicker recovery without an increase of complications.^{9,11,13} Therefore, the recommendations may potentially prevent work disability, increase quality of life and increase patient satisfaction with care. To investigate these hypotheses, further research using a randomized controlled trial will be conducted, in order to validate the recommendations developed in this study.

CONCLUSION

Consensus between gynaecologists, GPs and OPs was achieved on all relevant convalescence recommendations for recovery, regarding hysterectomy (AH, VH, LH) and laparoscopic adnexal surgery. These consensus-based multidisciplinary recommendations should be considered as an important first step towards improvement of perioperative care. Further study will be conducted to validate the guidelines and evaluate the effectiveness in clinical practice.

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CHAPTER 4

eHealth program to empower patients in returning to normal activities and work after gynaecological surgery:
Intervention Mapping as a useful method for development

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ABSTRACT

Background

Full recovery after gynaecological surgery takes much longer than expected regardless of surgical technique or the level of invasiveness. After discharge, detailed convalescence recommendations are not provided to patients typically, and postoperative care is fragmented, poorly coordinated, and given only on demand. For patients, this contributes to irrational beliefs and avoidance of resumption of activities and can result in a prolonged sick leave.

Objective

To develop an eHealth intervention that empowers gynaecological patients during the perioperative period to obtain timely return to work (RTW) and prevent work disability.

Methods

The Intervention Mapping (IM) protocol was used to develop the eHealth intervention. A literature search about behavioural and environmental conditions of prolonged sick leave and delayed RTW in patients was performed. Patients' needs, attitudes, and beliefs regarding postoperative recovery and resumption of work were identified through focus group discussions. Additionally, a literature search was performed to obtain determinants, methods, and strategies for the development of a suitable interactive eHealth intervention to empower patients to return to normal activities after gynaecological surgery, including work. Finally, the eHealth intervention was evaluated by focus group participants, medical doctors, and eHealth specialists through questionnaires.

Results

Twenty-one patients participated in the focus group discussions. Sufficient, uniform, and tailored information regarding surgical procedures, complications, and resumption of activities and work were considered most essential. Knowing who to contact in case of mental or physical complaints, and counselling and tools for work reintegration were also considered important. Finally, opportunities to exchange experiences with other patients were a major issue. Considering the determinants of the Attitude–Social influence–self-Efficacy (ASE) model, various strategies based on a combination of theory and evidence were used, resulting in an eHealth intervention with different interactive functionalities including tailored convalescence recommendations and a video to communicate the most common pitfalls during the perioperative period to patients and employers. Fifteen patients in the focus groups, 11 physicians, and 3 eHealth specialists suggested points for improvement to optimize the usability of the eHealth intervention and judged it an approachable, appropriate, and attractive eHealth intervention to empower gynaecological patients.

Conclusions

The IM protocol was a useful method to develop an eHealth intervention based on both theory and evidence. All patients and stakeholders judged the eHealth intervention to be a promising tool to empower gynaecological patients during the perioperative period and to help them to return to normal activities and work.

INTRODUCTION

Following gynaecological surgery, full recovery (including returning to work) takes much longer than expected regardless of surgical technique or the level of invasiveness.¹⁻³ In two prospective observational studies in the Netherlands, median sick leave after gynaecological procedures for benign conditions was 8 weeks.⁴ Prolonged absence from work often results in a lack of social structure and meaningful activities^{5,6} and can result in work disability, poorer general health, and increased risk of mental health problems.^{7,8} As a result, long periods of sick leave contribute to a reduced quality of life and induce unnecessary yet substantial costs for society through lost working hours, physician consultations, medication treatment, and higher hospital admission rates.^{9,10}

To reduce health care costs, there is an increasing trend to limit the duration of in-hospital care and to transfer postoperative care to outpatient and primary care.¹¹⁻¹³ However, after discharge, gynaecological care is given only on demand; detailed recommendations about resumption of work activities are not provided typically and patients often do not know who to contact for support in case of postoperative complaints.^{1,14} Furthermore, family physicians frequently do not give advice about resumption of work activities and occupational, or insurance, physicians are only consulted if patients have paid work and these consultations take place relatively late in the course of sick leave because of legislation.¹⁵⁻¹⁷ This contributes to irrational beliefs and avoidance of resumption of activities, resulting in a prolonged sick leave.¹⁸

Because a significant part of the recovery and return to work (RTW) problems of patients seem to be caused by counselling and communication deficiencies, the starting point of this study was to identify these problems. Many interventions aiming to improve communication with and counselling of patients have focused only on health care professionals.^{19,20} However, to improve communication and health outcomes, empowering patients to actively participate in their consultations with physicians is also important.^{21,22} Patient empowerment refers to the enhanced ability of patients to actively understand and influence their own health status.²³ It focuses on control in patients' experience of health, disease, and illness, as well as the roles of health care organizations, communities, and the broader health care system.^{24,25} eHealth interventions seem to be a promising way to empower patients by providing personalized education (e.g. detailed recommendations on resumption of work activities) and enhancing interaction between health consumers and professionals.²⁶⁻²⁸ Patients become more actively engaged in their own state of health (e.g. are aware which complications need additional consultation) and the communication between patient and health care provider becomes more efficient and equal.²⁹⁻³¹ Tailored eHealth interventions are more intensively used^{32,33} and have a greater impact on people's behaviour³³⁻³⁶ than generic materials and they provide the opportunity to deliver

information to a large audience³⁷ at any time and with lower costs.^{34,38} An important condition for a successful eHealth intervention is adequate implementation.^{39,40}

Therefore, the objective of this study was to develop a feasible and generally accepted eHealth intervention that empowers gynaecological patients during the perioperative period about returning to normal activities and work, to obtain timely RTW, and prevent work disability. To develop this intervention, we used the intervention mapping (IM) protocol^{41,42}, which has been shown to be a suitable systematic and scientifically accepted method for the development and implementation of a wide range of eHealth⁴³⁻⁴⁶ and RTW^{47,48} interventions based on theory and stakeholders' (including patients') involvement.

METHODS

Intervention mapping was used to tailor the eHealth intervention to patients' needs and wishes, taking into account the clinical evidence of the main determinants that influence patients' behaviour to reach timely RTW. The project group consisted of 1 research physician, 2 gynaecologists, and 2 occupational physicians. Although it is not a theoretical or conceptual framework, IM is a systematic description of a logical planning process involving 6 steps: (1) performing a needs assessment; (2) defining program objectives; (3) selection of theory-based methods and practical strategies; (4) design of the intervention program; (5) development of a plan for adoption and implementation; and (6) design of an evaluation plan (Figure 1). The iterative character of IM enables the intervention to be based on a combination of theory and evidence, which maximizes the applicability for the target population and minimizes the risk of choosing the wrong theory behind the intervention (theory failure) or of poor adoption of the intervention (program failure).⁴⁹

Step 1: Needs assessment

In needs assessment, the discrepancy between the current and the desired situation in a given group of people is studied. The needs assessment was structured by the Precede-Proceed model (PRECEDE: predisposing, reinforcing, and enabling constructs in educational diagnosis and evaluation; PROCEED: policy, regulatory, and organizational constructs in educational and environmental development), which analyses and correlates quality of life, health, behaviour, and environmental factors in a certain population.⁵⁰ The current situation has shown a large discrepancy between expected duration of physical recovery and actual RTW after (laparoscopic) gynaecological surgery, whereas there is strong evidence that long periods of sick leave can result in poorer general health, increased risk of mental health problems and work disability, and induces unnecessary costs for society.^{2,8} The most frequently performed gynaecological surgical procedures with a considerable postoperative effect on recovery and RTW (accounting for more than 17.500 procedures in the Netherlands per year) are hysterectomy (abdominal, vaginal, and laparoscopic)

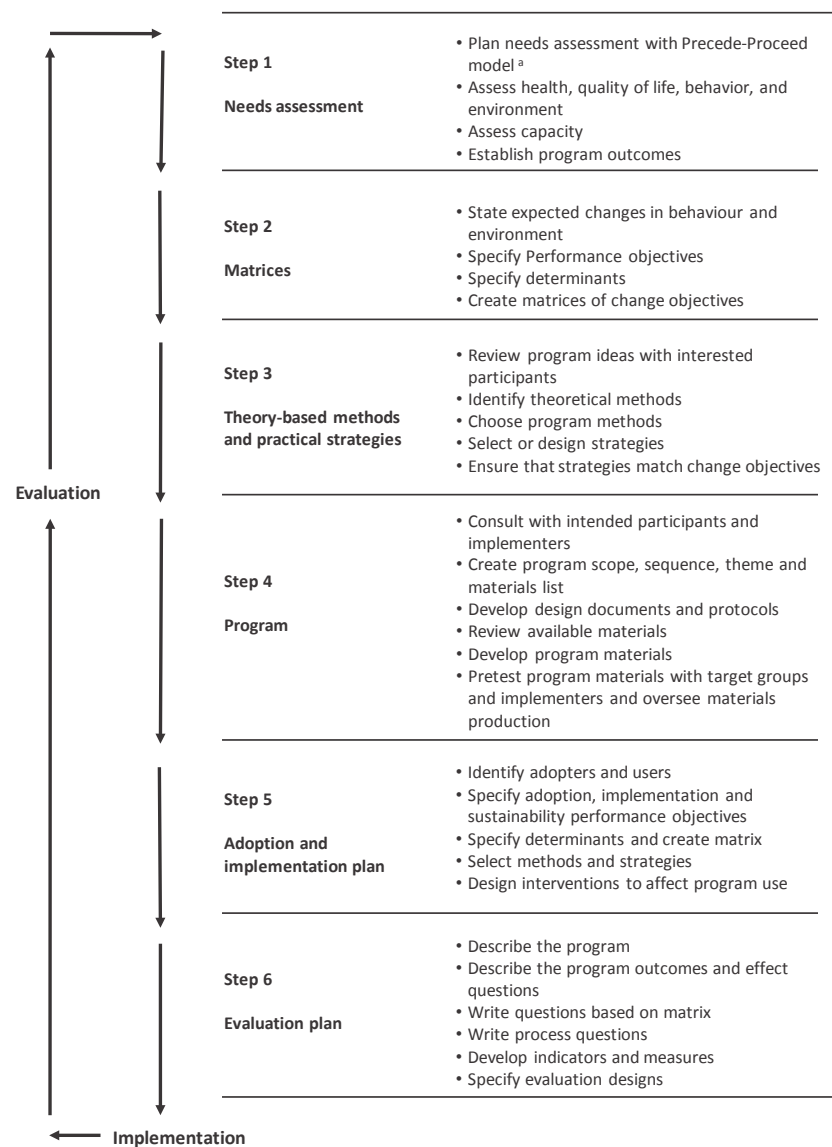


Figure 1. Intervention Mapping Process, based on the Intervention Mapping described by Bartholomew et al.^{41,42}

^a The Precede-Proceed model structures the analyses and correlation of quality of life, health, behaviour and environmental factors of a certain population.⁵⁰

or laparoscopic adnexal surgery on benign indication.⁵¹ Because approximately 67% of women aged 25-65 are in the workforce, these large numbers of surgical procedures have a great impact on absenteeism.⁵² Therefore, patients who underwent these types of surgical procedures were chosen as the target group for this intervention.

To clarify and find possible explanations of prolonged sick leave, a literature search in PubMed regarding behavioural and environmental conditions of (prolonged) sick leave and (delayed) RTW in the target group was performed. The focus group technique was considered the most suitable supplement to the literature search for identification of patient's needs, attitudes, and beliefs regarding postoperative recovery and resumption of work. In addition to supplying the results of the literature search, it was assumed that focus group discussions would make the results more aligned to the Dutch context and give more insight into specific requirements regarding the content of the prospective eHealth intervention that could be used during the developmental process. The participatory technique of focus group discussions is widely used and scientifically accepted to gain insight in public views and needs through group interaction.^{53,54}

Participants for the focus group discussions were recruited from the patient files of the VU University Medical Center, an academic hospital in the Netherlands. To mirror the intended target group, inclusion criteria for participation in the focus group discussions were age 18-65, a history of a laparoscopic adnexal surgery and/or hysterectomy on benign indication in 2008, and a job (paid or unpaid) of at least 8 hours per week. To create homogeneity within the focus groups but heterogeneity among the groups, the patients were recruited by means of purpose sampling into 3 groups: fast RTW, intermediate RTW, and delayed RTW. All of the participants had already returned to work after surgery (range 1-36 weeks).

The aim of the focus group discussions was to identify patients' needs regarding perioperative care and counselling in resumption of normal and work activities. In addition, patients were specifically asked for the important requirements of a useful eHealth intervention. The identification of patients' needs and requirements occurred in 3 different steps:

1. Identifying and prioritizing patients' perceived shortcomings and difficulties in received perioperative care and counselling in resumption of normal and work activities.
2. Inventory of possible solutions and improvements to overcome these shortcomings and difficulties, starting with the highest prioritized bottlenecks.
3. Brainstorming about favourable content, requirements, and specific tools that should be incorporated into an eHealth intervention that aims at empowering patients during the perioperative period and resumption of work activities.

The focus group discussions were all recorded and transformed into verbatim transcripts that were analysed by open coding using the ATLAS.ti software.⁵⁵ A detailed process evaluation of the focus group discussions to be found in chapter 5 of this manuscript.

The study design and procedures of the focus group discussions were approved by the Medical Ethics Committee of the VU University Medical Center (2009/42, February 9, 2009). Participants signed a privacy agreement to declare voluntary participation, to give permission for processing the information for the development of an intervention (such as an eHealth intervention), and to exclude transmittal of information to others.

As a starting point for the development of the intervention, the products of this first step were the main behavioural and environmental conditions of the chosen target group contributing to prolonged sick leave.

Step 2: Matrices

The purpose of this step was to transform the identified behaviours and environmental conditions causing prolonged sick leave into behaviours and conditions that prevent a prolonged sick leave. To achieve this, performance objectives were formulated. Performance objectives describe in detail patients' behavioural and environmental outcomes that are necessary for patients to reach the formulated behaviour objective of "timely RTW."

To select a suitable theoretical framework to reach the performance objectives, a literature search regarding main determinants of recovery and RTW was performed in PubMed. To elucidate, a suitable theoretical framework provides appropriate determinants that could be influenced to reach the behaviour objective. Based on this framework, the performance objectives of the target group were elaborated into matrices with change objectives, explaining how patients and their environment will change as a result of the eHealth intervention to reach the behaviour objective.

Step 3: Theory-based methods and practical strategies

In this step, theoretical methods and practical strategies to address the change objectives were searched for and applied. Research has shown that the effectiveness of interventions to change behaviour can be increased by the use of theory-based methods.⁵⁶ A theory-based method is a method derived from theory and research that describes a process that influences changes in determinants of behaviour and environmental conditions. A practical strategy is a technique for the application of the theory-based method in ways that fit the target group and the context in which the eHealth intervention will be applied. The required theoretical framework, theory-based methods, and translation into practical strategies were determined based on the book that describes the IM approach⁴², a

literature search in the PubMed database, the focus group discussions, and a brainstorm session of the researchers.

Step 4: Program plan and design of the intervention

During this step, information obtained in previous steps was translated into specific, tailored tools and information to empower gynaecological patients by the eHealth intervention. Furthermore, to obtain evidence-based information and instruments necessary to fulfil patients' needs, additional research was performed.

To verify if the eHealth intervention matched with the main target group and fitted the expectations of gynaecologists, family physicians, and occupational physicians, the first concept version was evaluated by focus group participants (n = 21), physicians (n = 22), eHealth specialists (n = 3), and a representative of a patient organization (n = 1) through questionnaires. The eHealth intervention was scored on 8 main areas used to describe how the intervention functions, empowers, and can be modified to provide the best behaviour change to obtain timely RTW and prevent work disability. The 8 areas included: appearance, behaviour prescriptions, burdens of using the website, content, delivery, message, participation, and assessment and tailoring. Ritterband et al describe these areas in detail.⁵⁷ This model is meant to ground Internet intervention research within a scientific framework. The 8 different areas were covered in the evaluation questionnaires with 23 unique open- and close-ended questions (Appendices 7 and 8). In addition, participants were also encouraged to propose recommendations. The results of the evaluation were used to optimize the design and usability of the eHealth intervention, which resulted in the final version.

Step 5: Design of an implementation plan

The focus of Step 5 is adoption of the intervention by the patients and relevant stakeholders, and the development of an implementation plan. With the input of patients and stakeholders during previous steps, the researchers identified facilitating factors and barriers regarding adoption and implementation of the eHealth intervention. With this information, an implementation plan to enable an extensive evaluation of the intervention was developed and an appropriate linkage system for future implementation was composed.

Step 6: Design of an evaluation plan

During Step 6, the main objective of this study (i.e. to develop a feasible and generally accepted eHealth intervention that empowers gynaecological patients during the perioperative period into returning to normal activities and work, to obtain timely RTW, and prevent work disability) was used to compose an evaluation plan. Although the eHealth intervention was based on both theory and evidence and was developed in

collaboration with the main target group and relevant stakeholders, its adoption, barriers for usage, and implementation possibilities still have to be evaluated in daily practice. In addition, the effectiveness of this eHealth intervention regarding a timely RTW to prevent work disability has to be investigated. Therefore, the project group approached 7 gynaecologists (1 university-based and 6 hospital-based), to participate in the evaluation of this intervention through implementation of the eHealth intervention as a supplement to the standard perioperative care given at their hospital. In addition, the project group formulated inclusion and exclusion criteria for patients to participate in the study and developed appropriate outcome measures to evaluate the intervention's effectiveness, adoption, usage, and implementation. Furthermore, a logistic plan to recruit patients and involve participating health care providers was developed.

RESULTS

Step 1: Needs assessment

Literature

The literature search revealed that most women extend their sick leave beyond the recommended period on their own initiative.² Patients with delays in RTW reported pain/discomfort, feelings of fear, and infections as delaying factors.¹ Those who reported multiple delaying factors reported a variety of combinations that included feelings of fear, anxiety, depression, and a difference in employer expectations.¹ Recovery and RTW time is shorter when the patient receives clear and few restrictions that are not too overly cautious at discharge, when the patient has been provided with RTW advice, or when the patient feels an urgency to RTW.^{1,3,58} Other important environmental conditions for prolonged sick leave and RTW of patients appeared to be the substantial variation on convalescence recommendations given by gynaecologists, family physicians, and occupational physicians.^{58,59} Their recommendations are not related to the most successful return to normal and work activities or the risks of complications.⁵⁸ In addition, a lack of clarity regarding absence duration can provide an obstacle for employers and employees who are keen and willing to establish earlier rehabilitation programs, but would not wish to go against the advice of health care providers.⁵⁹

Focus group discussions

Out of 105 invited patients, 38 met our inclusion criteria and were willing to participate in the focus group discussions. On the basis of availability on the selected dates for the focus group discussions, 31 patients were assigned to 3 focus groups. Of these patients, 21 were present at the meetings and participated in the focus group discussions (7 patients per meeting). A process evaluation of the focus group discussions to be found in chapter 5 of this manuscript.

Starting with the first aim of the focus group discussions, the most important reported shortcomings and difficulties of currently provided perioperative gynaecological and reintegration care were (in random order):

1. Insufficient or no information about the surgical procedure itself, the logistical process in the hospital from admission to discharge, detailed resumption of work activities after the surgical procedure, and the possible consequences of the surgery (physical and mental).
2. Inconsistency of convalescence recommendations given by gynaecologists, family physicians, and occupational physicians.
3. Lack of written instructions on resumption of work activities, tailored to individual conditions and work, and consequently insufficient information and instructions to relatives.
4. Insecurity with respect to physical or mental postoperative symptoms, complications, or delayed recovery. What to do and whom to contact?
5. Poor communication among gynaecologists, family physicians, and occupational physicians resulting in inadequate transfer of information about the procedure and one another's treatments.
6. Limited or inadequate guidance by occupational physicians because of a lack of knowledge about different types of surgery and corresponding recovery times. Patients experienced that the occupational physician forced the patient to RTW too early or slowed down the RTW process.
7. Difficulties with work reintegration because of insufficient involvement and understanding of the employee/employer during the perioperative and reintegration period.
8. Inability of patients to discuss the perioperative period and reintegration process at work (with employer and colleagues).
9. Lack of a reintegration plan before the surgery.
10. Few opportunities to contact other patients to exchange experiences.

In general, patients mentioned that when they were unsatisfied with the information or counselling that their doctors and nurses gave, they asked family and friends who had undergone surgery about their experiences. However, this led to unrealistic expectations because of the different types of surgical procedures and techniques, and the fact that recovery is affected by individual conditions and circumstances. In the second part of the focus group discussions, the patients brought up many possible solutions and improvements to overcome the mentioned shortcomings and difficulties, which were processed into performance objectives during Step 2.

Requirements, content, and specific tools that should be incorporated in an eHealth intervention to improve empowerment during the perioperative period, may be summarized as follows:

1. Reliable detailed and personalized information about mentioned shortcomings and difficulties in information supply. Pictures and videos were considered an accessible supplement to transfer this information.
2. Tools for communication with other patients, employers, gynaecologists, occupational physicians, and family physicians.
3. Functionalities to develop a personalized reintegration plan.

With the results of the literature search and focus group discussions, the project group concluded that the main determinants of patients behaviour regarding prolonged sick leave are: (1) Inadequate knowledge of important information about the surgery, recovery, and RTW; (2) tendency to extend their sick leave beyond the recommended period; (3) insecurity about postoperative symptoms, complications, and delayed recovery without knowing where to receive appropriate help; (4) lack of skills to compose a work-reintegration plan and to identify possible barriers for RTW; and (5) lack of knowledge about the opportunity to develop and discuss a work reintegration before surgery with employer and an occupational physician. In addition, important environmental conditions of patients behaviour are considered to be: (1) inconsistency and lack of clarity in convalescence recommendations given by gynaecologists, family physicians, and occupational physicians; (2) lack of communication among gynaecologists, family physicians, and occupational physicians; (3) lack of clarity from health care providers about who to contact in case of postoperative complaints; (4) lack of initiative of employer and/or occupational physician to develop and discuss a work-reintegration plan before surgery with employee; and (5) lack of involvement of employer and occupational physician during the perioperative and reintegration period.

Step 2: Matrices

In total, 12 performance objectives derived from the main behaviour objective were formulated (see Table 1). In addition to performance objectives for patients, there were also performance objectives formulated for gynaecologists, family physicians, occupational physicians, and employers (Table 1). Nevertheless, the primary focus during the next steps of the IM protocol (the development of the eHealth intervention) will be on patients. Ideally, for each group (patients, gynaecologists, family physicians, occupational physicians, and employers) an intervention should be developed specific to their needs, wishes, and behaviour outcomes to minimize the risks of theory and/or program failure. However, a balance had to be found between the ideal situation and what was within reach of this study. Secondly, the performance objectives of gynaecologists, family

Table 1. Performance objectives to empower gynaecological patients during the perioperative period and return to normal activities and work to obtain timely RTW and prevent work disability.

Who	Performance objectives
Patients	<p>Acquaint themselves with important information including: realistic detailed convalescence recommendations regarding RTW activities; the importance of timely and gradual resumption of (work) activities after the surgical procedure; the technical aspects of surgical procedures; the admission process of the hospital; the kind of anaesthesia that will be applied during surgery; main complications that could happen during and after surgery; symptoms that can be expected after surgery (e.g. vaginal blood loss and intestinal complaints); the cosmetic consequences of surgery; main psychological consequences of hysterectomy or adnexal surgery; telephone numbers of experts (e.g. gynaecologist, social workers, and homecare services); what to do and who to contact in case of physical or mental postoperative complaints or delayed recovery; and the risks of work disability after surgery.</p> <p>Do not extend their sick leave period beyond recommended period on own initiative.</p> <p>Develop a work-reintegration plan.</p> <p>Discuss their personalized work-reintegration plan with their employer and/or occupational physician.</p> <p>Identify possible barriers for a safe and appropriate RTW.</p> <p>Exchange experiences with other patients who underwent the same surgery.</p> <p>Receive answers to individual questions and uncertainties about recovery and RTW.</p>
Gynaecologists and family physicians	<p>Acquaint themselves with uniform, detailed convalescence recommendations for their patients.</p>
Occupational physicians	<p>Acquaint themselves with detailed convalescence recommendations for their patients.</p> <p>Provide the opportunity to develop a work-reintegration plan before surgery.</p>
Employers	<p>Provide the opportunity to develop a work-reintegration plan before surgery.</p> <p>Discuss the personalized work-reintegration plan composed by their employees.</p> <p>Show involvement with their employee during the perioperative and reintegration period.</p>

physicians, occupational physicians, and employers could be considered as external determinants of patients' behaviour. These determinants can either be influenced by the patients or the patients can learn these skills through the intervention and how to handle them adequately. Finally, the performance objectives of gynaecologists, family physicians, occupational physicians, and employers are relatively simple objectives to reach. The researchers are convinced that the main part of these objectives can be reached through making agreements with gynaecologists, family physicians, occupational physicians, and employers and by involving them in the evaluation and implementation plan (IM Steps 4-6), without the necessity of specifying determinants of their behaviour and applying specific theoretical methods and strategies for them.

The literature search showed that main determinants of recovery and return to normal activities and work – in addition to the physical condition of the patient, level of invasiveness of surgical procedures, and related complications –, are the patients' attitude, social influence, and self-efficacy.⁶⁰⁻⁶⁵ In addition, skills, barriers, and facilitators are important factors that influence RTW.⁶⁶⁻⁶⁸ For these reasons, the Attitude–Social influence–self-Efficacy (ASE) model, adapted for recovery and return to normal and work activities, was used to affect behaviour of patients (see Appendix 4).^{69,70} The ASE model is comparable to the theory of planned behaviour, which describes the relation between attitude and behavior.⁷¹ The modified ASE model describes that the behaviour of a patient after surgery regarding recovery and return to normal and work activities is determined by attitudinal beliefs, social influence, and self-efficacy beliefs and is influenced by skills, barriers, and resources. The ASE model was used to create matrices with change objectives. To fill out the matrices, available literature regarding the performance objectives and determinants was studied together with the results of the needs assessment and expertise of the project group. Appendix 5 presents an example of the change objective “Patients develop a work-reintegration plan.”

Step 3: Theory-based methods and practical strategies

Numerous practical methods and suitable strategies to affect all formulated determinants were identified and used for the development of tools and materials of the eHealth intervention. Appendix 6 presents some examples of these methods with preconditions for the method necessary to succeed and final tools/materials of the eHealth intervention.⁷² References and footnotes explain the source and development process of each method, strategy, and tools/materials.

Step 4: Program plan; design of the intervention

With the knowledge obtained in previous steps of the IM protocol, the project group convened at several meetings to invent various appropriate tools for the eHealth intervention. A website producer specializing in eHealth interventions and a screenwriter

of movies, were consulted at some of the meetings. In addition, an experienced gynaecologist outside the project team was consulted to judge the medical content of one of the tools.

In close collaboration with the website producer, the eHealth intervention was developed with MODX, an open-source hypertext preprocessor (PHP) Web application framework with a capable built-in content management system (CMS). The Internet address of the eHealth intervention is “www.ikherstel.nl,” which means, “I am recovering” (Appendix 9).⁷³ The eHealth intervention was developed with special attention to colours, layout, navigation, and readability to create confidence and user-friendliness. For the patient it consists of 2 main sections: an action list to assist in resumption of activities and a central home page. Gynaecologists, family physicians, and occupational physicians have access to a different section. Table 2 presents an overview of the tools of the eHealth intervention. For some tools, additional information about the development and functioning is described subsequently.

Action list

When a patient logs onto the eHealth intervention, she will be immediately directed to the action list. This list consists of different tools developed to target specific determinants, aimed at encouraging return to (work) activities, coaching patients in case of uncertainties, answering possible questions, prevention of common pitfalls, and improving communication among the patient, care providers, and the employer. An algorithm based on the date of surgery determines the priority in which the different actions should be performed to improve the recovery process. Tools of the action list are:

Composition of a work-reintegration plan

By using this tool, the patient is able to select activities that are required to fulfil her work activities and on what level (e.g., lifting 5 kilograms or walking 1 hour.). Consequently, on the basis of the operation date and how the surgery went (input of gynaecologist), the eHealth intervention provides the patient with tailored advice about when these activities are thought to be medically safe to resume. The recommendations are based on the results of a modified Delphi study, in which an expert panel of gynaecologists, family physicians, and occupational physicians developed detailed multidisciplinary convalescence recommendations for resumption of work activities after hysterectomy and/or laparoscopic adnexal surgery.⁷⁴ Moreover, this part of the eHealth intervention provides an overview of potential bottlenecks for reintegration and motivates patients to consider if work adaptations are required temporarily. A printout can be made to discuss the advice with the employer and/or occupational physician to develop an extended reintegration plan.

Table 2. Structure of the eHealth intervention.

Tool	Content	Target Meant for
Action list		
Compose a work-reintegration plan	Tool to compose a detailed reintegration plan with adaptations for work if necessary.	Patient, employer, occupational physician
Resume normal activities	Tool to compose detailed advice about when normal (private) activities can be carried out again	Patient, family
Evaluate complications	Estimate severity and consequences of a complication	Patient, gynaecologist
Recovery monitor	Monitoring recovery and offering assistance when relevant	Patient
Satisfaction with recommendations	Evaluation and explanation of convalescence recommendations	Patient
Satisfaction with the recovery process	Evaluation of satisfaction with recovery and reintegration process. Provision of advice regarding which care provider(s) to approach to receive appropriate help, when relevant.	Patient
Invite employer	Invite employer for (anonymous) section of the eHealth intervention which includes video and recommendations	Patient, employer
Home page		
Video	Illustrate common pitfalls during the perioperative and reintegration period	Patient, employer, gynaecologist
Recommendations for employee	Advice for a successful reintegration	Patient
Recommendations for employer	Advice for appropriate involvement regarding employee during the perioperative and reintegration period	Employer
Frequently asked questions	Extensive list of answers and pictures to most frequently asked questions	Patient
Glossary	Explanation of most frequently used medical terms	Patient
Forum	Ability to interact in public or through private messages with other patients	Patient
Links to other websites	Relevant websites concerning the perioperative and reintegration period	Patient

Table 2. Continued

Tool	Content	Target Meant for
Section aimed at gynaecologists, family physicians and occupational physicians		
Guidelines	Well-defined convalescence recommendations after hysterectomy and laparoscopic adnexal surgery	Gynaecologists, family physicians, occupational physicians
Casus	Indications, perioperative course and recovery regarding hysterectomy or laparoscopic adnexal surgery	Gynaecologists, family physicians, occupational physicians
Background information	Specialistic information regarding different kinds of hysterectomy and laparoscopic adnexal surgery	Gynaecologists, family physicians, occupational physicians

Resumption of normal activities

This functionality guides the patient to compose a detailed tailored plan about the gradual resumption of various daily activities (e.g., climbing stairs and vacuum cleaning). Recommendations are based on the results of the modified Delphi study.⁷⁴ This tool also evaluates if help is needed for tasks such as housekeeping or taking care of young children. A printout can be made to share with relatives or friends.

Evaluation of complications

When a complication has occurred, the eHealth intervention carefully determines through a survey which symptoms require additional consultation of care providers or adaptation of convalescence recommendations. The project group developed the survey and determined which symptoms are severe complications. If the tool is not able to provide recommendations under these circumstances, an email will be sent to inform the gynaecologist of the condition of the patient in order to evaluate her symptoms and possible consequences.

Home page

Video

Because of the influence of modelling behaviour on attitude, a video was chosen as the most appropriate medium to deliver an informative message to patients and relevant stakeholders about common pitfalls during the perioperative and reintegration period. The video aims to prevent these problems by stimulating patients and employers to discuss potential reintegration problems and to develop a reintegration plan to facilitate and improve reintegration. The experiences of the patients in the focus group discussions were converted by the researchers into common pitfalls for patients, employers, and health care providers during this period and a screenwriter processed them into a script for a video showing two cases of a good and bad interaction between a patient and her

environment. The screenwriter worked together closely with 3 gynaecological patients to make the video geared to the patients' perception of the perioperative and reintegration period.

Recommendations for employee and employer

Based on the experiences of the patients in the focus groups, the researchers formulated main recommendations for patients and employers regarding a successful reintegration.

Frequently asked questions

Answers to questions brought up during the focus group discussions and found as main topics in patients' brochures and discussions of gynaecological patients on the Internet were formulated by the researchers (based on the literature and clinical experience) and put into patient leaflets. An experienced gynaecologist outside the project team judged all questions and answers on reliability and clarity, and suggested possible adjustments.

Glossary

Based on the literature, an explanation of the most frequently used medical terms was provided by the researchers.

Links to other websites

The researchers searched the Internet for the most relevant websites for gynaecological patients and made a selection based on relevance, reliability, and clearness of the information.

Section aimed at gynaecologists, family physicians, and occupational physicians

Guidelines

Multidisciplinary guidelines with well-defined convalescence recommendations after uncomplicated hysterectomy (laparoscopic supracervical, total laparoscopic/laparoscopic-assisted, vaginal, and abdominal) and laparoscopic adnexal surgery on benign indication are provided. Recommendations are based on a modified Delphi study.⁷⁴

Casuistry

Classic examples of indications for surgery, perioperative course, and recovery after uncomplicated hysterectomy or laparoscopic surgery were developed based on literature and clinical experience of the project group.

Background information

Elucidation of different types of hysterectomy and laparoscopic adnexal surgery concerning surgical technique, level of invasiveness, and medical consequences were formulated by the researchers.

Test phase

Fifteen patients, 11 physicians (gynaecologists, family physicians, and occupational physicians), 3 eHealth specialists and 1 representative of a patient organization completed the evaluation form regarding the demo version of the eHealth intervention. Appearance and behaviour prescriptions were judged by most as pleasant, conveniently arranged, and helpful. With regard to burdens of using the eHealth intervention, almost all respondents judged the application navigation as clear and the intervention length as appropriate. However, a manual that provides an overview of the different tools of the eHealth intervention was found desirable by only one of the respondents. Furthermore, two software incompatibility problems were reported. Concerning the content of the information, the way it was delivered, and the message (source and style), most of the respondents were satisfied and expected that it could empower patients, employers, and physicians. Remarks for improvement were related to supplying more detailed information about the surgery, possible psychological complications after the operation, less complicated sentences, and a more prominent place for the source of the information. Finally, participation of the patient in the treatment and the eHealth intervention's ability to assess and tailor the recommendations to empower patients during the perioperative period and return to work activities, were judged as helpful by most of the respondents. There were no suggestions for improvement of these features.

The patients indicated that their input provided during the focus group discussions was recognizably integrated into the intervention. Additionally, almost all patients confirmed that they would recommend the eHealth intervention in the current form to a friend.

Modifications based on the test phase

As described previously, the respondents did not request major revisions of the eHealth intervention and only minor adjustments were proposed. Therefore, none of the original developed tools were removed from the eHealth intervention and no new functionalities were added. Following up on the suggested improvements, a manual with directions for use was added to the eHealth intervention, incompatibility problems with different kinds of software were solved, some information on the eHealth intervention was elaborated and explained in simplified sentences, and the logo of the university hospital was added in a prominent place on the eHealth intervention. This resulted in the final eHealth intervention that was used to perform a randomized controlled trial (RCT).⁷⁵ Screenshots of the eHealth intervention can be found in Appendix 9.

Step 5: Design of an implementation plan

In this study, anticipation of adoption and implementation started with the involvement of patients (target group) in all stages of the intervention development and evaluation. Health care providers, occupational physicians, and eHealth specialists participated

in the evaluation of the intervention during IM Step 4. In addition, a committee with representatives of the Dutch medical boards of gynaecologists, occupational physicians, and family physicians, and a representative of an umbrella patient organization were involved during the development of all steps of the intervention and agreed to stay involved during the final implementation steps of this intervention. Through this committee, a linkage system was created by involving the future users and implementers of the intervention from the start of the intervention development process. Furthermore, an important target of this study was to develop an eHealth intervention that could be used by patients, doctors, and employers without any support, to simplify implementation. Evaluation of self-reliant use by patients and important stakeholders was evaluated positively during the test phase of Step 4.

Within the context of a RCT with the eHealth intervention (Step 6), the project group will facilitate its implementation and maintenance. In collaboration with the relevant care providers, the eHealth intervention will be offered as a supplement to standard perioperative care and will involve minimal additional time investment for the care providers. Agreements about usage of the contents of the eHealth intervention will be made with the gynaecologists of participating hospitals and the family physicians and occupational physicians of participating patients. Therefore, the main purpose of this step was to create familiarity and support for the eHealth intervention and convalescence recommendations by all prospectively involved users. To reach these purposes for all different user groups, information letters will be distributed among patients and care providers. In addition, presentations with background information about the development of the eHealth intervention, its contents, and how to use it will be given to the gynaecologists during general teaching meetings at their hospitals. Employers will become familiar with the intervention through invitation for participation by the patients (i.e., employees). The eHealth intervention will primarily be used during the period of sick leave after surgery. Therefore, no agreement with the employers of the patients to use the eHealth intervention during work hours will be made.

With the information gathered during the process evaluation (Step 6), in collaboration with the committee with representatives of the Dutch medical boards of gynaecologists, occupational physicians, and family physicians, and the patient organization, a final implementation plan will be developed. In this plan, medical insurance companies and the Health Care Insurance Board (CVZ) are likely to be involved for the final implementation of the eHealth intervention.

Step 6: Evaluation plan

The evaluation of the eHealth intervention will be performed by a RCT, during which the eHealth intervention will be compared with usual given care at 7 participating medical

centers.⁷⁵ A power calculation was performed on the primary outcome sustainable RTW and showed that a total participation of at least 212 patients, their health care providers, and employers should be the goal. Patients will be recruited to participate in the RCT when they are placed on a waiting list for a hysterectomy or laparoscopic adnexal surgery on benign indication in one of the 7 participating medical centers, are aged 18-65, and they work (either paid or unpaid) for at least 8 hours per week. The main exclusion criteria are malignancy, deep infiltrating endometriosis, concomitant surgical procedures, major comorbidity, sick-listed for more than 2 months, currently in a lawsuit against their employer, and not able to use the Internet or unable to understand the Dutch questionnaires. If a patient participates, the researchers will inform her family physician and occupational physician by letter about the content of the intervention, the group allocation, and what is expected of them regarding the provision of health care. Follow-up will take place approximately 26 weeks after surgery.

Patients willing to participate and who meet the inclusion criteria will be randomized to the intervention or usual care group (control group). Main outcome measures of the RCT are the effectiveness of the eHealth intervention compared to usual care with respect to RTW, general recovery, quality of life, pain intensity, and complications. Part of the RCT will be a process evaluation of the patients, their care providers, and employers in the intervention group. Main outcome measures of the process evaluation are the extent to which the eHealth intervention and convalescence recommendations are used and followed up (compliance); appreciation of the different tools of the eHealth intervention and advice; perceived effectiveness, usage, and implementation barriers; and suggestions for improvement.

The outcome measures will be obtained by using questionnaires administered at baseline and at 2, 6, 12, and 26 weeks after surgery. Gynaecologists will complete questionnaires 1 day after surgery for each patient and at the end of the study. Employers will be asked to evaluate the eHealth intervention 8 weeks after their employee's surgery.

The study design and procedures of the RCT study were approved by the Medical Ethics Committee of the VU University Medical Center (#2009/218, October 22, 2009).

DISCUSSION

Main findings

In this study, the IM protocol turned out to be a useful method to develop and tailor an eHealth intervention aimed at the empowerment of gynaecological patients during the perioperative period including return to normal activities and work. By using available literature and focus group discussions, it became increasingly clear that to obtain timely RTW and prevent work disability, the intervention should target both behaviours of patients as well as environmental determinants. Performance objectives for obtaining timely RTW and prevention of work disability were formulated and matrices with change objectives, explaining how patients and their environment have to change as a result of the eHealth intervention to reach the performance objectives, were developed. Finally, based on the ASE model, theoretical methods and practical strategies, suitable tools, and materials for the eHealth intervention were developed.^{69,70} Most of the participating patients and stakeholders judged the intervention to be a promising eHealth tool to empower gynaecological patients during the perioperative period to return to their normal activities, including work.

Strengths and limitations

A primary strength of this study lies in the way the eHealth intervention is developed, tailored, and assessed. Both theory and evidence were combined and patients and most relevant stakeholders were involved, minimizing the risks of theory and/or program failure.⁷² The frequent involvement of patients in several steps of the IM process resulted in an eHealth intervention that was specifically tailored to their needs and wishes and therefore more likely to be implemented successfully. In addition to information supply, which is the primary aim of most websites, this eHealth intervention distinguishes itself by monitoring the recovery process, giving tailor-made advice based on patients' workloads, and informing patients when additional consultation of care providers is needed. By linking patients with their gynaecologists, convalescence recommendations can be adapted and insecurities regarding consequences of the complications can be solved. Connecting patients and employers facilitates a dialogue and the joint effort to compose a reintegration plan. Furthermore, this eHealth intervention is developed to be used without support and with minimal effort of care providers. Therefore, use of the intervention costs little and implementation is expected to be relatively easy. Moreover, like most eHealth interventions, an important strength is the possibility to use it at the time, place, and pace that fits the patient, care provider, and employer.³⁸ Finally, the combined approach of encouraging and helping patients to participate in their consultation and empowering clinicians with skills to identify and adapt to the needs of their patients is considered to produce long-term benefits for patients.²¹

Main limitations concerning the needs assessment of this study include a possible selection bias; patients assigned to the focus group discussions are a selection of the patients willing to discuss their perioperative problems. Patients less willing to discuss their problems may also experience different perioperative issues. However, through purposeful sampling and by proactively approaching all relevant patients for participation in the focus group discussions, we tried to minimize this selection bias as much as possible. In addition, the influence of dominant patients who might be overly influential cannot be excluded. On the other hand, specific observations on this matter showed that this rarely occurred (Chapter 5). Furthermore, these patients already underwent the surgery whereas the intervention is designed to be used both before and after surgery. It has to be determined whether this intervention is applicable to the entire target population and whether the intervention fits the needs of patients both before and after surgery. Due to practical reasons, not all stakeholders (e.g. employers and health care providers) were involved in the needs assessment and development process of this eHealth intervention. As a consequence, the intervention might be less supported by these groups. However, results of prior focus group discussions with supervisors and care providers in another comparable IM study⁴⁷ were used and some of those stakeholders were also involved in the test phase. Because this was an exclusively Dutch study directed at the Dutch health care system, a final limitation is that external validity of the eHealth intervention has to be examined before the results may be applied internationally.

Comparison with other studies

To our knowledge, this is the first study that tailors an eHealth intervention through the IM protocol to empower gynaecological patients during the perioperative period to obtain timely RTW and prevent work disability. Therefore, comparison with other studies is limited. However, previous research showed several developmental and interventional characteristics. For example, it was demonstrated that IM is a successful method to tailor eHealth^{45,76} as well as RTW^{47,48} interventions. Moreover, Web-based interventions show positive effects on empowerment.²⁵ Furthermore, it is proven that tailoring an eHealth intervention influences usage positively (e.g. time and frequency) and increases the effectiveness of the message.^{77,78} In contrast to most eHealth interventions, this intervention aims at secondary and tertiary prevention. Therefore, further research is needed to determine whether the characteristics mentioned previously also apply to the present study.

Although comparable studies are lacking, the approach followed in this study—involving relevant stakeholders in the development of an eHealth intervention—is in line with an observed trend of multi-stakeholder involvement in health care in general.^{79,80} Gained experiences in this study might contribute to additional insights for future initiatives on multi-stakeholder involvement in health care.

Interpretation of the results and policy implications

This study shows that the IM protocol can successfully be used for the development and tailoring of an eHealth intervention for gynaecological patients. The protocol led to a systematic development of the intervention, it made sure that collaboration with the main target group was realized, and both theory and evidence was used to tailor the intervention.

Furthermore, through the detailed convalescence recommendations provided by the eHealth intervention, patients will be better informed about when it is thought to be medically safe to resume daily and work activities after gynaecological surgery and it will give them the possibility to arrange workplace adaptations if necessary.⁷⁴ Prospective cohort studies exploring sick leave after general surgical procedures show that return to work is primarily influenced by the expectations of the patient and their supervisors rather than physical factors or the type of surgery.^{1,10,81} Therefore, it is assumed that these tailor-made convalescence recommendations will help to accelerate recovery and stimulate patients to resume activities with increasing gradations of strain, which will presumably bring about a quicker recovery and RTW and prevent work disability.⁸²⁻⁸⁴ Therefore, it is expected that this eHealth intervention fulfils patients' needs and is able to empower gynaecological patients during the perioperative period and return to normal activities and work.⁷⁷ However, its adoption, barriers for usage in daily practice, and implementation possibilities by patients and stakeholders still need to be evaluated more extensively in a process evaluation. Furthermore, a RCT will be needed to assess the effect of empowering gynaecological patients during the perioperative period and return to normal activities and work by this eHealth intervention on work disability prevention, resumption of activities, and quality of life.⁷⁵ The results are important to assess this intervention's true value and policy implications.

This eHealth intervention is developed for patients who underwent a hysterectomy or laparoscopic adnexal surgery. However, the strategy used to develop the intervention and the final result may also be used as a blueprint for other kinds of surgical procedures.

CONCLUSION

The development of an eHealth intervention according to the IM protocol to obtain timely RTW and prevent work disability by empowerment and improving communication after gynaecological surgery resulted in an intervention based on both theory and evidence and involvement of patients and most stakeholders. This eHealth intervention is well accepted by patients and stakeholders and is considered to be a promising tool to obtain timely RTW and prevent work disability after gynaecological surgery. Its effectiveness needs to be proven in a RCT.⁷⁵

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CHAPTER 5

The involvement of gynaecological patients in the development of a clinical guideline for resumption of (work) activities in the Netherlands

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ABSTRACT

Context

Most initiatives for patient involvement in guideline development have been carried out for chronic diseases. The involvement of patients with incidental and non-threatening diseases is more complicated. Little knowledge is available on how these patient groups can successfully be involved in guideline development.

Objective

To assess the effectiveness of the involvement of gynaecological patients in the guideline development for resumption of (work) activities after surgery.

Design

At three different stages patients were involved in the process: (1) three focus group discussions (FGDs) were organized, (2) patients were involved for the instruction video, and (3) patients tested the patient version of the clinical guideline. To assess the effectiveness an evaluation framework was used. The guideline development process was divided in two parallel trajectories in which patients and professionals were consulted separately. Patients were primarily consulted for the development of the patient version, although their input also influenced the recommendations for resumption of (work) activities after surgery. Professionals were mainly involved in the development of the recommendations of the clinical guideline.

Discussion and conclusions

The involvement of gynaecological patients in the guideline development for resumption of (work) activities after surgery was successful in many respects. Consultation of individual patients by means of FGDs and with regular feedback moments has been rather effective for a guideline development process related to an incidental, non-threatening disease for which there is no patient organisation. Patients' input contributed to applicability of the clinical guideline in daily practice. Increased patient involvement could be achieved by integration of the two parallel trajectories with additional participatory activities, such as a dialogue meeting.

INTRODUCTION

Patients are increasingly involved in clinical guideline development. Their involvement is generally motivated by three arguments.¹ Firstly, the experiential knowledge of patients - acquired by their daily personal experience with the disease - could complement scientific evidence, and thereby increase the rationality of decisions and ultimately the quality of clinical guidelines.²⁻⁵ Secondly, the involvement of patients could enhance the practical implementation of clinical guidelines.⁶ Thirdly, it can be argued that patients have the moral right to participate in decisions that could affect their lives.⁷

Most initiatives for patient involvement in clinical guideline development have been carried out for chronic diseases.⁸ These patient groups are often united in patient organisations, are usually motivated to participate, and are therefore relatively easily accessible. In The Netherlands, the inclusion of one or two patient representatives in a guideline workgroup (recruited through the patient organisation) is the most common approach to patient involvement.^{1,2,5,9-12} This approach is often complemented with participatory activities to explore patients' needs and preferences from a broader perspective, e.g. focus group discussions, a literature search into patient preferences, and sometimes dialogue meetings in which patients (representative) and professionals meet.^{5,8,11,13}

The involvement of patients in guideline development with incidental and non-threatening diseases (e.g. hysterectomy, treatment of pneumonia or concussion) is more complicated.⁹ These patient groups are most often not united in patient organisations and patients are only 'patient' for a limited period of time. As a consequence the inclusion of patient representatives in a guideline workgroup cannot easily be realised and is less appropriate because patients lack the broader input from the collective knowledge of the patient organisation and the experiences between individual patients differ greatly. Moreover, after recovery patients most often want to forget their (negative) disease experiences and want to continue with their life. Little knowledge is available on how patients with incidental and non-threatening diseases can most effectively be involved in clinical guideline development.

In this study we address the above mentioned challenges by assessing the effectiveness of the involvement of patients with an incidental and non-threatening disease in clinical guideline development by analysing a specific case concerning the involvement of gynaecological patients in an innovative guideline development process for resumption of (work) activities after surgery.

Case description

The development of the clinical guideline was initiated by the department of Obstetrics and Gynaecology and the EMGO Institute for Health and Care Research, both of the VU University Medical Center (Amsterdam, the Netherlands). The guideline development process was part of a larger project in which also a multi-disciplinary perioperative care program was developed and an extended pilot study among patients was executed.¹⁴ The results of the development of the care program are published elsewhere.¹⁵

A researcher and two project leaders monitored the process and combined the data obtained by consultation of professionals and patients. For substantive and practical tasks they were supported by an advisory committee. This clinical guideline for resumption of (work) activities after gynaecological surgery distinguishes itself from other clinical guidelines; it can be characterized as a transmutal agreement among professionals with consensus-based recommendations. As a consequence, the development process differs from more traditional clinical guidelines.

The guideline development process consisted of two parallel trajectories, which resulted in two products: (1) a clinical guideline with recommendations for resumption of (work) activities after gynaecological surgery,¹⁶ and (2) a web-based patient version of the clinical guideline.¹⁵ Both trajectories comprised several steps and were interconnected. In Figure 1 the entire process is visualised. The web-based patient version of the clinical guideline is an eHealth intervention. The aim of this intervention is to apply the recommendations for resumption of (work) activities into practice. As such the two trajectories were interconnected. The recommendations of the clinical guideline are integrated into the eHealth intervention, and patients' needs and preferences influenced the topics of the recommendations. Professionals were mainly involved in the development of the clinical guideline, while patients were primarily consulted for the development of the web-based patient version of the guideline. The researcher and project leaders integrated the obtained data.

The project team acknowledged the asymmetry between the types of knowledge of patients and professionals; the experiential knowledge of patients vs. the expert knowledge of professionals. Therefore, the project team felt that consultation of patients and professionals in two separate trajectories would be most appropriate to thoroughly identify these different types of knowledge. They also felt that the establishment of a guideline workgroup would not be suitable. This is further stressed, since patients were not united in a patient organization and no patient representative could be appointed. The results of the consultation of patients and professionals were processed in parts of the guideline development for which the knowledge was considered most relevant. As a result, the perspective of patients had a more central role in the development of the

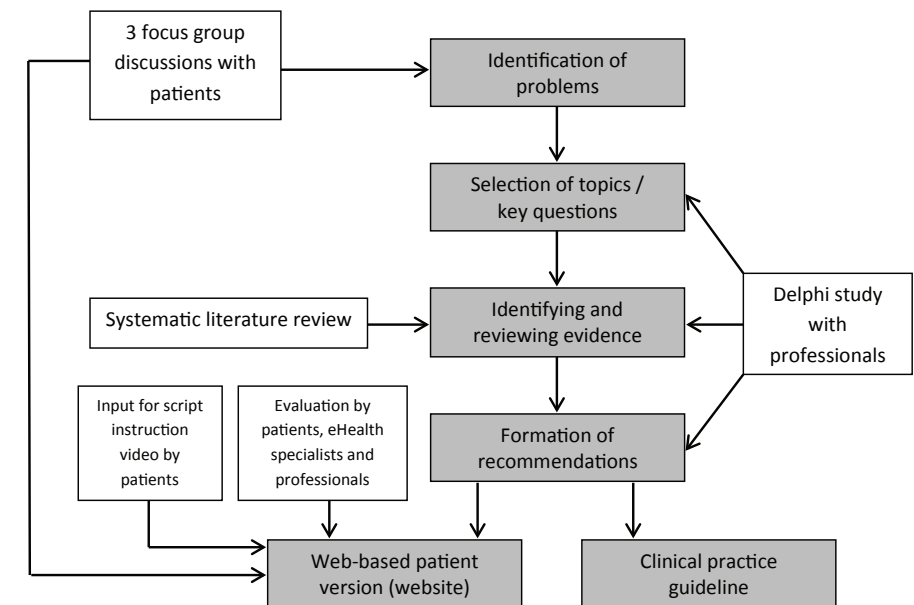


Figure 1. Visualisation of the development process of the clinical guideline for resumption of (work) activities after gynaecological surgery.¹⁵

patient version, although their input also influenced the recommendations for resumption of (work) activities after surgery. Professionals were mainly involved in the development of the recommendations of the clinical guideline.

METHODOLOGY

Patient involvement

At three different stages in the guideline development process patients were involved: (1) three FGDs were organized in order to identify patients' perceived problems and needs concerning received perioperative care and counselling in resumption of (work) activities, (2) patients were involved in the development of the script for an instruction video, which was part of the web-based patient version of the clinical guideline, and (3) patients tested the web-based patient version of the clinical guideline.

Focus group discussions

Three FGDs with 21 participants (seven participants per FGD) were organized in the period May – June 2009. For the involvement of these patients, both the researcher and the project leaders of the guideline development process were aware of the large differences

among patients. Purposeful sampling was used to capture the broadest set of information and to aim at maximum variation. Participants were recruited from the patient files of the VU University Medical Center. Broad inclusion criteria were used: (1) age between 18-65 years, (2) a history of a gynaecological surgery (i.e. hysterectomy or laparoscopic adnexal surgery), and (3) the presence of a paid or unpaid job of at least 8 hours a week.¹⁵ Participants were sampled for delayed, intermediate and rapid resumption of (work) activities, in order to create homogeneity within the FGDs but heterogeneity between the groups.

To meet the purposes of FGDs and the specific aims of the consultation, a tailor-made design of the meeting is required.^{17,18} The aims of the FGDs were to identify (1) patients' problems, needs and preferences regarding perioperative care and counselling in resumption of (work) activities, and (2) patients' ideas for the development of the web-based patient version to empower patients during the perioperative period and resumption of (work) activities (the patient version of the clinical guideline). To achieve the aims of the FGDs, specific tools were used to steer the discussion. Participants were actively involved through a structured step-by-step process with several individual and joint assignments. The facilitator ensured all participants were included in the discussion by using post-its and go-rounds. The issues discussed were visualized on flip charts. The focus group design comprised four different steps:

- Step 1:* Problems and needs in received perioperative care and counselling in resumption of (work) activities were identified. These problems were divided in two categories – 'before surgery' and 'after surgery' – and were subsequently prioritized by appointing a top five.
- Step 2:* Possible solutions and improvements, which could overcome the mentioned problems, were discussed.
- Step 3:* Patients brainstormed about favourable designs and content of the web-based patient version for empowering patients during the perioperative period and resumption of (work) activities.
- Step 4:* At the end of each FGD patients filled out a questionnaire containing factual questions regarding their gynaecological procedure, their personal recovery period, and their (work) activities.

FGDs were planned until no new perspectives emerged (data saturation), which was after three FGDs. All discussions were audio taped and verbatim transcribed by the note taker of the FGDs and checked by the researcher who observed the FGDs. A summary was sent to participants for member check (a process in which the participants are invited to react and reflect on the researcher's interpretations of the FGD). The verbatim transcripts

were analysed using an inductive approach, by means of Atlas.ti. software,¹⁹ comprising three steps: (1) open coding (identifying, categorizing and describing of concepts), (2) axial coding (creating subthemes by relating codes to each other) and (3) selective coding (developing storyline by relating subthemes to main themes). The analysis of the FGDs formed input for the development of the eHealth intervention (content and design), and the Delphi Study among professionals (selection of topics for the recommendations of the clinical guideline).

Results of the focus group discussions

In Box 1 the results of the FGDs are presented. Furthermore, the FGD results showed that patients would appreciate the development of an instruction video for patients and employers to stimulate communication and to illustrate common pitfalls during reintegration. It was therefore decided to develop such an instruction video and integrate it into the web-based patient version of the clinical guideline.

For the development of a script for the instruction video the FGD results were converted into common pitfalls for patients and employers during the reintegration period. In addition, the scenario-writer worked closely with three patients who participated in the FGDs to make the video more geared to the perception of patients. The main reason to involve patients in this part of the clinical guideline was to provide the scenario-writer more background information about gynaecological surgery and resumption of (work) activities. These patients voluntarily enlisted to be involved (convenience sample). They had different experiences with a gynaecological procedure, but did not represent the entire patient group. During the meeting the three patients and the scenario-writer talked about a most desirable script for the instruction video.

Testing of the web-based patient version

The patient version of the clinical practice guideline was developed with the aim to apply the recommendations for resumption of (work) activities into practice. An eHealth intervention was chosen as an appropriate tool since it has the ability to provide tailor-made information relatively easy in several forms to patients and to enhance interaction between patients and health care professionals.²⁰⁻²⁴ In this guideline development process testing of the patient version was included to assess the usability of the eHealth intervention and the recommendations in practice. Twenty participants of the FGDs agreed to test the web-based patient version. Of them, 15 participants completed a questionnaire regarding feasibility, content and design. Moreover, it was asked if the topics discussed in the FGDs are well reflected in the web-based patient version. The results were used to optimize design and content of the eHealth intervention.

BOX 1. Outcomes of the focus group discussions

The main experienced problems and needs during the perioperative care and resumption of (work) activities were related to insufficient information supply. Participants considered realistic information supply tailored to individual characteristics and conditions most essential for good recovery and resumption of (work) activities. Additionally, they experienced problems regarding the communication between professionals of different disciplines. The identified problems and corresponding solutions were divided into three main categories: (1) information supply before surgery, (2) information supply after surgery, and (3) communication between professionals of different disciplines. Regarding the website participants recommended functionalities which could provide detailed and personalized instructions for resumption of daily and work activities. Below the results of the FGDs are described in more detail per category.

Before gynaecological surgery

A main topic of discussion was the information supply regarding *surgical procedures* (e.g. logistic procedures in the hospital from admission to discharge, anaesthesia, specific technical aspects of the surgery). Participants pointed out that they had received no or insufficient information about these procedures before surgery. As a consequence some felt anxious during their time in hospital, while others had unrealistic expectations about the impact of the surgical intervention. Several participants specifically pointed out they received insufficient or even contradictory information concerning anaesthesia. For example, in some patients the impact of the general anaesthesia was bigger than they expected, and they were not prepared for that.

Participants also indicated that transparency in *planning* could be improved. Furthermore, the results revealed difficulties in estimating *realistic recovery periods*. Different disciplines provided contradictory information or professionals disagreed about convalescence recommendations. Also, the lack of information about the *psychological consequences* of a gynaecological surgery was mentioned.

After gynaecological surgery

Central in the discussions were the experienced problems regarding the provided *recommendations about resumption of (work) activities*. On the one hand, participants emphasised the importance of uniform recommendations by different professionals since they experienced inconsistency in convalescence advice. On the other hand, they mentioned the significance of tailored instructions, because of different types of surgery and specific individual characteristics and (work) conditions. Furthermore, participants felt they were not well-informed about the *discharge policy*. Participants emphasized that more information regarding the occurrence of *possible complications* was desired. Participants who suffered from complications could not remember receiving any information about potential risks. They stressed that in case of complications medical doctors should clarify directly the situation, the potential risks, and the further procedure.

Communication between professionals of different disciplines

Participants indicated they experienced several difficulties with the communication between professionals of different disciplines (e.g. the gynaecologist, the anaesthesiologist, the occupational physician, the general practitioner,) and inadequate handover of patients to other professionals. Professionals were not fully informed about the entire procedure, and participants experienced inconsistency in convalescence recommendations.

BOX 1. Continued*Recommendations for web-based patient version*

Participants were enthusiastic about the development of a patient website to empower patients during the perioperative period and resumption of (work) activities. The web-based patient version of the clinical guideline should provide in the need for more information about earlier mentioned problems, and for written instructions. The FGD results revealed the following desired content and specific functionalities for a website:

- (technical) Information about gynaecological procedures and recovery (including admission, anaesthetics and complications).
- Reliable detailed and personalised recommendations for resumption of (work) activities. It was emphasised that these instructions should be practical and related to daily activities.
- Functionalities to develop a personalised reintegration plan.
- Tools to communicate with other patients, employers, and medical doctors (e.g. a forum).
- Instruction video for patients and employers to stimulate communication and to illustrate common pitfalls during reintegration.
- Frequently asked questions (FAQ).

Monitoring and evaluation of patient involvement

To assess the effectiveness of the involvement of gynaecological patients in the clinical guideline for resumption of (work) activities, an evaluation framework was developed based on a literature review and comprising pre-defined evaluation criteria detailing the participation process and generated outcomes.²⁵⁻³⁶ These main criteria were divided in several sub criteria. Process criteria were subdivided in involvement of stakeholders, process structure and process management. For outcome criteria, direct and indirect outcomes were distinguished. The criteria are described in more detail in Box 2. The involvement of gynaecological patients is considered effective when it meets the evaluation criteria of the framework. Data concerning this evaluation were gathered and validated by means of a triangulated approach, involving (direct) observations, document analysis, semi-structured interviews, informal conversations with patients, and evaluation forms after the FGDs.

Observations were used to gain more insight in participatory aspects of the guideline development process. Direct observations were used for the three FGDs with gynaecological patients. The meetings with professionals as part of the Delphi study were indirectly observed by listening to the audio records (a detailed description of the Delphi study is published chapter 3¹⁶). Research logs were kept to document the observations. Minutes of meetings (including the meetings for the Delphi study and of the advisory committee), focus group reports (including the results of the questionnaire), the results of the testing of the web-based patient version (questionnaires) the clinical guideline and the web-based patient version were analysed to examine the influence of patients' input on the products.

BOX 2. Evaluation framework*Process criteria*

- *Involvement of stakeholders:* To successfully involve patients in guideline development processes, attention should be paid to the balance between involved patients (or patients representatives) and professionals. In addition, diversity among a patient population (e.g. demographics, ethnicity, and severity and duration of the disorder) should be acknowledged and effort should be made to take diversity into account. Also attention should go to representativeness.^{25,35}
- *Process structure:* A guideline development process needs to be structured clearly and transparently.³⁶ It is important that patients are informed about what is expected from them, what the aim of the overall project is, in which activities they participate, and what influence they have on the process and the clinical guideline.^{9,28,35,36} Additionally, to ensure rationality of the guideline development process, involvement of patients from start to completion should be affirmed, as well as direct interaction between patients and professionals.^{9,29,37} Patients should be involved in significant aspects of decision-making, so to ensure actual use of patients' input.^{9,25,38}
- *Process management:* Independent facilitation of patient involvement activities is crucial for equal treatment of patients (as compared to professionals) and should create an open and respectful atmosphere in order to enable patients to share their viewpoints.^{25,27,29,36,39} Good process management also includes the offer for support and the adjustment of the guideline development process to the abilities of patients. Moreover, there should be support amongst the involved professionals and the project team of the guideline development towards patient involvement.⁹

Outcome criteria

- *Direct outcomes:* Consensus on the content of a clinical guideline is an important indicator for success. In order to reach consensus the outcomes – in this case the web-based patient version of the clinical guideline – should reflect the input and perspectives of involved patients.^{29,40} Also important is the degree to which guideline developers responded to patients' input. What aspects are incorporated in the guideline, and why? Moreover, patients must be satisfied with the end result and they have to recognise the clinical guideline as relevant.^{25,27,29} Additionally, dissemination of the clinical guideline is considered important.
- *Indirect outcomes:* Indirect outcomes are related to the stimulation of learning processes and the achievement of mutual learning, resulting in changes of thinking of both patients and professionals.^{27,28} Mutual learning implies learning in a substantive way (concerning content-related matters), in a procedural way (concerning participatory approaches) and in a reflexive way (concerning their own and each others' knowledge, perspectives or roles).^{31,41}

Two in-depth evaluative interviews were held. One interview with the researcher of the guideline development process concerning experiences with and expectations about the involvement of gynaecological patients in the process, and one interview with the scenario-writer of the instruction video to gain insight in his experiences with the involvement of

patients in the development of the script. Throughout the guideline development process, various informal conversations took place with the researcher, the project leaders and patients. The aim of these conversations was to discuss and reflect on the participatory activities and results. These conversations were documented in the research logs by two researchers who were responsible for the evaluation of patient involvement. At the end of each FGD, patients filled out an evaluation form. The evaluation form gave participants the opportunity to give feedback on how they experienced the FGD, and to give possible recommendations for improvement of future FGDs.

RESULTS

In this section the findings of our study concerning patient involvement are presented. First, we describe the processes and the outcomes of the participatory activities in this guideline development process for both trajectories. Second, we reflect on the effectiveness of patient involvement along the lines of the evaluation framework.

Description of processes and outcomes*Processing of patients' input*

In this section we will describe how the FGD results were integrated in the clinical guideline and in the web-based patient version.

Clinical guideline

The Delphi study among professionals was the main method to arrive at the recommendations for the clinical guideline.¹⁶ Although patient involvement was primarily appointed to the trajectory for the development of the web-based patient version, the FGD results were processed into the clinical guideline to some extent. The researcher and the project leaders brought up some topics derived from the FGDs that in their opinion complemented the topics suggested by professionals i.e., the improvement of information supply for recovery and resumption of (work) activities (Box 1). These topics were not directly of use as input for the Delphi study, which required advice for when work activities are thought to be medically safe to resume. Therefore, the topics brought in by the researcher and project leaders were extracted from the arguments patients gave to support their point of views. Ultimately, the topics selected by professionals included several issues brought up by patients. These topics concerned mostly advices regarding resumption of daily activities (e.g. taking a bath, jumping). The topics of professionals mainly concerned movements like lifting, walking, and bowing.

Patient version of the clinical guideline

The ideas brought forward in the FGDs regarding design, topics and functionalities were leading in the development of the web-based patient version. The internet address of

the web-based patient version is www.ikherstel.nl, which means “I am recovering”. Box 3 shows which functionalities were included in the eHealth intervention, and reveals that the input of patients in the FGDs (Box 1) substantially contributed to the development of the eHealth intervention. Extra attention was paid to providing detailed and tailored instructions for resumption of both work and daily activities. A tool was included to compose tailored instructions for resumption of normal and daily activities including a personalised work integration plan. Moreover, interactive tools (e.g. a forum, FAQ) were included to exchange experiences between patients, and to provide information regarding (frequently asked) medical questions and common complications. The content of these tools were derived from the recommendations of the clinical guideline (the outcomes of the Delphi study), literature, patient leaflets and clinical experience.

BOX 3. Design of the web-based patient version

The web-based patient version aims at empowering patients during the perioperative period and resumption of (work) activities by increasing the applicability of the clinical guideline in daily practice. The website was designed with the following functionalities:

- Tool to compose a tailored work reintegration plan. Based on personalized characteristics and conditions, the tool provides the patient with a tailored advice for when work activities are thought to be medically safe to resume. Recommendations are based on the outcomes of the Delphi study.¹⁶
- Safe resumption of normal activities. This tool comprised a tailored plan for the gradual resumption of daily activities. Recommendations are derived from the Delphi study.⁴²
- A tool to signal complications with advice about what to do and who to contact.
- (self) Monitoring of recovery and offering assistance when relevant
- Instruction video for patients and employers to stimulate communication and to illustrate common pitfalls during reintegration.
- Recommendations for communication between patients and employers
- Detailed instructions and illustrations on various gynaecological surgical procedures
- Frequently asked questions.
- Glossary. Explanation of frequently used medical terms.
- Links to websites regarding gynaecological surgery and recovery.
- A forum where patients can exchange experiences.

Instruction video

Part of the web-based patient version is the instruction video for patients and employers to stimulate communication and to illustrate common pitfalls during reintegration. In the instruction video potential reintegration problems are discussed by showing two cases of a good and bad interaction between patients, employers, and occupational physicians. The scenario-writer appreciated the ideas brought forward by the three involved patients. He asked them about their experiences with the reintegration period and emphasised the

contact with the employer and occupational physicians during the perioperative period. Based on the experiences of the patients it became clear to him that there is not one common ground; patients have different experiences and needs. He responded to this by showing two cases in the video. In this way he tried to gear the instruction video towards patients' perception. The involved patients enjoyed working on the development of the instruction video and felt their input was taken serious. They were happy with the end-result; their input was well integrated in the video.

Testing of the web-based patient version

In total 15 participants of the FGDs were involved in the evaluation of the web-based patient version. The testing revealed how participants of the FGDs perceive feasibility, design and content of the website. The results also showed to what extent participants are satisfied with the processing of the FGD results. Since the content of the website is also based on the recommendations of the clinical guideline, the testing results also gave insight in the applicability of the recommendations in practice as well.

Participants experienced a strong connection between the FGD results and the web-based patient version. Except for one participant, participants indicated they would recommend the website to other patients. They indicated that almost all topics introduced in the FGDs were integrated. Especially in the FAQ and the recommendations for resumption of (work) activities the FGD results have been picked up well. Also the forum was recognized. Moreover, they mentioned that the website could improve the communication between employers and patients. Participants indicated that the content of the instruction video was clearly related to the discussions in the FGDs.

Some recommendations for the improvement of the web-based patient version were mentioned. Two participants emphasized that still more specific and tailored recommendations regarding resumption of daily activities would be desired to the currently provided information. Moreover, it was indicated that it would be preferred if more information about common complications would be offered. One participant suggested including positive experiences with resumption of work activities. In her opinion, the current patient version was mainly focused on pain. On the other hand, another participant considered the patient version to be too cheerful. She preferred more attention for problems regarding resumption of activities. Furthermore, a participant recommended providing more attention to possible causes for delayed recovery.

Process and outcome analysis

To assess the successfulness of the involvement of gynaecological patients in this guideline development process patient involvement was evaluated along the lines of the evaluative framework (Box 1).

Process criteria

Involvement of stakeholders

Next to professionals (representatives of the medical boards of gynaecologists, general practitioners and occupational physicians) individual patients and a patient representative of an umbrella patient organisation (The Federation of Patients and Consumer Organisations) were invited to participate in the guideline development process. The patient representative was not acquainted with the specific experiences of gynaecological patients. However, she was familiar with perspectives of surgical patients with resumption of (work) activities in general. The balance between patients and professionals was of less importance, since patients and professionals were consulted in parallel trajectories. In this way they could not influence each other directly.

After each FGD participants filled out a questionnaire to identify the contextual situation of the participants regarding their gynaecological history and their resumption of work activities. The results of these questionnaires reveal diversity regarding differences in type of gynaecological surgery, course of resumption of work activities, load of work activities, age and educational level among participants. Six out of 21 participants indicated a high load of activities on their work. The age of participants ranged from 20 to 40 years with an average of 29, and the educational level differed from low educated participants to high educated participants (equally divided). However, all participants were recruited through the VU University Medical Center, where most often patients with more complicated cases are treated. Nevertheless, there was variety in representation amongst involved participants observed; patients with minor and severe complications were involved.

Process structure

The focus group technique appeared to be successful for involving individual patients that are not united in a patient organisation. The interactive character of FGDs stimulated co-construction of meaning and understanding, and as a result provided broad and in-depth information regarding the perioperative period and resumption of (work) activities. In addition, the FGD results provided recommendations for the development of the web-based patient version and the instruction video. With the development of the instruction video (for which patients provided input) the researcher and the two project leaders specifically anticipated on the needs of patients. The testing of the web-based patient version gave participants the opportunity to reflect on the processing of their input. Participants indicated that they very much appreciated this testing. They felt taken seriously and the reflection contributed to increased support for the intervention among patients. However, participants were only able to reflect by means of a questionnaire, which provides little room for own input or argumentation.

The researcher and the project leaders had a central position in the guideline development process. They were responsible for supervision and decision-making. Patients were involved on the level of consultation, and had no role in integrative activities and in translation of the FGD results. The researcher and the project leaders were responsible for integrating patients' input. There was no interaction between involved parties. However, patients had the opportunity to verify the processing of their input as well as the input of professionals by the evaluation of the patient version of the clinical guideline. As a result, not only knowledge transfer was realized, but also knowledge exchange.

During a participatory process transparency towards all participants is important. By the involvement of FGD patients in the development of the instruction video and the testing of the web-based patient version transparency was created, since participants could verify the processing of their input. However, transparency regarding goals of the project was not for all participants clear. Although the goals of the FGDs and their contribution to the development of an eHealth intervention (the web-based patient version of the guideline) were clear, participants were only partly aware of the overall process (including the clinical guideline). The overall process was addressed briefly, in contrast to their contribution to the web-based patient version. As the evaluation forms participants filled out after the FGDs revealed, participants' expectations towards their participation in the FGDs were quite general, e.g. '*sharing of experiences*' and '*Contribute to improvement of care by the development of a website*'. In addition, there was little attention for discussion of expectations of patients and professionals concerning their contribution to activities and end products.

Patients and professionals were not equally involved. Patients were involved on the level of consultation, while professionals were involved on a higher level. By their participation in the Delphi study professionals had decision-making power about the recommendations for resumption of (work) activities.

Process management

The researcher and the project leaders of the guideline development process were responsible for process management. As a consequence the independent role of the managers was at stake. However, they took the input of patients seriously and adjusted the participatory activities to the needs of patients. Participation in the FGDs or the testing did not require specific skills of the patients. Patients could participate without preparation, their involvement required little efforts, and only their experiential knowledge was addressed.

During the FGD meetings it was observed that the participants felt at ease, and the discussions were not affected by one or more dominant participants. Observations

revealed that due to the FGD design, participants were able to formulate recommendations for resumptions of (work) activities by addressing their own experiences. The topic of discussion – information supply regarding perioperative care and recovery – was a topic participants could easily relate to and was important for them. They shared their experiences easily and reacted positively to each other's input, even if these did not correspond to their own experiences or visions.

The evaluation forms participants filled out after the FGDs revealed that participants were very positive about the design, focus and facilitation of the FGDs. They indicated: *'It is a good thing that attention is given to this', 'I am convinced that a website with the possibility to contact fellow-patients is very desirable'* and *'I hope these meetings result in even better care'*. Participants indicated they were pleased that they could share their experiences and that their input could be of use for improvement of information supply. Furthermore, they felt taken seriously. Also, participants indicated that all relevant topics were discussed.

The researcher and the project leaders were positive towards patient involvement in this guideline development process. They appreciated the experiential knowledge of patients, and were confident about the added value of this knowledge to the development of the web-based patient version. They believed specific medical and professional knowledge were required for the formulation and interpretation of the recommendations. As a consequence the involvement of patients was mainly restricted to the web-based patient version. The contribution of the representative of the umbrella organisation was appreciated by the other members of the advisory committee. They considered her as equal and professional.

Outcome criteria

Direct outcomes

For the web-based patient version, the contribution of patients to the intervention was substantial. Almost all topics introduced in the FGDs were integrated. The central position of the web-based patient version in this guideline development process contributed to the applicability of the clinical guideline in daily practice. Patients' input for the clinical guideline contributed to the formulation of some additional topics for the recommendations, mainly being reflected in the tailoring of the topics for recommendations to more complex daily activities. This was considered a valuable input by all parties.

Indirect outcomes

The absence of direct interaction between patients and professionals prevented optimal mutual learning, since the two groups did not meet at any point in time during the process. As a consequence mutual learning occurred only indirectly. The guideline development

process resulted to some extent in changes in thinking of involved parties (i.e. patients, professionals, the researcher and the two project leaders). Mutual learning occurred regarding medical content – professionals, the researcher and the two project leaders got acquainted with problems and needs of patients, and patients learned about medical related procedures by evaluating the web-based patient version – and in a procedural way – learning occurred concerning patient involvement procedures and methods.

It was also observed that the diversity among participants stimulated co-creation of solutions. At several moments it was observed that interaction between participants in the FGDs resulted in a broad variety of topics and in-depth reflection. Moreover, during the FGDs there was specific attention for interaction by the use of statements. These statements stimulated participants to react and to start a discussion. Furthermore, the statements appeared useful to stimulate the articulation of solutions.

DISCUSSION

Our findings reveal that consultation of individual patients by means of FGDs and with regular feedback moments has been quite successful for a guideline development process related to an incidental, non-threatening disease for which there is no patient organisation. There was diversity among participants of the FGDs and there was saturation of the results. In addition, the involvement of FGD patients in the development of the instruction video and the testing of the web-based patient version afterwards was valuable, since it gave patients the opportunity to verify the processing of their input, and assured continuity of patient involvement. As a result, not only knowledge transfer, but also knowledge exchange was realized between professionals and patients. Moreover, the web-based patient version was considered very valuable by patients, and as consequence the external validity can be regarded as high.

Patients were well able to participate in this clinical guideline development process, since their involvement did not require specific skills; only their experiential knowledge was addressed. This is in favour of the discussion where scholars argue whether training and support of patients in order to be able to participate on an equal level is desirable.⁸ Furthermore, literature on implementation of clinical guidelines report poor implementation with almost non-existing implementation among patients.^{1,43-45} The development of a web-based patient version may contribute to enhanced applicability of the clinical guideline in daily practice and to dissemination among patients. In a follow-up study a randomized controlled trial (RCT) started in the spring of 2010 to further evaluate the effects and effectiveness of the recommendations of the clinical guideline and the web-based patient version.¹⁴ Part of the RCT will be a process evaluation to assess (1) the extent to which the web-based patient version and convalescence recommendations

are used and followed up (compliance), and (2) the appreciation of the different tools of the eHealth intervention. The results of the process evaluation will be used to optimize the web-based patient version, and will contribute to enhanced implementation of the clinical guideline.

The guideline development process was divided in two parallel trajectories in which patients and professionals were consulted separately. Patients were primarily consulted for the development of the web-based patient version of the clinical guideline, while professionals were mainly involved for the development of the recommendations of the clinical guideline. This division was an explicit choice of the project team, who appreciated the experiential knowledge of patients and valued their input for the web-based patient version. However, they believed expert-knowledge was required for the formulation and interpretation of the recommendations. With this division, the project team followed a more Governance Discourse, as described by Boivin *et al.*,⁴² which has an emphasis on the synthesis of scientific evidence to clinical decision-making, predominantly informed by evidence-based medicine. Although the followed approach turned out to be quite successful, one could question to what extent a more interactive process would have had an added value on the quality of the recommendations. When another discourse was followed in which shared-decision making and patient-centred care have a more central place, patients would have been more involved in the development of the recommendations.^{42,46} To ensure the motivated involvement of an unorganised patient population, like gynaecological patients, the involvement of a skilled facilitator is required. On the other hand, the developed web-based version is able to monitor the actual achieved resumption of normal and work-related activities, enabling future adjustments of these recommendations. In addition the experiences of patients and care-providers will be registered in a randomised study evaluating the effect of this web-based version on return to work (RTW), quality of life (QOL) and pain. Patients reported experiences will be part of the final clinical guideline.

The FGD results were taken along in the formulation (and selection) of the topics of the recommendations of the professionals. The influence the FGD results had on these topics reveal that patients' input complemented the input of professionals and increased the applicability of the recommendations in daily practice. One might argue that a higher degree of involvement in this trajectory could have resulted in recommendations even more aligned to the daily practice. In participatory approaches for agenda setting in chronic disease domains together with active patient organizations, interaction between patients and professionals proved to stimulate mutual learning. Consultations complemented by collaboration breed partnerships and could, as a result, contribute to increased quality and relevance of health research.⁴⁷ Applied for clinical guideline development processes these insights could contribute to better tuning of clinical guidelines to daily practice

and a higher appreciation of each others' input. Particularly since this clinical guideline concerns a transmural agreement with consensus-based recommendations, patient involvement might more easily be achieved.¹ The development of such a clinical guideline is less dependent on scientific evidence, and therefore there tends to be more room (and need) for experience-based knowledge from both professionals and patients. Increased patient involvement could be achieved by integration of the two parallel trajectories with additional dialogue meetings with patients and professionals. However, follow-up research is required to assess the added value of these additional dialogue meetings, in which aspects like (practical and financial) feasibility and diversity among individual patient should be taken into account.

Limitations of the study

Patient involvement in guideline development processes is highly contextualized and our results are therefore difficult to generalize. Characteristics of this specific guideline development process and of the Dutch context might have shaped our findings. First, this guideline development process concerns an innovative process, in which individual patients and professionals were consulted separately in two different trajectories. Secondly, there was a specific emphasis on the development of a web-based patient version. As a consequence, this clinical guideline development process, including the patient involvement, differs from the more traditional development processes in the Netherlands and abroad, in which the inclusion of one or two patient representatives in a guideline workgroup is the most common approach.^{1,2,5,8-12} Although these factors might influence the dissemination of our findings to a broader context, we believe our findings may contribute to valuable directions for future guideline development processes in which patients groups are not united, e.g. for incidental and non-threatening diseases.

CONCLUSION

In conclusion, the involvement of gynaecological patient in an innovative guideline development for resumption of (work) activities after surgery can be regarded as quite successful; the consultation of individual patients by FGDs, as well as the testing of the web-based patient version resulted in meaningful input. Furthermore, patients' input contributed to applicability of the clinical guideline in daily practice and to implementation among patients. Although the choices for two parallel trajectories are legitimate and resulted in end-products aligned to patients' daily practice, we suggest that more patient involvement in the development of the recommendations of the clinical guideline may result in increased relevance and quality of the recommendations.

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CHAPTER 6

Effectiveness of a multidisciplinary care program on recovery and return to work of patients after gynaecological surgery; design of a randomized controlled trial

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ABSTRACT

Background

Return to work after gynaecological surgery takes much longer than expected, irrespective of the level of invasiveness. In order to empower patients in recovery and return to work, a multidisciplinary care program consisting of an eHealth intervention and integrated care management including participatory workplace intervention was developed.

Methods

We designed a randomized controlled trial to assess the effect of the multidisciplinary care program on full sustainable return to work in patients after gynaecological surgery, compared to usual clinical care. Two hundred twelve women (18-65 years old) undergoing hysterectomy and/or laparoscopic adnexal surgery on benign indication in one of the 7 participating (university) hospitals in the Netherlands are expected to take part in this study at baseline. The primary outcome measure is sick leave duration until full sustainable return to work and is measured by a monthly calendar of sickness absence during 26 weeks after surgery. Secondary outcome measures are the effect of the care program on general recovery, quality of life, pain intensity and complications, and are assessed using questionnaires at baseline, 2, 6, 12 and 26 weeks after surgery.

Discussion

The discrepancy between expected physical recovery and actual return to work after gynaecological surgery contributes to the relevance of this study. There is strong evidence that long periods of sick leave can result in work disability, poorer general health and increased risk of mental health problems. We expect that this multidisciplinary care program will improve perioperative care, contribute to a faster return to work of patients after gynaecological surgery and, as a consequence, will reduce societal costs considerably.

BACKGROUND

Health care problem

Research on duration of full recovery and return to work (RTW) after (laparoscopic) gynaecological surgery has shown large discrepancy between expected physical recovery and actual return to work.¹⁻³ This may be explained by the fact that duration of recovery and RTW is mainly influenced by the expectations of the patient and employer, rather than by physical factors or the type of surgery.⁴⁻⁶ However, in most cases there is hardly attention for RTW expectations.⁷ In general, gynaecologists do discuss the needs and risks concerning the surgical intervention and expected duration of hospitalization with their patient, but structural convalescence recommendations regarding the resumption of (work) activities are mostly not provided.^{1,8} In addition, after discharge the patient usually has only one post-operative check-up six weeks after surgery, which is focused on examination of the physical condition. Other medical care is fragmented and given only on demand, as a result of which patients often do not know whom to contact for support in case of postoperative complaints. Due to Dutch legislation, patients with paid work who do not RTW within six weeks after surgery, are generally consulted by their occupational physician (OP). However, as a result of the lack of recognised guidelines on the resumption of (work) activities and poor communication between the gynaecologists, general practitioners (GPs) and OPs, often indistinct and conflicting recommendations are given and additionally most physicians do not differentiate according to the type of surgery.⁹⁻¹¹ These factors contribute to uncertainties and irrational beliefs of patients, which may result in delayed recovery, prolonged sick leave and reduced quality of life.^{12,13}

The Dutch Health Council stated, in line with the International Classification of Functioning, disability and health (ICF) model that there is a strong need for multidisciplinary recommendations for resumption of postoperative work activities.^{14,15} However, little is known about patients' needs, (illness) beliefs and preferences regarding postoperative care and resumption of work activities.¹⁶ Therefore, we previously explored patients' perioperative needs using focus group discussions with gynaecological patients and performing a review of the literature.¹⁷ Detailed multidisciplinary convalescence recommendations were developed in collaboration with the medical board of gynaecologists, OPs and GPs through a modified Delphi consensus method with experts.¹⁸ To mirror the target group, the focus group discussions and Delphi study were geared towards patients who underwent a hysterectomy (abdominal, vaginal, laparoscopic) or laparoscopic adnexal surgery on benign indication. These types of surgeries were chosen, because they are the most frequently performed (major) gynaecological surgical procedures with a considerable postoperative effect on recovery and RTW and yearly count for more than 17.500 procedures in the Netherlands.¹⁹

Multidisciplinary care program

Based on the results of the modified Delphi study, the outcomes of the focus group discussions, the literature review and considering both the ICF model as well as the Attitude, Social influence and self-Efficacy (ASE) model in which important determinants of recovery and RTW are described^{20,21}, a multidisciplinary care program for gynaecological patients undergoing surgery was developed. The care program aims at the different aspects of curative treatment as well as at personal and external factors. In addition, it tries to encourage patients in resuming activities and participation in the society. The program consists of an interactive eHealth intervention, integrated care management and a participatory workplace intervention. The eHealth intervention was developed through an intervention mapping protocol²² and specifically aims at the empowerment of gynaecological patients and their environment during the pre- and postoperative period (from around four weeks before until eight weeks after surgery).¹⁷ This includes encouragement of patients in resuming daily and work activities. If the patient is still on sick leave 10 weeks after surgery, the integrated care management and participatory workplace intervention will be offered. This part of the intervention is based on a previous study with patients with chronic low back pain²³, and was adapted to our target group for this study.

Objectives

The main objective of this study is to evaluate the effectiveness of the multidisciplinary care program (eHealth intervention, integrated care management & participatory workplace intervention) compared to usual care regarding full sustainable RTW for patients after hysterectomy or laparoscopic adnexal surgery on benign indication. Secondary objectives of the study are 1) to study the effect of the multidisciplinary care program on general recovery, quality of life, pain intensity and complications; 2) to investigate how the program is evaluated by the patients, their health care providers and their employers and 3) to validate the multidisciplinary convalescence recommendations developed in the Delphi study.¹⁸

METHODS

The CONSolidated Standards Of Reporting Trials (CONSORT) statement was followed to describe the design of this study. This checklist is used worldwide to improve the reporting of Randomized Controlled Trials (RCT).²⁴⁻²⁶

Organization of the study

The design of the study is a multicentre prospective RCT in patients undergoing gynaecological surgery and will be conducted in the Netherlands. In this study, the intervention group will receive a multidisciplinary care program (eHealth intervention,

integrated care management & participatory workplace intervention) and will be compared with a control group that receives usual given perioperative care together with a placebo eHealth intervention. Figure 1 presents a brief outline of the design of the study.

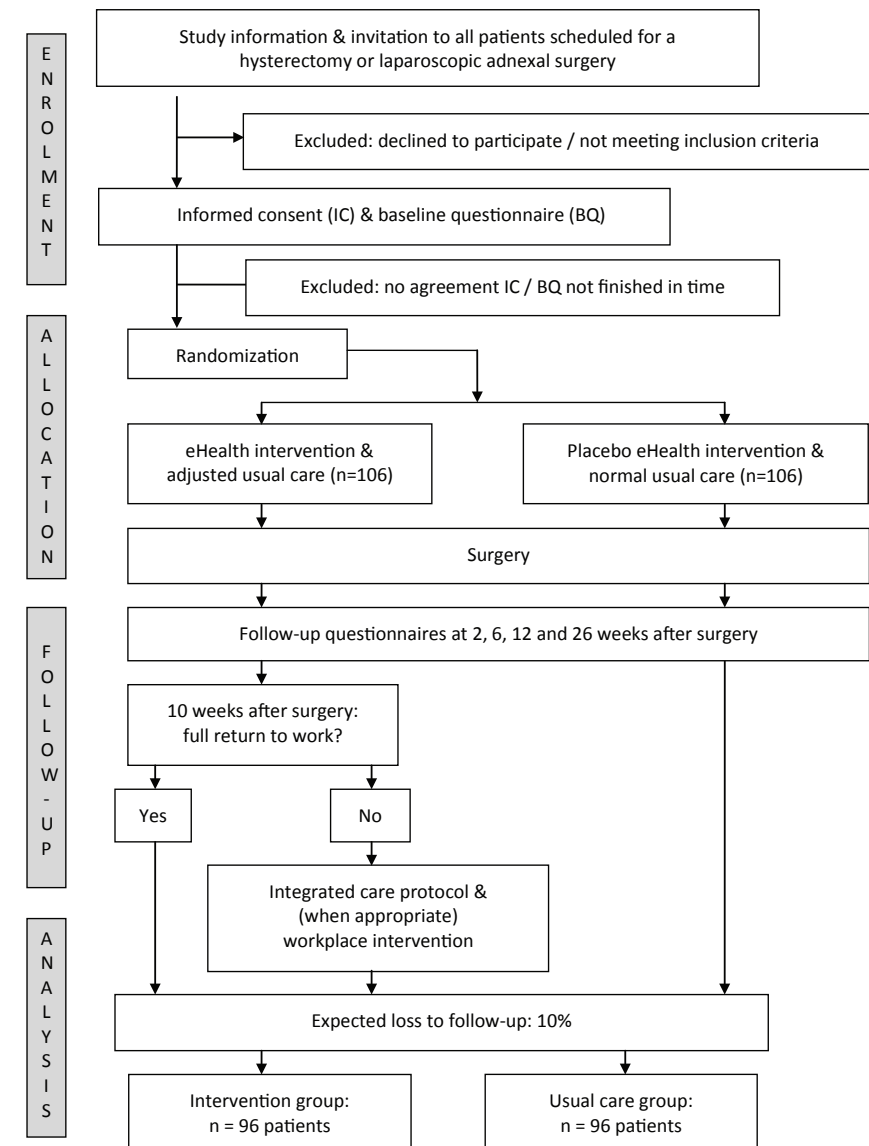


Figure 1. Design of the RCT

The seven participating hospitals in this study will be one University and six general (teaching) hospitals, all localized in or nearby Amsterdam: 1) The Amstelland Hospital; 2) The Flevo Hospital; 3) The Kennemer Gasthuis; 4) The Onze Lieve Vrouwe Gasthuis; 5) The Sint Lucas Andreas Hospital; 6) The Spaarne Hospital and 7) The VU University Medical Center.

Recruitment of patients

Participants for the study will be recruited from the waiting lists of participating hospitals. Patients scheduled for a hysterectomy or laparoscopic adnexal surgery because of benign disorders will receive an invitation letter on behalf of their gynaecologist, together with an information package consisting of: 1) patient information letter about the study, 2) informed consent (IC), 3) reply card to send to the researchers when not interested in participation in the study and finally, depending on the requirements of the particular hospital, 4) a leaflet about participating in scientific research in general.

When the researchers do not receive a reply card of the patient within two weeks after the delivery of the information package, they will make contact to evaluate whether she is interested in participation in the study. Phone numbers and addresses of these patients will be sent to the researchers by the participating hospitals weekly. Patients willing to participate and meeting the inclusion criteria will be asked to return the signed IC and will receive the baseline questionnaire about four weeks before surgery. Subsequently, when both are filled out and the surgery is scheduled within four weeks, the patient will be randomized for the intervention or usual care group.

Study population

Eligible patients for this study are women aged between 18-65 years, employed for at least 8 hours per week (paid or unpaid) and scheduled in one of the participating hospitals for a laparoscopic adnexal surgery and/or hysterectomy due to benign disorders. Exclusion criteria for this study are: 1) (suspicion of) malignancy; 2) (ectopic) pregnancy; 3) deep infiltrating endometriosis; 4) concomitant surgical procedures or major health problems/psychiatric disorders affecting recovery or daily activities; 5) being sick listed for more than 4 weeks, or when the operation is to cure the reason of the absence of work, sick listed for more than 2 months; 6) working temporarily for an employment agency without detachment; 8) dealing with a lawsuit against their employer; 9) not able to understand or complete the questionnaires written in the Dutch language and 10) no access to internet.

Randomization

To prevent unequal randomization between hospitals, patients will be pre-stratified by hospital and type of surgery (laparoscopic adnexal surgery, total laparoscopic-/laparoscopic assisted-, vaginal- and abdominal hysterectomy). A computer-generated

block randomization will be performed on individual level. The blocks consist of four characters to ensure roughly equal group sizes with each stratum and are randomly varying in sequence. Randomization will be executed by an (independent) research assistant, after the patient has completed baseline measurements and IC.

Control group; placebo eHealth intervention and usual perioperative care

In the Netherlands, there is a considerable variation in given perioperative care and convalescence recommendations for gynaecological patients. The number of consultations and also the available time for counselling differs per hospital. After discharge, in general the patient receives one appointment for a post-operative check-up in an outpatients' department for about six weeks after surgery. Other medical care by gynaecologists and GPs is given only on demand. Patients with paid work who do not RTW within six weeks after surgery, are generally consulted by their OPs due to Dutch legislation.

In addition to given usual care, patients in the control group of this RCT will get access to a placebo eHealth intervention. This website has five unique pages and provides the patient with a patient leaflet and telephone numbers of the participating hospitals. The patient leaflet is derived from The Dutch Society of Obstetrics and Gynaecology (NVOG) website and forms the basis of almost all leaflets provided in Dutch hospitals for hysterectomy or laparoscopic adnexal surgery on benign indication.^{27;28}

Intervention group; multidisciplinary perioperative care program

Patients in the intervention group, receive normal usual perioperative care with the adjustment that the care providers supply standardized detailed convalescence recommendations to the patients.¹⁸ In addition, this group will get access to an eHealth intervention and, when they have not returned to work completely within ten weeks after surgery, supplementary care of a clinical occupational physician and (if relevant) a workplace intervention by an occupational therapist (OT) will be offered. This stepped care approach of additional care will be described in detail below.

Step 1: all patients get access to an eHealth intervention from four weeks before surgery

To improve perioperative gynaecological care, an interactive eHealth intervention aiming at the empowerment of gynaecological patients during the perioperative period including return to normal activities and work was developed.¹⁷ This eHealth intervention targets at behaviours of patients as well as of gynaecologists, GPs, OPs, employers and family members. It provides tools to compose detailed tailored instructions on the resumption of (work) activities, based on the operation date and how the surgery went (input of gynaecologist). These recommendations are based on a Delphi study among gynaecologists, GPs and OPs, using a structural consensus method including a systematic review of available literature.¹⁸ The eHealth intervention additionally provides tools (e.g.

a video) to improve the communication between patients, care-providers and employers, to prevent conflicting recommendations and stimulate patients and employers to discuss potential RTW problems and to develop a work reintegration plan. Furthermore, general information on the surgical procedure itself, the (possible) consequences of the surgery and clear instructions about which symptoms require additional consultation of care providers or adaptation of convalescence recommendations, is available by the eHealth intervention. In addition, it supplies an extensive list of frequently asked questions and a forum to contact other patients. Finally, patients' recovery can closely be monitored by the website, allowing the eHealth intervention to advise the patient to contact a clinical occupational physician for support with reintegration when she has not RTW ten weeks after surgery. Table 1 presents an overview of the various tools of this eHealth intervention.

Step 2: if sick leave exceeds ten weeks, additional integrated care management including workplace intervention will be offered

This part of the intervention will only be offered to the patient when she is not fully returned to work ten weeks after surgery and consists of two main protocols; 1) Integrated care protocol and 2) Workplace intervention protocol and is based on a previous study of patients with chronic low back pain.²³

Integrated care protocol

A clinical occupational physician will be trained as RTW coordinator to fulfil an intermediate role between the patients' gynaecologist, GP, OP and a trained OT. The clinical occupational physician independently assesses the mental and physical condition of the patient and is responsible for the planning and the coordination of the continuation of care. First consultation of the clinical occupational physician will take place in the tenth or eleventh week after surgery. Table 2 presents an overview of the integrated care protocol. Depending on the diagnosis, the clinical occupational physician will work out a treatment and rehabilitation plan (with a RTW prognosis) and discuss it with the patient and her OP. If both agree with the plan, the recommendations will be executed by calling in the assistance of the OT (if relevant), the patients' employer and/or appropriate care provider(s). The patients' OP will not lose any responsibilities regarding the final RTW plan. Communication between medical care providers will be performed according to the GP-OP-coordination guideline.²⁹ Six and 12 weeks after the first consultation, the patient will visit the clinical occupational physician to evaluate the progress, discuss existing problems and if necessary adjust the date of RTW.

Workplace intervention protocol

The workplace intervention procedure starts when the clinical occupational physician refers the patient to the OT, an expert to provide work (place) adaptations. The clinical occupational physician will define the conditions (working hours, duties, etc.) under which

Table 1. Structure of the eHealth intervention ¹⁷

Tool	Content	Involved stakeholders
1. Compose a work reintegration plan	▪ Tool to compose a detailed reintegration plan with adaptations for work if necessary	➤ Patient, employer, OP
2. Resume normal activities	▪ Tool to compose detailed advice about when normal (private) activities can be carried out again	➤ Patient, family
3. Evaluate complications	▪ Estimate severity and consequences of a complication	➤ Patient, gynaecologist
4. Recovery monitor	▪ Monitoring recovery and offering assistance when relevant	➤ Patient
5. Satisfaction with recommendations	▪ Evaluation and explanation of convalescence recommendations	➤ Patient
6. Satisfaction with the recovery process	▪ Evaluation of satisfaction with recovery and reintegration process. Provision of advice regarding which care provider(s) to approach to receive appropriate help, when relevant.	➤ Patient
7. Invite employer	▪ Invite employer for (anonymous) section of the website which includes video (see below) and recommendations	➤ Patient, Employer
8. Video	▪ Illustrate common pitfalls during the perioperative and reintegration period	➤ Patient, employer, gynaecologist
9. Recommendations for employee	▪ Advice for a successful reintegration	➤ Patient
10. Recommendations for employer	▪ Advice for appropriate involvement regarding employee during the perioperative and reintegration period	➤ Employer
11. Frequently asked questions	▪ Extensive list of answers and pictures to most frequently asked questions	➤ Patient
12. Glossary	▪ Explanation of most frequently used medical terms	➤ Patient
13. Forum	▪ Ability to interact in public or through private messages with other patients	➤ Patient
14. Links to other websites	▪ Relevant websites concerning the perioperative and reintegration period	➤ Patient
15. Guidelines	▪ Well-defined convalescence recommendations after hysterectomy and laparoscopic adnexal surgery	➤ Gynaecologists

the patient may return to work, which should be adopted by the OT and communicated effectively to the patient and the employer. The workplace intervention is based on methods used in 'participatory ergonomics' ^{30,31} and presumes strong commitment of both the patient and employer. This intervention has been developed originally for patients with chronic low back pain ^{30,32} and has shown to be (cost) effective in this

Table 2. Integrated care management and workplace intervention protocol

Weeks after surgery	Integrated care protocol <i>Carried out by the clinical occupational physician</i>	Workplace intervention protocol <i>Carried out by the occupational therapist (OT)</i>
10-11	<p>First consultation:</p> <ol style="list-style-type: none"> History taking and physical examination to identify: <ul style="list-style-type: none"> adequacy of illness behaviour presence of psychosocial problems inadequate treatment limitations at work influencing RTW (e.g. physical heavy work, organizational obstacles). Contact patient's other care providers (if relevant). Diagnosis of the medical situation or problem(s) Propose a treatment and rehabilitation plan (with a RTW prognosis). Discuss the treatment and rehabilitation plan with the patient and her occupational physician. If both agree 	
12-13	<p>Call in the assistance of patient's employer and relevant care provider(s)</p> <p>Discuss the advisory plan (developed by the OT) with the OT</p>	<p>Contact OT to start the workplace intervention protocol (if relevant)</p> <p>First consultation:</p> <ol style="list-style-type: none"> Observation, inventory and ranking of patient's tasks and obstacles for RTW at the patient's workplace. Inventory and ranking patient's tasks and obstacles for RTW by the patient's employer. Patient, patient's employer and the OT brainstorm and discuss as many potential solutions as possible, for the problems identified in step a and b. Solutions are sorted and prioritized based on implementation time, costs and contribution to the problem(s). <p>The OT reports (in consultation with the clinical occupational physician) an advisory plan specifying what has to be done, how, when and by whom. This report is sent to the patient, the patient's employer, OP and the clinical occupational physician.</p>

Weeks after surgery	Integrated care protocol <i>Carried out by the clinical occupational physician</i>	Workplace intervention protocol <i>Carried out by the occupational therapist (OT)</i>
14-15		<p>Optional worksite visit to give additional instructions or training to the patient on working in the modified setting.</p>
16-17	<p>Second consultation:</p> <ol style="list-style-type: none"> Evaluate the diagnosis, effect of the treatment and progress If necessary, adjust the date of RTW 	<p>Evaluation between the patient, patient's employer and the OT (by telephone) with regard to the effects of the workplace adaptations. Further improvements are sought for when solutions have proven not to be totally effective.</p>
19-20		<p>Final report is sent to the patient, the patient's employer, OP and the clinical occupational physician.</p>
22-23	<p>Third and final consultation:</p> <ol style="list-style-type: none"> Evaluate the diagnosis, effect of the treatment and progress If necessary, adjust the date of RTW Hand the employee over to her own OP 	

Abbreviations: RTW = Return to work, OT = occupational therapist; OP = occupational physician

population.^{33,34} For this study, the protocol is adapted to post-operative gynaecological patients, regarding time-schedule and involved care providers. The consecutive steps of the workplace intervention protocol are described in table 2. The main aim of this intervention is patients' full RTW in their own or equal work. To achieve this aim, the OT will try to reach consensus between patient and her employer regarding feasible solutions for the obstacles for RTW. The solutions will be judged on short-term implementation possibilities, affordability and problem solving capability. After consensus has been reached, patient, patient's employer and OT will agree on an implementation plan, which will be evaluated during following weeks.

Outcome Measures

Data-collection

The follow-up period will be 26 weeks after surgery (baseline). All the outcome variables are measured using self-report online questionnaires³⁵ and will be taken at baseline, two, six, 12 and 26 weeks after surgery. In general, the longer the recall period, the less accurate individuals are in reporting for example the use of health care services. Although no evidence on the optimal period is provided by literature, 12 and 26 weeks are frequently used and generally accepted.³⁶ Little agreement exists on the accuracy and validity of self-reported health care utilization and absenteeism data.³⁷ However, regarding sickness absence general consistency in the self-reporting can be relied on when recall is required within one month.^{37,38} Therefore, in this study a monthly self-reported calendar of sickness absence per post was chosen to measure RTW. Furthermore, gynaecologists will complete questionnaires one day after surgery of each patient and at the end of the study. Employers will be asked to evaluate the eHealth intervention eight weeks after the surgery of their employee. When patients, gynaecologists and employers do not fill out the questionnaires within one week, they will receive a reminder per email. If no response follows, they will be reminded by a telephone conversation. In addition to the questionnaires and calendars, the eHealth intervention used by the intervention group will measure the use of the intervention, complications and (satisfaction with) recovery. Table 3 presents an overview of the outcomes and variables measured in this study.

Primary Outcome measures

1. The primary outcome measure in this study is sick leave duration until full RTW, defined as: duration of sick leave in calendar days from the day of surgery until full RTW in own or other work with equal earnings, for at least four weeks without (partial or full) recurrence.³⁹ This means that recurrences of sickness absence within four weeks after first day of full RTW, will be considered as belonging to the preceding period of sick leave, on condition that this is due to the consequences of the surgery. RTW will be measured by a monthly calendar of sickness absence.

Table 3. Overview of outcome measures & variables in this study

Outcome measures & variables	T ₀ Baseline ^d	T ₁ 2 wks after surgery	T ₂ 6 wks after surgery	T ₃ 12 wks after surgery	T ₄ 26 wks after surgery
<u>Primary</u>					
1) Return to work ^a					measured monthly ^e
<u>Secondary</u>					
2) Total duration of sick leave ^a					measured monthly ^e
3) First RTW ^a					measured monthly ^e
4) Recovery					
• Recovery specific QoL (RI-10)	X	X	X	X	X
• Performed activities			X		
• Performed activities measured by eHealth intervention ^{b,c}			at least 2, 4, 7, 14, 21, 28, 42, 56, 84 days after surgery		
5) Functional and general health status (SF36, EuroQoL)	X			X	X
6) Pain intensity (Von Korff)			X	X	X
7) Empowerment (GSES)		X	X	X	
8) Health care usage (TicP)				X	X
9) Occurrence of complications during the post-operative period			X	X	X
• Complications measured by eHealth intervention ^{b,c}			at least 7, 14, 21, 28, 42, 56, 84, 126 and 182 days after surgery		
<u>Prognostic variables</u>					
10) Socio-demographic variables	X				
11) Type of surgery	X				
12) Complications during surgery			X		
13) Work-related factors (DMQ, JCQ, additional questions)	X				
14) Pain perception and fear avoidance belief (Tampa scale)	X				
15) Sick leave duration in the past three months	X				
16) Expectations, intention and motivation for return to work	X				
<u>Process evaluation</u>					
17) Patients attitudes, opinions and compliance regarding the convalescence recommendations and tools of the eHealth intervention ^a		X	X	X	X

Table 3. Continued

Outcome measures & variables	T ₀ Baseline ^d	T ₁ 2 wks after surgery	T ₂ 6 wks after surgery	T ₃ 12 wks after surgery	T ₄ 26 wks after surgery
18) Physicians' and employers' attitude en opinion regarding the multidisciplinary care program ^b				X	
19) Satisfaction with care program and care providers (e.g. PSOHQ)				X	
20) Use of the eHealth intervention ^b		X		X	
21) Suggestions for improvement of the eHealth intervention		X		X	
22) Provided convalescence recommendations by the care providers according to the patients		X			

^a Return to work and total duration of sick leave is measured by a monthly calendar of sickness absence

^b Only measured in the intervention group

^c Besides the standard requested time points, the patients can fill out the recovery monitor/complication form as many times as requested

^d The baseline questionnaire will be filled out no longer than four weeks before the day of surgery

^e Measured from day of surgery

Secondary Outcome measures

- The total duration of sick leave (due to the consequences of the surgery) during the 26 weeks follow-up period; measured by a monthly calendar of sickness absence.
- First RTW; measured by a monthly calendar of sickness absence.
- Recovery; measured by a validated Recovery Specific Quality Of Life questionnaire RS-QOL(RI10)⁴⁰, an extended list of (graded) activities based on the detailed convalescence recommendations given to the patients of the intervention group¹⁸ and a recovery monitor which is a tool of the eHealth intervention of the intervention group.
- Functional and general health status (quality of life); assessed according to the standard Dutch version of the EuroQoL⁴¹ and the Short-form health survey (SF-36).^{42;43}
- Pain intensity; measured using Von Korff questionnaire.⁴⁴
- Empowerment; assessed by the Dutch adaptation of the General Self-Efficacy Scale.⁴⁵
- Health care usage; measured by the Tic-P questionnaire⁴⁶ and valued according to the prices in the guidelines for economic evaluation in the Netherlands.⁴⁷
- The occurrence of complications in the post-operative period; assessed by questions based on the complication registration form of The Dutch Society of Obstetrics and

Gynaecology (NVOG).⁴⁸ Patients in the intervention group do also answer these questions more frequently through a tool of the eHealth intervention, in order to register possible side effects of the intervention and to determine and inform them when symptoms require additional consultation of care providers or adaptation of convalescence recommendations.

