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Study protocol

RAPP, a systematic e-assessment of postoperative recovery in patients undergoing day surgery: study protocol for a mixed-methods study design including a multicenter, two-group, parallel, single -blind randomized controlled trial and qualitative interview studies

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ABSTACT

Introduction Day surgery is a well-established practice in many European countries, but only limited information is available regarding postoperative recovery at home though there is a current lack of a standard procedure regarding postoperative follow-up. Furthermore, there is also a need for improvement of modern technology in assessing patient related outcomes such as native software applications. This article describes the RAPP study protocol, a mixed-methods study to evaluate if a systematic e-assessment follow-up in patients undergoing day surgery is cost effective and improves postoperative recovery, health and quality of life.

Methods and analysis This study is a mixed-methods study design that includes a multicenter, two-group, parallel, single-blind randomized controlled trial (RCT) and qualitative interview studies. One thousand patients >17 years of age who are undergoing day surgery will be randomly assigned to either e-assessed postoperative recovery follow-up daily in 14 days measured via smartphone app including the Swedish web-version of Quality of Recovery (SwQoR) or to standard care (i.e. no follow up). The primary aim is cost effectiveness. Secondary aims are improvements 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.The primary will be measured at 2 weeks postoperatively and secondary outcomes b) at 1 and 2 weeks and c) at 1 and 4 months.

Ethics and dissemination This study was approved by the regional ethical review board in Uppsala, Sweden (approval number 2015/262). . The study findings will be published in peer-reviewed journals and presented at national and international conferences.

Trial registration number This trial was registered with the US National Institutes of Health Clinical Trials Registry: NCT02492191

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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[1]. 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 [2]. 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 [3]. 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 [4], increased use of emergency care, elevated risks for some chronic diseases and overall mortality, and poorer use of preventive health services [5]. 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 [3]. During the first 2 weeks of recovery, many patients experience symptoms that require unplanned health care contacts, phone calls, or outpatient clinic visits [6]. In North America, these unexpected visits and readmissions to hospitals cost billions of dollars annually [7].

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 [1]. However, studies report difficulty contacting between 15% and 27% of patients [8]. 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 [1].

Common complications in the postoperative recovery period include pain, nausea and vomiting, headache, backache, sore throat, hoarseness, urinary retention, coldness, nerve

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injuries, and injuries to the lips and mouth [9]. Yet, there is no systematic use of a validated questionnaire to measure postoperative recovery [1]. One well-validated instrument for measuring self-assessed postoperative recovery is the Quality of Recovery-40 (QoR-40) [10 9]. 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 [11]. 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 [12]. However, all of these studies relied on paper-based assessments postoperative recovery. Valderas et al [13] 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 [14]. Data suggest that self-monitoring applications can positively influence the users' health [15]. 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 [15], and they are increasingly used in health care [16]. 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 [17].

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 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

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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. 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 suitable for administration via a smartphone app [18], and includes 24 items [19] scored on a 11 point visual analog scale from 0 "none of the time" to 10 "all of the time" [18],. 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

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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 [20]. 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.

QoL will be assessed with the SF-36, which comprises eight scales that measure physical and mental health status [21]. The constructed summary score is standardized in relation to the population norm [22]. The instrument has been validated for use in the Swedish population, and normative data for the general population are available for comparisons [21].

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 [23].

To measure health literacy (i.e., the equality perspective), we will use the Japanese Communicative and Critical Health Literacy scale (C&CHL scale) [24], 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 [25].

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 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 postoperatively, 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

	Preoperatively RAPP/control	**7 days postoperatively RAPP/control**	**14 days postoperatively RAPP/control**	**1 month postoperatively RAPP/control**	**4 months postoperatively staff**
EQ-VAS	+/+		+/+		
SF-36	+/+		+/+		
Demographic data	+/+				
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					+

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

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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 postoperatively. Health care consumption will be considered at 4 months postoperatively.

