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Effectiveness of a multicomponent self-management intervention for adults with epilepsy (ZMILE study): A randomized controlled trial

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ABSTRACT

Background: The objective of the ZMILE study was to compare the effectiveness of a multicomponent self-management intervention (MCI) with care as usual (CAU) in adult patients with epilepsy (PWE) over a six-month period.
Methods: Participants (PWE & relative) were randomized into intervention or CAU groups.
Self-report questionnaires were used to measure disease-specific self-efficacy as the primary outcome measure and general self-efficacy, adherence, seizure severity, emotional functioning, quality of life, proactive coping, and side-effects of antiepileptic drugs (AED) as secondary outcome measures. Instruments used at baseline and during a six-month follow-up period were the following: disease-specific self-efficacy (Epilepsy Self-Efficacy Scale [ESES], General Self-Efficacy Scale [GSES]); adherence (Medication Adherence Scale [MARS] and Medication Event Monitoring System [MEMS]); seizure severity (National Hospital Seizure Severity Scale [NHS3]); emotional well-being (Hospital Anxiety and Depression Scale [HADS]); quality of life (Quality of Life in Epilepsy [QOLIE-31P]); proactive coping (Utrecht Proactive Coping Competence [UPCC]); and side-effects of antiepileptic drugs [SIDAED]. Multilevel analyses were performed, and baseline differences were corrected by inclusion of covariates in the analyses.
Results: In total, 102 PWE were included in the study, 52 of whom were in the intervention group. On the SIDAED and on three of the quality of life subscales QOLIE-31P, a significant difference was found ($p < 0.05$) in the intervention group. Self-efficacy, however, showed no significant differences between the MCI and the CAU groups. None of the other outcome measures showed any significant difference between the two groups.
Significance: Although we found no statistically significant difference in the primary outcome measure, disease-specific self-efficacy, this MCI could prove promising, since we found improvement in some domains of quality of life in epilepsy scale and a decrease in AED side-effects in the MCI group compared with the CAU group.

1. Introduction

Having epilepsy is associated with psychological and emotional problems, such as depression and anxiety, which are strongly reflected in a reduced quality of life [1,2]. Unpredictable seizures are likely to influence daily activities (e.g., employment) of PWE [2]. Thus, as well as managing their symptoms, PWE and their relatives [3] must acquire disease-specific knowledge, adhere to treatment and lifestyle regimes, and cope with the psychosocial consequences of the condition [4,5].

Most PWE use antiepileptic drugs (AED), and concordance is of great importance for achieving and maintaining positive seizure control [6]. Concordance refers to the consensual agreement about taking AED that has been established between patient and practitioner [7]. Poor concordance has been shown to be the most important cause of poorly controlled epilepsy [6]; many PWE seem to be unaware of missed drug intake [8]. To improve concordance, some self-management programs focus on the use of e-Health tools (e.g., digital pill dispensers) [9], although this is not very common in PWE [10].

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One of the options for increasing concordance could be self-management support for PWE (and relatives) using an evidence-based self-management program, which includes goal-setting, problem-solving, symptom management, and shared decision-making [11–13]. The aim of self-management support is to provide education and supportive interventions to increase skills and confidence in managing health-related problems [12]. Self-efficacy (i.e., confidence to behave with the intention of reaching a desired goal) is one of the mechanisms responsible for improvement in health outcomes and quality of life, as demonstrated by those attending self-management programs [4,14,15]. Proactive coping is helpful in dealing with anticipated challenges in order to reach the desired goal [16]. The concept of self-management is complex with many different definitions and conceptualizations and, therefore, many forms of support exist [17]. There is little evidence to prove the effectiveness of self-management programs within the care of PWE [18]. We, therefore, developed a multicomponent intervention (MCI), consisting of a self-management education program with e-Health interventions directed at improving self-efficacy, thus, improving the self-management skills of PWE.

The goal of this study (the ZMILE-study) was to evaluate the clinical effectiveness of the MCI. Our primary expectation was that we would find a higher level of disease-specific self-efficacy in the intervention group compared with those who received CAU. Secondarily, we expected to find higher levels of general self-efficacy, adherence (as a proxy for concordance), and proactive coping. We also expected to find a positive change in seizure severity, emotional functioning, quality of life, and experienced side-effects of AED, these outcome measurements are recommended outcomes in epilepsy research [19].

