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“How are you?”—A systematic e-assessment of postoperative recovery

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INTRODUCTION

Day surgery, in which patients are admitted to the surgical unit, undergo an operation, and are discharged on the same day, is a well-established practice in many European countries. National statistics for Sweden show that the majority of surgical procedures over the past 5 years were performed in day-surgery settings (approximately 2 million/year), with no age restrictions for day-surgery treatments (Stomberg et al 2013). Advances in surgical and anaesthetic techniques, particularly for day surgery, have dramatically reduced the frequencies of mortality and major morbidity. Yet, a patient admitted for day surgery is postoperatively monitored for only a few hours before being discharged, at which point the patient must assume primary responsibility for monitoring his or her own recovery (Young et al 2000). These practices leave many patients feeling insecure, worried, and lonely after discharge, due to a lack of feedback and information regarding normality and relevant expectations during the recovery process (Berg et al 2013). Furthermore, patients' capacity to obtain, process, and understand the information necessary to make appropriate health decisions can be limited; for example, by low health literacy. Individuals with basic or low-basic health literacy often enter healthcare areas feeling ashamed and frequently have poor outcomes (Ross 2013), increased use of emergency care, elevated risks for some chronic diseases and overall mortality, and poorer use of preventive health services (Kobayashi et al 2013). Regardless of low or high health literacy, patients may also feel dependent on primary care and confused about the accessibility and structure of such care (Berg et al 2013). During the first 2 weeks of recovery, many patients experience symptoms that require unplanned health care contacts, phone calls, or outpatient clinic visits (Segerdahl et al 2008). In North America, these unexpected visits and readmissions to hospitals cost billions of dollars annually (Semple et al 2015).

Swedish day-surgery units employ a wide variety of practices for routine follow-up assessments of adults who have undergone surgery. Some utilize a phone follow-up (usually only once) performed by a nurse from the day-surgery ward. The nurse usually calls the patient on the day after the surgery to ask about recovery and complications (Stomberg et al 2013). However, studies report difficulty contacting between 15% and 27% of patients (Gray et al 2010). Instead of telephone follow-up, other day-surgery unit contact the patient's general practitioner to inform them about the procedure and request their help with follow-up (Stomberg et al 2013).

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Common complications in the postoperative recovery period include pain, nausea and vomiting, headache, backache, sore throat, hoarseness, urinary retention, coldness, nerve injuries, and injuries to the lips and mouth (Myles et al 2000). Yet, there is no systematic use of a validated questionnaire to measure postoperative recovery (Stromberg et al 2013). One well-validated instrument for measuring self-assessed postoperative recovery is the Quality of Recovery-40 (QoR-40) (Myles et al 2000). The QoR-40 was previously tested in a population of Swedish patients who underwent day surgery, and it was found to be valid and reliable for detecting changes in postoperative recovery (Idvall et al 2009). This study, together with 17 international studies (including a total of 3459 patients), was included in a meta-analysis that showed that the QoR-40 has excellent validity, reliability, responsiveness, and clinical utility for use in a broad range of patient populations (Gornall et al 2013). However, all of these studies relied on paper-based assessments postoperative recovery. Valderas et al (2008) recommended that future studies should focus on the improvement and utilization of modern technology, as well as on the theoretical and organizational systems required to create a care structure that involves patient-reported outcome measures (PROM) as a fundamental element. While paper-based PROMs were originally used, since the late 1990s, different computerized applications have been tested, including touch-screen data entry and web-based systems (Rose & Bezjak 2009). Data suggest that self-monitoring applications can positively influence the users' health (Klasnja & Pratt 2012). Other viable options for real-time assessment include native software applications with graphical user interfaces that can be uploaded onto smartphone devices. Smartphone applications can be purpose-built, enabling greater flexibility and ease of use (Klasnja & Pratt 2012), and they are increasingly used in health care (Ainsworth et al 2013). Smartphones are ideal for this use, as they are ubiquitous and owned by a large majority of people of all ages. Smartphone ownership crosses socioeconomic and geographic boundaries, and these devices are capable of capturing large quantities of information. Smartphones can also increase patients' access to health expertise and make such information available when patients most need it. Automated systems can encode the types of feedback that clinicians should provide based on patients' tracked data (Weaver et al 2007).

The primary responsibility for monitoring recovery after discharge is with the patient. Patients may feel insecure about the recovery process and postoperative complications that could be

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avoided, and this may lead to unexpected visits to primary care and emergency departments, as well as hospital readmission, which is associated with multiplied costs as well as additional suffering for the patient. Furthermore, staff at day-surgery units do not get any feedback about patients' recovery after discharge; therefore, they are unable to perform any quality improvements in evidence-based care, which can lead to improvements in patients' postoperative recovery process.

