The effectiveness and cost-effectiveness of seizure dogs

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26140

Bron
NTR

Verkorte titel
EPISODE

Aandoening

Refractory epilepsy
Drug-resistant epilepsy
Refractaire epilepsie
Therapieresistente epilepsie

Ondersteuning

Primaire sponsor: Erasmus School of Health Policy and Management
institute for Medical Technology Assessment
Overige ondersteuning: ZonMw - DoelmatigheidsOnderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of the study will be seizure frequency.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE(S)/RESEARCH QUESTION(S)
Patients with epilepsy could have persistent seizures despite treatment with anti-epileptic drugs or epilepsy surgery. The aim of this study is to evaluate the (cost-)effectiveness of seizure dogs compared to standard care in patients with refractory epilepsy.

HYPOTHESIS

With the introduction of a seizure dog, we expect that the number of epileptic seizures decreases.
Besides the effect of seizure dogs on seizure frequency, we expect an impact on other outcomes measures, such as well-being and health-related quality of life. Furthermore, we expect seizure dogs to decrease the seizure severity, lower the burden on informal caregivers and reduce healthcare resource use.

STUDY POPULATION(S)/DATASETS

The study population consists of patients with refractory epilepsy (i.e. medication resistant epilepsy) who are not eligible for epilepsy surgery and have a high risk of injury or dysfunction.

INTERVENTION

The intervention consists of seizure dogs. The training of these dogs focuses on responding to seizures during or immediately after an epileptic seizure occurs in their human companion. Seizure dogs may also be able to develop alerting behaviour, which consist of anticipating on an impending seizure event and providing a warning signal to the human companion (before the seizure).

USUAL CARE /COMPARISON

Since there are no alternative treatment options available for patients with refractory epilepsy who are not eligible for epilepsy surgery, standard care consists of ‘doing nothing’.

OUTCOME MEASURES

The primary outcome of the study will be seizure frequency. Besides this outcome measure, the impact of seizure dogs on seizure severity, well-being, health-related quality of life and healthcare resource use will be evaluated.

STUDY DESIGN

We plan to evaluate the (cost-)effectiveness of seizure dogs with a stepped-wedge (or randomised-delay) design, which uses observations at multiple time points both before and after the intervention. This implies that we have for each subject a time series of measurements for each of the outcomes of interest. There is no separate control group; patients act as their own controls. We will start including patients at the end of the second quarter of 2018.

DATA COLLECTION AND ANALYSIS

Seizures will be recorded continuously using a seizure diary. Data regarding health-related quality of life will be collected using the EQ-5D and the QOLIE 31. The ICECAP will be used to measure the well-being of patients with epilepsy.
Furthermore, the iMCQ (iMTA Medical Consumption Questionnaire), the iVICQ (iMTA Valuation of Informal Care Questionnaire) and the iPCQ (iMTA Productivity Cost Questionnaire) will be used to collect data regarding health care use, informal care and productivity losses.

A simple before-and-after comparison will be conducted, by calculating per person the average of the measurements before the dog's training starts, during the dog's epilepsy training at home and after the training of the dog is completed, using repeated measures anova. Additionally, mixed effect models for repeated measurements will be used, with random patient effects and slopes.

SAMPLE SIZE CALCULATION

Within the total budget of €857,709, Stichting Hulphond Nederland and Bultersmekke can train a total of 35 dogs. With 35 patients (and dogs), we should be able to detect a significant difference in the number of seizures.

COST-EFFECTIVENESS ANALYSIS/ BUDGET IMPACT ANALYSIS

The cost-effectiveness analysis will adopt a societal perspective in line with the Dutch guidelines for economic evaluations in healthcare. The most important cost category within the cost-effectiveness analysis is the cost of training seizure dogs. Besides the costs of the intervention, costs within the healthcare sector will be incorporated, just as patient and family costs (i.e. time costs) and costs in other sectors (i.e. productivity costs). The cost-effectiveness study ultimately leads to an incremental cost per QALY gained.

Besides the cost-effectiveness analysis, a budget impact analysis will be conducted, taking into account the size and characteristics of the affected population, the current intervention mix and the new intervention mix.

TIME SCHEDULE

In three years (2018-2020), Stichting Hulphond Nederland and Bultersmekke will be able to train and match 35 seizure dogs. Data analyses and reporting will be conducted in 2021.

Doel van het onderzoek

We expect the number of seizures to decrease with the introduction of a seizure dog. Besides the effect of seizure dogs on seizure frequency, we expect an impact on participation, well-being, health-related quality of life, healthcare resource use (both formal and informal care).

Onderzoeksopzet

Seizures are recorded continuously using a seizure diary for a maximum of 36 months. In addition, the patient will be asked to fill in five questionnaires: EQ-5D, QOLIE-31, ICECAP, iPCQ and iMCQ. The questionnaires will be sent to patients every 3 months.The patients' primary caregiver will be asked to fill in the iVICQ at the same measurement moments.

Onderzoeksproduct en/of interventie

The intervention consists of seizure dogs. The training of these dogs focuses on responding to seizures during or immediately after an epileptic seizure occurs in their human companion. Seizure dogs may also be able to develop alerting behaviour, which consists of anticipating on an impending seizure event and providing a warning signal to the human companion (before the seizure).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Confirmed diagnosis of epilepsy by neurologist with video or EEG confirmation;

- Seizures have to be proven epileptic (exclusion of patients with only or mostly psychogenic non-epileptic seizures);

- Refractory epilepsy/medication resistant epilepsy (persistent seizures despite the use of at least two AEDs in monotherapy or combination);

- Not eligible for epilepsy surgery (or when epilepsy surgery has not resulted in seizure freedom);

- Average seizure frequency of at least 2 per week with a maximum seizure free period of 2 weeks (in last 6 months);

- High potential risk of injury due to:

i) Lack of warning signals prior to seizure (aura); and/or

ii) Reduced awareness; and/or

iii) Loss of balance;

- Minimum age of 18 years old (able to handle the responsibility for taking care of the dog);

- Cognitive able to take care of the dog adequately and fill in questionnaire/seizure diary independently (minimum IQ of 70 recommended);

- There must be adequate support in the patient’s environment to ensure that the dog’s needs can be met

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Institutionalized;

- Currently in possession of a trained epilepsy dog;

- Recipient or primary caregivers of recipient are allergic to dogs;

- Intention to undergo Nervus Vagus Stimulation or to follow a ketogenic diet during the duration of the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	35
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

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6682
NTR-old	NTR6852
Ander register	METC-2017-538 Erasmus MC (8-1-2018: METC Erasmus MC heeft bepaald dat het onderzoek niet WMO-plichtig is) : 80-84300-5002 ZonMw

Resultaten