Self-management Intervention for adults with epilepsy

Gepubliceerd: 02-04-2014 Laatst bijgewerkt: 18-08-2022

We believe that self-management can be a (cost) effective way to improve patients' ability to cope with their disease which can result, among others, in improved self-efficacy, adherence, and disease specific and generic quality of life.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25737

Bron
Nationaal Trial Register

Verkorte titel
ZMILE (Zelfmanagement Interventie Leven met Epilepsie)

Aandoening

Epilepsy, Epilepsie

Ondersteuning

Primaire sponsor: Maastricht University
School for Public Health and Primary Care (Caphri).
Department of Health Services Research
Postbus 616
6200MD Maastricht
Overige ondersteuning: This study is funded by ZonMW. Number 836011018

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) Epilepsy Self-Efficacy Scale-33 items (ESES). The ESES is a 33-item scale that measures different aspects of efficacy within the self-management of epilepsy. The items represent three dimensions of self-management: medication management, seizure management, and general management including safety and health. Items are rated on an 11-point Likert rating scale, ranging from 0, “not at all certain I can do”, to 10, “very certain I can do”. The total possible scores for the ESES range from 0 to 330. Higher scores correspond to higher levels of confidence in ability to manage epilepsy.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Epilepsy is a chronic disorder of the brain characterized by recurrent seizures, which are the result of excessive electrical discharges in the brains. It is estimated that only 70-80% of newly diagnosed adults with epilepsy can be successfully treated with anti-epileptic drugs. In epilepsy patients, poor adherence has been shown to be the most important cause of poorly controlled epilepsy. Furthermore it is emphasized that an increase in quality of life among patients with epilepsy could be reached by counseling and treatment aimed at increasing their self-efficacy. However, there is a need for evidence-based programs within epilepsy care. Hence the overall objective of this study is to assess the (cost-) effectiveness of a multi-component intervention (MCI; self-management/education program & e-health) aiming to improve self-efficacy and adherence in people with epilepsy compared to care as usual.

Methods/design: A randomized controlled trial in 2 parallel groups will be conducted to compare the MCI intervention with a waiting list control condition in epilepsy patients. One hundred eligible epilepsy patients will be recruited from the Kempenhaeghe epilepsy center and allocated to intervention or control group. Patients in the intervention group will be followed for 12 months and patients in the control group will be followed for 6 months. The study will consist of three parts: 1) a clinical effectiveness study, 2) a cost-effectiveness study, and 3) a process evaluation. The primary outcome will be self-efficacy. Other outcomes include: adherence, seizure severity & frequency, emotional functioning, quality of life, proactive coping, side effects, and health care resource use. Outcome assessments will be done using questionnaires at baseline and after 3, 6, 9, and 12 months.

Discussion: This study will determine the (cost-) effectiveness of a MCI intervention to improve the management of epilepsy in adult patients. The MCI is designed to stimulate self-management skills and awareness of epilepsy patients in combination with the use of e-health interventions. Hence, this study is aimed at patients, making them their own provider of health care and thus shifting management from professionals to self-care by patient

equipped with appropriate tools and training.

Doel van het onderzoek

We believe that self-management can be a (cost) effective way to improve patients' ability to cope with their disease which can result, among others, in improved self-efficacy, adherence, and disease specific and generic quality of life.

Onderzoeksopzet

Possible candidates for this study will be recruited from the outpatient clinic of Kempenhaeghe. Patients receive a face-to-face interview with the researcher in which the study is explained in detail. After patients have given informed consent, baseline measurements (T0) are conducted. After this baseline measurements randomisation will take place. Patients are either assigned to the intervention group or the CAU control group. Participants are told that a group will start as soon as 4-6 patients are recruited for each group. The expectation is that this will only last a few weeks. Once sufficient patients have been randomised, the MCI intervention is offered to the intervention group during a 9-week period. After finishing the intervention and at established follow up outcome measurements are conducted by sending the questionnaires to the participant's home. Participants are asked to fill in the
questionnaires and bring them with them when visiting a scheduled standard 3-monthly visit of the outpatient clinic. The researcher contacts the participant during these visits and asks them to provide missing information.

Onderzoeksproduct en/of interventie

A multi component intervention (MCI), which combines a self-management/education program with eHealth interventions (apps and Medication Event Monitoring System) aiming to improve
adherence to Anti-epileptic drugs.

Contactpersonen

Publiek

Verpleegkundig Specialist (Nurse Practitioner)
Kempenhaeghe, Centre for Epilepsy
Sterkselseweg 65
L.A.M. Leenen
Heeze 5591 VE
The Netherlands
+31 40 2279022

Wetenschappelijk

Verpleegkundig Specialist (Nurse Practitioner)
Kempenhaeghe, Centre for Epilepsy
Sterkselseweg 65
L.A.M. Leenen
Heeze 5591 VE
The Netherlands
+31 40 2279022

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosed with epilepsy
- Using anti-epileptic drugs
- Age at least 18 years
- Living at home (Netherlands)
- Able and willing to use a Smartphone in the program.
- Able to provide informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Insufficient mental ability to understand, learn from and profit from the self-management treatment on the basis of clinical judgement of the treating neurologist.
- Insufficient command of the Dutch language based on clinical judgement.
- Inability to function in a group because of mood or behavioural problems as assessed by the neurologist.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-04-2014
Soort:	Eerste indiening

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	NL4344
NTR-old	NTR4484
Ander register	ZonMW number 836011018 : METC ID: NL44203.068.13

Resultaten