Aim

The primary aim of this study is to analyze whether a systematic e-assessment follow-up of patients undergoing day surgery is cost effective. Secondary aims are (a) to explore whether a systematic e-assessment follow-up after day surgery has a positive effect on postoperative recovery, health-related quality of life (QoL), and overall health; (b) to determine whether differences in health literacy have a substantial and distinct effect on postoperative recovery, health, and QoL; and (c) to describe day-care patient and staff experiences with a systematic e-assessment follow-up after day surgery.

METHODS AND ANALYSIS

This will be a mixed-methods study design that includes a multicenter, two-group, parallel, randomized controlled trial (RCT) and qualitative interview studies. The trial will be conducted in four day-care units in Sweden: Mora hospital, Örebro University hospital, Capio Läkargruppen AB, and Länssjukhuset Ryhov in Jönköping.

Participants

One thousand patients >17 years of age who are undergoing day surgery will be included. All included patients must understand the Swedish language in speech and writing, have an Android or iPhone OS smartphone, and give their informed consent to participate. Patients will be excluded if they are undergoing abortion, if their journal entries indicate alcohol and/or drug abuse or memory impairment, or if they are participating in another clinical trial.

Sample size

Calculation of the sample size was based on the assumption of detecting a difference of 0.03 in quality-adjusted life year (QALY) weights between the patients (0.76 in control group vs.

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0.79 in the intervention group) for the primary outcome, with an alpha of 0.01 (two-sided) type I error and a power of 0.90. This assumption indicated a sample size of 477 participants per group, which would result in a sample size of 1000 patients to account for dropouts. To our knowledge, this intervention has not been tested in any previously published study or clinical trial protocol. Therefore, the sample size is guided by values of QALY weights in patients with asymptomatic gallstone diseases (0.76) and a surgical scar (0.76) (Bass et al 1994).

Randomization

During the preoperative stage, the participants will be stratified based on gender and randomized to either the intervention (follow-up of postoperative recovery measured via smartphone app) or the control (which will receive standard care; i.e., no follow-up) group. This will be completed using computer-generated randomization, including random permuted blocks to ensure similar numbers of participants in each group.

Blinding

Masking will be single-blinded; i.e., investigators will be blind to group assignment. However, due to the nature of the intervention, neither the patients, the staff at the day care department, or the research nurses can be blinded to randomization.

Recruitment

The surgeons will, during their preoperative consultation, provide brief oral information about the study. Written information will be provided to the patients preoperatively, together with the appointment for the operation. The details of the study and its potential benefits as well as risks will be explained thoroughly to the patient by the research nurse at the day-surgery department. If the patient agrees to study participation, written informed consent will be obtained, after which the patient will be assessed for eligibility by the research nurse.

Intervention

The study will begin preoperatively, when a native application, Recovery Assessment by Phone Points (RAPP) is installed on each patient's own smartphone. The application (app) includes the Swedish web version of the QoR (SwQoR). The SwQoR was developed to be

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suitable for administration via a smartphone app (Jaensson et al, submitted), and we are conducting an ongoing pilot study to evaluate the number of items the patient should answer on each day (Dahlberg et al, manuscript being prepared). Patients will be individually provided with information and the opportunity to test the application and input sample answers. The functionalities of the RAPP, including how to move from question to question, how to input a response, and how to use the navigation keys, will be carefully explained by the research nurse.

After a patient is discharged from the day-surgery department, the patients in the intervention group will answer the RAPP daily for 14 days. His or her smartphone will initiate the postoperative recovery measurements daily through a “push” function. Each question will appear separately on the mobile phone screen and will disappear from the screen immediately after a response is given. The RAPP also contains a question asking if the patient wants to be contacted by a nurse, which they will answer with a YES or NO. If YES, a nurse at the day surgery department will contact the patient and offer further information and assistance. The number of contacts and the reasons for contact requests will be documented.

Both preoperatively and prior to their discharge from the hospital, the patients in the smartphone group will be informed and thoroughly trained regarding how to document their postoperative recovery on the smartphone. Each participant will receive a daily reminder, either via the application or via an incoming short message service (SMS) communication. Participants in the control group will be provided with standard information regarding postoperative recovery and will be told who to contact in the event of any complications.

Primary outcome

The primary outcome is cost effectiveness compared to no use of the application. The analysis of cost effectiveness may consider the costs associated with the follow-up, gained QALYs from SF-6D. The SF-6D provides a means for using the SF-36 by estimating a preference-based single-index measure for health from these data using general population values (Braizer et al 2002). This analysis will be complemented with information regarding the individuals’ willingness to pay for the follow-up, number of healthcare contacts, and duration and degree of sick leave.

