# Promoting implementation of seizure detection devices in epilepsy care: the PROMISE study

Published: 23-02-2018
Last updated: 04-01-2025

1. To test the performance of the wearable SDD (Nightwatch) prospectively and the remote SDDs (video and audio) retrospectively in a family home setting. 2. To explore the feasibility of the Nightwatch

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Seizures (incl subtypes) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON50690

**Source**
ToetsingOnline

**Brief title**
the PROMISE study

### Condition

- Seizures (incl subtypes)

**Synonym**
convulsions, Epileptic seizures

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Stichting Epilepsie Instellingen Nederland
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** 'Epilepsy', 'Monitoring', 'Nightwatch', 'Seizure detection device(s)'

## Outcome measures

### Primary outcome

We will measure the performance of the Nightwatch and the video & audio algorithms through calculation of sensitivity, positive predictive value, false alarm rate and % time with valid signal allowing proper detection.

### Secondary outcome

We will evaluate feasibility of the Nightwatch through surveys on quality of life, sleep, pearental strain, and medical consumption and costs questionnaires and interviews with parent(s)/representative(s).

# Study description

### Background summary

Various remote and wearable sensor devices have been assessed for the detection of potentially dangerous seizures, with limited impact on epilepsy care so far. Our remote and wearable seizure detection devices (SDDs) have demonstrated promising results with high sensitivity.

### Study objective

1. To test the performance of the wearable SDD (Nightwatch) prospectively and the remote SDDs (video and audio) retrospectively in a family home setting.
2. To explore the feasibility of the Nightwatch

### Study design

A home-based prospective SDD study with prospective validation of our wearable SDD.

### Study burden and risks

Implementing SDDs is not considered to pose any substantial risk. Study participation can be a burden for the family though, due to impact of the devices on privacy and time spent on the questionnaires & interviews. Participation does, however, also offer better insight for the parents in the actual nocturnal seizure activity of their child, demonstrates the added value of the Nightwatch and may help them to timely alert to major seizures.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

### Inclusion criteria

• Age 4-16 years
• Diagnosis of refractory epilepsy with >=1 major nocturnal seizure per week.
• Treated at one of the following epilepsy centers: SEIN, Kempenhaeghe or UMCU.

• Written informed consent by legal representatives (mostly parents) and also by the subject when aged >=12 years and capable of signing informed consent.

### Exclusion criteria

• Intensive non-epileptic movement patterns such as severe choreatiform movements, intensive sleep walking, or frequent night terrors (> 1/week).
• Minor motor seizures only, i.e. non-generalized or short (< 10 sec.) tonic seizures or isolated myoclonias that are self-limited and do not require intervention.
• Presence of a pacemaker or cardiac arrhythmias that may generate false alarms (e.g. supraventricular tachycardia).
• Inability to comply to the trial procedure.
• Skin characteristics (e.g. tattoo) that may affect photoplethysmography and thereby influence performance of the Nightwatch .
• Dependence on another SDD (e.g. Emfit or saturation monitor). Simultaneous use of a baby phone (or other types of microphones) is permitted.
• Subjects who are not sleeping alone in the bed (i.e. co-sleeping in the parents*/guardians* bed influences the remote SDD). We do not allow subjects and parents/guardians to change their sleeping habits for the duration of the study only.

## Study design

### Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Completed |
| Start date (anticipated): | 26-04-2018 |
| Enrollment: | 60 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | Nightwatch |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 23-02-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 18-04-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 09-05-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 14-06-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 31-01-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 24-04-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 15-04-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |

# Study registrations

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

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL62995.041.17 |

# Study results

Date completed: 08-04-2021

Results posted: 21-10-2022

Actual enrolment: 2

**First publication**
21-10-2022