Prognostic factors

- Socio-demographic data; measured by the standard Dutch version of the EuroQoL⁴¹ and specific additional socio-demographic questions.
- Type of surgery.
- Complications during surgery; assessed by questions based on the complication registration form of The Dutch Society of Obstetrics and Gynaecology (NVOG).⁴⁸
- Work-related factors; measured by the Dutch Musculoskeletal Questionnaire (DMQ)⁴⁹, the Job Content Questionnaire (JCQ)⁵⁰ and specific additional work-related questions.
- Pain perception and fear avoidance belief; assessed by the Tampa scale.⁵¹
- Sick leave duration in the past 3 months.
- Expectations, intention and motivation of the employee about return to work after surgery.⁵²

Outcomes regarding process evaluation

A process evaluation will be performed only in the intervention group according to the Linnan and Steckler model.⁵³ These patients, their gynaecologists and employers will receive specific questions regarding the multidisciplinary care program, including the eHealth intervention. These questions will measure:

- Patient's attitudes, opinions and compliance regarding the convalescence recommendations and the tools of the eHealth program.
- Physicians' and employers' attitude en opinion regarding the multidisciplinary care program.
- Satisfaction with care program and care providers; measured with the short version of the Patient Satisfaction with Occupational Health Services Questionnaire (PSOHQ)⁵⁴ and specific additional questions related to health care and care providers.
- The use of the eHealth intervention during the follow-up period (e.g. total login time, amount of mouse-clicks, use of particular tools, etc.).
- Suggestions for improvement of the eHealth intervention.
- Provided convalescence recommendations by the care providers according to the patients.

Sample size

Power calculation was performed on the primary outcome (all kind of surgeries together). To achieve a power (1- β) of 80%, with a significance level (α) of 5% and considering a HR of 1.5 in favour of the intervention group, approximately 191 patients will be needed. Anticipating a 10 % drop out rate, in total a sample size of at least 212 patients will be aimed for. To recruit this number of patients, the study will anticipate on a ten-month inclusion period.

Blinding

Patients will be blinded for the allocated treatment. Treatment allocation (randomization) will take place by computer-generated block randomization after completion of baseline questionnaire and IC. After randomization, all patients will receive access to the eHealth intervention. However, after logging into the website with their personal login credentials, the kind of information provided by the eHealth intervention will depend on the group the patient is randomized for.

During recruitment, the patients will be told that in case they do not RTW within 10 weeks after surgery, they might be approached for supplementary care depending on the care program they are randomized for. Nevertheless, explanation will only be given about the comparison of two different types of information supply and perioperative guidance and not about the content of perioperative guidance according to the 'intervention' or 'control' group.

Due to the different treatments in both groups, therapists and researchers cannot be blinded for the allocated treatment of the patient.

Data analysis

All statistical analyses will be performed at patient level, according the intention-to-treat (ITT) principle. To assess whether protocol deviations have caused bias, the results of the ITT analyses will be compared to per protocol analyses in which the patients who were not treated according to the intervention protocol, will be excluded. To examine the success of the randomization, baseline characteristics of the patients in both groups will be compared using descriptive statistics. If necessary, analyses will be adjusted for prognostic dissimilarities.

A Kaplan Meier analysis (including the log rank test) will be used to describe the association between the group allocation and the duration of sick leave until the first period of full sustainable RTW. The Cox proportional hazard model will be used to estimate hazard ratios for RTW and the corresponding 95% confidence interval.

Details of ethics approval

The study design, protocols, procedures and IC were approved by the Medical Ethics Committees of all participating hospitals: the VU University Medical Center (date 22-10-2009, number 2009/218), the Amstelland Hospital (12-02-2010, number 10-54), the Flevo Hospital (date 10-12-2009, number FZ09/35), the Kennemer Gasthuis (03-03-2010, number 2010.02), the Onze Lieve Vrouwe Gasthuis (date 21-01-2010, number 09.067), the Sint Lucas Andreas Hospital (03-11-2009, number 09/114) and the Spaarne Hospital (20-01-2010, number 561.09).

DISCUSSION

This paper describes a RCT to study the effect of a multidisciplinary care program on recovery and full sustainable return to work of women who underwent a hysterectomy and/or a laparoscopic adnexal surgery on benign indication. Since work participation contributes to well-being and recovery of illness, the program particularly pays attention to stimulate patients in gradually resuming normal activities including RTW.^{13,55} During the first step of the multidisciplinary care program, all patients get access to the eHealth intervention, which primarily aims to empower patients' behavioural determinants and supports adequate beliefs regarding recovery and RTW in patients with an uncomplicated postoperative course.¹⁸ These are prognostic factors for recovery and RTW and account for the personal determinants in the ICF model. Secondary, the eHealth intervention provides tools through which environment (e.g. family, employer), clinical condition, participation and resuming of activities may be influenced. The second step of the care program is only offered when sick leave exceeds ten weeks and thus to patients with a complicated recovery and RTW. The goal of this step is to prevent work disability. It contains additional integrated care management by a multidisciplinary team consisting of a clinical occupational physician, gynaecologist and OT and includes a workplace intervention. This step mainly focuses on reducing barriers for RTW by improving communication between different care providers, OP, employer and patient.

Strengths and limitations

The implementation of this study in six general (teaching) and a University hospital is a good reflection of the Dutch health care situation. In addition, the selection bias of patients will be restricted through the proactive way of inviting all patients on the waiting lists to participate in the RCT. Therefore, selection will take place only based on clearly defined in- and exclusion criteria. A third strength is the blinding of the patients, which will minimize the Hawthorne and placebo effect.⁵⁶ Furthermore, the primary outcome measure in this study is full sustainable RTW, which takes into account recurrences of sick leave within four weeks after RTW and therefore reduces underestimation of

work-loss days.⁵⁷ Another strength regarding the outcome measures is the evaluation of patients' health and recovery through clinical, participatory and activity outcome measures. By doing so, the influence of the care program on the different aspects of human functioning and state of health according to the ICF model, will be evaluated.¹⁴ All patients receive their own research code according to which all data were stored in the databases. This ensures blinded analysis of the data by the researchers. Finally, this is the first study to extensively evaluate consensus-based guidelines with detailed convalescence recommendations regarding return to normal and work activities after gynaecological surgery.^{18;58} The guidelines represent a consensus opinion of expert-based knowledge between gynaecologists, GPs and OPs and this study will show whether these recommendations reflect realistic recovery times for gynaecological patients and will bring about a quicker recovery without an increase in complications compared with usual care.

The main limitation of this study is that contamination between the intervention and control group cannot completely be prevented, because the randomization will be performed on patient level. With regard to the health care providers, it is impossible to blind them for the intervention allocation, because the allocation determines the kind of convalescence recommendations that should be given to the patient. Therefore, it is important for them to follow and distinguish consequently the protocol belonging to the intervention versus the control group. Contamination may occur when care providers use acquired insights received through the convalescence recommendations for the intervention group to adapt their usual care and convalescence recommendations given to the control group. To minimize this effect, we will only proactively work on the familiarity of the protocols among the health care providers and not on the detailed contents of the convalescence recommendations for the patients in the intervention group. The patients' gynaecologists will only receive a summary of the guideline by means of their patients' record, in order to pass it on to the patient at discharge from the hospital. GPs and OPs will only receive the guideline when the patient hands over her tailored convalescence recommendations or work reintegration plan to them. A learning curve of the health care providers to flawlessly execute the protocol in the intervention group may be expected. This implementation curve may result in less effect of the intervention during the beginning of the study, which should receive attention during the analysis of the results. To accelerate the implementation of the protocol, pocket maps with the description of the intervention will be distributed, teaching meetings with the health care providers about the protocol will be organized and the protocol will be added to the medical file of the patient. Although therapists and researchers cannot be blinded for the allocated treatment of the patient, they will not be involved in measuring the outcomes, since all outcome measures are self-reported and the questionnaires will be sent by email or post to the patients. Therefore, it is unlikely that the way patients complete the questionnaires, will be influenced by

the researcher and care providers. Moreover, the therapists of the multidisciplinary team (RTW-coordinator, OT, and other care providers), will not be involved in the assessment of the outcomes. With concern to contamination between patients of the intervention and control group, a chance meeting cannot be excluded. According to the protocol, patients from different groups should not be placed in the same hospital room, but it cannot be prevented that patients will meet outside the room. Another limitation of this study is the fact that the integrated care management and the workplace intervention will be carried out by one clinical occupational physician and OT, which might affect the execution of the intervention. However, both will work according to a detailed standardized protocol in order to minimize their personal influence on performance of the intervention as much as possible. Compliance to eHealth interventions is sometimes low. We tried to minimize the risk of low compliance as much as possible by spending extra effort and time on involving the stakeholders (end-users) in the development of this intervention and adapting it to their specific needs by use of the intervention mapping protocol.²² Finally, although the participating hospitals reflect the proportion of (non) university hospitals in the Netherlands, they are all located in the urban agglomeration in the Western part of the Netherlands, which might be of influence on the educational level of the patient population. Because research has shown that both living in the city as well as higher educational level are associated with more frequent use of the internet for health or illness matters, it should be determined whether the educational level and internet use of the participating patients reflects that of the general Dutch population, before the results of this study can be interpreted as representative of all gynaecological patients in the Netherlands.⁵⁹

Policy implications

Yearly more than 17.500 women receive a hysterectomy or laparoscopic adnexal surgery on benign indication in the Netherlands.¹⁹ These large numbers of surgeries have a great impact on absenteeism since it is expected that approximately 67 percent of women aged between 25 and 65 years have paid work.⁶⁰ Therefore, if this multidisciplinary care program reduces medical consultation by providing patients with tailored, detailed and unambiguous convalescence recommendations, improves communication between care providers and stimulates patients in a faster sustainable RTW, this relatively cheap intervention may potentially decrease the sick leave costs of gynaecological patients in the Netherlands.

If the multidisciplinary guidelines evaluated in this study will bring about a quicker recovery without an increase in complications, they will be implemented broadly in the Netherlands in collaboration with the participating medical board of gynaecologists, OPs and GPs. After implementation, the expectation is that the guidelines will result in more unambiguous

detailed convalescence recommendations given by gynaecologists, GPs and OPs, through which patients will be better informed about when it is medically safe to resume daily and work activities after gynaecological surgery and give them the possibility to arrange (workplace) adaptations if necessary. Furthermore, the unambiguous recommendations will likely enhance the compliance to advice given by medical specialists and stimulate the patient to resume activities with increasing gradations of strain, which will presumably bring about a quicker recovery without an increase of complications.^{61,62} Therefore, the guidelines may potentially prevent work disability, increase quality of life (QoL) and increase patient satisfaction with care.

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CHAPTER 7

Process evaluation of a multidisciplinary care program for patients undergoing gynaecological surgery

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ABSTRACT

Purpose

This study describes the process evaluation of an innovative multidisciplinary care program for patients undergoing benign gynaecologic surgery. This care program aims at improving recovery and preventing delayed return to work and consists of two steps: (1) an interactive eHealth intervention for all participants, and (2) integrated clinical and occupational care management for those participants whose sick leave exceeds 10 weeks.

Methods

Eligible for this study were employed women aged between 18–65 years scheduled for a laparoscopic adnexal surgery and/or hysterectomy. Data were collected from patients, their supervisors and their gynaecologists, by means of electronic questionnaires during a 6 month follow-up period and an automatically generated, detailed weblog of the patient web portal (www.ikherstel.nl). Investigated process measures included: reach, dose delivered, dose received, and fidelity. In addition, attitudes towards the intervention were explored among all stakeholders.

Results

215 patients enrolled in the study and accounted to a reach of 60.2% (215/357). All intervention group patients used their account at least once and total time spent on the patient web portal was almost 2 hours for each patient (median 118 min, interquartile range [IQR] 64–173 min). Most patients visited the website several times (median 11 times, IQR 6–16). Perceived effectiveness among patients was high (74%). In addition, gynaecologists (76%) and employers (61%) were satisfied with the web portal as well. Implementation of the second step of the intervention was suboptimal. Motivating patients to consent to additional guidance and developing an accurate return-to-work prognosis were two important obstacles.

Conclusions

The results of this study indicate good feasibility for implementation on a broad scale of the eHealth intervention for patients undergoing benign gynaecological surgery. To enhance the implementation of the second step of the perioperative care program, adaptations in the integrated care protocol are needed.

INTRODUCTION

In gynaecology – as in other surgical specialties – there is an increasing interest in accelerating recovery after conventional surgery as well as minimal invasive surgery. Although procedure costs may be higher in minimal invasive surgery than with more conventional approaches, there is a perception that minimal invasive surgery gains in cost-effectiveness through shorter length of hospital stay and quicker and better convalescence.¹⁻³ Reduction of inpatient stay can easily be measured and directly benefits a hospital financially. Convalescence, on the contrary, is not on top of the agenda of many health care policy makers. A reason might be the fact that convalescence is much more difficult to influence and monitor, especially now hospital stay is minimized and post-operative care is transferred to outpatient and primary care, and therefore, fragmented. In addition, there is a lack of recognised evidence-based convalescence recommendations for gynaecological procedures,^{4,5} resulting in a situation in which structural convalescence recommendations regarding the resumption of (work)activities are mostly not provided at discharge, or when given, are based on tradition and anecdote.⁶⁻⁸

The current poor organisation of perioperative care in gynaecology may lead to delayed recovery, prolonged sick leave and higher risk of work disability^{7,9,10} which is associated with a poorer quality of life.^{11,12} In addition, as women comprise 45% of the workforce in the Netherlands,¹³ as well as in many other Western countries,¹⁴ the unnecessary absenteeism related to gynaecological procedures causes a considerable economic burden on society.¹¹

The ikherstel.nl-study (“I recover – study”) is a randomized controlled trial (RCT) in which the effectiveness was evaluated of a multidisciplinary care program aimed at improving recovery and preventing delayed return to work following gynaecological surgery.¹⁵ The intervention program, consisting of two steps, provides guidance to patients from the moment the surgery is planned until full resumption of all (work) activities after the procedure. The intervention program was developed systematically, based on the intervention mapping protocol, involving all stakeholders in the development process.^{16,17}

Besides developing an intervention systematically, it is of equal importance to evaluate the process of implementation systematically.¹⁸⁻²⁰ A good understanding of the extent to which the program was applied as intended, helps to interpret the outcome results in an effectiveness study. For example, in case positive effects of the program are not found, this could be attributable to either theory failure (the underlying theory is incorrect) or program failure (the program is potentially effective when implemented better).²¹ Moreover, a process evaluation helps to gain insight into the facilitators and barriers to future implementation which may expedite the challenging transition from research into daily practice.

This current paper describes the process evaluation of the intervention program of the '1 recover-study'. The primary goal is to investigate the feasibility of the intervention by describing the process systematically. The second objective is to explore facilitators and barriers to future implementation.

METHODS

This process evaluation was carried out alongside a RCT studying the effectiveness of a multidisciplinary care program aimed at improving recovery and preventing delayed return to work following benign gynaecological surgery. The study design was approved by the Medical Ethics Committees of all participating hospitals and all participants signed informed consent. Details of the study design have been published elsewhere.¹⁵ The effectiveness of the multidisciplinary care program was not evaluated in this feasibility study; these results will become available in the near future.

Participants

All women aged between 18-65 years, employed for at least 8 hours per week (salary-employed, self-employed or voluntary work) and scheduled for a surgery for benign gynaecological disease in one of the participating hospitals were eligible to participate. The types of surgeries that were included were: laparoscopic adnexal surgery (LAS) and/or total laparoscopic hysterectomy (TLH), vaginal hysterectomy (VH) or total abdominal hysterectomy (TAH). Excluded were patients with health problems or psychiatric disorders affecting daily life, as well as patients who were being sick-listed for more than 4 weeks prior to surgery or were involved in a lawsuit against their employer. Not being able to understand or complete the Dutch questionnaires, having no access to internet or internet-illiteracy were also exclusion criteria. This process evaluation was only performed for the participants randomised to the intervention group, because only they were exposed to the intervention care program.

Recruitment

Waiting lists from participating hospitals were used to recruit prospective program participants. Patients were contacted by phone one week after they had received an invitation letter on behalf of their gynaecologist, together with an information package. Patients willing to participate and meeting the inclusion criteria were asked to return the signed informed consent. Patients were randomized to an intervention group (n=110) or a control group (n=105). As stated before, the current paper focuses only on the patients randomised to the intervention care program.

Intervention

The intervention care program consists of a stepped care approach and contains two steps. The first step, an interactive eHealth intervention, was provided to all participants in the intervention group. The second step, integrated care management, consisted of supplementary care coordinated by a clinical occupational physician and (if relevant) a workplace intervention by an occupational therapist (OT), and was only given to those participants whose sick leave exceeded 10 weeks.

The intervention care program was systematically developed applying the principles of Intervention Mapping.¹⁶ Both theory and practise were combined and all stakeholders were involved in the process. The Attitude, Social influence and self-Efficacy (ASE) model was used as a theoretical framework for determinants of behaviour regarding return to work (RTW).^{22,23} Below, both steps of the program are summarized.

Step 1: eHealth intervention

The eHealth intervention <http://www.ikherstel.nl> was accessible to all patients, ideally 4 weeks prior to surgery. However, this period was shorter if the patient was enrolled closer to the surgery date. The patient web portal consisted of 47 unique pages and provided several tools aimed at empowering its users and improving communication between patients, employers and healthcare professionals during the perioperative period. The most important tools are:

1. Tool to compose reintegration plan

This tool enabled patients to generate detailed tailored instructions on the resumption of activities after the surgery. These recommendations were based on a multidisciplinary guideline developed by an expert panel of gynaecologists, general practitioners (GPs) and occupational physicians (OPs), using a structural consensus method prior to the RCT.²⁴ The tool was accessible before surgery, allowing planning of (work)activities and work reintegration. After surgery, the gynaecologist who had performed the surgery was asked to approve the reintegration plan electronically, allowing making adjustments to the standard advice in case of (surgical) complications.

2. Video

A film was developed and available to watch on the patient web portal illustrating common pitfalls during the perioperative and reintegration period.

3. Tool to invite employer

Patients were stimulated to invite their employer to an (anonymous) section of the web portal, including the video. This tool aimed to improve communication between employee and employer and to stimulate to develop a reintegration plan (before surgery) and discuss potential RTW problems. For both the employee as the employer a list of recommendations was provided.

4. Recovery monitor

Patients' recovery was closely monitored by the patient web portal after surgery. At 2, 4, 7, 14, 28, 56 and 84 days after surgery, patients were encouraged to fill out the monitor, inventorying which activities they had resumed already and which they had not. If patients were not satisfied with their recovery or reintegration process, an alerting system advised them to contact a specific health professional, depending on the cause of dissatisfaction.

5. Tools to increase knowledge and forum

Several tools were available to provide additional information, such as an extended list with answers to frequently asked questions (FAQ), a glossary, and links to other useful patient web portals. In addition, there was a forum enabling patients to interact (privately or publicly) with other patients.

Step 2: Integrated care management

Integrated care management refers to a multidisciplinary approach to assist those patients who exceeded 10 weeks of sick leave. A clinical occupational therapist was trained as RTW coordinator and fulfilled an intermediate role between the involved health professionals, including a trained occupational therapist (OT) and the patients' own gynaecologist, general practitioner (GP), and occupational physician (OP). The integrated care protocol consisted of two steps:

1. Consultation with clinical occupational physician

All patients exceeding 10 weeks of sick leave were offered a consultation with a clinical occupational physician in the 10th or 11th week after surgery. During the first contact the clinical occupational physician assessed the mental and physical condition of the patient and discussed the job profile and demands. Taking all factors into consideration, a treatment and reintegration plan with a RTW prognosis was made. If both the patient and her own OP agreed to the plan, the recommendations were executed by calling in the assistance of the OT (if relevant), the patients' employer and/or appropriate health care provider(s).

2. If necessary, participatory workplace intervention

When a patient was referred to the OT the workplace intervention procedure would start. The workplace intervention consists of three meetings: (1) OT with patient, (2) OT with supervisor and (3) OT, supervisor and patient together. The three meetings focus on identifying and prioritizing obstacles for RTW, finding solutions and achieving consensus between the patient and their supervisor with regard to work adjustments to facilitate RTW. The protocol was originally developed and proved effective for patients with chronic low back pain^{25,26} and is based on methods used in 'participatory ergonomics'.²⁷ The protocol was adapted to post-operative gynaecologic patients regarding time schedule and involved care providers.

Data Collection

Data for this process evaluation were collected from the patients using online questionnaires at baseline and during the 6 month follow up (2, 6, 12 and 26 weeks after surgery). Besides data collection from the patients, we collected data from: (1) the patients' employers (online questionnaire at 8 weeks after surgery), (2) the patients' gynaecologists (online questionnaire after the trial), and (3) the occupational physician involved in the study (evaluation interview after the trial). In addition, data were also obtained by means of an automatically generated weblog of the web portal.

Process measures

According to the recommendations of Linnan and Steckler²⁰ the following process items were assessed: (1) the context of the intervention; (2) reach; (3) dose delivered; (4) dose received; (5) fidelity; and (6) participants' attitudes towards the different steps of the intervention program. Table 1 gives an overview of these process measures.

Context of the intervention

Context refers to the larger physical, social and political environment that can affect an intervention program. In this process evaluation we did not assess contextual influences, however, in order to consider future implementation of the intervention program, an understanding is needed of the Dutch social and political situation. Appendix 10 provides a short overview on sickness benefit guidance in the Netherlands. In summary, in the Netherlands, employers are obliged to continue to pay wages of their employees during the first two years of sickness. During this two year period, both the employer as the sick listed employee share a mutual responsibility to increase the probability of return to work. If the employer fails to pursue an active absenteeism policy, he might be required to continue paying that employee's salary for another year. However, if the employee hinders an early return to work, the payment of his sickness benefit may be suspended or reduced.

Reach

Reach concerns the degree to which an intended audience participated in the intervention.

Step 1. The eHealth intervention was intended for all patients allocated to the intervention arm of the RCT. A detailed telephone log and the study database were used to determine what proportion of recruited potential participants did decide to engage in the study and who declined to participate. Reasons for exclusion were registered, as well as the number and reasons for drop-outs.

Step 2. Integrated care management was intended for only those patients whose sick leave exceeded 10 weeks. Return to work data were collected through the patient web portal

Table 1. Process-measures, definitions and data-collection methods

Process measure	Step 1: eHealth Intervention	Step 2: Integrated care management
Reach Proportion of the target population that received the intervention	<u>Definition:</u> Proportion of recruited potential participants that met all inclusion-criteria and decided to engage in the study <u>Data collection-method:</u> Telephone-log Baseline-questionnaire	<u>Definition:</u> Proportion of participants whose sick-leave exceeded 10 weeks that received consultation with OP <u>Data collection-method:</u> RTW-calendars Study database
Dose delivered Proportion of intended intervention that was actually delivered to target population	<u>Definition:</u> Proportion of study population that received an account for the patient web portal <u>Data collection-method:</u> Weblog	<u>Definition:</u> Proportion of patients whose sick leave exceeded 10 weeks that received appointment with OP <u>Data collection-method:</u> Appointment system OP
Dose received Extent to which the participants used the intervention as recommended	<u>Definition:</u> Proportion of patients with an account that used the web portal to compose a reintegration plan at least once <u>Data collection-method:</u> Weblog	<u>Definition:</u> Proportion of patients with an appointment that received a consultation and consented with the recommendations of the OP regarding follow-up <u>Data collection-method:</u> Patient records OP
Fidelity Extent to which the intervention was delivered as planned	<u>Definition:</u> Proportion of patients who had their reintegration plan electronically approved by their gynaecologist <u>Data collection-method:</u> Weblog	<u>Definition:</u> Proportion of consultations that took place without violation of the study protocol (e.g. referral to participatory workplace intervention if sick leave exceeded 12 weeks) <u>Data collection-method:</u> RTW-calendars Patient records OP
Participants' attitudes Satisfaction Perceived effectiveness Usage barriers Suggestions for improvement	<u>Target:</u> Patients Gynaecologists Employers <u>Data collection-method:</u> Online questionnaire	<u>Target:</u> Clinical occupation physician <u>Data collection-method:</u> Face-to-face interview

OP = clinical occupational physician, RTW = return to work

as well as through monthly self-reported calendars of sickness absence. Retrospectively, the proportion could be determined of the patients actually receiving the second part of the intervention considering the total number of patients who should have received it.

Dose delivered

Dose delivered refers to the proportion of the intended intervention that is actually delivered to the program participants and is determined by the actions of the intervention provider.

Step 1. Accounts for the patient web portal were provided by the research team. The number of generated accounts divided by the total number of participating patients was defined as dose delivered.

Step 2. According to the protocol, the clinical occupational physician should have offered a consultation to all patients exceeding 10 weeks of sick leave. Dose delivered was determined by the number of invitations divided by the total number of patients with extended sick leave.

Dose received

Dose received is a measure of the extent to which participants actively engage with the intervention. For this paper dose received was defined as the proportion of patients that used the intervention as recommended by the health care providers, likewise the definition of adherence used by World Health Organization (WHO).²⁸

Step 1. Activity on the patient web portal was continuously and automatically registered in a weblog. Because of user authentication (username and password) every participant had a unique ID, which made it possible to analyse website activity for each individual participant. Information stored in the weblog included visited page numbers, time stamps (start and end-time) and number of sessions. To prevent over-estimation of activity time, a timer was built in the system which stopped time registration when participants were not active (scrolling, click or mouse movement) for a period of 8 minutes. The minimum recommended use of the website was defined as usage of the tool to compose an integration plan at least once, as a tailored schedule with convalescence recommendations enables patients to plan their daily and work activities after the surgery and to anticipate on facing problems as well. In addition, possible irrational beliefs about recovery could be rectified with this reliable source of information.

Step 2. For the integrated care management dose received was defined as the proportion of patients that received a consultation with the clinical occupational physician and who consented with the recommendations of the OP regarding follow-up, e.g. a referral for the workplace intervention.

Fidelity

Fidelity refers to the quality of the deliverance of an intervention and the extent to which the intervention was delivered as planned.

Step 1. Each gynaecologist who performed a surgical procedure on a participating patient received an electronic request to approve the reintegration plan that the patient had composed on the patient web portal. This essential step prevented that the standardized convalescence recommendations were given to patients with (surgical) complications. If thought relevant, the gynaecologist could adjust the recommendations, and the patient received a confirmation. If a patient experienced complications after discharge from the hospital, she could notify her gynaecologist through the web portal, and he or she was asked to review the patient's reintegration plan again. Fidelity was defined as the proportion of patients whose reintegration plan was approved and/or adjusted by their gynaecologist.

Step 2. Fidelity for the integrated care management was determined by the number of consultations that took place without violation of the study protocol (e.g. accuracy of scheduled appointments, visits or telephone-consultations). Retrospectively, it was determined in how many cases a good assessment was made of the patient's situation, and if the participatory workplace intervention was indicated correctly (sick leave > 12 weeks).

Implementation Score

For each step of the care program an implementation score was calculated using the average of the four process measures.

Participants' Attitude

Participants' attitudes towards the eHealth intervention were assessed among patients, gynaecologists and employers. Patients were requested to rate their satisfaction with the (different tools of the) patient web portal. In addition, perceived effectiveness was scored on a 5 point Likert Scale and patients were asked if they would recommend the eHealth intervention to a friend (yes/no). Reasons for (non-)compliance were evaluated and patients could give suggestions for improvement.

Among employers satisfaction with the different items on the anonymous section of the web portal was assessed, as well as their satisfaction with the guidance the web portal offered their employee during the perioperative period (both on 5 point Likert scale). Suggestions for improvement were evaluated.

Gynaecologists' opinion on the feasibility of the eHealth intervention was evaluated through named facilitators and barriers to future implementation and their answers to

the question if they would offer the intervention to their patients if widely available (yes/no). Again, suggestions for improvement were registered.

The clinical occupational therapist involved in the study was asked about her experience with the integrated care management during an evaluation interview after the trial.

Data analysis

MATLAB version 7.1 (The MathWorks Inc., Natick, MA, USA) was used to transform the weblog into user and page statistics. SPSS version 20.0 (IBM Corporation, Armonk, NY, USA) and Excel 2003 (Microsoft, Washington, DC, USA) were used for descriptive and statistical analyses. Quantitative data were analysed by means of descriptive statistics such as frequencies, means, medians and interquartile ranges. To compare differences in groups, independent t-tests or Mann Whitney U-tests were used for continuous variables, depending on the distribution. All tests were performed two-sided. Statistical significance was defined as $p < 0.05$.

RESULTS

Step 1. eHealth Intervention

Reach

Between March 2010 and January 2011 a total of 673 patients were scheduled for a hysterectomy and/or laparoscopic adnexal surgery in one of the participating hospitals. Fifty-two patients (7.7%) returned the reply card which was included in the information package, indicating they were not interested in participation. Of the 621 patients to be contacted by telephone, 49 patients were unreachable and 215 patients were excluded because they did not meet the inclusion criteria of the study. The main reason for exclusion was the lack of employment or working less than 8 hours a week (99/215; 46%). A total of 357 patients were eligible for the study, of which 142 patients declined to participate. The remaining 215 patients enrolled in the study and accounted to a reach of 60.2% (215/357). Figure 1 shows a flow-diagram of the study participants.

Randomization was performed after informed consent and the baseline measurement. The present paper, only reports on the participants allocated to the intervention group (110 patients). Table 2 shows the baseline characteristics of these participants. These participants did not differ significantly from the patients who were allocated to usual care.

The primary outcome full sustainable return to work was complete for all participants. The questionnaires assessing secondary outcome measures at 2, 6, 12, and 26 weeks were completed by 93.6 to 95.6% of all participants.

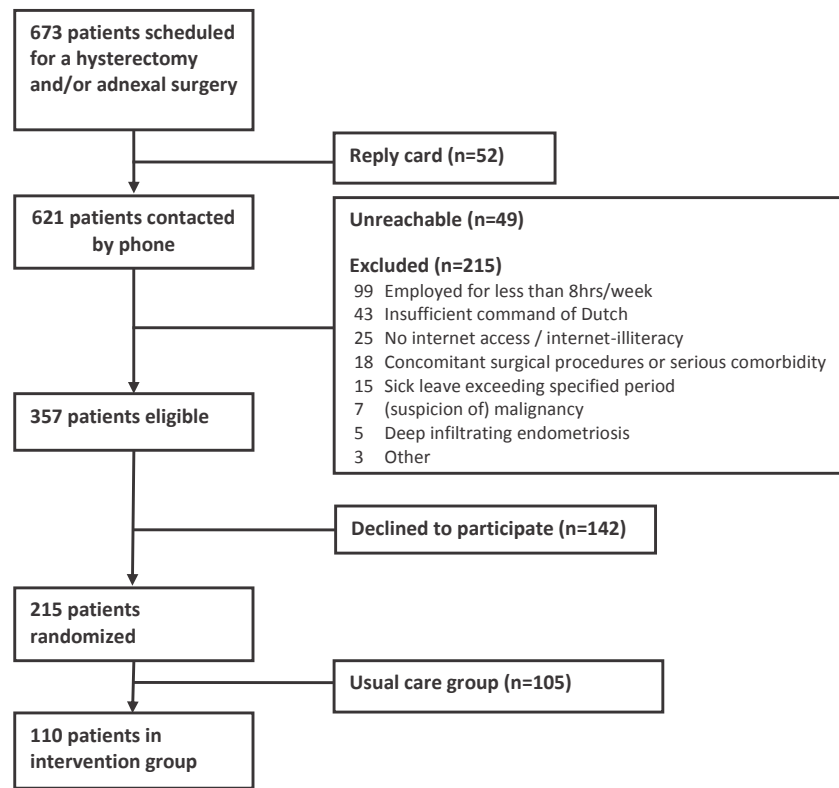


Figure 1. Study flow diagram

Dose delivered

All 110 patients were given access to the patient web portal www.ikherstel.nl before their surgery by the principal investigator or research-assistant (dose delivered: 100%). The median number of days patients accessed the web portal prior to their surgery was 16 days (IQR 9 – 29days). In 12.7% of the cases, patients were given access only a week prior to the surgery. These cases can be explained because surgeries were planned on short notice or patients failed to complete the baseline questionnaire earlier.

Dose received

Table 3 presents data about the usage of the patient web portal and the different tools. All patients used their account at least once, with the vast majority (98.8%) doing this before surgery. Total time spent on the patient web portal by each patient was almost 2 hours (median 118 minutes, IQR 64 – 173 minutes) (Table 3). Most patients visited the website several times with a median number of 11 sessions (IQR 6-16).

Table 2. Baseline characteristics – intervention group (N = 110)

Patient characteristics	
Age (years ± SD)	43.5 ± 7.8
Education level ^a	
low	10 (9.1)
intermediate	50 (45.5)
high	50 (45.5)
Surgery related characteristics	
adnexal surgery (LAS)	51 (46.0)
laparoscopic hysterectomy (TLH)	17 (15.5)
vaginal hysterectomy (TVH)	25 (23.0)
abdominal hysterectomy (TAH)	17 (15.5)
Health related characteristics	
Self-rated health status (mean ± SD) ^b	78.4 ± 15.7
Work related characteristics	
Type of work	
salaried employed	89 (80.9)
self-employed	19 (17.3)
voluntary work	2 (1.8)
Work hours per week (mean ± SD)	30.3 ± 9.2

Numbers present frequencies and percentages unless otherwise specified

^a low = preschool, primary school; intermediate = lower and upper secondary; high = tertiary education, university or postgraduate

^b EuroQol VAS-scale ranging from 0 (= worst imaginable health) to 100 (= best imaginable health)

Activity on the patient web portal was highest in the week before surgery and the first 3 weeks after surgery (Figure 2). An average session lasted 12 minutes and 15 pages were viewed per session. There was no significant statistical difference in usage of the patient web portal between patients undergoing different types of surgery.

Before surgery, 63 patients (57.2%) used the tool to compose a reintegration plan. Taken the total follow up into account, the majority of patients used the tool (dose received: 95/110; 86.4%).

Fidelity

Reintegration plans were electronically approved in 3 out of every 4 patients accounting to a fidelity score of 74.5% of all cases (82/110). In 25 remaining cases (22.7%), the principle

Table 3. Patient use of web portal

Overall	Total visit duration per patient (minutes)	118 (64 – 173)
	Number of sessions	10.5 (6 – 16)
	First login before surgery	108 (98.2%)
	First login after surgery	2 (1.8%)
	≤ 2 sessions	7 (6.4%)
	> 2 sessions	103 (93.6%)
Website tools		
Reintegration plan	Composition before surgery	63 (57.3%)
	Composition after surgery	32 (29.1%)
	No composition	15 (13.6%)
Video	Number of unique visitors	77 (70.0%)
	Total visit duration per patient (minutes)	8.9 (3.9 – 11.4)
Interaction with employer	Number of invitations ^a	41 (46.1%)
	Number of unique visitors to page displaying Recommendations for employee	73 (66.4%)
	Number of unique visitors to page displaying Recommendations for employer	55 (50.0%)
Recovery monitor	Number of unique visitors	106 (96.4%)
	Total visit duration per patient (minutes)	46.2 (28.5 – 69.8)
	Number of visits per patient	13 (10 – 16)
Frequently Asked Questions	Number of unique visitors	58 (52.7%)
	Total visit duration per patient (minutes)	9.3 (2.1 – 17.6)
Forum	Number of unique visitors	61 (55.5%)
	Total visit duration per patient (minutes)	2.2 (0.9 – 6.5)
	Number of visits per patient	6 (3 – 15)

Numbers present frequencies (%) or medians (IQR)

^a Only relevant for patients with an employer (n = 89)

investigator approved the schedules after having had contact with the surgeon. Reasons given by surgeons for not approving the schedule themselves were: lack of time, loss of electronic invitation or sudden change of surgeon. In 7 cases the surgeon adjusted the standard reintegration schedule because of complications during or after the surgery.

Implementation Score

Using the average of the four process-measures, the implementation score of the first step of the intervention was 80.3% ((60.2% + 100% + 86.4% + 74.5%) / 4).

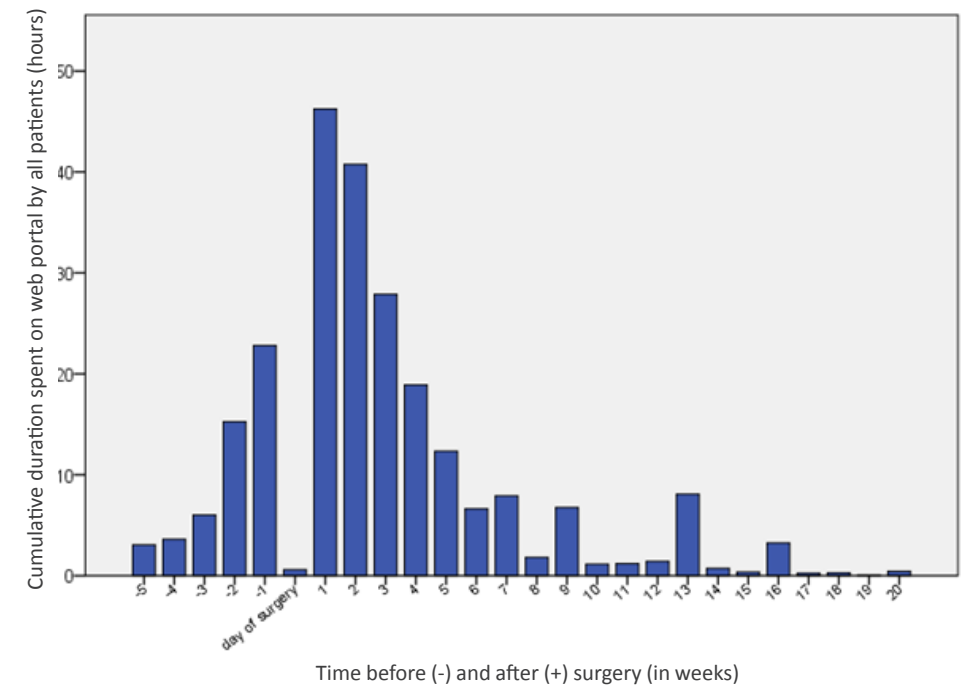


Figure 2. Use of patient web portal related to date of surgery

Participants' attitudes towards the intervention

Patients

Satisfaction-scores with the different tools of the website are presented in table 4. The vast majority of patients (75/102; 73.5%) were (very) satisfied with the tool to compose a reintegration plan and found it (very) useful to plan normal activities (67.6%) and work-activities (56.8%). The majority of patients (87/105; 82.9%) followed most convalescence recommendations. Twelve patients explained they did not need a schedule because they rather resumed activities when their body felt ready for it. Another reason for non-compliance was finding the reintegration schedule too optimistic (23 times), while others stated the recommendations were too conservative (12 times).

Perceived effectiveness of the eHealth intervention was high. At 12 weeks, 73.5% (75/102) of all participants felt usage of the web portal contributed positively to their recovery. People who did not perceive an additional effect explained they did not need the web portal (8 times), they felt pushed by the convalescence advice (5 times) or they felt the eHealth intervention did not apply to their personal situation (4 times). Eighty-seven

Table 4. Satisfaction with different tools of patient web portal

Degree of satisfaction	1= totally dissatisfied			5= very satisfied		
	1	2	3	4	5	not applicable
Patients (n=102)						
Graded activity schedule for general well-being ^a	2.0	5.9	18.6	32.4	41.2	-
Graded activity schedule for planning normal activities ^a	3.9	6.9	21.6	39.2	28.4	-
Graded activity schedule for planning work related activities ^a	5.9	11.8	25.5	33.3	23.5	-
Links to other websites	1.0	1.0	28.4	33.3	6.9	29.4
Forum	5.9	4.9	26.5	16.7	3.9	42.2
FAQ	1.0	1.0	25.5	40.2	9.8	22.5
Film	2.9	3.9	32.4	29.4	2.9	28.4
Employers (n=26)						
Film	7.7	0.0	19.2	30.8	11.5	30.8
Recommendations for patients	0.0	0.0	23.1	42.3	7.7	26.9
Recommendations for employers	0.0	7.7	30.8	42.3	7.7	11.5

Numbers present percentages

FAQ = frequently asked questions

^a obligatory choice of score 1 to 5

patients (87/102; 85.3%) would recommend the web portal to a friend. Suggestions for improvement included an extra section with experiences of other women (3 times).

Employers

Almost half of the salary-employed participants invited their employer to visit an anonymous section of the website (42/89; 47.2%). Reasons given for not using this tool included: finding it unnecessary because of a fast recovery or good relationship with employer (16 times), not wanting to be a burden or anticipating the employer not to be interested (8 times) or not wanting to share private information with their employer (5 times). Satisfaction about guidance provided by their employer did not differ statistically between patients who did and patients who did not invite their employer.

Twenty-six employers (63.4%) completed the digital questionnaire 8 weeks after the surgery of their employee. Satisfaction-scores with the different tools offered by the web portal are presented in table 4. In total, 61.1% of the employers (11/18) were (very) satisfied with the guidance the web portal offered to their employee. One employer suggested including extra information about reintegration-schedules.

Gynaecologists

In total, 40 gynaecologists were involved in the study, with a median number of 2 patients each (range: 1-9). Thirty-one gynaecologists (77.5%) finished (part of) an electronic questionnaire at the end of the trial. Of the 28 gynaecologists answering the questions about usefulness of the intervention, seven gynaecologists found themselves unable to give an answer because of too little experience with the intervention. Of the remaining 21 gynaecologists, 76.2% rated the eHealth-intervention as (very) useful (16/21). The vast majority would offer it to their patients, would it be widely available (20/21; 95.2%).

Possible future usage barriers for patients included: required access to internet (3 times) and the inflexibility of the eHealth intervention in case of complications (2 times). Possible usage barriers for gynaecologists were an increased time-investment (7 times). However, only 2 gynaecologists (2/28; 7.1%) were unsatisfied with their own actual time-investment in delivering the intervention.

Step 2. Integrated Care Management

Reach

At 10 weeks after surgery 25 patients (25/110; 22.7%) had not fully returned to work and represented the target audience for the second part of the intervention program, the integrated care management. In total, 12 consultations with the clinical occupational physician took place, accounting for a reach of 48% (12/25).

As expected, patients with less invasive surgeries were more likely to have resumed their work-activities than those with more invasive surgeries. For the different types of surgeries the proportion of patients eligible for a consultation with the clinical occupational physician (OP) was as follows: TAH: 53% (9 out of 17), VH: 28% (7 out of 25), TLH: 29% (5 out of 17), and LAS: 8% (4 out of 51). In this group of delayed recovery, five patients (5/25, 20%) suffered from a complication during or related to the surgery. Complications were defined as an enlargement of the wound with > 8 centimetre or re-surgery within two weeks after initial surgery.

Dose delivered

When patients had not resumed their work-activities 8 weeks after surgery, information about the integrated care management appeared on the patient web portal. Simultaneously, the clinical occupational therapist received the contact information of these patients and approached them by telephone to schedule an appointment in the 10th or 11th week after surgery.

In total, 17 appointments were scheduled, resulting in a dose delivered of 68% (17/25). In two cases patients were not considered eligible for a consultation, due to medical

reasons (severe complications related to the gynaecologic surgery) or personal reasons (recent death of partner). Six patients declined a consultation because they had already partly resumed their work activities and expected to fully return to work shortly. Four of them did resume completely within 12 weeks after surgery. Return to work of the last two patients took much longer than expected (16 weeks).

Dose received

Of the 17 scheduled appointments, 12 consultations took place. Two patients cancelled because they had fully returned to work before the appointment and three patients cancelled because they did not feel the need for a consultation anymore. Given reason were: 1) the patient had partially resumed, 2) the patient had already consulted her own occupational physician, and 3) the patient did not wish to re-schedule the appointment when the clinical occupational therapist was forced to cancel the appointment.

Of the 12 consultations, 2 patients turned out to be sick-listed for other reasons than the gynaecologic surgery at time of the appointment (personal problems due to broken relationship and longer existing shoulder complaints). Two patients decided to decline further guidance from the OP during the first consultation. They did not disclose their reasons; however, they stayed sick-listed for 17 and 24 weeks respectively. Lastly, two patients declined a referral for the workplace intervention after discussing this treatment option with their supervisor and/or own occupational physician. One patient expected no additional benefit because she was satisfied with the guidance offered by her own occupational physician. The last patient experienced the consultation as unpleasant, because she felt pushed to return to work, while she felt she was not ready yet and therefore declined follow-up. Both patients stayed sick-listed during the complete follow up of 6 months.

In six cases follow up or referral to the occupational therapist was not indicated by the clinical occupational therapist because of a good RTW-prognosis. In these cases, the patients were already partially resuming their work-activities and did receive sufficient guidance from their own occupational physician and employer. Considering all consultations that were scheduled, the dose received calculated was 24% (6/25) because in six consultations care was delivered according to the protocol.

Fidelity

The fidelity of the six remaining consultations was very poor (0%). In all cases in which follow-up or a referral to the occupational therapist was not considered relevant, the good RTW prognosis was incorrect retrospectively. Average time to full RTW after the consultation with the clinical occupational physician was still more than 2 months (mean: 66 days; range: 40-78) with one participant not reaching full RTW at all. Further guidance

of the clinical occupational therapist in these cases would probably have been beneficial. Moreover, only 3 patients visited the clinical occupational physician, the other nine consultations took place by telephone. Telephone consults were offered because patients were not willing to pay an actual visit because of the investment of time and money. In addition, only 3 cases were scheduled in the 10th or 11th week after surgery as indicated by the protocol, with 4 appointments scheduled too early (week 9) and 5 appointments too late (week 13-15).

Implementation Score

The implementation score of the second step of the intervention program was calculated to be 35% $((48\% + 68\% + 24\% + 0\%) / 4)$.

Experiences of clinical occupational physician

At the end of the trial the clinical occupational physician involved in the study was interviewed to evaluate the integrated care management. The most important topics discussed included the high number of patients that declined additional care and the difficulty to estimate RTW-prognosis. Moreover, possible solutions to these barriers were reviewed.

The clinical occupational physician explained she experienced most difficulties persuading participants to schedule an appointment with her. Because she met patients relatively late after the surgery, most patients were already partly resuming their work-activities and had already made a reintegration-plan often with help of their supervisors or own OPs. It was then very difficult to explain the additional value of a consultation, and in case of an appointment, make alterations in the plans already made. Secondly, most consultations took place by telephone, because patients were not willing to make a visit, making it very hard to develop an accurate RTW-prognosis.

In order to enhance the impact of a consultation, the clinical occupational physician advised to incorporate the consultation in standard care, e.g. women who are planned for a surgery should automatically receive an invitation for the clinical occupational physician. In addition, the moment of contact should be at a much earlier stage, even maybe before surgery, to be able to support the development of a solid RTW-plan and to influence irrelevant cognitions about their recovery. In the current format, the occupational physician was doubtful about the effectiveness of this part of the intervention.

DISCUSSION

Main findings

The aim of this paper was to evaluate the implementation process and experiences with an innovative care program for women undergoing benign gynaecological surgery. As the care program consisted of two different steps – an eHealth intervention and integrated care management – both steps were evaluated separately, using the criteria outlined by Linnan and Steckler.²⁰ Overall, the eHealth intervention was implemented fairly well with an implementation score of 80%. Patients, gynaecologists and employers were all highly satisfied with the web portal www.ikherstel.nl. The implementation of the integrated care management protocol was less successful with a final implementation score of 35%. Convincing patients about the additional value of a consultation with the occupational physician and developing an accurate RTW-prognosis were the two most important obstacles for the second step of the intervention program.

Interpretation of the findings

Step 1. eHealth intervention

The use of eHealth technologies is considered to be an important key to improving efficiency and quality of health care.^{29,30} Possible benefits include enhancing (self-) monitoring activities, increasing delivery of care based on guidelines, and decreasing utilization of health services. However, there remains a gap between the postulated and empirically demonstrated benefits.²⁹ The current process evaluation is an essential step towards improving implementation of evidence-based eHealth interventions. To the best of our knowledge, our patient web portal is the first evaluated eHealth intervention in both fields of postoperative care and gynaecology.

The reach of the eHealth intervention was moderately high (60%). In total, only 25 women were excluded because of having no access to the internet or internet-illiteracy (25/376; 3.7%). In the Netherlands, the general internet-access rate is 96%.³¹ Compared to national numbers under working females, highly educated women were overrepresented in our study: 50% versus 35%.³² Partly, this might be explained by regional differences and the location of some hospitals in and near the capital of the Netherlands. However, selection bias might have played a role as well, when highly educated women might be more interested in the eHealth intervention (and fast recovery) and decided to participate more often.

Compliance towards web-based interventions varies among different studies and target populations.³³ For depression and anxiety disorders adherence rates to online treatments are generally found between 50 and 70%.³⁴ In our study we were able to objectively measure usage of the eHealth intervention and 86% of all participants used the web

portal as intended. This is relatively high, but in concordance with the high satisfaction scores and an overall high perceived effectiveness of the eHealth intervention.

Step 2. Integrated care management

Unfortunately, the second part of the intervention did not unfold and reasons might be found in the characteristics of the target population. Participatory workplace programs have been shown to be effective in patients sick-listed due to musculoskeletal disorders and distress.^{25,35-37} Generally, targeted patients were characterized by a history of chronic disease and complaints, whereas the target population in the current study consisted of patients working at the time of recruitment and facing only a temporary period of sick leave during the recovery of their surgery. This temporary nature of the sick leave is probably the most important barrier to full implementation, demonstrated by a number of issues. Firstly, more than half of the patients (13 out of 25) declined additional care at some time during the integrated care management, indicating a general lack of perceived value of additional guidance. This could be related to Dutch legislation which ensures salary income at least during the first 24 months of sick leave (see Appendix 10). In absence of financial consequences, people might not be urged to return to work as soon as possible, and therefore less interested in initiatives to facilitate return to work. Moreover, a commonly given reason for rejecting a consultation was that the patient had already partly resumed and expected full return to work shortly. However, perception of the own situation turned out to be problematic as it took these patients still 3.5 months to resume all work activities after starting partly. Finally, developing an accurate RTW prognosis was challenging for the occupational physician as well (poor score on fidelity). Up to date, not much is known about prognostic factors for RTW in this specific population.

Strengths and limitations of this study

A strength of this study is that data collection was performed systematically using an established theoretical framework to assess the process outcomes. Moreover, multiple sources were employed such as online questionnaires and the weblog generated from the patient web portal. The latter allowed a detailed and objective evaluation of patient compliance to the eHealth intervention. Finally, all stakeholders of the intervention program (patients, employers, gynaecologists and the clinical occupational physician) were included in this process evaluation.

This study also has limitations. For example, we failed to measure contextual factors that might have influenced implementation. Moreover, we should be aware that a research setting can be advantageous towards an intervention, due to highly involved health professionals, motivated patients (selection bias) and interference of the research team. In the current study this can be illustrated by the artificial score of 100% for dose delivered. Earlier research showed that adherence rates to open access websites can be

much lower compared to a research environment (up to 50% less),³³ so this needs to receive special attention when implementing the intervention program into daily practice. Some procedures that were carried out by the research team should be automated, such as generating accounts. Other procedures will have to be transferred to the health care providers. However, we presume the intervention to receive enough support, as 9 out of 10 gynaecologists indicated they would offer the intervention to their patients would it be widely available.

Practical and Research Implications

A considerable large number of patients reported that the reintegration plan they had composed on the web portal was too optimistic for their own situation (23/110; 21%). Some participants said this increased insecurities and anxiety, as they fell behind the schedule, which is a negative outcome of the intervention. Before broader implementation, it is essential to take measures to prevent this, as it will influence compliance negatively. The solution should not necessarily mean to loosen the convalescence recommendations, but could also be providing more information and targeting coping mechanisms.

Moreover, this process evaluation showed important directions to improve the second step of the intervention program and these lessons should be taken into account when implementing the intervention program on a wider scale. First of all, the importance of a prosperous recovery in means of improving quality of life and preventing long term sickness should be emphasized to patients. The patient web portal provides an excellent platform for this. In addition, possibilities to incorporate a consultation with a clinical occupational physician in standard care should be explored with all involved stakeholders. Possibly, patient's own occupational physicians can perform this part of the intervention themselves in the future, as this would also increase support in the direct environment of the patient. Contact with the patient in an early stage seems to be crucial to influence patients' attitudes and (irrational) beliefs about their recovery.

CONCLUSIONS

This current paper describes the process evaluation of a new intervention program to provide additional guidance during the perioperative period to gynaecological patients. The results of this study indicate good feasibility for implementation on a broad scale of the eHealth intervention. Compliance, perceived effectiveness and satisfaction were high among patients. In addition, other stakeholders such as gynaecologists and employers, assessed the intervention as potentially very useful. To enhance the implementation of the second step of the perioperative care program, adaptations in the integrated care protocol are needed.

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CHAPTER 8

A personalised eHealth programme reduces the duration until return to work after gynaecological surgery: results of a multicentre randomised trial

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ABSTRACT

Objective

To evaluate the effectiveness of an eHealth intervention on recovery and return to work after gynaecological surgery

Design

Randomised multicentre trial that ran from March 2010 until September 2011.

Setting

Secondary care in seven general and university hospitals in the Netherlands

Population

A cohort of 215 women (aged 18–65 years) who had a hysterectomy and/or laparoscopic adnexal surgery for a benign indication.

Methods

The women were randomly assigned to the intervention group (n=110) or the control group (n=105). The intervention group received an eHealth programme which provided personalised tailor-made pre- and postoperative instructions on resumption of daily activities including work, and tools to improve self-empowerment and to identify recovery problems. The control group was provided access to a control website.

Main outcome measures

The primary outcome was the duration of sick leave until a full sustainable return to work. Secondary outcome measures were quality of life, general recovery, and pain intensity.

Results

In intention-to-treat analysis the eHealth intervention was effective on time to return to work (hazard ratio=1.43, 95% confidence interval 1.003 to 2.04, p=0.048). The median duration of sick leave until full sustainable return to work was 39 days (interquartile range 20-67 days) in the intervention group and 48 days (interquartile range 21-69) in the control group. After 26 weeks, pain intensity was lower (visual analogue scale, cumulative odds ratio=1.84, 95% confidence interval 1.04 to 3.25, p=0.035) and quality of life was higher (Rand-36 health survey, between-group difference=30, 95% confidence interval 4-57, p=0.024) in the intervention group compared with the control group.

Conclusions

The use of the eHealth intervention by women having undergone gynaecological surgery results in a faster return to work, with a higher quality of life and less pain.

INTRODUCTION

A delayed recovery and return to work after surgery reduces quality of life (QoL) of postoperative women and generates unnecessary yet substantial costs for society.^{1,2} It has been reported that recovery and return to work time following (laparoscopic) gynaecological surgery frequently exceeds what can be reasonably expected from a medical perspective.³⁻⁵ This has been explained by a substantial variation in convalescence recommendations regarding resumption of work and daily activities between different health care providers and by fragmented perioperative care.^{6,7} A strong need was therefore felt for the development of a stepped care programme to empower women during the perioperative period, with a special focus on recovery and return to work. Women that had undergone a hysterectomy (abdominal, vaginal, laparoscopic) and/or laparoscopic adnexal surgery for a benign indication, were chosen as the target group for this new programme.⁸ Detailed multidisciplinary guidelines on well-defined postoperative recovery recommendations were developed in collaboration with the medical boards of gynaecologists, occupational physicians (OPs) and general practitioners (GPs) through a modified Delphi consensus method with experts and a literature study.⁹ To explore the needs, illness beliefs, preferences and important behaviour determinants regarding recovery, perioperative care and resumption of (work) activities, focus group discussions were performed with women who had undergone these procedures.¹⁰ Based on these data, an eHealth programme was developed aimed at empowering women during the perioperative period by supporting them with personalised tailor-made pre- and postoperative instructions on resumption of work and daily activities, and tools to improve self-empowerment and identify recovery problems.¹⁰ The aim of the present study was to compare the effectiveness of the eHealth intervention with a control website on return to work, QoL, general recovery and pain intensity through a multicentre randomised controlled trial (RCT).

METHODS

Trial design and participants

A randomised, single blinded, controlled trial was carried out in six general and/or teaching hospitals and one university hospital located in the Netherlands. Eligible participants for this study were women aged between 18-65 years, scheduled for laparoscopic adnexal surgery and/or hysterectomy for benign disorders, and were employed for at least 8 hours per week (paid or unpaid). The main exclusion criteria were 1) malignancy or suspicion of malignancy; 2) pregnancy (intrauterine or ectopic); 3) deep infiltrating endometriosis; 4) concomitant surgical procedures or major health problems/psychiatric disorders affecting recovery or daily activities; 5) being signed off work for more than 4 weeks or – when the surgery aimed to cure the reason for absence from work – being signed off work for more

than 2 months; 6) working temporarily for an employment agency; 7) dealing with a lawsuit against the employer; 8) not able to understand or complete the questionnaires written in the Dutch language, and 9) no access to the internet. Participants were recruited from the waiting lists of participating hospitals and received an invitation letter to take part in the study. Consenting women who met all selection criteria, who completed the baseline questionnaire, and who were scheduled for surgery within four weeks, were allocated to the intervention or control group. A detailed description of the intervention and design of this multicentre RCT has been published elsewhere (chapter 6).¹¹

Interventions

Control group

Participants allocated to the control group received access to a control eHealth intervention, besides the normal usual care. This website provided the women with telephone numbers of their hospitals and patient leaflets of the Dutch Society of Obstetrics and Gynaecology (NVOG), which amounts to almost all leaflets provided in Dutch hospitals for a hysterectomy or a laparoscopic adnexal surgery on benign indication.^{12;13}

Intervention group

The intervention group had access to an eHealth intervention with detailed tailored pre- and postoperative instructions on the resumption of work and daily activities and with tools (e.g. a video) to improve self-empowerment, communication with care providers and employer, and to identify recovery problems.¹⁰ Furthermore, the eHealth intervention supplied general information on the surgical procedure itself, an extensive list of frequently asked questions and a forum enabling contact with other patients. The eHealth intervention was part of a stepped care programme that is described elsewhere.¹¹ Box 1 presents the detailed content of the interventions (for printscreens, see Appendix 9).

Outcome measures

The primary outcome measure in this study was sick leave duration until full sustainable return to work, which was a continuous outcome measure and was defined as the duration of sick leave in calendar days from the day of surgery until full return to work in own or other work with equal pay, for at least four weeks without recurrence (partial or full).^{14;15} Recurrences of sick leave within 4 weeks of the first full day of a return to work were considered as part of the preceding period of sick leave if this was caused by the surgical treatment. A monthly self-reported calendar of sickness absence per post was chosen to measure return to work.¹⁶

Secondary outcome measures were: functional and general health status (QoL) as assessed according to Rand-36 Health Survey^{17;18}; recovery as measured by a validated Recovery

Box 1. Content of the interventions

eHealth intervention (4 weeks before through to 7 weeks after surgery)	Control eHealth intervention (4 weeks before through to 7 weeks after surgery)
Detailed personalised pre- and postoperative instructions on the resumption of work and daily activities	Usual care given by gynaecologists, occupational physicians and general practitioners
Extensive list of answers to the most frequently asked questions about the applied surgical procedure and practical issues, with pictures	Patient leaflets of the Dutch Society of Obstetrics and Gynaecology concerning the applied surgery
Evaluation of complications with online feedback from the gynaecologist if necessary	Telephone numbers of participating hospitals
Instructional video for employee and employer to illustrate common pitfalls during the perioperative and reintegration period	
Advice for employee and employer about a successful work reintegration	
Evaluation of recovery and advice on which care provider or providers to approach in case of problems	
Forum enabling contact with patients	
Links to other relevant websites	
Glossary with frequently used medical terms	

Specific QoL questionnaire RS-QoL (RI10)¹⁹; and pain intensity measured using a Visual Analogue Scale (VAS) questionnaire.²⁰ Prognostic factors that may influence the duration of sick leave were recorded for adjustment in case of dissimilarities between the intervention group and the control group. Among these factors were sociodemographic data, type of surgery, complications during or related to the surgery (defined as an enlargement of the wound to ≥ 8 cm or re-surgery within 2 weeks of the initial surgery, assessed by questions based on the NVOG complication registration form),²¹ work-related factors measured by the Job Content Questionnaire (JCQ)²² and specific additional work-related questions, pain perception and fear avoidance belief assessed by the Tampa scale,²³ duration of sick leave in the previous 3 months before baseline, and expectations and intention of the employee concerning returning to work after surgery.²⁴ The secondary outcome measures and prognostic factors were evaluated by self-report online questionnaires, which were taken at baseline, 2, 6, 12 and 26 weeks after surgery.

Compliance

Through user authentication, for each patient the use of the eHealth intervention was registered by date and time; e.g. web page requests, duration of page views, use of particular tools, etc. Overestimation of activity time was limited through a stop in time registration when the patient was not active for a period of 8 minutes.

Sample size

A power calculation was performed on the primary outcome return to work. To achieve a power of 80%, with a two-sided significance level of 5% and considering a hazard ratio of 1.5 in favour of the intervention group, approximately 191 women would be needed in the study. Anticipating a 10 % drop-out rate, a total sample size of at least 212 women was required.¹¹

Randomisation

To prevent unequal randomisation between hospitals and type of surgery, women were prestratified by hospital and type of surgery (laparoscopic adnexal surgery, and total laparoscopic or laparoscopic-assisted, vaginal, and abdominal hysterectomy). A computer-generated block randomisation was performed at the individual level. The blocks consisted of four characters to ensure roughly equal group sizes within each stratum and were randomly varied in sequence. An independent research assistant performed the randomisation.

Blinding

Women were blinded for the allocated treatment. Although all women received access to an eHealth intervention, after logging into the website with their personal login credentials, the kind of information provided by the eHealth intervention depended on the group the patient was assigned to. The differing content of the eHealth interventions for both groups meant that therapists and researchers could not be blinded to the treatment allocation of the women.

Statistical analyses

The analyses were performed using SPSS 16.0 and STATA 11.2. All statistical analyses were performed at patient level, according to the intention-to-treat (ITT) and per protocol (PP) principle. P-values were two-tailed and a value of ≤ 0.05 was considered to be significant. The Cox proportional hazard model was used to estimate hazard ratios for return to work after surgery. Both crude and adjusted analyses were performed. In the adjusted analyses, hospital and type of surgical procedure were included in the model as design covariates, given the fact that randomisation was prestratified for these factors.^{25;26} Furthermore the Cox regression analyses were adjusted for prognostic factors when they showed a coincidental and meaningful difference between groups.¹¹ As the recommendations

provided by the eHealth interventions were limited to the first 7 weeks after surgery, the hazard ratio for this period was presented. The assumption that the hazard ratio remained constant over time was checked.

To assess whether protocol deviations have caused bias, participants from both groups who logged into the eHealth intervention at least once were included in the PP analyses.¹¹ The median duration of sick leave until the first period of full sustainable return to work was analysed by descriptive statistics. Differences in secondary outcome measures (i.e. QoL and recovery) between the groups were assessed by mixed models, using measurements at 2, 6, 12 and 26 weeks, with the baseline score as covariate.²⁷ As a result of skewness, pain-intensity was analysed with generalised mixed ordered logistic regression models, using all measurements that were available at 6, 12 and 26 weeks.²⁸ The pain intensity scores were divided into four categories; score 0 (no pain), 1-3, 4-6 and ≥ 7 (moderate to severe pain). Transforming weblogs into user and page statistics was done using MATLAB version 7.10.

RESULTS

From March 2010 till January 2011, 673 women were scheduled for a hysterectomy and/or laparoscopic adnexal surgery on benign indication in the participating hospitals. Of these 673 women, 194 declined to participate in this study for unknown reasons and 49 women were not accessible before their surgery took place. Of the remaining 430 women, 215 were excluded. The main exclusion reasons were: not meeting the inclusion criteria (n=99), insufficient command of Dutch language (n=43), no access to internet (n=25) and concomitant surgical procedures or serious comorbidity (n=18). As a result, 215 women were randomised with 110 women being allocated to the intervention group and 105 women to the control group. Figure 1 presents the patient flow throughout this trial.

Loss to follow-up

Baseline characteristics, prognostic factors and data on sick leave (i.e. primary outcome measure), were available for all 215 women. Secondary outcome measures after 2, 6, 12 and 26 weeks were respectively complete for 97%, 97%, 96% and 97% of the women. There were no differences in drop-out rates for secondary outcome measures between the intervention group and the control group.

Compliance

In the intervention group, 110 women (100%) logged into the eHealth intervention at least once, whereas for the control group this figure was 99 women (94%). The median time spent on the eHealth intervention was 118 minutes (interquartile range 66-173) in the intervention and 11 minutes (interquartile range 5-22) in the control group.

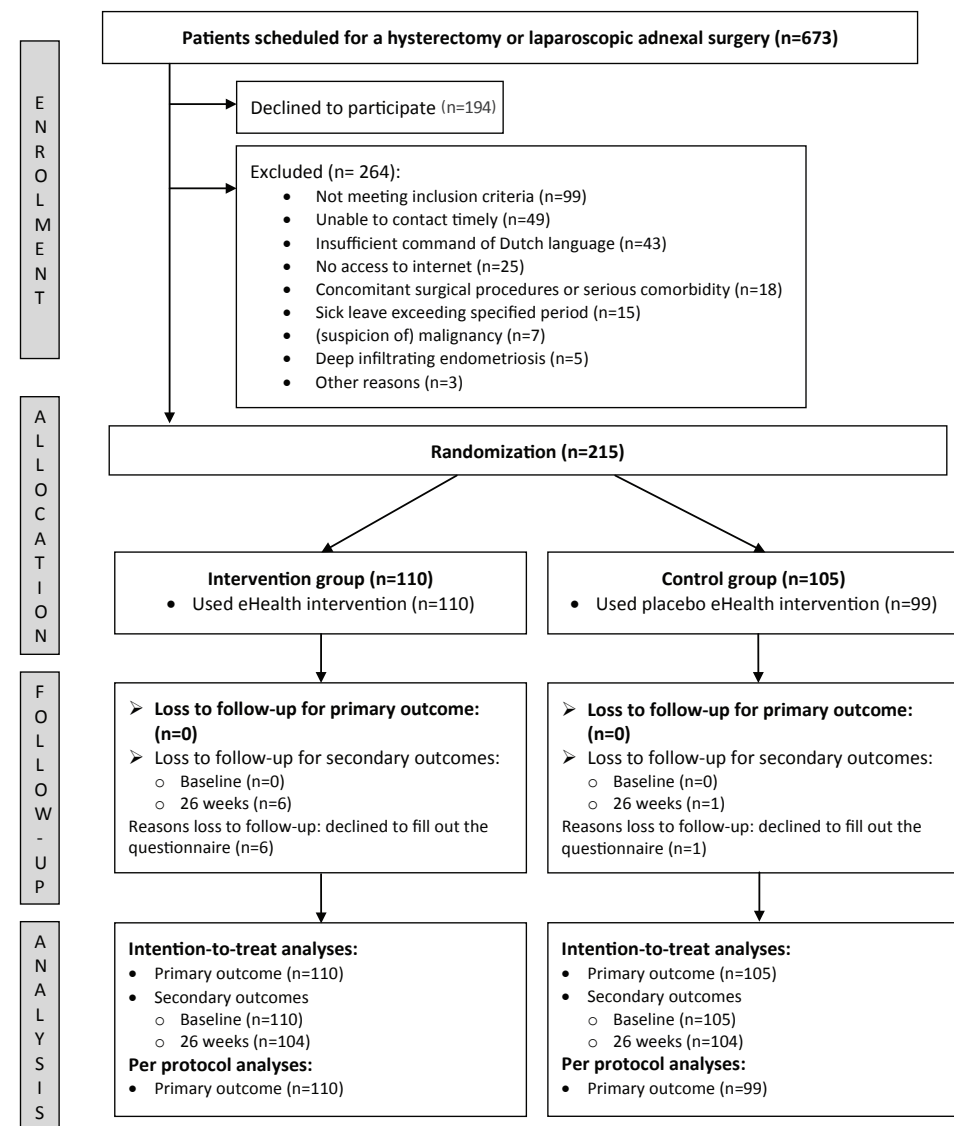


Figure 1. Flowchart for the study.

Characteristics of the women

Table 1 presents the baseline characteristics and prognostic factors of the intervention and control groups. In the intervention group there were more complicated surgeries than in the control group, which is a coincidental but meaningful difference. It has been shown that this factor affects the outcome measure,²⁹ but has no relation to the eHealth intervention studied.

