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 were 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 an 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**

Volledig herstel en RTW (RTW= terugkeer naar werk) na (minimaal invasive) chirurgie bij goedadaardige 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 invasive) 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 activeren. Daarbij is het belangrijk dat we zorgen voor een betere communicatie rondom de perioperatieve zorg en begeleiding na de operatie, in kaart te brengen. Ook denken wij dat het belangrijk is om patiënten realistischer verwachten 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 sociale en demoografische factoren die het risico op langdurig ziekteverzuim na een gynaecologische operatie voorspellen.
2. Vaststellen welke activiteiten in relatie tot RTW een hersteladvies ontwikkeld moeten worden na een baarmoederverwijdering (laparoscopisch, vaginaal, abdominaal) en/of een eistekoperatie op goedardige indicatie. Vervolgens zal dit voor deze activiteiten een op basis van consensus gebaseerde multidisciplinaire richtlijn ontwikkeld worden.
3. Het ontwikkelen van een interactieve website en geïntegreerd zorg (inclusief een werkplek interventie) die patiënten in de perioperatieve periode bij RTW