Quality of Recovery after day care surgery with app controlled Remote Monitoring: a randomized controlled trial

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To assess the experienced quality of recovery after day care surgery between patients provided with a smartphone application for remote monitoring and patients receiving standard of care (no remote monitoring).

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

Summary

ID

NL-OMON51950

Source
ToetsingOnline

Brief title
QuReMo trial

Condition

- Other condition

Synonym
day care surgery

Health condition

Dagbehandeling chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: OLVG;CWZ en Maasstad

Intervention

Keyword: DayCare, Postoperative, Recovery, RemoteMonitoring

Outcome measures

Primary outcome

The main study endpoint is the overall score on the Quality of Recovery-15

questionnaire (QoR-15) at post discharge day 4.

Secondary outcome

Secondary endpoints are the overall score on the Quality of Recovery-15 at

day*s 1 and 7 post discharge.

Study description

Background summary

To date the majority of surgical interventions is performed in day care and patients are being discharged soon after the first critical postoperative period. At home, patients have limited options to contact the hospital in case of severe pain and nausea. We have provided day care surgical patients with a smartphone application to self-record postoperative pain and nausea after being discharged from hospital. Furthermore, it provides a tool to immediately contact the hospital in case of (severe) pain or nausea. Despite the promising initial patient experiences of this application, we do not know whether is improves the patients experience of the recovery period.

Study objective

To assess the experienced quality of recovery after day care surgery between patients provided with a smartphone application for remote monitoring and patients receiving standard of care (no remote monitoring).

Study design

(Non blinded) randomized controlled trial

Intervention

The intervention group receives remote monitoring during weekdays from 8 am to 17 pm up to 7 days postoperative by providing them a smartphone application. With this application, patients are able to record experienced pain and nausea. In-addition they can send a text messages to the hospital. Daily monitoring is performed by an anaesthesia professional who will contact the patient in case severe pain or nausea is reported in the app. The control group receives standard of care (with post-discharge verbal and paper instructions).

Study burden and risks

Participating in this study does not pose any additional risks for patients allocated to either the intervention group with remote monitoring or for patients allocated to the standard of care group. Patients in the remote monitoring group are being asked to use a smartphone application to record pain and nausea daily for up to 7 days post discharge. Recording pain and nausea will take 2 minutes daily. Patients from both groups are being asked to fill in the validated QoR-15 questionnaire one day before admission and on the 1st, 4th and 7th day post discharge this will take 2.5 minutes. No extra hospital visits, physical examinations or tests are required. Patients in the remote monitoring group could benefit from participating in the study because they are monitored daily by a healthcare professional. Therefore, severe pain, nausea and possibly other complications can be noticed and managed earlier.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age: older than or equal to 18 years
Pre-anaesthesia conclusion: ASA I to III
Speaking and understanding of the Dutch language
Scheduled for day care surgery
In possession of a smartphone

Exclusion criteria

Age: younger than 18 years
Pre-anaesthesia conclusion: ASA >= IV
Not able to speak or understand the Dutch language
Mentally impaired (e.g. dementia, retardation)
Scheduled for non-day care surgery with discharge the next day following the day of the surgical intervention
Not in possession of a smartphone

During study:
Patients who experience a unexpected post-operative complication or prolonged recovery with the result that discharge on the same day of the surgical intervention is not possible will be excluded

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2022
Enrollment:	310
Type:	Actual

Medical products/devices used

Generic name:	Home monitoring smartphone application
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-02-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	01-07-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05244772
CCMO	NL78144.100.21