Table 1. Baseline characteristics and prognostic factors of outcome measures

Baseline characteristics	Intervention group (n=110)	Control group (n=105)
Lapsc. adnexal surgery [n, (%)]	51 (46.4)	45 (42.9)
Hysterectomy	Laparoscopic surgery [n, %]	17 (15.5)
	Vaginal surgery [n, %]	25 (22.7)
	Abdominal surgery [n, %]	17 (15.5)
Age (years) [mean (SD)]	43.5 (7.8)	43.2 (8.5)
Level of education* [n, (%)]		
Low	10 (9.1)	6 (5.7)
Intermediate	50 (45.5)	51 (48.6)
High	50 (45.5)	48 (45.7)
Most representative daily work description [n, %]		
Salaried employment	89 (80.9)	86 (81.9)
Voluntary employment	2 (1.8)	3 (2.9)
Self-employed	19 (17.3)	16 (15.2)
Work sector [n, (%)]		
Business and financial services	46 (41.8)	46 (43.8)
Health care and public welfare	30 (27.3)	30 (28.6)
Government, public safety and security	13 (11.8)	10 (9.5)
Education	11 (10.0)	13 (12.4)
Industry	5 (4.5)	2 (1.9)
Other	5 (4.5)	4 (3.8)
Kind of work [n, (%)] (DMQ)		
Often manually lift loads >20 kg	13 (11.8)	13 (12.4)
Often manually carry loads >20 kg	9 (8.2)	7 (6.7)
Work hours per week [mean (SD)]	30.3 (9.2)	30.9 (9.3)
Job content questionnaire** [mean (SD)]		
Decision latitude (range: 24-96)	73.5 (14.4)	72.0 (14.4)
Social support (range: 8-32)	25.1 (3.2)	24.7 (3.4)
Psychological job demands (range: 12-48)	30.2 (7.3)	30.2 (7.5)
Physical job demands (range: 5-20)	8.8 (3.2)	9.2 (3.2)
Absence from work last three months (work days)[median, (interquartile range)]	5 (2-10)	4 (2-6)
Tampa scale for kinesiophobia [mean (SD)]***	32.6 (5.5)	33.5 (5.4)
Absence from work before surgery [n, %]	12 (10.9)	6 (5.7)
RTW expectation (days) before surgery [mean (SD)]	28.2 (17.9)	30.5 (20.1)

Table 1. Continued

Baseline characteristics	Intervention group (n=110)	Control group (n=105)
Intention to RTW despite symptoms (1-5) [mean (SD)]****	3.0 (1.0)	2.9 (1.1)
Complicated surgery [n, (%)]*****	7 (6.4)	1 (1.0)

* Low = preschool, primary school, lower vocational education; Intermediate = Secondary education, Intermediate Vocational Education; High = Higher Vocational Education, University, postgraduate.

** Higher score means a higher level of decision latitude, social support, psychological jobs demands or physical job demands

*** Total score varies between 17 and 68. A higher score indicates a greater fear for physical activity or injury.

**** Higher scores indicate a higher intention to RTW despite symptoms

***** Defined as extension of the incision(s) with more than eight centimetres or re-surgery related to and within two weeks of the initial surgery

Table 2. Difference in return to work between intervention and control groups

Model	HR	95% Confidence interval	p-value
Univariate Crude analyses (ITT)	1.34	0.94 - 1.90	0.108
Adjusted analyses (ITT)*	1.43	1.003 - 2.04	0.048
Adjusted analyses (PP)*	1.54	1.07 - 2.22	0.022

* Adjusted for type of surgery, hospital (prestratification) and complicated surgery (unequally distributed)

Primary outcome measure

Regarding return to work, a hazard ratio of 1.43 (95% confidence interval 1.003 to 2.04, p=0.048) in favour of the eHealth intervention was found, which remained constant over time. The PP analyses resulted in a hazard ratio of 1.54 (95% confidence interval 1.07 to 2.22, p=0.022), comparable to the ITT analyses (table 2).

The median duration of sick leave until full sustainable return to work was 39 days (interquartile range 20-67 days) in the intervention group and 48 days (interquartile range 21-69) in the control group.

Secondary outcome measures

Table 3 presents the long-term effects of the intervention on QoL and recovery. Both physical and mental QoL improved more in the intervention group than in the control group. No difference between both groups was measured for the recovery index.

Table 3. Quality of life and recovery after 26 weeks of follow-up by intention-to-treat analysis

Outcome	Mean (standard error) *		Between-group difference (95% confidence interval) **	p-value
	Intervention	Control		
QoL (RAND-36)				
Total	660 (17)	630 (19)	30 (4 - 57)	0.024
Physical health	345 (9)	330 (10)	15 (2 - 29)	0.028
Mental health	317 (10)	301 (11)	16 (0 - 32)	0.044
Recovery (RI-10)	40.8 (1.1)	39.3 (1.2)	1.5 (-0.2 - 3.3)	0.091

* Mixed model analyses using measurements at 2, 6, 12 and 26 weeks after surgery with baseline score as covariate. Baseline score RAND-36: total 594, mental health 292, physical health 302. Baseline score recovery index: 19.7

** Difference in improvement between intervention group and control group adjusted for type of surgery, hospital (pre-stratification) and complicated surgery (unequally distributed)

Table 4. Pain intensity after 26 weeks of follow-up by intention-to-treat analysis

Outcome	Mean (standard error)		Cumulative Odds Ratio*, **	95% Confidence Interval***	p-value***
	Intervention	Control			
VAS pain score	1.92 (0.41)	3.52 (0.58)	1.84	1.04 to 3.25	0.035

* Generalised mixed ordered logistic regression analyses using measurements at 6, 12 and 26 weeks after surgery

** Adjusted for type of surgery, hospital (prestratification) and complicated surgery (unequally distributed)

*** Confidence interval and p-value belongs to the cumulative odds ratio

Table 4 presents the pain intensity. The cumulative odds ratio of 1.84 at 26 weeks implies that the women in the intervention group were 1.84 times more likely to be included in a lower pain intensity category compared with the control group.

DISCUSSION

Main findings

The use of the eHealth intervention had a significant beneficial effect on sustainable return to work rate, pain intensity and QoL (both physical health and mental health scale) in women after a hysterectomy and/or laparoscopic adnexal surgery on benign indication, compared to the use of the control intervention. Median duration of sick leave until full sustainable return to work was 39 days in the intervention group and 48 days in the control group.

Strengths and weaknesses

The first strength of this study is the high internal validity through the proactive method of inviting all women scheduled for a hysterectomy and/or laparoscopic adnexal surgery to participate in the RCT, and through selection being based on clearly defined inclusion and exclusion criteria alone. In addition, the execution of this study in six general or teaching and a university hospital is a good reflection of the Dutch health care situation. Moreover, this RCT is of high quality, due to the high compliance to the eHealth intervention (100%), no loss to follow-up on the primary outcome measure and only 3-4% loss to follow-up on the secondary outcomes. In addition, the blinding of the women for allocation to the intervention minimised the Hawthorne and placebo effects.³⁰ This is confirmed by the fact that 32 (31%) of women in the control group indicated that the control website contributed to their recovery. Furthermore, the primary outcome measure of a full sustainable return to work takes into account recurrences of sick leave within 4 weeks of a return to work, and therefore reduces any underestimation in the number of work days lost.³¹ Finally, according to the International Classification of Functioning (ICF) model, both participation and the clinical outcomes for women were measured to evaluate the clinical as well as the societal benefits.³²

A weakness of this study is the randomisation at the level of the individual: contamination between the intervention group and control group cannot be excluded. Care providers were not blinded to the intervention, and may have used acquired insights received through the convalescence recommendations for the intervention group to adapt their recommendations to the control group. Furthermore, women had to provide their GPs and OPs with the standardised convalescence recommendations, which may have restricted the implementation of the guidelines in some cases if women failed to do so. However, considering the results of this study, these limitations may only have led to an underestimation of the effect of the intervention.

Although care providers and researchers could not be blinded for the allocated treatment of the patient, they were not involved in measuring the outcomes, since all outcome measures were self-reported and the questionnaires were sent by email or post to the women and filled out at home. The self-reported duration of sick leave might be susceptible to information bias. Nevertheless, a monthly recall is generally considered as reliable and there is no reason why women should report their sick leave differently in the intervention or the control groups.^{33;34}

Regarding the secondary outcomes, an effect of the intervention in the second step of the stepped care program cannot be ruled out; however, it is not plausible that this was of influence, because no one received the workplace intervention in the second step.

Finally, external validity could be reduced as a result of women being excluded and the higher educational level of the women in this study, compared to the average female working population in the Netherlands.³⁵ Both living in the city (participating hospitals were located in the urban agglomeration of the Netherlands) and a higher educational level are associated with more frequent use of the internet for health or illness matters.³⁶ Therefore, the results can not automatically be generalised to all Dutch gynaecological patients.

Interpretation

This is the first study to evaluate the effect of an eHealth intervention aimed at improving care and the return to work after surgery. The result of a faster return to work in the intervention group is in line with other (cohort) studies in our target group that have reported a shorter return to work time when women received clear and unambiguous convalescence recommendations at discharge, and return-to-work advice, which was one of the main components of this eHealth intervention.^{6;37} Another study revealed, however, that the majority of women extend their sick leave beyond the recommended period on their own initiative.⁴ Therefore, an explanation for the effect of this intervention on return to work may also be found in the fact that tailored eHealth interventions make women more actively engaged in their own recovery and improve the communication between women, health care providers and their environment.^{38;39} Moreover, this eHealth intervention aimed to empower both women and employers to discuss a return to work, which is experienced as difficult,⁴⁰ and helped them to timely arrange a timely return to work, with modified duties if necessary. Besides enhancing these skills and reducing barriers, this intervention also aimed to influence women's intention to return to work by affecting attitudinal beliefs, social influence and self-efficacy beliefs about recovery and return to work.¹⁰ The larger improvement of QoL and reduction of pain in the intervention group compared to the control group is in line with a review that described that work improves QoL and may have beneficial influence on outcomes such as pain.^{2;41}

Implications for practice

Considering the positive influence of this eHealth intervention on return to work, pain intensity and QoL, it has the potential to induce a considerable improvement of perioperative care. Because sick leave costs are the main cost drivers after surgery, this eHealth intervention also has a high potential to reduce costs drastically for women undergoing hysterectomy and/or laparoscopic adnexal surgery for a benign indication. It has been developed to be used with minimal burden to care providers and can even reduce the number of postoperative consultations. Therefore, the use of the eHealth intervention is cheap compared to other medical interventions and its implementation is expected to be relatively easy, partly because 95 (91%) women in the intervention group would recommend the eHealth intervention to other women.

The generalizability of this eHealth model should be evaluated by external validation in another population of gynaecological patients. Furthermore, a cost-effectiveness study is recommended to evaluate the potential savings by this intervention. Finally, taking into consideration the positive results, it is also recommended to adapt this eHealth intervention for other types of surgeries.

Return to work recommendations do not take priority among doctors, but in view of the great relevance of providing clear convalescence recommendations regarding a return to work, shown through this intervention, more attention for this aspect of health care is recommended.⁴²

CONCLUSION

In conclusion, this paper presents a valuable effect of this eHealth intervention on sustainable return to work rate, pain intensity and QoL in women undergoing a hysterectomy and/or laparoscopic adnexal surgery for a benign indication in the Netherlands.

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CHAPTER 9

General discussion



This thesis started with an exposition of delayed return to work (RTW after major benign gynaecological surgery, the consequences of this, and possible correlates and explanations for prolonged sick leave. From this, the hypothesis was brought on that before the full advantage of improvements of (minimal invasive) surgery regarding reduced recovery, time to RTW and improved quality of life can be proven, perioperative care has to be improved. To realise this, 4 aims were formulated:

1. To measure the impact of the level of invasiveness of gynaecological procedures on time to full RTW and identify most important predictors of prolonged sick leave;
2. To develop evidence- and consensus-based multidisciplinary postoperative convalescence recommendations;
3. To develop an eHealth intervention and integrated care management (including a workplace intervention), which is suited to empower patients during the perioperative period in recovery and RTW and help other relevant stakeholders (e.g. care providers, employers) to support their patient/employee;
4. To evaluate the feasibility (including exploration of facilitators and barriers to future implementation) and effectiveness of the developed eHealth intervention and integrated care management & workplace intervention.

In this chapter, the main findings of this thesis are summarized, and methodological considerations and recommendations for implementation and future research are discussed.

MAIN FINDINGS

The impact of the level of invasiveness of gynaecological procedures and most important predictors of prolonged sick leave

In a prospective cohort study in patients who underwent benign gynaecological surgery, we found that time to RTW after surgery was faster in case of less invasive surgery (chapter 2). While RTW after minor surgery took 2 weeks, RTW after intermediate and major surgery took median more than 8 weeks, which is longer than what can be reasonably expected from a medical perspective. In line with this finding, strongest predictive value of RTW 1 year after surgery was shown for level of invasiveness of surgery (minor surgery hazard ratio [HR] 0.51, 95% CI 0.32–0.81; intermediate surgery HR 0.20, 95% CI 0.12–0.34; major surgery HR 0.09, 95% CI 0.06–0.16), RTW expectations before surgery (HR 0.55, 95% CI 0.36–0.84), and preoperative functional status (HR 1.09, 95% CI 1.04–1.13). These factors together explained 58% of the variance in time to RTW between the patients in this study. A prediction model was developed, by which patients with a high risk of prolonged sick leave may be identified and can be selected for additional perioperative care. Considering

the importance of patients' expectations of time to RTW, which may relatively easily be influenced, it seems advisable to optimize perioperative counselling and develop guidelines regarding RTW after gynaecological surgery.

Postoperative convalescence recommendations

We developed multidisciplinary detailed recommendations for graded resumption of relevant (work) activities after an uncomplicated hysterectomy and laparoscopic adnexal surgery on benign indication (chapter 3). Twelve expert physicians were recruited in collaboration with the participating medical boards of gynaecologists, occupational physicians and general practitioners. Based on a literature review and a modified Delphi procedure with anonymous questionnaire rounds and two group discussions, they judged 38 activities relevant for convalescence recommendations. Gaps in evidence were filled by the expert opinion and consensus was achieved for all 38 graded activities. The recommendations were judged as feasible by a representative sample of 63 medical doctors.

Development and evaluation of patient participation in eHealth intervention and integrated care management

The Intervention Mapping (IM) protocol was used to develop and tailor an eHealth intervention to empower gynaecological patients during the perioperative period and to help other relevant stakeholders (e.g. care providers, employers) to support their patient/employee. Focus group discussions showed that sufficient, uniform, and tailored information regarding surgical procedures, complications, and resumption of activities and work were considered as most essential. Knowing whom to contact in case of mental or physical complaints, and counselling and tools for work reintegration were also considered important. With available literature, the results of the focus group discussions and the theory of planned behaviour, suitable tools and materials for the eHealth intervention were developed. This intervention provides an opportunity to compose detailed tailored instructions on the resumption of (work) activities, based on the Delphi method described in chapter 3. The intervention additionally provides tools (e.g. a video) to improve the communication between patients, care-providers and employers, to prevent conflicting recommendations and to stimulate patients and employers to discuss potential RTW problems and to develop a work reintegration plan. Furthermore, general information on the surgical procedure itself, the (possible) consequences of the surgery and clear instructions about which symptoms require additional consultation of care providers or adaptation of convalescence recommendations, is available in the eHealth intervention. The vast majority of the participating patients and stakeholders judged the intervention to be a promising eHealth tool to empower gynaecological patients during the perioperative period including return to (work) activities.

The involvement of gynaecological patients in the development of the eHealth intervention, which is considered as a patient version of a clinical perioperative guideline, was assessed by means of an evaluation framework with pre-defined evaluation criteria. Consultation of patients with regular feedback moments appeared rather effective for the development process of the web-based clinical guideline for patients. Patients' input contributed to applicability of the eHealth intervention in daily practice, which positively contributed to the embedding of the developed knowledge.

The integrated care management including a workplace intervention was based on a previous study of patients with chronic low back pain. This intervention will only be offered when sick leave exceeds ten weeks and thus to patients with a complicated recovery and RTW. It will be performed by a multidisciplinary team consisting of a clinical occupational physician, an occupational therapist and a gynaecologist. The goal of this intervention is to prevent work disability by reducing barriers for RTW by improving communication between different care providers, occupational physician, employer and patient.

Process evaluation and effectiveness of the eHealth intervention and integrated care management

A process evaluation within a randomized single blinded controlled trial to assess the effectiveness of the eHealth intervention as part of a multidisciplinary stepped care program on recovery and full sustainable return to work, was performed (Chapter 7 en 8). Eligible participants in the RCT were women aged between 18-65 years, scheduled for a hysterectomy and/or a laparoscopic adnexal surgery on benign indication and who were employed for at least 8 hours per week (paid or unpaid). During the first step of the care program, all patients were given access to an eHealth intervention. The intervention group received access to the eHealth intervention which provided personalized tailor-made pre- and postoperative instructions on resumption of daily activities including work, and tools to improve self-empowerment and to identify recovery problem (extensively described in chapter 4). The control group was provided access to a placebo website which provided the patients with telephone numbers of their hospitals and patient leaflets of the Dutch Society of Obstetrics and Gynaecology (NVOG). The second step of the care program consisted of the integrated care management including a workplace intervention, and was only offered to the intervention group if sick leave exceeded ten weeks. Through computerized block randomisation 110 patients were assigned to the intervention and 105 patients to the control group.

A systematic process evaluation of the multidisciplinary stepped care program (chapter 7) showed that the eHealth intervention was intensively used and highly appreciated by the majority of the patients, employers and gynaecologists. The second step with the integrated care management including a work place intervention was hardly used. Most

likely, the impact of this step could be increased by having the first consultation earlier in the recovery process and by increasing patients' internal motivation to use this second step.

In intention-to-treat analysis the eHealth intervention was effective on time to return to work (HR=1.43, 95% CI 1.003 to 2.04, p=0.048). Median duration of sick leave until full sustainable return to work was 39 days (IQR 20-67 days) in the intervention group and 48 days (IQR 21-69) in the control group. After 26 weeks, pain intensity was lower (VAS, cumulative OR=1.84, 95% CI 1.04 to 3.25, p=0.035) and quality of life was higher (Rand-36 health survey, between-group difference 30, 95% CI 4-57, p=0.024) in the intervention group compared to the control group.

METHODOLOGICAL CONSIDERATIONS

In the previous chapters of this thesis, methodological strengths and limitations regarding each respective chapter were already discussed. Therefore, in this chapter I will focus on the development of the main intervention and RCT described in this thesis.

Development of multidisciplinary convalescence recommendations

Through a modified Delphi method representatives from the stakeholder groups of gynaecologists, general practitioners and occupational physicians achieved a consensus opinion on detailed convalescence recommendations for resumption of (work) activities after hysterectomy and laparoscopic adnexal surgery. These multidisciplinary recommendations are based on evidence and consensus, and should be considered as an important first step towards improvement of perioperative care.¹⁻³ However, gaps in evidence were bridged by the consensus opinion of a single group of Dutch experts, and cannot be taken to be representative for all Dutch experts. Moreover, the recommendations developed in this study are based on data and practical experience of actual time to full RTW after gynaecological surgery of patients who did not receive structural convalescence recommendations. Given that -besides physical factors and the type of surgery- RTW is mainly influenced by the expectations of the patient and economic interests, it is reasonable to expect that these recommendations still overestimate the period of a realistic recovery.⁴⁻⁷

Regarding the feasibility, it can be reported that in total 11% (12/110) of the patients in the RCT stated that the recommendations were too conservative. On the other hand, 21% (23/110) of these patients reported that the reintegration plan they had composed on the eHealth intervention was too optimistic for their own situation. The majority of patients, 83% (87/105), followed most convalescence recommendations. A future analysis of the monitored graded activities, as completed by all participants in the recovery monitor

(in the intervention group) allows the validation of previous defined recommendations. In case of substantial deviations, adjustments of the recommendations need to be discussed. However, current recommendations as a part of the eHealth intervention, had a substantial beneficial effect on the rate of a sustainable return to work, pain intensity, and quality of life without an increase in complications, compared to usual care. We do not know if eventual adjustments of the recommendations affect this beneficial effect of our intervention.

Development of the eHealth intervention

The eHealth intervention was developed according to the intervention mapping protocol; a stepwise approach for theory and evidence based development and implementation of interventions.⁸ Both theory and evidence were combined and patients and most relevant stakeholders were involved, minimizing the risks of theory and/or program failure.⁹

However, regarding the patients involved in the development of the eHealth intervention, a possible selection bias may have occurred. Through purposeful sampling and by pro-actively approaching all patients eligible for participation in the focus group discussions, we tried to minimize selection bias as much as possible. But, in general patients who volunteer for focus group discussions are a selection of the patients willing to discuss their perioperative problems. Patients less willing to discuss their difficulties may also experience different perioperative issues. For example, in the focus group discussions, the lack of opportunities to contact other patients to exchange experiences was brought on as a very important shortcoming in current perioperative care. As best solution to overcome this shortcoming, a public forum and the ability to send private messages to other patients on the eHealth intervention was incorporated. In the RCT however, few messages were posted on the forum and no private messages were sent. Furthermore, patients' satisfaction with the forum was the lowest of all tools of the eHealth intervention. Also the influence of dominant patients, who might be overly influential during the focus group discussions, cannot be excluded. On the other hand, specific observations on this matter showed that this hardly occurred (chapter 5).

Effectiveness and feasibility of the eHealth intervention

With regard to the overall quality of this study, we think that this study meets most of the CONSORT statement requirements for high quality trials.^{10;11} However, several methodological aspects should be acknowledged and discussed.

Randomisation

A weakness of this study is the randomisation at the patient level; this way, contamination between the intervention group and control group cannot be excluded. Care providers were not blinded to the intervention and may have used acquired insights received

through the convalescence recommendations for the intervention group to adapt their recommendations to the control group. Furthermore, patients had to provide their GPs and OPs with the standardised convalescence recommendations. This may have restricted the distribution of the guidelines in some cases if patients failed to do so. However, considering the results of this study, these limitations may only have led to an underestimation of the effect of the intervention. Although care providers and researchers could not be blinded for the allocated treatment of the patient, we blinded the patients for the intervention. Moreover, the professionals were not involved in measuring the outcomes. Since all outcome measures were patient-reported and the questionnaires were sent by email or post to the patients and filled out at home, information bias was limited.

Blinding

In addition, blinding of the patients for allocation to the intervention minimised the Hawthorne and placebo effects.¹² This is confirmed by the fact that 31% (32/104) of patients in the control group indicated that the control website contributed positively to their recovery and 66% (69/104) of them would recommend the web portal to a friend. Therefore, it is not implausible that the effect of the eHealth intervention might have been even larger after better implementation of the multidisciplinary convalescence recommendations and removal of the placebo and Hawthorne effect in the control group.

Outcome measures

The evaluation of patients' health and recovery was studied using clinical, participatory and activity outcome measures. By doing so, the influence of the eHealth intervention on the different aspects of human functioning and state of health according to the ICF model were evaluated.¹³ However, we did measure with patient goal attainment scales (GAS) which target they wanted to reach as indication for a desirable recovery after surgery. This may be considered as a shortcoming, because attaining personal goals are associated with patient satisfaction after surgery.^{14;15}

The primary outcome measure in this study, full sustainable RTW in own or other work with equal earnings, was self-reported by a monthly calendar of sickness absence per post. General agreement exists that self-reporting regarding sickness absence can be relied on when recall is required within one month.^{16;17} Furthermore, sustainable RTW takes into account recurrences of sick leave within four weeks after RTW and therefore reduces underestimation of work-loss days.¹⁸

Loss to follow-up

There was no loss to follow-up on the primary outcome measure RTW and only 3 to 4% loss to follow-up on the secondary outcomes. Therefore, the results have a high internal validity.

Analysis and results

As a result of the multidisciplinary recommendations provided by the eHealth intervention, in which point estimations were restricted to a maximum of six weeks after surgery with a natural range, its maximum effect on time to RTW was expected between six to eight weeks after surgery. However, if patients had not fully RTW at eight weeks after surgery, the eHealth intervention started encouraging them to make an appointment for the integrated care management at ten weeks. Therefore, in order to prevent any interaction of both interventions, it was decided to report the effect of the eHealth intervention from the day of surgery till seven weeks after surgery. This decision, based on both theoretical (i.e. the recommendations) and practical (i.e. preventing an interaction effect with the second intervention) grounds, may have influenced the results of the primary outcome measure. In fact, more extensive analyses regarding the primary outcome measure showed a larger effect of the intervention between 7 to 8 weeks after surgery.

We cannot rule out an effect of the second step (i.e. integrated care management) of our stepped care program on the secondary outcomes (quality of life, recovery index, pain intensity). Performing a second randomisation regarding the assignment of the integrated care management for patients, who were still sick listed 8 weeks after surgery, might have prevented a potential effect of the integrated care management. However, we consider this unlikely because of an implementation score of 35% of the integrated care management and none of the patients received the workplace intervention in this second step.

If applicable, the baseline score of the questionnaires were added as a covariate in the analysis of the outcome measures. This way influence of possible dissimilarities between the intervention group and the control group were excluded.

Internal and external validity

The proactive way of inviting all patients scheduled for a hysterectomy and/or laparoscopic adnexal surgery to participate in the RCT and selection based only on clearly defined inclusion and exclusion criteria increased the internal validity of our study results. The execution of this study in six general or teaching hospitals and a university hospital was a good reflection of the Dutch health care situation. External validity might be reduced as a result of the research setting- , the excluded patients and the higher educational level of the patients in this study, compared to the average female working population in the Netherlands.¹⁹ Both living in the city (participating hospitals were located in the urban agglomeration of the Netherlands) and a higher educational level are associated with more frequent use of the internet for health or illness matters.²⁰ Therefore, the results cannot automatically be generalised to all Dutch gynaecological patients.

RECOMMENDATIONS FOR IMPLEMENTATION AND FUTURE RESEARCH

During recovery after surgery, patients and health care providers often focus primarily on the treatment of the physical health condition, which often goes together with performing few activities until full recovery had occurred. An important aim of this research project was to empower and stimulate patients in performing activities starting shortly after surgery, even if they still may have some complaints. Tailored convalescence recommendations stimulated patients to perform activities in increasing levels of strain and provided them and their environment with a detailed reintegration plan and clear expectations about time to RTW. This focus on activities and participation is based on the ICF model.²¹ According to the results of this study, this seems to be a meaningful approach for patients who underwent a hysterectomy or laparoscopic adnexal surgery on benign indication and therefore we want to discuss the implementation and future research regarding the main components of this approach.

Multidisciplinary convalescence recommendations

In the past two decades, an increasing number of surgical procedures have undergone a transition from a standard open surgical approach to a minimal invasive one. This trend towards less invasive procedures, which is ongoing, is not only better for the patient but also for society because it results in shorter admission periods and a lower risk of prolonged sick leave, which has already been shown for some types of surgeries.²² In this thesis, expectation of time to RTW before surgery was identified as a strong predictor for the risk of prolonged sick leave. Convalescence recommendations given by health care providers however, are often not specified per surgical technique and show a great diversity.²³⁻²⁵ Therefore, in order to take full advantage of the potential benefits of minimal invasive surgery, it seems of great importance to give more attention to preoperative counselling and the use of multidisciplinary guidelines regarding RTW.²⁶

In the Netherlands, there's a strict separation in the curative treatment by medical specialists, the reintegration guidance by occupational physicians and the evaluation of the reintegration process by insurance physicians. Therefore, RTW recommendations given by medical specialists are vulnerable as a result of a lack of knowledge about the physical demands of the patient's job, a critical evaluation of given RTW recommendations by occupational physicians and a lack of social structure to judge the provided RTW recommendations. In this study, we aimed to make the focus on RTW after gynaecological surgery a common purpose for all involved health care providers without them hindering each others' plans. The gaps in opinions regarding convalescence recommendations were bridged in the development of multidisciplinary recommendations, which were based on the knowledge of gynaecologists, general practitioners and occupational physicians

(also on behalf of insurance physicians) alike. With these guidelines, gynaecologists and general practitioners were able to provide their patients with well-defined uniform recommendations which could be used to work towards work reintegration. For occupational physicians the guidelines were the foundations of the final reintegration plan. Moreover, the more unambiguous recommendations between different health care providers were likely to enhance the compliance of the patients.

Considering the positive results of this study regarding reduction of the sick leave period and satisfaction of the patients and health care providers with the guidelines, we recommend to extend the development of multidisciplinary recommendations towards more types of surgeries. Abolition of the financial and organisational separation of curative and health & safety care, will probably accelerate this process. It will lead to a mutual purpose for medical specialists and occupational physicians since both optimal curative care as well as a successful reintegration process for labour participation will be aimed for. A way to implement the guidelines is to record them as a national transmural agreement between gynaecologists, general practitioners, occupational and insurance physicians.

Integrated care management

The integrated care management including a work place intervention was based on studies in patients sick-listed due to musculoskeletal disorders and distress, where its effectiveness is reported.^{27;28} In our study, the implementation of this intervention was very poor, which can be considered as a program failure; even if the theory behind it was right, it could not possibly be effective.²⁹ Moreover, a possible theory failure, which means that the theoretical idea and hypotheses behind the intervention were wrong, cannot be excluded because the fidelity score was 0%.²⁹ This means that the quality and the extent to which this intervention was used to support patients was very low. To enhance the implementation of this integrated care program, adaptations in the integrated care protocol are needed. To tailor this intervention to the needs of postoperative gynaecological patients, focus group discussions with patients with prolonged sick leave may be advisable.

According to our experience in this study with the integrated care program, motivating patients to consent to additional guidance and developing an accurate return-to-work-prognosis were two important obstacles. Contrary to the patients sick-listed due to musculoskeletal disorders and distress, at the time of recruitment, patients in our study were only facing a temporary period of sick leave due to their surgery. This temporary nature of the sick leave period is probably an important barrier to full implementation, demonstrated by the fact that more than 50% of the patients indicated a general lack of perceived value of additional guidance by the integrated care management. The Dutch legislation, which ensures salary income for at least the first 24 months of sick leave and

hardly stimulates partial RTW from an economical perspective, may contribute in this matter. Furthermore, the low compliance to an accurate RTW plan may also be explained by the fact that this intervention started too late after surgery (10 weeks). As a result, most patients had already made a RTW plan with their own occupational physician and were not motivated to start this intervention as well. In future research, it is recommended to offer this intervention much earlier in the recovery period. For instance, all patients could be screened before surgery with a questionnaire on important predictors regarding time to RTW such as 'expectation to time to RTW before surgery', 'intention to resume work activities while recovering' and 'preoperative functional status'.^{28;30;31} This way, patients at risk for prolonged sick leave may be identified even before surgery and they could receive additional care management from the clinical occupational physician to develop a solid RTW-plan, or receive guidance to overcome negative attitudes and (irrelevant) beliefs about their recovery or organisational difficulties. In future, this selection procedure and guidance could possibly be performed by the patient's own occupational physician.

eHealth intervention

With a general internet-access rate of 97% in the Netherlands, eHealth interventions are considered to be an important way to improve efficiency and quality of health care.³²⁻³⁵ An important strength is the possibility to use it at the time, place and pace that fits the patient, care provider and employer.³⁶ Besides information supply, which is the main aim of most websites, the developed eHealth intervention in this study distinguishes itself by monitoring the recovery process, giving tailor-made advice based on patients' workload and informing patients when additional consultation of care providers is needed. By bringing patients into contact with their gynaecologists, convalescence recommendations can be adapted and insecurities regarding consequences of the complications can be solved. Connecting patients and employers facilitates a dialogue and thereby the joint effort to compose a reintegration plan, which is experienced as being difficult.³⁷ Although it is hard to distinguish the effect of each tool separately, we think that this eHealth intervention contributed to increased activity and work participation by enhancing skills, reducing barriers and affecting attitudinal beliefs, social influence and self-efficacy beliefs about recovery and RTW, and with this to a better health condition.¹³ Considering the positive influence of this relatively cheap and minimal invasive intervention regarding reduction of sick leave and improvement of quality of life and pain in this population, it has the potential to induce a considerable improvement of perioperative care.

This eHealth intervention also has a high potential to drastically reduce compensation costs -which are the main cost drivers after surgery-, for patients undergoing hysterectomy and/or laparoscopic adnexal surgery. Considering 20.000 surgeries per year are performed in the Netherlands, approximately 67% of women aged between 25 and 65 years has

paid work, the productivity costs are € 200,- per women per day, and one third of this population can be estimated to use the intervention (based on the inclusion of the RCT), every reduced day of sick leave would save almost 1 million Euro in compensations costs.³⁸⁻⁴⁰ Moreover, the intervention has been developed to be used with minimal burden to care providers and can probably reduce the number of consultations, which makes the intervention even more interesting for hospitals and insurance companies from an economical point of view.

Regarding the implementation of this eHealth intervention in daily practice, several issues should be discussed. Based on the results of the process evaluation, implementation is expected to be relatively easy. In the RCT the implementation score, which took in consideration the reach, dose delivered, dose received, and fidelity score, was 80%. Moreover, 78% (78/104) of the patients in the RCT felt use of the eHealth intervention contributed positively to their recovery and 91% (95/104) of them would recommend the web portal to a friend. In total 61% (11/18) of the employers were (very) satisfied with the guidance the web portal offered to their employee. Of the gynaecologists, 76% (16/21) rated the intervention as (very) useful and the vast majority would offer it to their patients if it would be widely available. It should be noted that by nature the RCT took place in a research setting, which does not directly reflect daily practice because the researchers played an important role in the implementation of the eHealth intervention. Furthermore, in this research setting the intervention was mainly used by motivated patients and gynaecologists. Moreover, a possible system barrier for implementation of the eHealth intervention can be found in the insurance system of the Netherlands. Health insurance companies pay for the care patients receive and employers or income insurance companies pay for sick leave benefits. The question rises who will pay for the implementation and maintenance of this eHealth intervention. The current study has shown a reduction in sick leave by the patients who used the intervention. Therefore, the employers and income insurance companies will financially benefit of the intervention, which makes it plausible that they will pay the costs. On the other hand, the intervention is part of the curative health care; it is offered by the hospitals, linked to the type of gynaecological surgery and gynaecologist, and may also reduce the curative health care costs (e.g. reduction in the number of consultations). Therefore, in the current situation, it is also plausible for the health insurance companies to finance the implementation of this eHealth intervention.

To support implementation of the eHealth intervention in daily care, the generalizability of this eHealth intervention should be evaluated by external validation in another population of gynaecological patients. Economic evaluation of this intervention from a societal perspective (costs of the intervention, health care utilization costs and cost

associated with lost productivity) compared to usual care, is recommended alongside a second effectiveness study. Using cluster randomized controlled design will minimize the risk of contamination, as the intervention targets both the health care providers as the patients. Moreover, added value of this cost-effectiveness-study will be reached when it includes enough patients to perform subgroup analyses for e.g. type of surgery and patients with different risk profiles regarding prolonged sick leave.

In our study, 86% of all participants used the eHealth intervention as intended, which is relatively high but in concordance with the high satisfaction scores.⁴¹ However, one should be aware that the research setting could also have contributed to this outcome. Therefore it is important to distinguish which tools of the eHealth intervention helped (specific groups of) patients most in their recovery process in order to tailor the kind of tools offered to its user.

Questionnaires in this study showed a high level of satisfaction with all different tools of the eHealth intervention during the RCT, and page statistics confirmed good use of all of them. The forum scored lowest of all, but was still visited 750 times, and more than 20% of the patients was (very) satisfied with this tool. Moreover, the patients did not mention specific tools as unnecessary. In fact they would like to extend the eHealth intervention with a page with experiences of other patients with the surgery. Therefore, in this study we were not able to distinguish which tools were surplus and it would be advisable to measure and evaluate the impact of each tool also in the validation study in order to offer only the most effective tools in future. Increased influence of the intervention may also be reached through a mobile app for the patient or, after consent of the patient, automatic sharing of the composed tailored convalescence recommendations with the general practitioner and occupational physician per email. Furthermore, more extensive feedback on the recovery process over time and in comparison with the guidelines could possibly stimulate patients to carry out activities and increase participation in daily live. An opportunity to increase the personalization of the consultation with the clinical occupation physician or gynaecologist may be found in the use of a webcam. In future, the recovery monitor of the eHealth intervention may also provide unique opportunities to study patient reported outcomes, which for example can be used as a quality indicator of surgical performance.