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. 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 [26], 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. 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 [27] 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[28]. 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. The project has been approved by the regional ethical review board in Uppsala, Sweden (number 2015/262). The trial was registered at the US National Institutes of Health Clinical Trials Registry: NCT0249219, a global registry and results database of publicly and privately supported clinical studies of human participants.

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 [7] 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 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 [18, 19]. 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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CONTRIBUTORSHIP STATEMENT

UN and KD conceived the study in conjunction with staff located in the day surgery departments. LH contributed with facts about the health economy evaluation and SO with the qualitative design. UN led the calculation of the sample size and UN, KD, MJ and ME the quantitative outcomes. UN drafted the grant proposal and is responsible for study implementation All authors critically reviewed and approved the final version of the manuscript. All authors participated in the preparation of the manuscript, providing written comments on drafts and approving the final version.

COMPETING INTEREST

Author Ulrica Nilsson and Örebro University Enterprise AB hold shares in RAPP-AB. None of the other authors have any potential conflicts of interest.

DATA SHARING STATEMENT

The results of the study will be disseminated at several research conferences and as published articles in peer-reviewed journals. The study will be implemented and reported in line with the CONSORT statement.

Study protocol

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Not applicable Study protocol
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	NCT02492191 2
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

RAPP, a systematic e-assessment of postoperative recovery in patients undergoing day surgery: study protocol for a mixed-methods study design including a multicenter, two-group, parallel, single -blind randomized controlled trial and qualitative interview studies

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Study protocol

RAPP, a systematic e-assessment of postoperative recovery in patients undergoing day surgery: study protocol for a mixed-methods study design including a multicenter, two-group, parallel, single -blind randomized controlled trial and qualitative interview studies

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Study protocol

ABSTRACT

Introduction Day surgery is a well-established practice in many European countries, but only limited information is available regarding postoperative recovery at home though there is a current lack of a standard procedure regarding postoperative follow-up. Furthermore, there is also a need for improvement of modern technology in assessing patient related outcomes such as mobile applications. This article describes the RAPP study protocol, a mixed-methods study to evaluate if a systematic e-assessment follow-up in patients undergoing day surgery is cost effective and improves postoperative recovery, health and quality of life.

Methods and analysis This study has a mixed-methods study design that includes a multicenter, two-group, parallel, single-blind randomized controlled trial (RCT) and qualitative interview studies. One thousand patients >17 years of age who are undergoing day surgery will be randomly assigned to either e-assessed postoperative recovery follow-up daily in 14 days measured via smartphone app including the Swedish web-version of Quality of Recovery (SwQoR) or to standard care (i.e. no follow up). The primary aim is cost effectiveness. 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 postoperative recovery have an association with patients characteristic, type of surgery and anesthesia: (c) to determine whether differences in health literacy have a substantial and distinct effect on postoperative recovery, health, and QoL; and (d) to describe day surgery patient and staff experiences with a systematic e-assessment follow-up after day surgery.
The primary aim will be measured at 2 weeks postoperatively and secondary outcomes (a-c) at 1 and 2 weeks and (d) at 1 and 4 months.

Trial registration number This trial was registered with the US National Institutes of Health Clinical Trials Registry: NCT02492191

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.

Study protocol

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[1]. 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 [2]. 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 [3]. 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 [4], increased use of emergency care, elevated risks for some chronic diseases and overall mortality, and poorer use of preventive health services [5]. 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 [3]. During the first 2 weeks of recovery, many day surgery patients experience symptoms that require unplanned health care contacts, phone calls, or outpatient clinic visits [6]. In North America approximately 70 million day surgery procedures are conducted yearly an unexpected visits and readmissions to hospitals due to a day surgery procedure cost billions of dollars annually [7].

In Sweden and internationally day-surgery units employ a wide variety of practices for routine follow-up assessments of adults who have undergone surgery[7]. 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 [1]. However, studies report difficulty contacting between 15% and 27% of patients [8]. Instead of telephone follow-up, other day-surgery units contact the patient's general practitioner to inform them about the procedure and request their help with follow-up [1].

