

# Postoperative continuous telemonitoring at the surgical ward

<b>Submission date</b> 11/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/05/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Telemonitoring, a sub-category of eHealth, may play a role in the early detection of postoperative deterioration, lower workload for nurses and facilitate the migration of care towards home. Wearable sensors are available for the continuous monitoring of vital signs, including skin temperature, heart rate, respiratory rate, blood oxygenation, and activity parameters. It is still unknown, however, how to incorporate continuous telemonitoring in the perioperative trajectory of surgical patients. As a pilot for further trials, the aim of this study is to assess the feasibility and applicability of telemonitoring by continuous monitoring of vital signs and physical activity of patients at the post-anesthesia care unit (PACU) and a surgical ward.

### Who can participate?

Patients aged 18 years or older admitted to the surgical ward and planned for surgery with an expected postoperative stay of 48 hours

### What does the study involve?

During a period of 3 months patients receive standard care and wear two wearable sensors for continuous monitoring. No medical decisions will be made using the data collected by the telemonitoring devices.

### What are the possible benefits and risks of participating?

The burden of this study is low. Patients receive extra monitoring by wearing two sensors during their postoperative hospital stay. Patients are not expected to experience physical, psychological or mental strain due to the monitoring. All measurements are safe and non-invasive.

### Where is the study run from?

University Medical Center Groningen (Netherlands)

### When is the study starting and how long is it expected to run for?

June 2021 to December 2025

Who is funding the study?  
Stichting Lijf & Leven (Netherlands)

Who is the main contact?  
1. Rianne van Melzen, r.van.melzen@umcg.nl  
2. Marjolein Haveman, m.e.haveman@umcg.nl  
3. Prof. Dr. Jean-Paul de Vries

## Contact information

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

202000231

## Study information

**Scientific Title**

Postoperative continuous telemonitoring; an observational study

**Acronym**

TRUST

**Study objectives**

Telemonitoring may play a role in the early detection of postoperative deterioration, lower workload for nurses and facilitate the migration of care towards home. Wearable biosensors are available for continuous monitoring of vital signs, including temperature, heart rate, respiratory rate, blood oxygenation, and activity parameters. It is still unknown, however, how to incorporate continuous telemonitoring in the perioperative trajectory of surgical patients. The aim of this prospective, observational trial is to assess the feasibility and applicability of telemonitoring by continuous monitoring of vital signs and physical activity of patients at the post-anesthesia care unit (PACU) and a surgical ward.

**Ethics approval required**

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**Ethics approval(s)**

Approved 11/11/2021, Ethical Committee University Medical Center Groningen (Hanzeplein 1, Groningen, 9713 GZ, Netherlands; +31 (0)6 55 25 76 00; nwmoloket@umcg.nl), ref: 202000231, METc nr. 2021/440

**Study design**

Single-center observational cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Patients admitted to the surgical ward after surgery

### **Interventions**

Patients receive standard care, and in addition will be wearing two wearable sensors for continuous monitoring of heart rate, respiratory rate, temperature and oxygen saturation. No medical decisions will be made using data collected by the wearable sensors in this trial. Patients wear the sensors during their postoperative hospital stay for up to 7 days.

1. The VitalPatch enabling (non-invasive) ECG-based measurements of heart rate (variability), respiration rate, oxygen saturation, body temperature, fall detection and physical activity (step count, and type of activity) at a frequency of once per second.
2. The Masimo Radius PPG sensor enabling (non-invasive) saturation-based measurement of heart rate, respiration rate, body temperature, and oxygen saturation at a frequency of once per minute.

### **Intervention Type**

Device

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

VitalPatch, Masimo Radius PPG sensor

### **Primary outcome measure**

Feasibility for each sensor during the study period (stay at the surgical ward for a maximum of 7 days) assessed by the following measures:

1. Participation rate: number of patients willing to participate/complete the study protocol
2. Acceptability in terms of satisfaction about the logistics and wearing the sensor, measured by experiences of patients collected using a questionnaire before discharge and at the end of the study
3. Practicality by aspects of (tele)monitoring that involve the actual experience:
  - 3.1. Compliance with the amount of days/hours that the sensor is worn
  - 3.2. Time spent by nurses concerning telemonitoring versus vital parameter measurements in current practice, measured through daily evaluation form and by recording the time needed for intermittent measurements of vital signs manually
  - 3.3. Experiences and recommendations of nurses, assessed with evaluation forms and interviews
  - 3.4. Data quality: missing data, artefacts and reasons for data losses

### **Secondary outcome measures**

Applicability (for each sensor) during the study period (stay at the surgical ward for a maximum of 7 days):

1. Continuous data stream of vital functions: heart rate, saturation, respiration rate, body temperature, daily step count, type of activity and fall detection

2. Measurements of vital signs in usual care from the electronic medical record
3. Comparison of the characteristics and quality from both wearable sensors will take place for the following outcomes: participation rate, acceptability, practicality, data quality and continuous data stream of vital functions
4. The following clinical and surgical data will be obtained via electronic medical records: age, gender, primary diagnosis, comorbidities, surgery date, procedure type, length of hospital stay, reported early warning scores, incidence and moments of postoperative complication (including falling), treatment, and incidence, moment and duration of unplanned readmission within 30 days after surgery.

**Overall study start date**

01/06/2021

**Completion date**

31/12/2025

## Eligibility

**Key inclusion criteria**

1. Patients admitted to the surgical ward
2. Planned for surgery
3. 18 years or older
4. Expected postoperative stay of 48 hours

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200

**Total final enrolment**

124

**Key exclusion criteria**

1. Mentally incapable of participation
2. Unable to wear wearable devices

**Date of first enrolment**

01/04/2022

**Date of final enrolment**

01/07/2023

## Locations

### Countries of recruitment

Netherlands

### Study participating centre

University Medical Center Groningen

Hanzeplein 1

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9713 GZ

## Sponsor information

### Organisation

University Medical Center Groningen

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### Website

<http://www.umcg.nl/EN>

### ROR

<https://ror.org/03cv38k47>

## Funder(s)

### Funder type

Charity

### Funder Name

Stichting Lijf en Leven

**Alternative Name(s)**

Lijf en Leven Foundation, Stichting Lijf & Leven

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

Netherlands

## **Results and Publications**

**Publication and dissemination plan**

Planned publications in a high-impact peer-reviewed journal

**Intention to publish date**

01/01/2026

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from R. van Melzen (r.van.melzen@umcg.nl).

**IPD sharing plan summary**

Available on request