2. Method

2.1. Design

The ZMILE-study was a randomized controlled trial with two parallel groups in which we evaluated the impact of the MCI in comparison with CAU. The complete study protocol has already been published [20]. In this paper, we report the clinical effectiveness. Outcome measurements were assessed at baseline (BS) and at 3 and 6 months' follow-up (FU3M and FU6M). The primary outcome measure of the study was disease-specific self-efficacy; secondary outcomes measures were the following: general self-efficacy, adherence, seizure severity, emotional functioning, quality of life proactive coping, and side-effects of AED. Instruments used to assess outcome measurements are shown in Table 1. The cost-effectiveness and the process evaluation of the ZMILE-study are reported elsewhere [21,22].

2.2. Participants

Eligible PWE for this study were adults who were 18 years or over, living at home, diagnosed with epilepsy, and using AED; who understood the Dutch language; and who were willing and able to use e-Health devices belonging to the MCI [20]. Excluded were PWE who were not able or willing to function in group activities, or when, based on clinical judgment, it was considered that they would not be able to comprehend topics discussed within the MCI (e.g., PWE with cognitive deficits). Patients were not selected or referred based on a preexisting measure of epilepsy self-management as this was a pragmatic trial and this more closely resembles actual practice.

2.3. Procedure

Between March 2014 and December 2015, the Academic Centre for Epileptology recruited PWE during regular attendances at the neurology clinic, via press releases in national epilepsy magazines (Epilepsie, Transmissie) and via social media (Facebook). All potential candidates were informed about the procedure at an initial meeting with one of the researchers. One week later, PWE who wanted to participate were invited for a second visit, were asked to sign an informed consent form, and were allocated randomly to either the intervention or CAU group.

Baseline measurements (BS) were conducted after randomization. All participants received at baseline the Medication Event Monitoring System (MEMS) and a set of questionnaires. Participants were asked to fill in the questionnaires at home and send them back in a prestamped envelope. Prior to the follow-up visits (FU3M, FU6M), the questionnaires were sent by post so that participants could complete them at home. They were collected during the follow-up visits, and the MEMS was read (i.e., the number of times the container was opened). The procedure was approved by the Ethics Committee of Maastricht University/Hospital Maastricht, The Netherlands; an overview is presented in Fig. 1.

2.4. Randomization

To ensure parallel provision of both groups (intervention & CAU), two equal cohorts of PWEs were needed at the moment of randomization. Patients with epilepsy were assigned to the intervention group or the CAU group by means of block randomization. Instead of the intended blocks of 10 PWE, we also used blocks of six, eight, or ten PWE for practical reasons. An assistant, not involved in the treatment nor in the trial, executed the procedure using a randomization program (www.randomization.com). The randomization scheme was distributed to the researcher in sealed envelopes during the first visit, prior to BS.

Table 1
Overview of measurements per time point.

Outcomes	Instrument	Range poor–good	BS	FU3M	FU6M
Primary outcome measure					
Self-efficacy	Epilepsy Self-efficacy Scale (ESES) [37]	33–330	X	X	X
Secondary outcome measures					
General self-efficacy	Generic Self-efficacy Scale (GSES) [38]	10–40	X	X	X
Adherence	MEMS [39]	NA	X	X	X
Adherence	Medication Adherence Scale (MARS-5) [40]	5–25	X	X	X
Seizure frequency	Questionnaire seizure frequency	–	X	X	X
Seizure severity[a]	National Hospital Seizure Severity Scale (NHS3) [41]	27–1	X	X	X
Emotional functioning	Hospital Anxiety and Depression Scale (HADS) [42]	42–0	X	X	X
	Subscale anxiety	21–0			
	Subscale depression	21–0			
Quality of life	Quality of Life in Epilepsy (QOLIE-31P) [24,43]	0–100	X	X	X
Proactive coping	Utrecht Proactive Coping Competence (UPCC) [44]	21–84	X	X	X
Side-effect[b]	Side-effects of antiepileptic drugs (SIDAED) [45]	138–0	X	X	X

BS = baseline outcome assessments; FU3M & FU6M = follow-up outcome assessments at 3 & 6 months.
[a] If no seizures had occurred in the past year, a score of 0 was allocated.
[b] Only the severity of the side-effects was measured.

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