Cost-effective application of seizure detection devices for high-risk night-time epileptic seizures

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Ethical review	Approved WMO
Status	Pending
Health condition type	Seizures (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON57154

Source
ToetsingOnline

Brief title
KANS - Cost-effective application of seizure detection

Condition

- Seizures (incl subtypes)

Synonym
Epilepsy

Research involving
Human

Sponsors and support

Primary sponsor: Epilepsiecentrum Kempenhaeghe
Source(s) of monetary or material Support: ZonMw,LivAssured B.V., Leiden,QuoVadis Nederland BV, Baarn

Intervention

Keyword: cost-effectiveness analysis, epilepsy, quality of life, wearable electronic devices

Outcome measures

Primary outcome

The primary objective of this research is to investigate the effect of seizure detection devices on the number of valid and missed visits by caregivers to clients following an alarm.

Secondary outcome

Secondary parameters are the effect of seizure detection devices on quality of life (both general and disease specific), number of complications after 12 months and user experience of both healthcare workers and patients. Furthermore, specifically designed cost questionnaires will be designed based on the latest HTA-insights, in order to perform a cost-utility and cost-effectiveness analysis of the intervention.

Due to randomized allocation of the two seizure detection devices, there will be data available regarding possible differences between these two devices. Even though this is not a part of the primary goal of this study, these data will be analyzed in order to determine whether there are differences between the two devices.

Study description

Background summary

In around one in three epilepsy patients, seizures cannot be properly controlled with anti-seizure medication. Having continued seizures can lead to serious complications such as injuries or status epilepticus. Having seizures during the night increases the risk of sudden unexpected death in epilepsy. On top of that, healthcare costs related to, among other, complications and societal costs for the group with continued epileptic seizures are high (>3000 euro per patient per year).

Study objective

The objective of this study is to determine what the differences are between care as usual and care where a seizure detection device is used in addition to care as usual. Specifically, this study will compare the number of missed and correct visits from healthcare workers after an epileptic seizure, as well as cost-effectiveness, quality of life, user experience and number of complications.

Study design

This study was designed as a pre-post study in which an intervention will take place after a baseline period.

Intervention

After a baseline period of three months, participants will start wearing a seizure detection device with medical CE (either NightWatch or Epi-Care Free) during the night.

Study burden and risks

Participants will not have to undergo any extra tests or visit any research locations because the study will be done at the healthcare facility where participants live. The cost questionnaires and one of the user experience questionnaires will be filled out by healthcare workers. Participants will fill out questionnaires themselves (with help if necessary) at four different timepoints. Three times, participants will fill out a general quality of life questionnaire (EQ-5D-5L or EuroQol by Proxy) and a disease specific quality of life questionnaire (QOLIE-31-P). Furthermore, participants will fill out a user experience questionnaire twice. If needed, questionnaires can be filled out by, or with the help of, someone close to the participant. The risk for participants of this study are negligible.

Benefit for the participants in this study is that they will be able to use a seizure detection device for 12 months, which will likely reduce the number of night-time epileptic seizures missed by healthcare workers. This reduces the chance of (serious) complications these seizures can cause. If the outcomes of

this study are positive (such as fewer missed seizures and positive user experiences among caregivers), the results of this study could contribute to healthcare institutions' decisions to start using seizure detection devices. This could help reduce the risks of missed night-time epileptic seizures across the entire population. Since the study focuses on the cost-effectiveness of seizure detection tools in healthcare settings and the number of valid and missed visits by healthcare workers, it is not feasible to conduct this research in a different population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

At least 18 years old
Living in a Dutch long-term care facility

At least 1 suspected major, night-time epileptic seizure that requires medical assistance per month (this includes tonic-clonic seizures, tonic seizures longer than 30 seconds and/or hypermotor seizures)
Willing to wear a seizure detection device
No objection to video monitoring during the study
Sufficient proficiency in the Dutch language to fill out the required questionnaires (with assistance if needed)

Exclusion criteria

Already has adequate seizure detection available
Will start using a seizure detection device within 3 months or less
Has a movement disorder that manifests during the night

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2024
Enrollment:	44
Type:	Anticipated

Medical products/devices used

Generic name:	NightWatch; Epi-Care Free
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-10-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-12-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL86903.015.24