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 [9]. Yet, there is no systematic use of a validated questionnaire to measure postoperative recovery [1]. One well-validated instrument for

Study protocol

measuring self-assessed postoperative recovery is the Quality of Recovery-40 (QoR-40) [10 9]. 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 [11]. 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 [12]. However, all of these studies relied on paper-based assessments postoperative recovery. Valderas et al [13] 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 [14]. Data suggest that self-monitoring applications can positively influence the users' health [15]. 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 [15], and they are increasingly used in health care [16]. 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 [17].

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 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.

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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 postoperative recovery have an association with patients characteristic, type of surgery and anesthesia: (c) to determine whether differences in health literacy have a substantial and distinct effect on postoperative recovery, health, and QoL; and (d) to describe day surgery 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 in Örebro, 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, if they are participating in another clinical trial or suffering from visual impairment.

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. 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) or a surgical scar (0.76) (Bass et al 1994).

Randomization

During the preoperative stage, the participants will be 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 mobile 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 suitable for administration via a smartphone app [18], and includes 24 items [19] scored on a 11 point visual analog scale from 0 "none of the time" to 10 "all of the time" [18]. 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 [20]. This analysis will be complemented with information regarding number of healthcare contacts, and duration and degree of sick leave (Figure 1).

Secondary outcomes

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

Study protocol

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 (Figure 1).

QoL will be assessed with the SF-36, which comprises eight scales that measure physical and mental health status [21]. The constructed summary score is standardized in relation to the population norm [22]. The instrument has been validated for use in the Swedish population, and normative data for the general population are available for comparisons [21].

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 [23].

To measure health literacy (i.e., the equality perspective), we will use the Japanese Communicative and Critical Health Literacy scale (C&CHL scale) [24], 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 [25].

Patient experience of assessing postoperative recovery and being contacted by a nurse

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 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 assessing patients' postoperative recovery

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 and Figure 1). EQ VAS and SF-36 will also be assessed preoperatively in connection with the operation. Within 1 month postoperatively, semi-structured 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. + indicates that data will be collected at this time and – that no data will be collected for the control group.

	Preoperatively RAPP/control	**7 days postoperatively RAPP/control**	**14 days postoperatively RAPP/control**	**1 month postoperatively RAPP/control**	**4 months postoperatively staff**
EQ-VAS	+/+		+/+		
SF-36	+/+		+/+		
Demographic data	+/+				
Sick leave, number of days			+/+		
Number of and reasons for health contacts			+/+		
SwQoR		+/+	+/+		
Number of and reasons for contacts with the nurse			+/-		
Critical Health Literacy scale			+/+		
Interviews				+/-	

Focus interviews and willingness to pay					+

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 postoperatively. Health care consumption will be considered at 4 months postoperatively.

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. 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 between the groups, 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. The magnitudes of between-group differences will be analysed by calculating effect size. Moreover, differences in postoperative recovery and health-literacy differences among patients are expected to be found. To examine these aspects more closely, analyses aimed at determining whether differences in postoperative recovery associate with patients characteristics, in type of surgery or anesthesia, or in health literacy have significant and distinct effects on postoperative recovery, health or QoL, and patients characteristics 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 and Clarke [26], 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. 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 [27] 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 [28]. 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. The project has been approved by the regional ethical review board in Uppsala, Sweden (number 2015/262). The trial was registered at the US National Institutes of Health Clinical Trials Registry: NCT0249219, a global registry and results database of publicly and privately supported clinical studies of human participants.

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 [7] 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 to convince the healthcare system to also adopt the costs for all of the devices that would need to be obtained if they were provided to patients. Even so, to implement this e-assessed follow-up there is a need to show cost-effectiveness of such intervention particularly to the decision-makers and politicians.

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 [18], [19]. Notably, patient participation is a core element in patient-centered care. In the present study the patients have also the opportunity to get support of a nurse after discharge by using the mobile app. In our preliminary findings[19], patients express that this opportunity gives a sense of security as it is usually hard to get in contact with the care provider after discharge and that this app was a simple solution for that problem.

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.