Taking into consideration the positive results regarding effectiveness and evaluation of this eHealth intervention and the fact that it could be easily modified and expanded, it is recommended to adapt this intervention for other types of surgeries.

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CHAPTER 10

Appendices



APPENDIX 1

Baseline questionnaire of the Recovery Index

Clarification of the questionnaire

The following questions refer to how you felt last week. There are no wrong answers. Per question, only one answer can be encircled. The answers are on a five point scale. If you strongly agree with the statement, please encircle 1, if you agree a bit, circle 2, etc. If you totally disagree, than you encircle 5.

	Completely agree			Completely disagree	
1. Slight exertion makes me feel tired	1	2	3	4	5
2. During the day I need to rest regularly	1	2	3	4	5
3. Even without activity, I am bothered by abdominal pain	1	2	3	4	5
4. Any light work (e.g., making coffee) exhausts me	1	2	3	4	5
5. I cannot finish my daily activities at home without effort	1	2	3	4	5

APPENDIX 2

Calculation of risk score of sick leave more than 6 weeks

Instruction

Each categorical predictor that is not relevant for a particular patient should be multiplied by zero and each predictor which is relevant by one. For the baseline recovery index, the score itself can be used. The weight of all positively scored predictors needs to be added up to form the total risk score. The total risk score can vary between -25 and +31. The higher the score, the higher the risk of prolonged sick leave. With the total risk score, the predicted risk of sick leave extending 6 weeks after surgery for that particular patient can be found in table 4.

Predictor

• Diagnostic laparoscopy	0 / 1 ^a	x	1	=
• Minor surgery	0 / 1 ^a	x	8	=
• Intermediate surgery	0 / 1 ^a	x	20	=
• Major surgery	0 / 1 ^a	x	29	=
• RTW expectation before surgery	0 / 1 ^b	x	7	=
• Total score of recovery index at baseline ^c	x	-1	=
Total score:			

RTW = return to work

^a No = 0, Yes = 1,

^b RTW expectation before surgery; normal expectation on time to RTW = 0, low expectation = 1; Low expectation on time to RTW is defined as longer than 1, 2, 4 and 6 weeks for respectively diagnostic, minor surgery, intermediate surgery and major surgery. A shorter or equal expected time to full RTW is regarded as a normal expectation on time to RTW.

^c Total score of the recovery index at baseline = sum up the scores (1-5) for all five questions of the baseline questionnaire of the Recovery Index (appendix 1). Range 5-25.

Example: a patient who underwent minor surgery, with a normal RTW expectation and with a total score on the baseline recovery index of 18, had a total risk score of $1*8$ (minor surgery) + score $0*7$ (normal RTW expectation) + $-1*18 = -10$. The predicted risk of sick leave extending 6 weeks after surgery for this patient is 16% (table 4).

APPENDIX 3**Functional ability list of the 38 items presented in Table 1 and Figure 3**

Personal functioning	213
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<i>Ability to bend frequently when working (roughly 10 times a minute)</i>	215
<i>Turning/twisting round</i>	216
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<i>Climbing</i>	217
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<i>Jumping</i>	220
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<i>Cycling</i>	220
<i>Driving</i>	220

Personal functioning*Focusing attention*

0. normal, can concentrate on a single information source (book, documentary on TV or radio) for at least half an hour;
1. limited, cannot concentrate on a single information source (newspaper, current affairs programme on radio or TV) for more than half an hour;
2. very limited, cannot concentrate on a single information source (advertising brochure, TV or radio advert) for more than 5 minutes.

Dividing attention

0. normal, can concentrate for at least half an hour on a number of information sources (manages to drive or cycle in busy traffic);
1. limited, cannot concentrate for more than half an hour on a number of information sources (cannot drive or cycle in busy traffic);
2. very limited, cannot concentrate for more than 5 minutes on a number of information sources (cannot cross a busy street alone).

Memory

0. normal, can generally remember relevant things promptly, without resorting to unusual aids;
1. limited, frequently has to write things down, as a memory aid, to safeguard the continuity of their actions;
2. very limited, never able to remember essential everyday things (time, place, person, subject), and cannot compensate for this using memory aids.

Insight into own abilities

0. normal, generally able to assess their own abilities and limitations with reasonable accuracy;
1. limited, generally greatly overestimate their own abilities;
2. limited, generally greatly overestimate their own limitations.

Action tempo

0. normal, there are no specific limitations to the individual's action tempo in the course of daily life;
1. limited, the individual's action tempo is considerably slower.

Social functioning**Transportation**

0. normal, can drive or cycle, or use public transport without assistance;
1. limited, is reliant on others for transportation.

Adjusting to physical environment**Vibration**

0. normal, no specific limitations;
1. limited*

* denotes that the criterion for this score is not specified because it is very difficult to measure the functional ability in 'numbers or units' in a valid way based on the medical history and physical examination alone. The examining medical doctor will have to judge the individual situation and quantify and describe the specific limitation in his/her report.

Dynamic movement**Reaching out**

0. normal, arms fully extended when reaching out (serve coffee);
1. slightly limited, arms slightly bent when reaching out (shoulder-hand distance = 50-60 cm);
2. limited, can stretch arm only slightly when reaching out (shoulder-hand distance = less than 50 cm).

Ability to reach out frequently when working (roughly 20 times a minute)

0. normal, if required can reach out frequently during each hour of the working day (cashier's work in wholesale company, packaging work);
1. slightly limited, if required can reach out frequently for roughly 4 hours of the working day;
2. limited, if required can reach out frequently for roughly 1 hour per working day;
3. very limited, cannot reach out frequently for even 1 hour per working day.

Bending

0. normal, can bend roughly 90 degrees (pick up a piece of paper from the ground);
1. limited, can bend roughly 60 degrees (pick up a bag from the ground);
2. very limited, can bend roughly 45 degrees (pick up crumbs from the seat of a chair).

Ability to bend frequently when working (roughly 10 times a minute)

0. normal, if required, can bend frequently during each hour of the working day;
1. slightly limited, if required can bend frequently for roughly 4 hours of the working day;
2. limited, if required can bend frequently for roughly 1 hour per working day.
3. very limited, cannot bend frequently for even 1 hour per working day.

Turning/twisting round

- 0. normal, can turn torso at least 45 degrees (look behind while cycling, reach into the back seat of the car to get a bag while sitting in the front);
- 1. limited*

* denotes that the criterion for this score is not specified because it is very difficult to measure the functional ability in 'numbers or units' in a valid way based on the medical history and physical examination alone. The examining medical doctor will have to judge the individual situation and quantify and describe the specific limitation in his/her report.

Pushing or pulling

- 0. normal, can exert a force of roughly 15 kg when pushing or pulling (removing a stubborn cork from a wine bottle);
- 1. limited, can exert a force of roughly 10 kg when pushing or pulling (full rubbish container)
- 2. very limited, can exert a force of roughly 5 kg when pushing or pulling (open a door fitted with a door-closer)

Carrying or lifting

- 0. normal, can lift or carry a weight of roughly 15 kg (toddler)
- 1. slightly limited, can lift or carry a weight of roughly 10 kg (infant);
- 2. limited, can lift or carry a weight of roughly 5 kg (bag of potatoes);
- 3. very limited, can lift or carry a weight of roughly 1 kg (a 1 litre container of milk).

Ability to handle light objects frequently when working (roughly 10 times a minute)

- 0. normal, if required can handle objects weighing at least 1 kg frequently during every hour of the working day (order picking);
- 1. slightly limited, if required, can handle objects weighing at least 1 kg for roughly 4 hours per working day
- 2. limited, if required, can handle objects weighing at least 1 kg frequently for roughly 1 hour per working day;
- 3. very limited, cannot handle objects weighing at least 1 kg frequently for even 1 hour per working day.

Ability to handle heavy loads frequently when working (roughly 10 times per hour)

- 0. normal, if required, can handle loads of approximately 15 kg frequently for roughly 1 hour per working day;
- 1. limited, cannot handle loads of approximately 15 kg frequently for 1 hour per working day.

Walking

- 0. normal, can walk for roughly 1 hour at a time (a walk);
- 1. slightly limited, can walk for roughly 15-30 minutes at a time (a stroll);
- 2. limited, can walk for roughly 5-15 minutes at a time (to the letterbox);
- 3. very limited, can walk for less than roughly 5 minutes at a time (indoors).

Walking while at work

- 0. normal, if required, can spend most of the working day walking (postal worker);
- 1. slightly limited, if required can walk for half of the working day (roughly 4 hours);
- 2. limited, if required can walk for a limited part of the working day (roughly 1 hour);
- 3. very limited, can walk for less than half an hour per working day.

Climbing stairs

- 0. normal, can walk up **and** down at least 2 flights of stairs at one go (2 floors of a house)
- 1. slightly limited, can walk up **and** down at least 1 flight of stairs at one go (1 floor of a house);
- 2. limited, can walk up **or** down at least 1 flight of stairs at one go (1 floor of a house);
- 3. very limited, can only walk up **or** down one section of a tiered staircase in one go.

Climbing

- 0. normal, can at least climb up and down a ladder (1 floor);
- 1. slightly limited, can at least climb up and down a household stepladder;
- 2. limited, can at least step onto and off a raised surface (50 cm, step stool);
- 3. very limited, cannot step up or down.

Kneeling or squatting

- 0. normal, can reach the ground with hands when kneeling down or squatting (picking up a coin);
- 1. limited, can barely touch the ground with hands when kneeling or squatting, if at all.

Static movements*Sitting*

- 0. normal, can sit for roughly 2 hours at a time (car journey);
- 1. slightly limited, can sit for roughly 1 hour at a time (film);
- 2. limited, can sit for roughly half an hour at a time (meal);
- 3. very limited, can sit for less than 15 minutes at a time (TV news).

Sitting while at work

- 0. normal, if required, can sit for almost the whole working day (assembly work, cashier work, administrative work);
- 1. slightly limited, if required can sit for most of the working day (6-8 hours);
- 2. limited, if required can sit for half of the working day (roughly 4 hours);
- 3. very limited, can sit for less than 4 hours per working day.

Standing

- 0. normal, can stand for roughly 1 hour at a time (spectator at sports events);
- 1. slightly limited, can stand for roughly half an hour at a time (waiting in line for a theme park attraction);
- 2. limited, can stand for roughly 15 minutes at a time (washing up);
- 3. very limited, can stand for less than 5 minutes at a time (brushing teeth).

Standing while at work

- 0. normal, if required, can stand for almost the whole working day (sales jobs, production-line jobs);
- 1. slightly limited, if required can stand for half of the working day (roughly 4 hours);
- 2. limited, if required can stand for a limited part of the working day (roughly 1 hour);
- 3. very limited, can stand for less than half an hour per working day.

Activities requiring kneeling or squatting

- 0. normal, can perform activities while kneeling or squatting for at least 5 minutes (gardening);
- 1. limited, can perform activities while kneeling or squatting for less than 5 minutes at a time (cleaning kitchen cupboard door).

Activities requiring bending and/or twisting

- 0. normal, can perform activities while bending or twisting for at least 5 minutes at a time (sweeping steps);
- 1. limited, can perform activities while bending or twisting for less than 5 minutes at a time (tying shoelaces).

Performing activities above shoulder level

- 0. normal, can perform activities above shoulder level for at least 5 minutes at a time (hanging curtains);
- 1. limited, can perform activities above shoulder level for less than 5 minutes at a time (changing a light bulb).

Changing position

- 0. normal, no specific sequence of different positions required;
- 1. specific requirements concerning changes of position*

* denotes that the criterion for this score is not specified because it is very difficult to measure the functional ability in 'numbers or units' in a valid way based on the medical history and physical examination alone. The examining medical doctor will have to judge the individual situation and quantify and describe the specific limitation in his/her report.

Working hours*Hours per day*

- 0. normal, can work for at least 8 hours per day on average;
- 1. somewhat limited, cannot work for more than about 8 hours per day on average;
- 2. slightly limited, cannot work for more than about 6 hours per day on average;
- 3. limited, cannot work for more than about 4 hours per day on average;
- 4. extremely limited, cannot work for more than about 2 hours per day on average.

Hours per week

- 0. normal, can work for at least 40 hours per week on average;
- 1. somewhat limited, can work for roughly 40 hours per week on average;
- 2. slightly limited, can work for roughly 30 hours per week on average;
- 3. limited, can work for roughly 20 hours per week on average;
- 4. extremely limited, can work for roughly 10 hours per week on average.

Periods of the day

- 0. normal, if required can work at any time of the day or night;
- 1. limited, cannot work at night (00:00 – 06:00);
- 2. limited, cannot work during the evening (18:00 - 24:00).

Other*Taking a bath*

- 0. normal, permitted;
- 1. not permitted (recommendation).

Coitus

- 0. normal, permitted;
- 1. not permitted (recommendation).

Jumping

- 0. normal, permitted;
- 1. not permitted (recommendation).

Vacuum cleaning

- 0. normal, permitted;
- 1. not permitted (recommendation).

Cycling

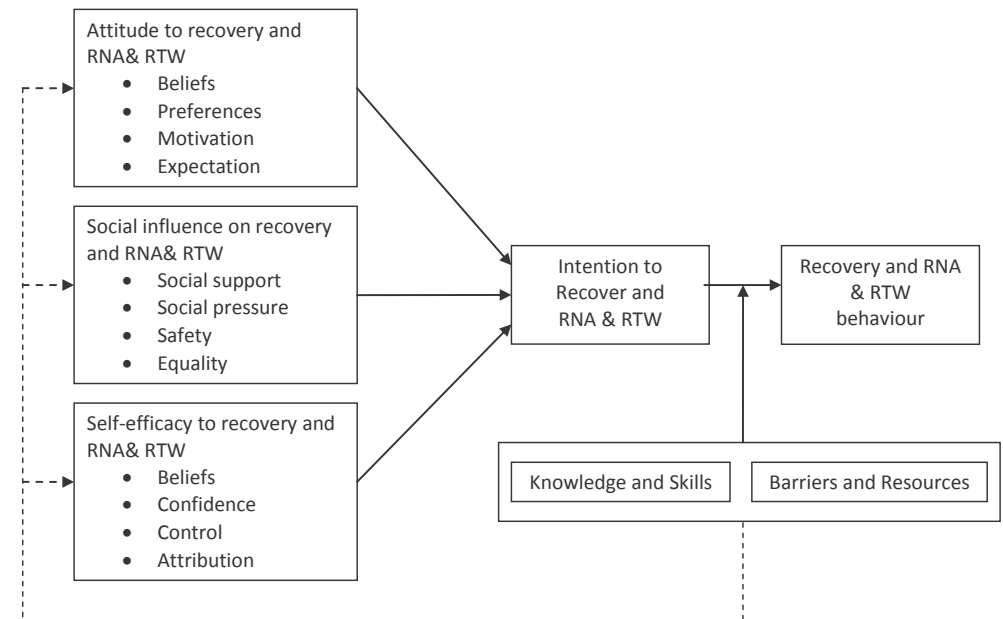
- 0. normal, permitted;
- 1. not permitted (recommendation).

Driving

- 0. normal, permitted;
- 1. not permitted (recommendation).

APPENDIX 4

Attitude Social influence-self-Efficacy model (ASE) adapted for recovery and return to normal activities (RNA) and return to work (RTW) after gynaecological surgery.



APPENDIX 5

Example of change objectives of patients

Performance objective	Personal determinants			External determinants		
	Attitudinal beliefs	Knowledge	Skills	Self-efficacy beliefs	Barriers	Support
Patients develop a work-reintegration plan	<ul style="list-style-type: none"> • Are willing to accept the convalescence recommendations² • Acknowledge that RTW in an early stage is important for their health⁸ • Take the effort to develop a reintegration plan^b 	<ul style="list-style-type: none"> • Know about the importance of gradual resumption of activities after gynaecological surgery^c • Know about health and financial consequences of work disability^{b,d} • Know about the risks of work disability after surgery⁸ 	<ul style="list-style-type: none"> • Have skills to make a reintegration plan^b • Find solutions to identify possible barriers for RTW¹ 	<ul style="list-style-type: none"> • Are confident concerning the tailor made medical content of their RTW-plan^b • Feel self-confident about discussing the RTW-plan with their employer^b 	<ul style="list-style-type: none"> • Feel encouraged by Health care providers to RTW^{1,82} • Employers give the opportunity to formulate a reintegration plan before surgery^b 	<ul style="list-style-type: none"> • Receive help (if necessary) of their OPs by composing a reintegration plan⁵⁹ • Feel receptiveness of their employers and OPs to think about adjustments in order to make an appropriate reintegration plan⁶⁷ • Different expectations regarding RTW are prevented by discussion of work-reintegration plan with employers¹

^{1,2,etc} See reference list Chapter 4

^bInformation obtained in the focus group discussions

^cExpertise of the project group

^dCassidy JD, Carroll LJ, Cote P, Lemstra M, Berglund A, Nygren A. Effect of eliminating compensation for pain and suffering on the outcome of insurance claims for whiplash injury. *N Engl J Med* 2000 April 20;342(16):1179-1186.

APPENDIX 6

Theoretical methods and practical strategies for recovery and return to normal and work activities

Determinant	Methods	Precondition	Strategy: Tools/Materials	Tool of eHealth intervention (table 2)
Attitudinal beliefs	<ul style="list-style-type: none"> • Persuasive Communication^d 	<ul style="list-style-type: none"> ▪ Credibility and clarity of the source ▪ Knowledge of Gynaecologists, OPs and GPs about multidisciplinary guidelines 	<ul style="list-style-type: none"> ➢ Uniform advice of Gynaecologists, OPs and GPs through implementation of a multidisciplinary guideline with well-defined convalescence recommendations after all types of hysterectomy and laparoscopic adnexal surgery. In the eHealth intervention, the care providers can find the guidelines, information about different types of surgery and casuistry.^{56,59,74,b} ➢ Provide reasons why prolonged recovery time and sick leave is not desirable can be found on the eHealth intervention.^{8,b} ➢ In order to have a reliable layout, the eHealth intervention is developed with attention for colours and correct comprehensible usage.^{b,c} 	<ul style="list-style-type: none"> ✓ Guidelines ✓ Casuistry ✓ Background information
• Self-reevaluation ⁴²	▪ Motivation		➢ Recovery monitoring by the eHealth intervention and feedback in case of abnormal or unrealistic recovery beliefs or RTW time. ^{56,c}	✓ Recovery Monitor
• Modelling ⁴²	▪ Acceptance and reinforcement of the model		➢ The eHealth intervention provides a video with models expressing tools for an appropriate recovery and RTW. ^{b,c}	✓ Video
• Goal setting ⁴²	<ul style="list-style-type: none"> ▪ Acceptance of recommendations ▪ Right balance between feasibility and challenge 		<ul style="list-style-type: none"> ➢ The eHealth intervention encourages and provides tools to compose a reintegration plan, including a schedule for private life and the home situation.^{59,b} ➢ Possibility to print out the individualized reintegration plan to discuss it with the employer and/or Op.^{b,c} ➢ The eHealth intervention provides realistic information regarding the recovery and RTW process. 	<ul style="list-style-type: none"> ✓ Compose reintegration plan ✓ Resume activities ✓ Compose reintegration plan ✓ Resume activities ✓ Recommendations for employee ✓ Frequently asked questions

APPENDIX 6 Continued

Determinant	Methods	Precondition	Strategy: Tools/Materials	Tool of eHealth intervention (table 2)
Social influence	<ul style="list-style-type: none"> • Mobilizing social support from family and friends⁴² 	<ul style="list-style-type: none"> ▪ Acceptance of assistance ▪ Helpful family and friends 	<p>▲ The eHealth intervention encourages and provides tools to consider the need for social support during the recovery period.^{b, c}</p>	<ul style="list-style-type: none"> ✓ Resume activities ✓ Frequently asked questions
	<ul style="list-style-type: none"> • Mobilizing support from other patients⁴² 	<ul style="list-style-type: none"> ▪ Openness about surgery and recovery to other patients 	<p>▲ The eHealth intervention contains a forum to contact other patients (peer support) and has functionality to send private messages. With these tools, personal strategies to deal with difficult situations and barriers may be shared and meetings can be organized if needed.^b</p>	<ul style="list-style-type: none"> ✓ Forum ✓ Links to other websites
	<ul style="list-style-type: none"> • Mobilizing social support / create openness and respect from work environment⁴² 	<ul style="list-style-type: none"> ▪ Openness about (implications of) surgery to employer ▪ Involvement of employer 	<p>▲ The employee can invite her employer for a section of the eHealth intervention, which shows common pitfalls and provides tools to help support the patient during the perioperative period and RTW process.^c</p> <p>▲ Possibility to print out the reintegration plan and share it with the employer.^{b, c}</p>	<ul style="list-style-type: none"> ✓ Video ✓ Recommendations employee ✓ Recommendations Employer
	<ul style="list-style-type: none"> • Create openness with partner⁴² 	<ul style="list-style-type: none"> ▪ Comprehension of partner 	<p>▲ Possibility to print out individualized convalescence recommendations to share with partner.^b</p>	<ul style="list-style-type: none"> ✓ Resume normal activities

^{1,2, etc.} See reference list Chapter 4
^b Information obtained in the focus group discussions
^c Expertise of the project group
^d Strader MK, Katz BM. Effects of a persuasive communication on beliefs, attitudes, and career choice. *J Soc Psychol* 1990 April;130(2):141-150.

APPENDIX 7

Evaluation questionnaire of the eHealth intervention ikherstel.nl for focus group participants

Questions asked to the focus group participants

1. Please indicate the degree you agree or disagree with the statement. In the last column you are able to explain your answer.

	Completely disagree	Disagree	Neutral	Agree	Completely agree	Explanation
The website was easy accessible	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
It was clear to me where I had to log into the website	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Navigating the website was easy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Finding answers to personal questions was easy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Obtaining recommendations for resumption of activities was easy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
It was clear to me where I could get help for problems regarding the website	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
I appreciated the layout of the website	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
The website is conveniently arranged	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
The texts on the website were easy to understand	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
The website is a good support for patients who want to resume their daily activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
The website is a good support for patients to communicate with their employer about reintegration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
The website offers enough opportunities to exchange experiences with other patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>

2. Please indicate on a five point scale how helpful the following tools of the website are:

	Not helpful at all	Not helpful	Neutral	Helpful	Very helpful	Not applicable
The movie on the website is	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The links to other websites are	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The forum on the website is	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The FAQ-list is	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Are there unnecessary tools on the website?

- Yes, namely:
- No

APPENDIX 8

Evaluation questionnaire of the eHealth intervention ikherstel.nl for professionals

Questions asked to medical doctors, eHealth specialists and a representative of a patient organisation

1. Please give your opinion about the different tools of the eHealth intervention ikherstel.nl (e.g. action list, movie, recommendations for employee/employer, FAQs, forum, guidelines, etc)?

2. Was it easy to navigate the website?

3. Are the texts on the website easy to understand?

4. Are there tools on the website that did not work properly?

5. Do you have any ideas to improve this website?

6. Do you have any other comments?

APPENDIX 9

Screenshots of the eHealth intervention 'ikherstel.nl' (<http://www.ikherstel.nl>)

The screenshot displays the ikherstel.nl website interface. At the top, a navigation menu includes 'startpagina', 'contact', and 'colofon'. The main header features the 'ikherstel' logo and a navigation bar with 'het onderzoek', 'deelname', 'team', 'nieuws', and 'nieuws'. Below the header, a large banner image shows a smiling woman. To the right, a login form is visible with the following text: 'Inloggen als deelnemer', 'gebruikersnaam:', 'wachtwoord:', 'Inloggen', and 'Klik hier als u uw wachtwoord bent vergeten'. Below the login form, a welcome message reads: 'Welkom bij ikherstel.nl', 'Deze website heeft tot doel om ondersteuning te bieden rondom (een aantal soorten) gynaecologische operaties. Momenteel worden verschillende vormen van zorg in onderzoeksverband geëvalueerd.', 'Wanneer u aan dit onderzoek deelneemt, kunt u rechts van deze tekst inloggen met uw gebruikersnaam en wachtwoord.', and 'Wilt u deelnemen aan het onderzoek? Bekijk de informatie voor deelname'. At the bottom right, logos for 'VU medisch centrum' and 'ZonMw' are displayed.



Actielijst

Hieronder, in het roze, staan de onderdelen welke van belang zijn om op korte termijn uit te voeren. Wanneer u een onderdeel van deze actielijst heeft afgerond, schuift het betreffende roze blok naar rechts en krijgt een grijze kleur.

- tevredenheid adviezen en herstel
- complicaties
- herstelmonitor
- vragenlijsten

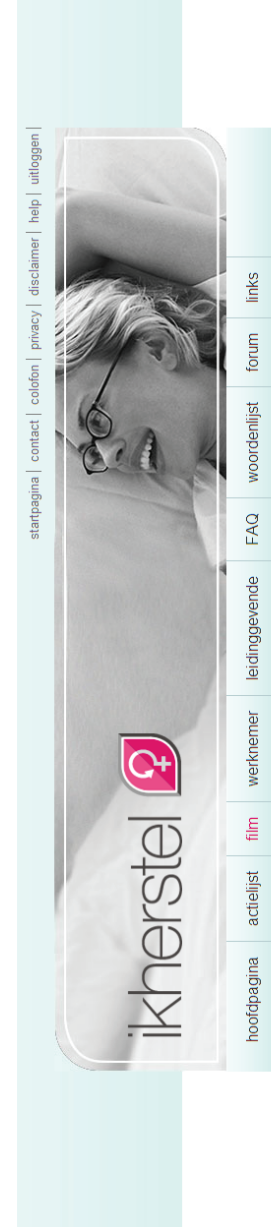
Overige Items

Hieronder, in het grijs, staan de onderdelen waarmee u voor het onderzoek niet op korte termijn iets hoeft te doen maar die wel beschikbaar zijn voor gebruik. De blauw gekleurde functionaliteiten adviseren we om zowel voor als na de operatie regelmatig te raadplegen.

- advies hervatten werkactiviteiten
- advies hervatten privé activiteiten
- uitnodigen leidinggevende

Snelmenu

- Mijn gegevens
- PDF privé advies
- PDF werk advies
- Nodig uw leidinggevende uit om de website te bekijken
- Handleiding bij gebruik website

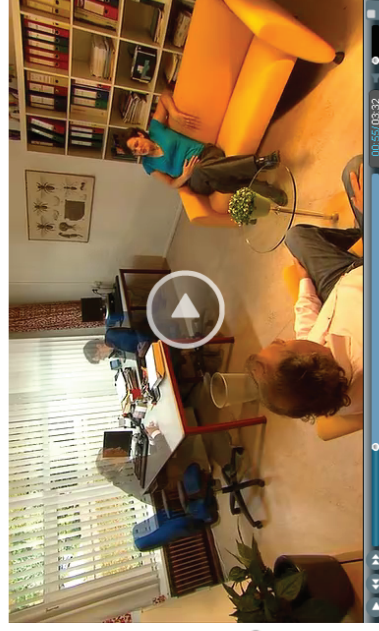


Informatie over de film

Deze film is gemaakt om inzicht te geven in de valkuilen en tips aan te dragen voor het oppakken van (werk) activiteiten na een gynaecologische operatie. De inhoud is gebaseerd op ervaringen van patienten die reeds een gynaecologische operatie hebben ondergaan. In de film spelen twee verhaallijnen. Eén waarin het herstel en terugkeer naar werk goed verloopt en één waarin dit niet goed verloopt. De nadruk wordt steeds gelegd op factoren die het herstel en terugkeer naar werk positief of negatief kunnen beïnvloeden. Deze factoren zijn soms uitvergroet om het contrast te scheppen, maar komen in de realiteit wel voor en zijn hierdoor zinvol om bij stil te staan.

De gehele film duurt ongeveer 9 minuten. Voor het gemak is de film opgedeeld in drie hoofdstukken: 'Voor de operatie', 'Na de operatie' en '5 maanden later', zodat u niet genoodzaakt bent de gehele film te bekijken.

- Trailer**
Samenvatting
- Deel 1**
Voor de operatie
- Deel 2**
Na de operatie
- Deel 3**
Vijf maanden later



TIPS VOOR WERKNEMERS

TIPS VOOR LEIDINGGEVENDEN

startpagina | contact | colofon | privacy | disclaimer | help | uitloggen



hoofdpagina | actielijst | film | werknemer | leidinggevende | FAQ | woordlijst | forum | links

Tips voor de werknemer [\(download PDF\)](#)



Vraag je gynaecoloog wat je wanneer weer kan na de operatie



Denk na over (aangepast) werk en maak een planning

Snelmenu

- Mijn gegevens →
- PDF privé advies →
- PDF werk advies →
- Nodig uw leidinggevende uit om de website te bekijken →
- Handleiding bij gebruik website →

startpagina | contact | colofon | privacy | disclaimer | help | uitloggen



hoofdpagina | actielijst | film | werknemer | leidinggevende | FAQ | woordlijst | forum | links

Baarmoeder verwijdering via een snede in de buikwand (AUE)

Zoek hier... Zoek!

Voer a.u.b. een woord in om te zoeken.

- Zoeken
- Bevolkingsonderzoek baarmoederskanker (BVO)
- Bloecherlies
- Buikwond
- Complicaties
- Eierstokken en eileiders
- Hechtingen
- Herstel thuis
- Lichamenlijk niet-verklaarbare of onduidelijke klachten
- Menstruatie/overgang
- Onduidelijkheid bij de adviezen voor het hervatten van activiteiten
- Operatie
- Overig
- Problemen in het algemeen
- Problemen met de urineweg/stoelgang
- Psychische gesteldheid
- Tedenen voor operatie
- Sexualiteit
- Telefoonnummers
- Vrouwelijke geslachtsorganen
- Woordlijst

Overzicht

- Baarmoeder verwijdering via een snede in de buikwand (AUE) →
- zoeken →
- bevolkingsonderzoek baarmoederskanker (BVO) →
- bloecherlies →
- buikwond →
- complicaties →
- eierstokken en eileiders →
- hechtingen →
- herstel thuis →
- lichamelijk niet-verklaarbare of onduidelijke klachten →
- menstruatie/overgang →
- onduidelijkheid bij de adviezen voor het hervatten van activiteiten →
- operatie →
- overig →
- problemen in het algemeen →

startpagina | contact | colofon | privacy | disclaimer | help | uitloggen



hoofdpagina actielijst film werknemer leidinggevende FAQ woordenlijst forum links

Toon ongelezen berichten sinds je laatste bezoek.
Toon nieuwe reacties op jouw berichten.
Totale tijd ingelogd: 6 minuten.

Zoek

Startpagina Help Zoek Mijn berichten

ikherstel.nl deelnemersforum

Algemeen

 Algemene discussie Praat gerust over van alles en nog wat op dit board.	2 Berichten 1 Topics	Laatste bericht door Patricia in Raaiingen Gepost op 15 augustus 2010, 16:43:17
 Werk Werkgerelateerde onderwerpen	0 Berichten 0 Topics	
 Prive Prive gerelateerde onderwerpen	0 Berichten 0 Topics	
 Operatie Operatie gerelateerde onderwerpen	2 Berichten 1 Topics	Laatste bericht door Shidy in Rechts gaat het na de ob... Gepost op 28 Juli 2010, 21:20:30

 Nieuw bericht  geen nieuw bericht **MARKER ALLE BERICHTEN ALS GELEZEN**

ikherstel.nl deelnemersforum - Infocentrum

startpagina | contact | colofon | privacy | disclaimer | help | uitloggen



hoofdpagina richtlijnen actielijst film werknemer leidinggevende FAQ woordenlijst forum links

Richtlijnen

Op deze pagina vindt u per ingreep richtlijnen betreffende het hervatten van activiteiten, casuïstiek, achtergrondinformatie en factoren die het herstel kunnen beïnvloeden.

Laparoscopische adnexchirurgie

- Richtlijn →
 - Samenstelling richtlijn in tabelvorm
 - Samenvatting richtlijn in tekstvorm
 - Gedetailleerd overzicht voor het hervatten van activiteiten
 - Bijlage 1: definitie en gradering van de gebruikte items in het gedetailleerde overzicht
 - Casuïstiek
 - Achtergrondinformatie
 - Medische factoren die het herstel beïnvloeden (nog niet beschikbaar)
 - Niet-medische factoren die het herstel beïnvloeden (nog niet beschikbaar)

Laparoscopische Supracervicale Hysterectomie (LSH)

Totale Laparoscopische Hysterectomie (TLH)

Vaginale Uterus Extirpatie (VUE)

Abdominale Uterus Extirpatie (AUE)



Definitief advies prive

Gebaseerd op operatiedatum: 11-11-2010

Uw operatie: TLH = Baarmoeder verwijdering via een kijkbuisoperatie

De gegeven adviezen geven aan wanneer de betreffende handelingen en activiteiten na een TLH operatie, door een expertgroep van artsen medisch gezien weer mogelijk worden geacht. Uw behandelend gynaecoloog heeft het schema (indien nodig) naar aanleiding van de operatie aangepast. De adviezen houden echter geen rekening met individuele beperkingen waardoor u bepaalde handelingen misschien niet mag verrichten. Raadpleeg bij twijfel uw behandelend gynaecoloog. Waar u in het document leest 'toegestaan vanaf' betekent dit: 'mag medisch gezien uitgevoerd worden vanaf'

Aantal dagen na de operatie	0	2	4	7	14	21	28	42
Tillen of dragen								
1 kg	toegestaan vanaf 11-11-2010							
5 kg	toegestaan vanaf 15-11-2010							
10 kg	toegestaan vanaf 18-11-2010							
15 kg	toegestaan vanaf 25-11-2010							
Een aaneengesloten periode lopen								
Minder dan 5 minuten	toegestaan vanaf 11-11-2010							
Ongeveer 15 minuten	toegestaan vanaf 15-11-2010							
Ongeveer 30 minuten	toegestaan vanaf 18-11-2010							
Ongeveer 1 uur	toegestaan vanaf 25-11-2010							
Totale duur lopen per dag								
Minder dan 30 minuten	toegestaan vanaf 11-11-2010							
Ongeveer 1 uur	toegestaan vanaf 18-11-2010							
Ongeveer 4 uur	toegestaan vanaf 25-11-2010							
Gehele dag (gedurende ± 8 uur)	toegestaan vanaf 02-12-2010							
Frequent traplopen (ong. 5x / uur)								
Ik moet één trap op- en aflopen	toegestaan vanaf 18-11-2010							
Frequent knielen of hurken (ong. 10x per uur)								
toegestaan vanaf	18-11-2010							
Stofzuigen								
toegestaan vanaf	25-11-2010							
Fietsen								
toegestaan vanaf	25-11-2010							
Autorijden								
(controleer ook altijd bij uw verzekering vanaf wanneer u verzekerd bent bij schade)	toegestaan vanaf 18-11-2010							
Een aaneengesloten periode zitten								
Minder dan 15 minuten	toegestaan vanaf 11-11-2010							
Ongeveer 30 minuten	toegestaan vanaf 13-11-2010							
Ongeveer 1 uur	toegestaan vanaf 13-11-2010							
Ongeveer 2 uur	toegestaan vanaf 15-11-2010							
Totale duur zitten per dag								
Minder dan 4 uur	toegestaan vanaf 11-11-2010							
Ongeveer 4 uur	toegestaan vanaf 18-11-2010							
6 tot 8 uur	toegestaan vanaf 18-11-2010							
Gehele dag (gedurende ong. 8 uur)	toegestaan vanaf 25-11-2010							
Een aaneengesloten periode staan								
Minder dan 5 minuten	toegestaan vanaf 11-11-2010							
Ongeveer 15 minuten	toegestaan vanaf 13-11-2010							
Ongeveer 30 minuten	toegestaan vanaf 18-11-2010							
Ongeveer 1 uur	toegestaan vanaf 25-11-2010							
Totale duur staan per dag								
Minder dan 30 minuten	toegestaan vanaf 11-11-2010							
Ongeveer 1 uur	toegestaan vanaf 18-11-2010							
Ongeveer 4 uur	toegestaan vanaf 25-11-2010							
Gehele dag	toegestaan vanaf 02-12-2010							

APPENDIX 10

Sickness benefit guidance in the Netherlands

In the Netherlands, employers are obliged to continue to pay—at least 70% of—the salaries of sick employees during the first two years of sickness. According to the Gatekeeper Improvement Act (April 2002) during this two year period, both the employer as the sick listed employee share a mutual responsibility to increase the probability of return to work. Both the employer as the employee may be sanctioned in case of noncompliance.

When an employee is sick listed for six weeks a reintegration report should be opened, which starts with a consultation with a company doctor (occupational physician [OP]) of the official Health and Safety Executive Organisation ('arbodienst'). The OP assesses the situation and makes a problem analysis, containing all the information relevant to the recovery, return to work and reintegration of the employee. Within two weeks, the employer and employee will then draw up a plan of action based on the concrete recommendations provided by the OP, which will be evaluated regularly, at least once every six weeks. Further consultations with the OP find place regularly as well.

The UWV (Institute for Employee Benefit Schemes) is the body commissioned by the Dutch Ministry of Social Affairs and Employment (SZW) to implement employee insurance schemes and acts as gatekeeper. When an employer did not reintegrated into the employment process within the two year period the UWV assesses if both parties have done everything possible to improve the chances of returning to work, by studying the total reintegration file. When both parties did make enough efforts, the employee can apply for a sickness benefit under the Work and Income according to Labour Capacity Act (WIA). However, if the employer failed to pursue an active absenteeism policy, sanctions may follow such as continuation of payment of the employee's salary. On the other side, if the employee hindered an early return to work, the payment of his sickness benefit may be suspended or reduced.

Workers without an employer are granted a benefit for two years under the Sickness Benefit Act, also provided by UWV. In these cases, UWV is responsible for sickness absence counselling and reintegration as well.

CHAPTER 11

Summary & Samenvatting



SUMMARY

Recovery and Return to Work after Gynaecological Surgery

Full recovery and RTW (return to work) following benign (laparoscopic) gynaecological surgery often takes much longer than expected from a medical perspective. This may have considerable consequences for the patient, her surroundings and her work environment.

We hypothesized that before the full advantage of improvements of (minimal invasive) surgery regarding reduced recovery, time to RTW and improved quality of life can be proven, perioperative care has to be improved. Furthermore, identification of the most important predictors for prolonged sick leave would provide an opportunity to identify patients with a high risk of prolonged sick leave and anticipate on this by giving them for example additional care. To improve perioperative care, patients' needs, beliefs and preferences regarding perioperative care and resumption of work activities needed to be studied. We hypothesized that expectations of patients regarding recovery and RTW could be optimized through the development of multidisciplinary guidelines, and improved perioperative communication between patients, physicians and employers. An eHealth intervention seemed to be a promising way to empower patients in their recovery process and with RTW.

In summary the aims of this project were:

1. To measure the impact of the level of invasiveness of gynaecological procedures on time to full RTW and to identify the most important sociodemographic, medical, and work-related factors that predict the risk of prolonged sick leave after gynaecological surgery;
2. To identify which activities are in need of recommendations for RTW after laparoscopic adnex surgery and all kinds of hysterectomy (laparoscopic, vaginal, abdominal) on benign indication and develop evidence- and consensus-based multidisciplinary recommendations for these types of surgery;
3. To develop an eHealth intervention and integrated care management (including a workplace intervention) to empower patients during the perioperative period in recovery and RTW, and to help other relevant stakeholders (e.g. care providers, employers) to support their patient/employee;
4. To evaluate the feasibility (including exploration of facilitators and barriers to future implementation) and effectiveness of the developed eHealth intervention and integrated care management & workplace intervention.

1. The impact of the level of invasiveness of gynaecological procedures on time to RTW and most important predictors of prolonged sick leave

Chapter 2 presents a prospective cohort study in 148 patients who underwent elective benign gynaecological surgery. In this study, we found that time to RTW after surgery was shorter in case of less invasive surgery. While RTW after minor surgery took 2 weeks, RTW after intermediate and major surgery took median more than 8 weeks, which is longer than what can be reasonably expected from a medical perspective. Secondly, we identified the most important sociodemographic, medical, and work-related preoperative factors that predict the risk of prolonged sick leave after gynaecological surgery. Baseline factors with the strongest predictive value of RTW 1 year after surgery was shown for: 1) level of invasiveness of surgery (minor surgery hazard ratio [HR] 0.51, 95% CI 0.32–0.81; intermediate surgery HR 0.20, 95% CI 0.12–0.34; major surgery HR 0.09, 95% CI 0.06–0.16); 2) RTW expectations before surgery (HR 0.55, 95% CI 0.36–0.84); and 3) preoperative functional status (HR 1.09, 95% CI 1.04–1.13). These factors together explained 58% of the variance in time to RTW between the patients in this study.

A prediction model was developed, by which patients with a high risk of prolonged sick leave may be identified and can be selected for additional perioperative care. When its recommended threshold value for high risk of prolonged sick leave is used, a sensitivity of 89% and a specificity of 86% is found. However, the generalizability of the prediction model has not yet been evaluated by external validation in another population of gynaecological patients which is necessary before clinical application. Considering the importance of patients' expectations of time to RTW, which may relatively easily be influenced, it seems advisable to optimize perioperative counselling and develop guidelines regarding RTW after gynaecological surgery.

2. Postoperative recommendations regarding resumption of (work) activities

Chapter 3 describes the development of structured detailed uniform convalescence recommendations after gynaecological surgery by a modified Delphi method amongst experts and a representative group of physicians. Multidisciplinary detailed recommendations for graded resumption of relevant activities were developed for an uncomplicated hysterectomy (laparoscopic supracervical, total laparoscopic/laparoscopic assisted, vaginal and abdominal hysterectomies) and laparoscopic adnexal surgery on benign indication. Recommendations were based on a literature review and a modified Delphi procedure among 12 experts, recruited in collaboration with the participating medical boards of gynaecologists, general practitioners and occupational physicians. Out of initially 65 activities, the expert panel judged 38 activities to be relevant for convalescence recommendations.

Gaps in evidence were filled by the expert opinion and consensus was achieved for all 38 graded activities after four Delphi rounds and two group discussions. The recommendations were judged as feasible by a representative sample of 26 gynaecologists, 19 general practitioners and 18 occupational physicians.

3. Development and evaluation of patient participation in an eHealth intervention and integrated care management

In **chapter 4** the development of an eHealth intervention to empower gynaecological patients during the perioperative period in order to obtain timely RTW, is described. The Intervention Mapping protocol was used to develop and tailor the eHealth intervention. Focus group discussions showed that sufficient, uniform, and tailored information regarding surgical procedures, complications, and resumption of activities and work were considered as most essential. Knowing whom to contact in case of mental or physical complaints, and counselling and tools for work reintegration were also considered important. With available literature, the results of the focus group discussions and the theory of planned behaviour, suitable tools and materials for the eHealth intervention were developed. This intervention provides an opportunity to compose detailed tailored instructions on the resumption of (work) activities, based on the operation date and how the surgery went (input of gynaecologist). These recommendations are based on the results of the Delphi method described in chapter 3. The eHealth intervention additionally provides tools (e.g. a video) to improve the communication between patients, care-providers and employers, to prevent conflicting recommendations and to stimulate patients and employers to discuss potential RTW problems and to develop a work reintegration plan. Furthermore, general information on the surgical procedure itself, the (possible) consequences of the surgery and clear instructions about which symptoms require additional consultation of care providers or adaptation of convalescence recommendations, is available in the eHealth intervention. The vast majority of the participating patients and stakeholders judged the intervention to be a promising eHealth tool to empower gynaecological patients during the perioperative period including return to (work) activities.

Chapter 5 focuses on the involvement of gynaecological patients in the development of the eHealth intervention. This eHealth intervention is considered as the patient version of a clinical guideline because it contains among others the web based version of the multidisciplinary convalescence recommendations developed by professionals during the Delphi method. The involvement of patients with incidental and nonthreatening diseases is complicated as little knowledge is available on how these patient groups can successfully be involved in guideline development, because these patient groups are most often not united in patient organizations and patients are only 'patient' for a limited period of time. Therefore, the participatory activities and the effectiveness of patient involvement in

this process was assessed by means of an evaluation framework based on a literature review and comprising predefined evaluation criteria detailing the participation process and generated outcomes. Patients were involved in the development process at three different stages: 1) 21 patients participated in three focus group discussions which were organized to identify the problems and needs of patients regarding perioperative care and resumption of employment; 2) 3 patients were involved in the development of the script for an instruction video which was part of the eHealth intervention; 3) 15 patients tested and evaluated the prototype of the eHealth intervention.

Consultation of individual patients by means of focus group discussions and with regular feedback moments proved to be effective for the development process of the web-based clinical guideline for patients. Patients' input contributed to applicability of the eHealth intervention in daily practice, which positively contributed to the embedding of the developed knowledge. Increased patient involvement by development of the multidisciplinary recommendations augmented the relevance and quality of the recommendations.

The integrated care management including a workplace intervention was based on a previous study of patients with chronic low back pain. This intervention was only offered when sick leave exceeds ten weeks, thus including only patients with a complicated recovery and RTW. It was performed by a multidisciplinary team consisting of a clinical occupational physician, an occupational therapist and a gynaecologist. The goal of this intervention was to prevent work disability by reducing barriers for RTW by improving communication between different care providers, occupational physician, employer and patient.

In **chapter 6**, the design of a randomized single blinded controlled trial to assess the effectiveness and feasibility of the eHealth intervention as part of a multidisciplinary stepped care program on recovery and full sustainable return to work is described.

Eligible participants for this study were women aged between 18-65 years, scheduled for a hysterectomy and/or a laparoscopic adnexal surgery on benign indication who were employed for at least 8 hours per week (paid or unpaid). Power calculation showed that a total sample size of at least 212 patients was required. A computer generated block randomisation was performed on an individual level in which patients were prestratified by hospital and type of surgery.

During the first step of the care program, all patients gained access to an eHealth intervention. The intervention group received access to the eHealth intervention which provided personalized tailor-made pre- and postoperative instructions on resumption of

daily activities including work, and tools to improve self-empowerment and to identify recovery problems (extensively described in chapter 4). The control group was provided with access to a placebo website which offered the patients telephone numbers of their hospitals and patient leaflets of the Dutch Society of Obstetrics and Gynaecology (NVOG) for a hysterectomy or a laparoscopic adnexal surgery on benign indication. The second step of the care program was only offered to the intervention group when sick leave exceeded ten weeks and thus to patients with a complicated recovery and RTW. It contains additional integrated care management by a multidisciplinary team and includes a workplace intervention. The goal of this step was to prevent work disability.

Sick leave duration until full sustainable RTW was the primary outcome measure. Secondary outcome measures were functional and general health status (QoL) as assessed according to Rand-36 Health Survey, recovery as measured by a validated Recovery Specific QoL questionnaire RS-QoL (RI10), and pain intensity measured using a Visual Analogue Scale (VAS) questionnaire. Prognostic factors that may influence the duration of sick leave such as sociodemographic data, type of surgery and complications during or related to the surgery, were recorded for adjustment in case of dissimilarities between the intervention group and the control group.

4. Process evaluation and effectiveness of the eHealth intervention and integrated care management

In **Chapter 7**, a systematic process evaluation of the multidisciplinary stepped care program was performed within the randomized controlled trial according to the recommendations of Linnan and Steckler. The first step including the eHealth intervention was intensively used and highly appreciated by the majority of the patients, employers and gynaecologists. The second step which contained the integrated care management including a work place intervention was hardly used. Most likely, the impact of this step could be increased by having the first consultation earlier in the recovery process and by increasing patients' internal motivation to use this second step.

Chapter 8 describes the results of the randomized controlled trial in which patients scheduled for a hysterectomy and/or laparoscopic adnexal surgery on benign indication were randomly assigned to the intervention (n=110) or the control (n=105) group. The intention-to-treat analysis showed that the eHealth intervention was effective on time to return to work (hazard ratio=1.43, 95% confidence interval 1.003 to 2.04, p=0.048). Median duration of sick leave until full sustainable return to work was 39 days (interquartile range 20-67 days) in the intervention group and 48 days (interquartile range 21-69) in the control group. After 26 weeks, pain intensity was lower (visual analogue scale; cumulative odds ratio=1.84, 95% confidence interval 1.04 to 3.25, p=0.035) and quality of life was

higher (Rand-36 health survey; between-group difference=30, 95% confidence interval 4-57, p=0.024) in the intervention group compared to the control group.

GENERAL DISCUSSION

In **chapter 9** main findings of this thesis are summarized, methodological considerations of the studies are discussed and recommendations for implementation and future research are provided.

The main conclusions are:

1. Most important predictors for prolonged sick leave were the level of invasiveness of surgery, RTW expectations before surgery and preoperative functional status.
2. Time to RTW after intermediate and major gynaecological surgery took longer than what can be reasonably expected from a medical perspective.
3. It seems of great importance to give more attention to preoperative counselling and the use of multidisciplinary guidelines regarding RTW, in order to take full advantage of the potential benefits of minimal invasive surgery. Therefore, we recommend to extend the development of multidisciplinary recommendations towards more types of surgeries.
4. The eHealth intervention 'www.ikherstel.nl' which was developed in this project, can be considered as an effective empowerment tool to help patients in their recovery process and with RTW. The vast majority of the users (patients, gynaecologists and employers) judged the intervention as (very) positive. Considering the reduction of sick leave and improvement of quality of life and pain in patients who underwent a hysterectomy and/or laparoscopic adnexal surgery, it has the potential to induce a considerable improvement of perioperative care and reduction of compensation costs.
5. The integrated care management including a work place intervention was hardly used. It is recommended to offer this intervention much earlier in the perioperative period.
6. To support implementation of the eHealth intervention in daily care, the generalizability and cost-effectiveness of this eHealth intervention should be evaluated by external validation in another population of gynaecological patients.
7. Considering the positive influence of this relatively cheap and minimal invasive intervention, it is recommended to extend this eHealth intervention to apply to other types of surgeries.

SAMENVATTING

Herstel en Terugkeer naar Werk na Gynaecologische Chirurgie

Volledig herstel en RTW (RTW= terugkeer naar werk) na (minimaal invasieve) chirurgie bij goedaardige gynaecologische aandoeningen, duurt vaak veel langer dan vanuit medisch perspectief kan worden verwacht. Dit vertraagde herstel kan aanzienlijke gevolgen hebben voor de patiënt en haar (werk)omgeving. Het is onze hypothese dat door verbetering van de zorg en begeleiding rondom de operatie en bij RTW, het effect van alle verbeteringen op het gebied van (minimaal invasieve) chirurgie met betrekking tot een afname in herstelduur, kortere tijd tot RTW en een betere kwaliteit van leven meer zichtbaar wordt. Hiernaast geeft identificatie van de belangrijkste voorspellers voor een verlengd ziekteverzuim de mogelijkheid om patiënten met een hoog risico op langdurig verzuim te identificeren en hierop te anticiperen door hen bijvoorbeeld extra begeleiding aan te bieden. Om de zorg gericht te kunnen verbeteren, is het van belang om de problemen, behoeften en wensen van patiënten met betrekking tot perioperatieve zorg en begeleiding bij de RTW na de operatie, in kaart te brengen. Ook denken wij dat het belangrijk is om patiënten realistischere verwachtingen met betrekking tot het hervatten van activiteiten en RTW na de operatie te bieden en dat dit kan door het ontwikkelen van multidisciplinaire hersteladviezen en verbeterde communicatie tussen patiënten en artsen. Een interactieve website lijkt ons een geschikte interventie om deze herstel- en werkadviezen aan patiënten aan te bieden en ook om de communicatie tussen patiënten, artsen en werkgevers te verbeteren. Voor patiënten met langdurig verzuim lijkt ons een geïntegreerd zorgprogramma inclusief een werkplaats interventie relevant.

Samengevat waren de doelstellingen van dit project:

1. Het meten van de impact van de mate van invasiviteit van de gynaecologische operatie op de tijd tot volledige RTW en de identificatie van de belangrijkste sociaal demografische, medische en werk-gerelateerde factoren die het risico op langdurig ziekteverzuim na een gynaecologische operatie voorspellen.
2. Vaststellen voor welke activiteiten in relatie tot RTW een hersteladvies ontwikkeld moet worden na een baarmoederverwijdering (laparoscopisch, vaginaal, abdominaal) en/of een eierstokoperatie op goedaardige indicatie. Vervolgens zal voor deze activiteiten een op bewijs en consensus gebaseerde multidisciplinaire richtlijn ontwikkeld worden.
3. Het ontwikkelen van een interactieve website en geïntegreerde zorg (inclusief een werkplek interventie) die patiënten in de perioperatieve periode bij RTW

ondersteunen. Tevens moet deze website andere relevante betrokkenen (b.v. zorgverleners, werkgevers) helpen bij de begeleiding van hun patiënt/werknemer.

4. Het uitvoeren van een procesevaluatie (inclusief het in kaart brengen van de mogelijkheden voor toekomstige implementatie) voor de interactieve website en het geïntegreerde zorgprogramma (inclusief de werkplek interventie) en tevens de effectiviteit van de interventies te evalueren.

1. De impact van de mate van invasiviteit van gynaecologische operaties op de tijd tot RTW en de belangrijkste voorspellers van langdurig ziekteverzuim

Hoofdstuk 2 beschrijft een prospectieve cohortstudie met 148 patiënten die een geplande gynaecologische operatie op goedaardige indicatie ondergingen. Uit deze studie bleek dat de tijd tot RTW na de operatie korter was als de chirurgie minder invasief was. Tijd tot RTW na een lichte chirurgische ingreep kostte 2 weken, terwijl de tijd tot RTW na matig zware en zware operaties mediaan meer dan 8 weken kostte, wat langer is dan wat redelijkerwijs vanuit medisch perspectief verwacht kan worden. Verder identificeerden we de belangrijkste sociaal demografische, medische, en werk-gerelateerde preoperatieve factoren die het risico op langdurig ziekteverzuim na de gynaecologische operatie voorspellen. Preoperatieve factoren met de sterkst voorspellende waarde op RTW 1 jaar na de operatie waren: 1) mate van invasiviteit van de chirurgie (lichte chirurgie hazard ratio [HR] 0.51, 95% CI 0.32 – 0.81; matig zware chirurgie HR 0.20, 95% CI 0.12-0.34; zware chirurgie HR 0.09, 95% CI 0.06 – 0.16); 2) RTW verwachtingen voorafgaand aan de operatie (HR 0.55, 95% CI 0.36-0.84); en 3) preoperatieve functionele status (HR 1.09, 95% CI 1.04-1.13). Deze factoren samen verklaarden 58% van de variatie in tijd tot RTW tussen de patiënten in deze studie.

We ontwikkelden een model waarmee patiënten met een hoog risico op langdurig ziekteverzuim kunnen worden geïdentificeerd en geselecteerd voor bijvoorbeeld extra perioperatieve zorg. Bij gebruik van de aanbevolen drempelwaarde voor een hoog risico op langdurig ziekteverzuim vonden we een sensitiviteit van 89% en een specificiteit van 86%. Echter, het predictiemodel is nog niet gevalideerd in een andere populatie gynaecologische patiënten, wat nodig is voordat het model klinisch toegepast kan worden. Gezien het belang van de verwachting van patiënten betreffende tijd tot RTW, iets wat relatief gemakkelijk kan worden beïnvloed, lijkt het wenselijk om de perioperatieve counseling te optimaliseren en richtlijnen met betrekking tot RTW na gynaecologische operaties te ontwikkelen.

2. Postoperatieve adviezen betreffende het hervatten van (werk) activiteiten

Hoofdstuk 3 beschrijft de ontwikkeling van multidisciplinaire gedetailleerde hersteladviezen voor het hervatten van activiteiten na een gynaecologische operatie. De adviezen werden ontwikkeld met behulp van een gemodificeerde Delphi methode onder een groep expert

artsen en werden tevens beoordeeld door een andere grote groep representatieve artsen. De aanbevelingen voor gegradueerde hervatting van activiteiten werden ontwikkeld voor een ongecompliceerde baarmoederverwijdering (laparoscopisch supracervicaal, totaal laparoscopisch/laparoscopisch geassisteerd, vaginaal en abdominaal) en laparoscopische adnex chirurgie, allen op goedaardige indicatie. De hersteladviezen waren gebaseerd op een overzicht van de literatuur en een gemodificeerde Delphi procedure onder 12 specialisten, geworven in samenwerking met de beroepsverenigingen van gynaecologen, huisartsen en bedrijfsartsen. Uit aanvankelijk 65 activiteiten beoordeelde het expert panel 38 activiteiten als relevant om hersteladviezen voor te ontwikkelen. Lacunes in de literatuur werden ingevuld door advies van het expert panel en voor alle 38 gegradueerde activiteiten werden na vier Delphi ronden en twee groepsdiscussies consensus bereikt. De aanbevelingen werden als relevant en goed werkbaar beoordeeld door een representatieve steekproef van 26 gynaecologen, 19 huisartsen en 18 bedrijfsartsen.

3. Ontwikkeling en evaluatie van patiëntparticipatie aan een interactieve website en geïntegreerde zorg

In **hoofdstuk 4** wordt de ontwikkeling beschreven van een interactieve website gericht op de ondersteuning van gynaecologische patiënten in de perioperatieve periode, met als doel een tijdige RTW. Het Intervention Mapping-protocol is gebruikt voor het ontwikkelen en op maat maken van de interactieve website. Focusgroep discussies toonden aan dat adequate, uniforme en op maat gesneden informatie over chirurgische ingrepen, complicaties en hervatting van activiteiten en werkzaamheden na de operatie, werden beschouwd als het meest essentieel. Duidelijkheid over met welke hulpverlener contact op te nemen in geval van mentale of lichamelijke klachten na de operatie en begeleiding en hulpmiddelen bij re-integratie op het werk werden eveneens belangrijk geacht. Met behulp van de beschikbare literatuur, de resultaten van de focusgroep discussies en de theorie van 'gepland gedrag', werden geschikte functionaliteiten en materialen voor de interactieve website ontwikkeld. De interactieve website biedt de mogelijkheid om gedetailleerde instructies op maat op te stellen over de gegradueerde hervatting van (werk) activiteiten, gebaseerd op de operatiedatum en het verloop van de operatie (m.b.v. input van gynaecoloog). Deze aanbevelingen zijn gebaseerd op de uitkomsten verkregen met de in hoofdstuk 3 beschreven Delphi methode. Daarnaast biedt de interactieve website hulpmiddelen (zoals een video) ter verbetering van de communicatie tussen patiënten, zorgverstrekkers en werkgevers, om zo conflicterende adviezen te voorkomen en om patiënten en werkgevers te stimuleren potentiële RTW problemen al voor de operatie te bespreken en een plan voor re-integratie te ontwikkelen. Bovendien is algemene informatie over de chirurgische procedure zelf, de (eventuele) gevolgen van de operatie en duidelijke instructies over symptomen die extra raadpleging van zorgverleners of aanpassing van de herstel-adviezen vereisen beschikbaar. De overgrote meerderheid van de deelnemende patiënten, zorgverstrekkers en werkgevers beoordeelden de interventie

als een veelbelovend middel om gynaecologische patiënten tijdens de perioperatieve periode inclusief de terugkeer naar (werk)activiteiten te ondersteunen.

Hoofdstuk 5 richt zich op de betrokkenheid van gynaecologische patiënten bij de ontwikkeling van de in hoofdstuk 4 beschreven interactieve website. Deze interactieve website wordt beschouwd als de patiënten versie van een klinische richtlijn, omdat het o.a. de web-based versie van de multidisciplinaire herstelsteladviezen bevat welke door de experts tijdens de Delphi studie zijn ontwikkeld (hoofdstuk 3). De betrokkenheid van patiënten met incidentele ziekten in de ontwikkeling van richtlijnen is ingewikkeld en over succesvolle betrokkenheid is weinig bekend, omdat deze groepen patiënten meestal niet verenigd zijn in patiëntenorganisaties en patiënten alleen 'patiënt' zijn voor een beperkte periode. Daarom zijn de participatieve activiteiten en de doeltreffendheid van de betrokkenheid van patiënten bij dit proces beoordeeld met behulp van een evaluatiekader. Dit evaluatiekader is gebaseerd op een literatuuronderzoek en bestaat uit vooraf gedefinieerde evaluatiecriteria om het participatieproces en de uiteindelijke resultaten te beoordelen. Patiënten waren betrokken bij het ontwikkelingsproces in drie verschillende fasen: 1) 21 patiënten hebben deelgenomen aan drie focusgroep discussies, welke werden georganiseerd om de problemen, behoeften en wensen van de patiënten met betrekking tot perioperatieve zorg en hervatting van het werk na de operatie te identificeren; 2) 3 patiënten waren betrokken bij de ontwikkeling van het script voor een instructie-video die deel uitmaakt van de interactieve website; 3) 15 patiënten hebben het prototype van de interactieve website getest en geëvalueerd.

Consultatie van individuele patiënten door middel van focusgroep discussies en met regelmatige feedbackmomenten bleek effectief voor het ontwikkelingsproces van de web-based versie van de klinische richtlijn. De input van patiënten heeft bijgedragen aan de toepasbaarheid van de interactieve website voor de dagelijkse praktijk, wat positief bijdraagt aan de implementatie. Toegenomen betrokkenheid van patiënten bij de ontwikkeling van de multidisciplinaire hersteladviezen vergroot de relevantie en kwaliteit ervan.

De geïntegreerde zorg en de werkplek interventie waren gebaseerd op een eerder onderzoek verricht onder patiënten met chronische lage rugpijn klachten. Dit deel van de interventie werd in ons onderzoek alleen aangeboden als het verzuim langer dan tien weken duurde en dus ook alleen aan patiënten die een gecompliceerd herstel en RTW meemaakten. De interventie werd uitgevoerd door een multidisciplinair team bestaande uit een klinische arbeidsgeneeskundige, een ergotherapeut en een gynaecoloog. Het doel van deze interventie was om arbeidsongeschiktheid te voorkomen door belemmeringen voor RTW weg te halen en door de communicatie tussen de verschillende zorgverleners, de bedrijfsarts, de werkgever en de patiënt te verbeteren.

In **hoofdstuk 6** wordt het ontwerp van een gerandomiseerde blind gecontroleerde trial beschreven. Dit onderzoek is verricht om de effectiviteit en de toepasbaarheid van de interactieve website als onderdeel van een multidisciplinair zorgprogramma gericht op herstel en volledige duurzame terugkeer naar werk te beoordelen. Voor deze studie werden vrouwen benaderd voor deelname als zij tussen de 18 en 65 jaar oud waren, gepland stonden om een baarmoederverwijdering en/of eierstokoperatie op goedaardige indicatie te ondergaan in één van de 7 aan dit onderzoek deelnemende ziekenhuizen en als zij tenminste 8 uur per week (betaald of onbetaald) werk verrichtten. Uit een power berekening bleek dat er een totale steekproef van ten minste 212 patiënten nodig was. Een computer gegenereerde blok randomisatie werd uitgevoerd op individueel niveau waarin patiënten werden gestratificeerd naar ziekenhuis en type chirurgie.

In de eerste stap van het zorgprogramma kregen alle patiënten toegang tot de interactieve website: www.ikherstel.nl. Na inloggen kreeg de interventiegroep toegang tot de uitgebreide interactieve website die persoonlijke, op maat gemaakte pre- en postoperatieve instructies voor hervatting van de dagelijkse en werk activiteiten verschaft. Tevens waren op deze website hulpmiddelen te vinden ter ondersteuning van de patiënt bij het herstel en terugkeer naar werk en voor een tijdige identificatie van problemen bij het herstel (de inhoud van deze website is uitgebreid besproken in hoofdstuk 4). Als patiënten van de controlegroep op www.ikherstel.nl inlogden, kregen ze toegang tot een placebo-website waarop de telefoonnummers van hun ziekenhuizen en patiëntfolders betreffende een baarmoederverwijdering en/of eierstokoperatie op goedaardige indicatie, afkomstig van de Nederlandse Vereniging voor Obstetrie en Gynaecologie (NVOG), terug te vinden waren. De tweede stap van het zorgprogramma werd alleen aangeboden aan de interventiegroep als hun ziekteverzuim de tien weken overschreed en daarmee alleen aan patiënten met een gecompliceerd herstel en RTW. Deze stap bestond uit het aanbieden van geïntegreerde zorg door een multidisciplinair team en een werkplek interventie en had als doel om arbeidsongeschiktheid te voorkomen.

De primaire uitkomstmaat was de duur van het ziekteverzuim tot volledige, duurzame RTW. Secundaire uitkomstmaten waren kwaliteit van leven beoordeeld volgens de Rand-36 vragenlijst; herstel zoals gemeten door de herstelindex-10 (RI10); en de mate van pijnintensiteit, gemeten aan de hand van de visueel analoge-schaal (VAS) vragenlijst. Prognostische factoren die invloed kunnen hebben op de duur van ziekteverzuim zoals sociaal demografische gegevens, type chirurgie en complicaties tijdens of in verband met de operatie, werden geregistreerd om hiervoor te kunnen corrigeren voor het geval dat er in deze variabelen belangrijke verschillen waren tussen de interventiegroep en de controlegroep.

4. Procesevaluatie en het effect van de interactieve website en geïntegreerde zorg

In **hoofdstuk 7** werd binnen de gerandomiseerde gecontroleerde trial een systematische procesevaluatie van het multidisciplinaire zorgprogramma uitgevoerd volgens de aanbevelingen van Linnan en Steckler. De resultaten van deze procesevaluatie lieten zien dat de interactieve website intensief werd gebruikt en tevens door de meerderheid van de patiënten, gynaecologen en werkgevers zeer positief beoordeeld werd. Het geïntegreerde zorgprogramma met inbegrip van de werkplek interventie, was nauwelijks gebruikt. Waarschijnlijk kan het effect van deze 2^e interventie worden vergroot door het eerste consult al eerder in het herstelproces plaats te laten vinden en door de intrinsieke motivatie om deze interventie te gebruiken, te vergroten.

Hoofdstuk 8 beschrijft de resultaten van de gerandomiseerde gecontroleerde trial waarin patiënten die gepland stonden voor een baarmoederverwijdering en/of een eierstokoperatie op goedaardige indicatie willekeurig aan de interventie (n = 110) of aan de controlegroep (n = 105) toegewezen werden. De intention-to-treat analyse toonde aan dat de interactieve website een positieve invloed had op tijd tot RTW (hazard ratio = 1.43, 95%-betrouwbaarheidsinterval 1.003 - 2.04, p = 0.048). Mediane duur van ziekteverzuim tot volledige, duurzame terugkeer naar werk bedroeg 39 dagen (interkwartielafstand 20-67 dagen) in de interventie groep en 48 dagen (interkwartielafstand 21-69) in de controlegroep. Na 26 weken was in de interventiegroep de pijnintensiteit lager (VAS; cumulatieve kansen verhouding = 1.84, 95%-betrouwbaarheidsinterval 1.04-3.25, p = 0,035) en de kwaliteit van leven hoger (Rand-36; verschil tussen groepen = 30, 95% betrouwbaarheidsinterval 4-57, p = 0.024) dan in de controlegroep.

ALGEMENE DISCUSSIE

In **hoofdstuk 9** worden de belangrijkste bevindingen van dit proefschrift samengevat, worden methodologische overwegingen van de studies besproken en worden aanbevelingen voor implementatie en toekomstig onderzoek verstrekt.

De belangrijkste conclusies zijn:

1. De belangrijkste voorspellers voor langdurig ziekteverzuim zijn de mate van invasiviteit van chirurgie, verwachtingen met betrekking tot RTW voorafgaand aan de operatie en preoperatieve functionele status.
2. Tijd tot RTW na matig zware en zware gynaecologische operaties duurt in de praktijk langer dan wat vanuit een medische perspectief redelijkerwijs kan worden verwacht.
3. Het lijkt van groot belang om meer aandacht aan preoperatieve counseling en het gebruik van multidisciplinaire richtlijnen met betrekking tot RTW te schenken, om hierdoor optimaal te kunnen profiteren van de potentiële voordelen van minimaal

invasieve chirurgie. Daarom raden we aan om de ontwikkeling van multidisciplinaire richtlijnen naar meer soorten operaties uit te breiden.

4. De interactieve website 'www.ikherstel.nl' die werd ontwikkeld in dit project, kan worden beschouwd als een effectief instrument om patiënten in hun herstelproces en met RTW te helpen. De overgrote meerderheid van de gebruikers (patiënten, gynaecologen en werkgevers) hebben de interventie als (zeer) positief beoordeeld. Gezien de afname van de duur van het ziekteverzuim, de verbetering van de kwaliteit van leven en de vermindering van pijn bij patiënten die een baarmoederverwijdering en/of een eierstokoperatie ondergingen na gebruik van de interventie, heeft de interactieve website potentie voor een aanzienlijke verbetering van de perioperatieve zorg en het verminderen van verzuimkosten bij deze groep patiënten.
5. Het geïntegreerde zorgprogramma met inbegrip van een werkplekinterventie werd nauwelijks gebruikt. Wij raden aan om deze interventie veel eerder in de perioperatieve periode aan te bieden.
6. Ter ondersteuning van implementatie van de interactieve website in de dagelijkse zorg, moet de (kosten) effectiviteit onderzocht worden in nog een groep gynaecologische patiënten die een baarmoederverwijdering en/of laparoscopische adnexoperatie ondergaan.
7. Gezien de positieve invloed van deze relatief goedkope en minimaal invasieve interventie wordt aanbevolen om deze interactieve website uit te breiden naar andere type operaties.

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LIST OF ABBREVIATIONS

AH	Abdominal Hysterectomy
ASE	Attitude–Social influence–self-Efficacy
BQ	Baseline Questionnaire
CI	Confidence Interval
CMS	Content Management System
DWP	Department for Work and Pensions
FAL	Functional Ability List
FAQ	Frequently Asked Questions
FGD	Focus Group Discussion
GAS	Goal Attainment Scales
GP	General Practitioner
HR	Hazard Ratio
IC	Informed Consent
ICF	International Classification of Functioning
IM	Intervention Mapping
IP	Insurance Physician
IQR	Inter Quartile Range
ITT	Intention-To-Treat
LAVH	Laparoscopic Assisted Vaginal Hysterectomy
LSH	Laparoscopic Supracervical Hysterectomy
MDA	Medical Disability Advisor
NHG	The Dutch College of General Practitioners
NVAB	The Dutch Association of Occupational Physicians
NVOG	The Dutch Society of Obstetrics and Gynaecology
OP	Occupational Physician
OT	Occupational Therapist
PP	Per Protocol
QoL	Quality of Life
RCT	Randomized Controlled Trial
RI	Recovery Index
RNA	Return to Normal Activities
RTW	Return To Work
TLH	Total Laparoscopic Hysterectomy
VH	Vaginal Hysterectomy

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