Direct Patient Feedback

Published: 31-08-2021
Last updated: 13-01-2025

A direct patient feedback system can lead to earlier detection of pain and a more timely treatment resulting in improved patient reported outcomes on postoperative pain.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20330

Source
Nationaal Trial Register

Brief title
DPF

Health condition

(chronic) post-operative pain

Sponsors and support

Primary sponsor: University Medical Center Groningen, dept of Anaesthesiology
Source(s) of monetary or material Support: funding=sponsor

Intervention

Outcome measures

Primary outcome

Primary outcome during clinical hospital admission is the patient reported time in severe pain per separate clinical admission day. The duration of severe pain is determined as a percentage of time over 24 hours from 8 a.m. till 8 a.m. the following day.

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

A direct patient feedback system can lead to earlier detection of pain and a more timely treatment resulting in improved patient reported outcomes on postoperative pain.

Study design

During clinical admission four types of patient reported data will be collected: - On the day of hospital admission, participants will be questioned for the existence of a persistent painful condition for 3 months or more before coming into hospital for surgery. If yes, they will be asked to report pain severity by NRS (0-10) and location of this persistent pain. - Starting the first day following surgery participants will receive the APS-POQ-R every day at 8 a.m.. - Starting after discharge from post anesthetic care unit participants will receive an SMS text message every full two hours between 10 a.m. and 10 p.m.. In this SMS participants are encouraged to deliver a self-reported NRS pain score by clicking a link attached to the SMS. - Between the afore mentioned 2 hour time intervals and between 10 p.m. and 8.a.m. participants can report a pain-score on their own initiative with a maximum of one report per hour. Process of data collection after discharge After hospital discharge participants will receive the BPI-sf every two weeks for a period of three months.

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.

Contacts

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Eligibility criteria

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. - 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.

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:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 51889
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9697
CCMO	NL78324.042.21
OMON	NL-OMON51889

Study results