Secondary outcomes

Secondary outcomes will include postoperative recovery, QoL, overall health, and health literacy. All participants will evaluate their postoperative recovery using the SwQoR.

Participants in the intervention group will answer by using the smartphone app, and those in the control group will use a conventional paper-based questionnaire. To ensure that there are no differences in answers between the app-based and the paper-based SwQoR, we are calculating the intraclass correlation coefficient in our ongoing pilot (Dahlberg et al, manuscript being prepared).

QoL will be assessed with the SF-36, which comprises eight scales that measure physical and mental health status (Taft et al 2001). The constructed summary score is standardized in relation to the population norm (Sullivan et al 2002). The instrument has been validated for use in the Swedish population, and normative data for the general population are available for comparisons (Taft et al 2001).

Overall health will be measured by the EQ visual analog scale (EQ-VAS). This scale consists of a vertically graduated scale with endpoints (anchors) of 0 indicating worst imaginable health state and 100 indicating best imaginable health state (EuroQol Group 1990).

To measure health literacy (i.e., the equality perspective), we will use the Japanese Communicative and Critical Health Literacy scale (C&CHL scale; Ishikawa et al 2008), which includes items covering the major aspects of communicative and critical health literacy. The C&CHL scale has been translated into Swedish and demonstrated to be understandable, stable over time, and equivalent to the Japanese C&CHL scale in terms of language and content (Wångdahl & Mårtensson 2014).

Patient experience of the intervention

Following the RCT, inductive qualitative research will be conducted to explore the perceptions, views, experiences, and expectations of the participants from the intervention group. Data will be collected based on 20 semistructured interviews. A purposeful sampling will be conducted. Patients who wished to be contacted by a nurse via the RAPP during the intervention period will be selected, with variation regarding age and gender. The aim of this study is to explore the participants' experience of postoperative recovery and how using the

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RAPP for postoperative follow-up influenced this recovery. Further questions will be asked regarding the participants' experience of being contacted by a nurse; in addition, descriptions and eventual expectations about the help that was received will also be solicited. All interviews will be recorded and transcribed verbatim.

Staff experience of the implementation

As part of this RCT, we will also describe the staffs' experience of using a systematic postoperative follow-up tool and their willingness to pay for the follow-up service. We plan to make the data from the patients' daily postoperative recovery measurements available to the staff at the day-surgery departments and to record the experiences and opinions of the clinicians. The study design will be qualitative and will use focus-group interviews. One to two focus-group interviews with 5–8 participants each will be conducted at each hospital, depending on the size of the day-surgery department. Staff from the day-surgery department (nurses, surgeons, and anesthesiologists) will be asked to participate in the interviews. All interviews will be recorded and transcribed verbatim.

Data collection procedure

Data for both primary and secondary quantitative outcomes will be collected at specified time points over the first 14 postoperative days (Table 1). EQ VAS and SF-36 will also be assessed preoperatively in connection with the operation. Within 1 month postoperation, semistructured one-on-one interviews will be conducted with patients from the RAPP group. Focus group interviews with the staff will be conducted within 4 months from the start of implementation of the systematic assessment of postoperative recovery (Table 1).

Table 1. Data collection procedure

	Preoperation RAPP/control	1–7 days postoperation RAPP/control	14 days postoperation RAPP/control	1 month postoperation RAPP/control	4 months postoperation staff
EQ-VAS	+/+		+/+		
SF-36	+/+		+/+		
Demographic data	+/+				

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Sick leave, number of days			+/+		
Number of and reasons for health contacts			+/+		
Willingness to pay			+/+		
SwQoR		+/+	+/+*		
Number of and reasons for contacts with the nurse			+/-		
Critical Health Literacy scale			+/+		
Interviews				+/-	
Focus interviews and willingness to pay					+

*8–14 days.

RAPP, Recovery Assessment by Phone Points; SwQoR, Swedish web-based Quality of Recovery.

Health economic analysis method

The analysis in this study will be a cost-utility analysis with a societal perspective; gained quality adjusted life years (QALY) will be used to measure health effects (Huang et al 2012). Cost-effectiveness ratios will be based on changes in QoL, health care consumption, production losses (being on sick leave), and costs for the RAPP group compared with the control group. Gained QALY will be calculated from the difference in QoL between the intervention and control groups at 2 weeks postoperation. Health care consumption will be considered at 4 months postoperation.

A scatter plot of bootstrapped incremental cost-effectiveness ratios will be created by repeatedly drawing a random sample, with replacement using parameters estimated from the study. Individual values will be used for gained QALY, health care consumption, and production losses, and mean values will be used for costs related to the intervention (RAPP) that participants received. This method will be used to calculate the likelihood that the intervention was cost effective using several thresholds of willingness to pay for a QALY. Further, mean net monetary benefit and confidence intervals of net monetary benefit will be estimated for these threshold values. The result will be presented in a cost-effectiveness acceptability curve. As a complement, an analysis of willingness to pay for the application may be conducted. This analysis will capture process values about user experience of the app.

