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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51889

Source
ToetsingOnline

Brief title
Direct Patient Feedback on postoperative pain

Condition

- Other condition

Synonym

1 - Smartphone reported direct patient feedback on postoperative pain that is direct ... 29-05-2025

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

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

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, gyneacology, 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 sent 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: Nationaal Trial Register
Title:

In other registers

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