Current study status The study began recruiting participants in October 2014 and depending on eligible participant the data collection will be completed in June 2015.

Contributors UN and KD conceived the study in conjunction with staff located in the day surgery departments. LH contributed with facts about the health economy evaluation and SO with the qualitative design. UN led the calculation of the sample size and UN, KD, MJ and ME the quantitative outcomes. All authors participated in the preparation of the manuscript, providing written comments on drafts and approving the final version.

Competing interests Author Ulrica Nilsson and Örebro University Enterprise AB hold shares in RAPP-AB. None of the other authors have any potential conflicts of interest.

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Data sharing statement According to Swedish regulations, other researchers who want to retrieve the data can do so after approved application to the Swedish Ethical Board.

Study protocol

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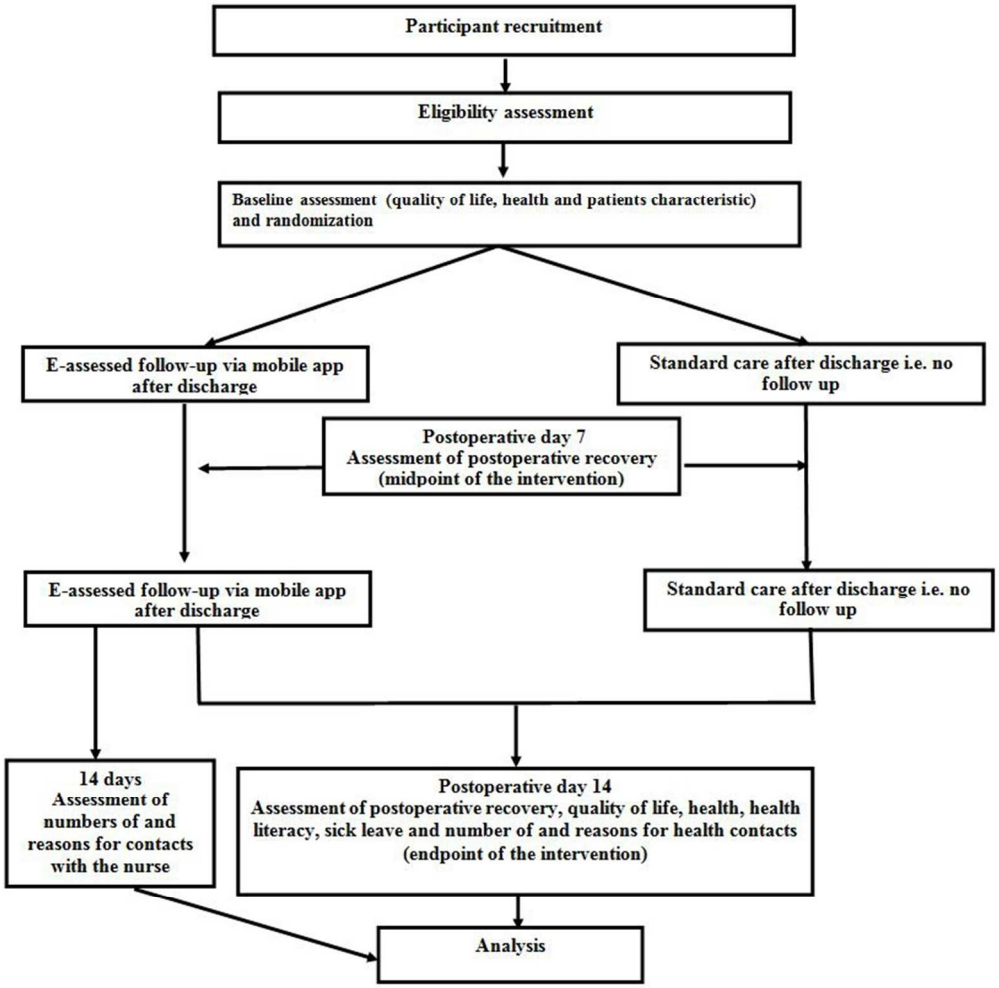

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Not applicable Study protocol
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	NCT02492191 2
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.