

# Smartphone reported direct patient feedback on postoperative pain that is directly passed on to surgical ward nurses, effects on patient reported postoperative pain outcomes and pharmaco-therapy. A prospective, randomized, single-blinded, controlled trial.

Published: 03-06-2022

Last updated: 13-01-2025

To establish the effect of a smartphone application for direct patient feedback on patient reported postoperative pain outcomes and pharmaco-therapy in clinical patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON51889

### Source

ToetsingOnline

### Brief title

Direct Patient Feedback on postoperative pain

### Condition

- Other condition

### Synonym

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chronic postoperative pain, postoperative pain

## **Health condition**

(chronic) post-operative pain

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## **Intervention**

**Keyword:** Chronic post-surgical pain, Direct patient feedback, Post-operative pain, Smartphone application

## **Outcome measures**

### **Primary outcome**

Patient reported time in severe pain per separate clinical admission day (8 a.m.-8 a.m.), as reported by APS-POQ-R.

### **Secondary outcome**

During clinical admission measured as reported by APS-POQ-R.

-Patient reported least pain and worst pain level over past 24 hours.

-Number of patient self-reported pain scores per 24 hours.

-Patient reported impact of pain on activity and sleep.

-Patient reported wish for more treatment.

-Patient reported abilities to participate in pain treatment decisions.

-Patient reported adverse effects (nausea, tiredness, dizziness, itching).

-Patient reported anxiety and helplessness.

- Patient reported satisfaction on pain treatment result.
- Numbers and dose of analgesics administered over a period of 24 hours, starting after discharge from post anesthetic care unit (PACU).
- Median patient reported least and worst pain score in the intervention and control group for each separate hospital admission day, this will be determined for day time (08 a.m.-10 p.m.) and night time (10 p.m. - 8 a.m.) separately.
- All nurse documented pain-scores in the electronic health record.

After hospital discharge measured as reported by BPI-sf.

- Median patient reported pain score over the past 24 hours (NRS 0-10) prior to the moment of measurement.
- Patient reported least pain, worst pain and current pain (NRS 0-10)
- Any pain treatment (including pharmacological) received and percentage of pain relief.
- Functional impact of pain (NRS 0-10), social impact of pain (NRS 0-10) and emotional impact of pain (NRS 0-10).

## Study description

### Background summary

Postoperative pain is common, can be severe, has a negative impact on outcomes after surgery and brings along major economic costs for society. A substantial part of patients may develop persistent post-surgical pain. Severity and duration of pain after surgery appear to have a role in this process but the transition from acute postoperative pain to chronic pain is only partially understood. Effective treatment of postoperative pain is hampered by several

barriers, including the way measurement of pain and registration of pain-scores are carried out by nurses in clinical practice.

Modern technology offers new opportunities for pain measurement and direct patient feedback on postoperative pain, during and also after clinical admission. We developed a smartphone application that allows clinical patients to report pain scores and other pain related outcomes on postoperative pain with their own telephone device. Patient reported pain scores > 3 on a Numeric Rating Scale (NRS) 0-10 are immediately passed on to the nurse who receives a message of the reported pain score. This can lead to earlier detection of pain and a more timely treatment resulting in improved patient reported outcomes on postoperative pain.

## **Study objective**

To establish the effect of a smartphone application for direct patient feedback on patient reported postoperative pain outcomes and pharmaco-therapy in clinical patients.

## **Study design**

A single center, prospective, randomized, single-blinded, controlled trial.

## **Intervention**

Applying a system in which patients undergoing surgery can report pain scores and other pain-related outcomes with their own smartphone, both during hospitalization and for three months after discharge. During clinical admission patient reported pain scores > 3 (NRS 0-10) in the intervention group are immediately passed on to the nurse who will receive a notification on a smartphone. In the control group this is not the case. After discharge, patients will report pain scores every two weeks for three months.

## **Study burden and risks**

During the study, apart from the interventions mentioned earlier, all participants will receive care as usual. These include regular pain checks during standard nursing rounds multiple times a day, and the use of the bed bell to contact a nurse if a patient wants to discuss about perceived pain. The pharmacological post-operative pain therapy will be fully performed in accordance with the current guidelines that apply to the participating departments.

We see no additional risks for study participants.

Direct patient feedback may lead to earlier recognition and treatment of postoperative pain, this can be a benefit for participants of the intervention group.

## 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

- Participants have to be 18 years or older
- Participants need to undergo a clinical surgical procedure for one of the three medical specialties mentioned above (abdominal oncology, gynecology, urology).
- Participants must be admitted to one of the participating surgical wards directly following discharge from the post anesthetic care unit after surgery.
- Participants have to stay admitted to the wards at least till the next day after surgery.
- Participants have to be in the possession of a smartphone that is able to receive a SMS text message and can send data to a web based server.
- Participants must master the Dutch language and provide their written informed consent on forehand

-- Participants answered the first questionnaire (APS-POQ-R part I) before surgery

## Exclusion criteria

- Patients who do not wish to participate.
- Patients that for physical or cognitive impairments are unable to participate.
- Patients who do not possess a smartphone.
- Patients who are transferred to another ward during hospital admission e.g. the intensive care unit the first night after surgery.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	12-07-2022
Enrollment:	160
Type:	Actual

## Ethics review

Approved WMO	
Date:	03-06-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 01-12-2022

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20330

Source: NTR

Title:

### In other registers

Register	ID
CCMO	NL78324.042.21
Other	NL9697
OMON	NL-OMON20330