

(Cost-) effectiveness of a Multi-Component Intervention for adults with epilepsy: a Dutch randomized controlled trial

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The overall objective is to assess the (cost-) effectiveness of MCI (self-management/education program & e-health) aiming to improve self-efficacy and adherence in people of with epilepsy compared to care as usual (CAU).The study consist of 3...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40155

Source

ToetsingOnline

Brief title

ZMILE (Self-management intervention: Living with Epilepsy

Condition

- Other condition

Synonym

Epilepsy

Health condition

epilepsie

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: ZonMW: Goed Gebruik Geneesmiddelen

Intervention

Keyword: Epilepsy, multi-component intervention, Self-management

Outcome measures

Primary outcome

The primary outcome for the (cost) effectiveness study is self-efficacy measured with Epilepsy Self-Efficacy Scale (ESES);

Secondary outcome

Secondary outcomes for the (cost)-effectiveness study are adherence measured by Monitor Adherence Response Scale (MARS) and Medication Event Monitoring System (MEMS), general self-efficacy measured by Generalized Self-efficacy Scale (GSES) and generic quality of life as measured with the EuroQol-5D and the AQOL-8D.

Other outcome measures are side effects, depression/mood, quality of life, coping skills, societal costs, seizure frequency.

Study description

Background summary

HEALTH PROBLEM

Epilepsy is a neurological disorder characterized by recurrent unprovoked seizures. Seizures are the result of sudden, excessive electrical discharges in

a group of brain cells. The clinical manifestations of seizures will vary and depend on where in the brain the disturbances first start and how far they spread. Transient symptoms can occur, such as loss of awareness or consciousness and disturbances of movement, sensation, mood or mental function. Recent studies have shown that up to 70% of newly diagnosed children and adults with epilepsy can be successfully treated (i.e. completely controlled) with AEDs. In summary, epilepsy is a large societal problem, which can, in the majority of the patients, be treated successfully with AEDs.

The prevalence of epilepsy treated with anti-epileptic drugs (AEDs) is about 5.15 per 1,000 people. For the Netherlands this implies that currently about 80,000 patients are treated with AEDs. The Dutch health care costs for epilepsy are $\approx$ 221 million ³. This is comparable to the cost in other western countries. Next to that, productivity losses account for the largest part of the total costs of epilepsy.

CONCORDANCE IN EPILEPSY

Concordance to AEDs is a health issue of major relevance in patients with epilepsy. Haynes (2008) even argued that *Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments*. Patients with uncontrolled epilepsy heavily depend on informal care (family and friends) and health care professionals (neurologists, nurse practitioners, nurses, social workers, psychologists etc.).

Complications due to epilepsy result in frequent hospitalizations. Growing up with seizures affects the patient's personality and interferes with many aspects of everyday life including schooling, leisure and occupational activities. People with epilepsy are often confronted with reduced access to health and life insurance, a withholding of the opportunity to obtain a driving license, and barriers to enter particular occupations, among other limitations. In summary, non-adherence to AEDS will have a huge impact on the patient and to the society as whole.

MULTICOMPONENT INTERVENTION

The Multicomponent intervention (MCI), which combines a self-management/education program with eHealth interventions (apps and Medication Event Monitoring System) aiming to improve self-efficacy, and thus adherence to AEDs.

Several studies in other chronic diseases, such as hypertension and diabetes, have shown that a MCI can be efficient in increasing concordance. In the field of epilepsy, scientific evidence that a MCI is effective and efficient is lacking. Due to several reasons the results of the other studies relating to chronic patient groups, cannot be generalized to patients with epilepsy. One reason is that the consequences of not taking AEDs are not always time related; seizure deregulation can appear the same day or a couple of days later. So for patients the direct link to taking AEDs and the frequency of seizures is not transparent. There are also no direct quantitative measures for the consequences of non-adherence as there are in hypertension (blood pressure) or

diabetes (blood sugar level). As a result, patients with epilepsy cannot directly monitor the influence of concordance. Finally, AEDs causes side effects in 88% of the patients, leading to non-adherence to AEDs. As a result, it is of major importance to study the effectiveness and efficiency of an MCI in the group of epilepsy aimed at stimulating concordance to AEDs.

Study objective

The overall objective is to assess the (cost-) effectiveness of MCI (self-management/education program & e-health) aiming to improve self-efficacy and adherence in people of with epilepsy compared to care as usual (CAU).