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Willingness to pay will not be used together with gained QALY and loss of production due to risk of overestimation.

Statistical analysis

Analyses of the primary and secondary outcomes will be performed with the full analysis set. For baseline variables, summary statistics will be constructed using frequencies and proportions for categorical data and means and standard deviations (SDs) for continuous variables. Intention-to-treat analysis will be performed in all participants, and patients without major protocol violations will have a per-protocol analysis. For baseline variables, summary statistics will be constructed using frequencies and proportions for categorical data and means and SDs for continuous variables. The baseline characteristics age, gender, type of surgery and anesthesia, American Society of Anesthesiologists classification, health (EQ-VAS), and QoL (SF-36) will be described and assessed for any imbalance between the two groups. Patient characteristics will be compared using Fisher's exact test for categorical outcomes and *t*-tests or the Wilcoxon rank-sum test for continuous variables, as appropriate. An imbalance will be considered if any of these characteristics between the two groups have a *p* value of <0.01.

Differences between groups will be analyzed using Fisher's exact test for categorical outcomes and *t*-tests or the Wilcoxon rank-sum test for continuous variables, as appropriate. Moreover, health-literacy differences among patients are expected to be found. To examine these aspects more closely, analyses aimed at determining whether differences in health literacy have significant and distinct effects on postoperative recovery, health or QoL, gender, age, and educational levels will be performed. This will be explored statistically using linear mixed models (LMM). A *p* value of <0.01 in the two-tailed test will be considered statistically significant for all outcomes.

Qualitative analysis

Thematic analysis, described by Braun & Clarke (2006), will be used to provide in-depth analyses on patients' experience of postoperative recovery. Qualitative analyses will be carried out by researchers, all of whom are trained and experienced in qualitative approaches.

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These analyses will start with the researchers reading through the transcribed interviews to familiarize themselves with the data. After reading through the interviews, the coding process will be conducted and the codes will be put together in themes and sub-themes. Themes and codes will be reviewed and refined to ensure correspondence with the original data and to ensure that themes and sub-themes are internal homogenous and external heterogeneous. Finally, the results of all analyses will be discussed by the whole research team. Qualitative analyses will adhere to the quality criteria outlined by Lincoln and Guba (1985) to assure trustworthiness and rigor; that is, credibility, transferability, dependability, and confirmability.

Ethical perspective

The study will conform to the principles outlined in the Declaration of Helsinki, and approval from the ethical review board will be sought. Participants will be given written informed consent forms to sign after receiving written and verbal information about the study, including the purpose and procedures, the voluntary nature of participation, and the option to withdraw at any time. They will also be guaranteed confidentiality and secure data storage. Those who refrain from taking part or who do not participate in the entire study will not receive a lower level of care or treatment. We will follow good clinical practice in the conduct of clinical trials on medicinal products for human use and await ethical approval from the regional review board before starting the project. The ongoing pilot project has been approved by the regional ethical review board in Uppsala, Sweden (number 2014/456). The trial will be registered at Clinicaltrials.gov, a global registry and results database of publicly and privately supported clinical studies of human participants (<https://clinicaltrials.gov/>).

DISCUSSION

To our knowledge, there are presently no systematic assessments of patients' postoperative recovery—whether paper-based, web-based, or smartphone-based. This project is also unique in its intention to develop a smartphone application to be used with the patient's own smartphone. By contrast, the majority of national and international studies have developed mobile apps for use on devices owned by the researchers. For example, to study the use of a mobile app to monitor postoperative recovery, Semple et al (2015) gave the patients either a smartphone or a tablet, with the app downloaded to the device prior to discharge. This unique aspect of the present study is a strength with regard to implementation, as it would be difficult

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to convince the healthcare system to adopt the costs for all of the devices that would need to be obtained if they were provided to patients.

The present project is based on the patient perspective, and patient participation is important when determining which questions/items it is most important to ask about during the recovery period (Dahlberg et al in manuscript). Notably, patient participation is a core element in patient-centered care.

Our project also aims to integrate society's need for quality auditing and assurance in healthcare with patients' need for safe and reliable information and communications about their postoperative recovery. The project will increase patients' self-care. This systematic follow-up can be used for remote symptom monitoring during postoperative recovery and will enable evaluations and comparisons of the utility and cost effectiveness of different technical approaches to factors such as care, drug treatment, care activities, and competence development. This systematic follow-up will also be useful in helping to guide improvements in the areas of anesthesia and postoperative care of patients who currently have low-quality postoperative recovery.

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