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The effects of medication education and behavioral intervention on Chinese patients with epilepsy

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ABSTRACT

Objectives: The objectives of this study were to evaluate the effects of medication education and behavioral intervention on Chinese patients with epilepsy and to compare the difference between them.
Methods: A total of 109 patients with epilepsy who did not to take their antiepileptic drugs (AEDs) more than once were randomly assigned to two intervention groups: the medication education group (group I) and the medication education with behavioral intervention group (group II). Group I was initially provided with medication education in the form of oral education and written materials, and this education was reinforced by monthly calls from the pharmacist over the next six months. The behavioral intervention provided to group II consisted of a modified medication schedule which was based on cue–dose training therapy. The outcomes that were evaluated both in the beginning and in the end of the study included adherence, which was measured using the four-item Morisky Medication Adherence Scale (MMAS-4), the number of seizures, knowledge of AEDs, and the number of patients who missed a dose of their AEDs. Differences within and between the groups were analyzed.
Results: After intervention, the adherence and knowledge of AEDs increased greatly in all patients, and the number of patients who had seizures or missed AEDs decreased. However, no significant differences were observed between groups I and II. The observed changes were (group I vs group II, p value) increased adherence: 62.3% vs 64.3%, 0.827; increased knowledge of AEDs: 88.7% vs 80.4%, 0.231; and improved seizure control: 64.2% vs 64.3%, 0.988. In addition, the percentage of patients who forgot to take their AEDs decreased to 45.0% from more than 70%, and 44.9% of these patients took the missed AEDs as soon as they remembered.
Discussion: These findings clearly demonstrate that medication education and reinforced telephone calls from pharmacists can help to increase adherence to AEDs, the knowledge of patients regarding AEDs, and seizure control. However, the inclusion of a behavioral strategy that was easy to administer and use in this program did not lead to any significant effects on improving adherence. The results indicate that pharmacists can play an important role in improving the effects of medication regimens, but further research is required to identify strategies for improving adherence to behavioral theory.

1. Introduction

Poor adherence to treatment regimens for chronic diseases is an increasing worldwide problem and is one of the primary causes of treatment failure in drug therapy. Data suggest that patients exhibit an approximately 50% adherence to long-term therapy for chronic illnesses in developed countries, and the rates are even lower in developing countries [1]. This poor adherence increases the burden of chronic disease worldwide. Epilepsy is a chronic disease for which antiepileptic drugs (AEDs) need to be taken for a long period of time. Adherence to AEDs is also suboptimal, and the rate of nonadherence ranges from 30% to 50% [2]. Nonadherence to AEDs is associated with higher rates of serious clinical events, including in a threefold increase in mortality risk [3] and an increased likelihood and cost of hospitalization and emergency room treatment [4]. Most people who are afflicted with epilepsy live in developing counties, with over half of the world's 50 million patients with epilepsy living in Asia [5]. There are nine million cases in China alone [6], which accounts for nearly one-sixth of the cases in the world. Therefore, nonadherence to AEDs is a large problem in China that needs to be solved.

The World Health Organization (WHO) has concluded 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" [1]. The effects of various

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interventions to improve adherence have been proven in many studies [7–10]. Many researchers consider educational and behavioral strategies to be the two main interventions that can lead to improved adherence [11,12]. Although education has been shown to have mixed effects on adherence, behavioral interventions have been suggested to have better effects on adherence [12]. Providing instruction about the methods of incorporating drug administration into patients' daily lives, as one type of behavioral intervention, was also found to improve adherence to AEDs; however, no studies demonstrated this [1]. In all of the current studies regarding improving medication adherence for chronic health problems, researchers have compared a single treatment to "usual care", in which no specific intervention is performed; no published studies have compared two different interventions [12]. In this study, we not only evaluated the effects of medication education and behavioral intervention on patients with epilepsy but also compared the effects of the two intervention strategies to reveal the value of behavioral intervention. Based on the prominence of Fudan University's Huashan Hospital in treating epilepsy, patients with epilepsy were the first targeted population we evaluated to explore the effect of interventions on improved adherence in this program.

2. Methods

2.1. Participants

We focused on patients with epilepsy who were treated between September 2011 and March 2013 at the outpatient clinic of Neurology in Huashan Hospital, University of Fudan, Shanghai, China. Eligible patients were recruited if they were diagnosed with epilepsy, were older than 16 years of age, took antiepileptic drugs for more than six months, and did not take their AEDs at least once over the past six months. Patients were excluded if they only took traditional Chinese medicine (TCM)/Chinese patent medicine, had barriers in communication or cognitive impairment and could not communicate with researchers, stopped taking antiepileptic drugs, or lost contact immediately after being recruited into the study. The attending physician asked each patient whether he or she had forgotten to take their AEDs at any point within the past six months.

All patients who met the inclusion criteria in the clinic of Doctor Guoxing Zhu were included in the study and assigned to one of the two groups with different levels of intervention. One group was provided medication education (group I), and the other group was provided medication education and behavioral intervention (group II). A list of 300 random numbers between "0" and "9" was generated using IBM SPSS statistics 19. The patients were numbered according to the order in which they were recruited. Patients who had received an even randomly generated number were assigned to group I, and patients who received odd numbers were assigned to group II.

The Research Ethics Committee of Huashan Hospital approved this study. Among the 154 eligible patients who were approached for informed consent, 124 initially volunteered to participate in the study.

2.2. Interventions

2.2.1. Educational intervention

2.2.1.1. Oral and written education. All patients were educated by a pharmacist according to the guidelines of the American Society of Health-System Pharmacists (ASHP) regarding pharmacist-conducted patient education and counseling [13]. After their baseline knowledge of AEDs was assessed, all patients were educated orally. Written material was then given to the patients to provide them with more details about AEDs.

2.2.1.2. Monthly calls from the pharmacist. To strengthen the effects of medication education, the patients were followed up by telephone every month by the pharmacist to check whether they were nonadherent. Patients were again instructed about their medications and asked to adhere to their AEDs.

2.2.2. Behavioral intervention

The behavioral intervention utilized in this program consisted of a modified medication schedule, which was based on cue–dose training therapy [14] and the strategies described by Roter et al. [11]. The design of the modified medication schedule was modeled after the schedules developed by Kripalani et al. [15] and Cordasco et al. [8].

The medication schedule used in this program was presented in the form of a table that illustrated the daily medication therapy of patients with pictures of AEDs, and it provided patients with cues to take their medications (see Fig. 1). It was modified from a useful tool reported by Cordasco with permission. This individualized schedule was developed for each patient, and the pharmacist pasted a picture of the AEDs that each patient was taking in the first column along with a picture corresponding to the number of pills in the column for "Breakfast," "Lunch," "Dinner," or "Bedtime." In the last column, the pharmacist wrote down the most common activities that patients were performing each time they took their medication and the approximate time they would be taking it. This last column was included to help patients incorporate AED administration into their daily lives and to transform their daily routines into cues to take their AEDs. This method is based on the hypothesis that cue–dose training, which uses personalized cues for remembering particular dose times, can improve medication adherence [14]. It has been reported that the most common cue for patients was to link the dose with an event in their daily life [16,17], such as embedding medication habits at mealtime or during the patients' standard wake-up and sleep routines. Coincidentally, the most common cue for the patients involved in the current program was mealtime.

2.3. Measures

2.3.1. Adherence

Self-report methods have been widely used to study adherence in epilepsy [18]. In this program, adherence was measured using the four-item Morisky Medication Adherence Scale (MMAS-4) [19], which is a widely used and validated self-report method. This scale is categorized into three levels: low, medium, and high. The MMAS-4 is a feasible, reliable, and valid measure of patient adherence that can rapidly assess the adherence of patients at a low cost [20]. In addition, it is easy to use in clinical settings and has been reported to be comparable with pill counts, electronic monitoring, drug refills [21,22], and other measures of adherence [23]. The MMAS-4 is considered to be the correct measure to evaluate adherence in clinical trials. Furthermore, the MMAS-4 has been shown to be adaptable to in China, and its validity has been proven by many researchers in China [24–26].

Each item of the four items was answered by a simple "yes" or "no". A response of "yes" was scored as 0 point, and a "no" response was counted as 1 point. A total score of 0 represented a high level of adherence, scores of 1 and 2 represented medium adherence, and scores of 3 or 4 represented low adherence.

2.3.2. Seizure control

Because decreasing the number of seizures by 50% is the critical point that is often used to distinguish whether a medication is effective, this method was adopted as the measure of seizure control for the current study. The baseline for each patient was considered to be the number of seizures during the preceding six months prior to beginning this program, and this number was self-reported by patients. The number of seizures each patient experienced during the follow-up period was reported according to the patients' records and telephone follow-ups by the pharmacist.