The study consist of 3 parts

PART 1. CLINICAL EFFECTIVENESS

PART 2. ECONOMIC EVALUATION

PART 3. PROCESS EVALUATION

Study design

A pragmatic randomised controlled trial (RCT) in 2 parallel groups will be conducted that compares the MCI intervention with a waiting list control condition, which reflects CAU as naturalistically as possible. One hundred epilepsy patients will be recruited from the centre for epilepsy Kempenhaeghe. Subjects who are involved in the study will be followed for approximately 12 months for the intervention group and 6 months for subjects in the CAU control group.

Intervention

MULTICOMPONENT INTERVENTION

The components of the MCI are methods of enhancing self-management skills & usages of different eHealth tools, which can be used to (self) monitor their condition.

Group sessions

The MCI intervention will last 9 weeks. During the first 5 weeks group sessions will take place. Followed 4 weeks later by a booster session.

The first session is aimed at providing information about the course, including materials, and to get to know the other participants and therapists. During the next sessions participants will practice with the 5-step model (Aspinwall & Taylor) and three fixed themes. 19

The first theme is self-monitoring and self-monitoring (eHealth) tools. The last two themes will be risk-management and shared decision-making. The group sessions will have the same basic structure. The start will always be looking back at the goals set in the previous meeting and how that worked out in the last week. Then the theme of the session will be introduced. Patients and caregivers will be invited to share their beliefs, emotions and experiences

with regard to the theme. Subsequently, patients and caregivers will formulate their own action plan in order to attain a goal relevant for the theme. The goals will be limited and feasible and caregivers are stimulated to select their own goals. Group members will give feedback on the quality of the goals in terms of concreteness and attainability. They will help each other to recognize additional conditions and barriers which need to be addressed. After the feedback discussion, patients and caregivers will formulate their final plan in a SMART-form (i.e. what are they going to do, how, when and where). The group sessions last for 2-2,5 hours and 4-6 patients with their possible caregivers will be present (total 4-12 participants). The group sessions are led by a nurse practitioner, with experience in working in groups and with epilepsy patients.

The eHealth tools used in the intervention consists of 3 elements; 1) the Medication Event Monitoring System (MEMS), 2) a smart phone app 20 3) an internet accessible patient database. The Medication Event Monitoring System (MEMS) (AARDEX Ltd., Switzerland) operates as follows; MEMS caps are electronic caps that fit on standard pill bottles. They register date and time of every opening of the pill bottle, and the data can be downloaded from the MEMS cap with a communication device and a computer. The Powerview software presents the data in simple plots. These plots can be used to provide feedback about behaviour, and to identify suboptimal adherence patterns.²¹ The smart phone contains a special smartphone application (app) for persons with epilepsy in order to register seizure frequency and other facts, which can influence the condition. Information gathered this way can be used through a website application, to provide feedback for a shared decision making process with the health care professional.²⁰

Booster session

During this session the nurse practitioner will rehearse the theory around the 5-step model. Patients and caregivers will have the possibility to discuss their experiences related to their goals and other aspects of the course.

The nurse practitioners offering the MCI will receive training beforehand on motivational interviewing (MI), as a technique to empower patients to set their own sustainable goals and look into conflicting beliefs. The intervention will be explained in a detailed protocol for the nurse practitioner and a workbook for patients and caregivers.

Motivational Interviewing (MI) a client-centred counselling method will be used. This counselling style, used by the group leaders, will help patients to explore and resolve ambivalence and bring about changes in their behaviour.²²

CARE AS USUAL

The control condition will be a waiting list control condition with unrestricted access to CAU. As this will be a pragmatic trial, CAU will not follow a standardised protocol. Medical support provided in the control group might be variable but is expected to be in agreement with the multi-disciplinary epilepsy guidelines.²³

In (economic) evaluation studies preferred as naturalistic in comparison with real situation

Study burden and risks

Next to the investment in the programme there are no disadvantages by participating in this study. There are no risks.

The possible positive results from the Multi component intervention (MCI) are, subjects

1) will receive information about epilepsy and the use of eHealth-tools, 2) have contact with peers and health care professionals, 3) have a forum to discuss their feelings, cognitions and experiences with others and 4) have a (possibly) shared activity with their caregiver and. The subjects of the CAU control group will receive the same intervention after T2 (6 months). There are no known risks for subjects participating in this study. There are no risks

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

- 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

Exclusion criteria

- Insufficient mental ability to understand, learn from and profit from the self-management intervention 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date: 04-12-2013

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 28-05-2014

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 04-02-2015

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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

CCMO

ID

NL44203.068.13

Study results

Date completed: 16-11-2016

Actual enrolment: 102