

# Direct Patient Feedback

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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.

|                             |                          |
|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Niet van toepassing      |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## Samenvatting

### ID

NL-OMON20330

### Bron

Nationaal Trial Register

### Verkorte titel

DPF

### Aandoening

(chronic) post-operative pain

## Ondersteuning

**Primaire sponsor:** University Medical Center Groningen, dept of Anaesthesiology

**Overige ondersteuning:** funding=sponsor

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

## Doel van het onderzoek

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.

## Onderzoeksopzet

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.

## Onderzoeksproduct en/of interventie

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.

## Contactpersonen

### Publiek

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Parallel              |
| Toewijzing:      | Gerandomiseerd        |
| Blinding:        | Enkelblind            |
| Controle:        | Placebo               |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2021               |
| Aantal proefpersonen:   | 160                      |
| Type:                   | Verwachte startdatum     |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

|                     |                     |
|---------------------|---------------------|
| Niet van toepassing |                     |
| Soort:              | Niet van toepassing |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51889

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten