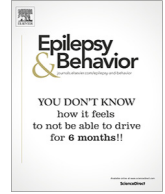




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Evaluation of a self-management intervention for adults with epilepsy in Taiwan: A longitudinal randomized controlled trial



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ABSTRACT

Purpose: Epilepsy is a neurological disease that causes recurrent seizures and can have a significant impact on a person's quality of life (QOL). A self-management intervention (SMI) can allow adults with epilepsy to modify behaviors in order to manage their seizures and evaluate the impact of medication and treatments on their daily lives. The purpose of this study was to investigate the effects of a SMI for adults with epilepsy.

Methods: This was a longitudinal randomized controlled trial. Adults with epilepsy between the age of 20 and 65 years were recruited from a medical center in northern Taiwan. Participants were assigned to an intervention group (IG) or control group (CG) through simple randomization. Data regarding demographic and clinical characteristics were collected at baseline (T0). In addition, participants answered nine validated self-report questionnaires, which were used as outcome measures. Following collection of baseline data, the CG received routine monthly counseling over the next 3 months. The IG received the routine monthly counseling, as well as individual face-to-face health counseling on self-management 1 h/month and remote counseling via the phone or computer network at least twice per month. After the first month (T1) and at the end of the third (T2) and sixth months (T3) participants answered the nine questionnaires again. Differences in outcomes between the IGs and CGs were analyzed by comparing scores for the nine outcome variables at T0 with scores at T1, T2, and T3 with generalized estimating equations.

Results: A total of 210 adults agreed to participate in the study; however, only 155 participants completed the questionnaires for all three time points: 75 in the CG and 80 in the IG. The mean age of the 155 participants was 39.6 years (SD = 10.9). There was no significant difference between demographic or clinical variables between the two groups. The only difference in baseline scores (T0) among the nine self-report questionnaires was in epilepsy knowledge, measured with the Epilepsy Knowledge Profile questionnaire, which were significantly higher for the CG (mean = 32.28, SD = 3.92) than the IG (mean = 23.01, SD = 2.79) ($p < 0.001$). Generalized estimating equations (GEE) analysis showed scores decreased significantly at T3 from baseline for the CG for epilepsy knowledge and QOL ($p < 0.001$). Improvements in scores for sleep quality, anxiety, depression, self-efficacy, coping, and social support did not differ between groups.

Classification of the IG by gender showed a significantly greater increase for males compared with females from baseline to T3 for epilepsy knowledge ($p < 0.001$). If we further classified the IGs by seizure frequency, participants with a seizure frequency of ≥ 1 per year had a more significant increase in epilepsy knowledge and increase in QOL compared with participants with a seizure frequency of < 1 per year at T3 compared with T0.

Conclusion: The lack of improvement in health-related quality of life (HRQoL) following the SMI may indicate that additional time is required to change behaviors that impact this variable for patients with epilepsy. Additional research should focus on variables associated with medication compliance, epilepsy knowledge, medicine symptom distress, self-efficacy, anxiety, and HRQoL.

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1. Introduction

Epilepsy is a neurological disease that causes recurrent seizures [1,2]. Educating adults with epilepsy about self-management of the disease helps modify behaviors in order to manage seizures, treatments, and evaluate the impact of epilepsy on their daily lives [1]. Self-management interventions (SMI) have been shown to be an effective method of helping people with epilepsy improve their health status, gain control of seizures [2–4] in a cost-effective manner [5] that also increases health-related quality of life (HRQoL) [4,6,7].

The six indicators for evaluating outcomes of self-management consist of self-efficacy, health behaviors/attitudes, health status, health service utilization, psychological indicators and quality of life (QOL) [8]. Self-management for patients with epilepsy can be approached from three levels: treatment management, seizure management, and life management [1,9], which should include medication-related issues, safety-related issues, and general lifestyle issues [9]. Psychotherapy, such as cognitive-based or mindfulness-based therapies, can also be incorporated into self-management programs to help patients manage the impact of epilepsy on their lives [10]. Goal-setting is also important in a self-management program which can provide positive feedback for patients with epilepsy and can increase feelings of empowerment and self-efficacy [1,9].

Interventions for patients with epilepsy to provide information about the disease have been demonstrated to improve QOL and reduce seizure frequency [6,11,12]. Other studies on SMIs that included epilepsy knowledge and medication management demonstrated improvements in several areas: sleep quality and social support [13,14], medication compliance [13,15], self-efficacy [14–16], self-management ability [15–17], medication management outcome expectance [18], and QOL [6,14,16]. Several studies have also demonstrated self-management can help to reduce anxiety and/or depression [19–21], medication symptom distress [19,20,22], and seizure frequency [6,14,23] and physical limitations [22,24].

Structured nurse-lead SMI programs for patients with epilepsy that include counseling and provide information about epilepsy and concomitant problems can improve QOL for patients [12,24] and increase patient satisfaction [12]. It has also been suggested that SMI programs that include both verbal instruction and written educational materials can lead to better health outcomes for patients with epilepsy [9]. In addition, incorporating technology-focused information can enhance patient reminders about self-management skills, which are well-received by patients and beneficial for establishing adherence to behaviors [10].

A systematic review of the literature found that heterogeneity of SMI programs for patients with epilepsy made it difficult to compare the effects of different interventions on outcomes [6]. However, what has been shown to be critical for successful SMI programs is a multidimensional educational component [6,10]. Therefore, the purpose of this study was to investigate the effects of a SMI program for adults with epilepsy that included information about epilepsy treatment, seizures, living with epilepsy, and emotional responses to epilepsy.

2. Methods

2.1. Study design and participants

This was a longitudinal randomized controlled trial. Adult patients with epilepsy were recruited from a medical center in northern Taiwan from August 2012 to December 2015 and assigned to either the intervention group (IG) or control group

(CG) through simple randomization. The inclusion criteria for participants were a diagnosis of epilepsy by a neurologist, age 20–65 years, and able to communicate in Mandarin or Taiwanese. Patients were excluded if they were not taking any antiepileptic medications, or had been diagnosed with cognitive impairment, psychological dysfunction, or a psychiatric disorder.

2.2. Usual care

Participants in the CG received routine monthly counseling about epilepsy in the epilepsy outpatient department of the study hospital for 3 months. This counseling is provided to all patients with epilepsy by a clinical nurse. The routine counseling includes individual discussion with the patient about their seizure frequency over the last month, how to identify and monitor seizure auras, recording and tracking frequency of seizures, adherence to antiepileptic drugs (AEDs) and how to improve adherence, and identification of adverse events of AEDs and any occurrence over the previous month. The length of each monthly counseling session is 30 min.

2.3. The self-management intervention (SMI)

The SMI was developed based on the literature regarding interventions for adults with epilepsy, which employed semi-structured sessions on self-management [18,25,26] and additional telephone-based support [2,18,24]. In addition, we obtained input from physicians, nurses, and psychologists who were specialists in epilepsy and treating patients with epilepsy. The content of the sessions, including statements and questions, and a handout on epilepsy was reviewed by a panel of experts in epilepsy: a clinical specialist, a physician, a nurse, an academic researcher, and a counseling psychologist. Panel members scored the items on a 4-point Likert scale from 0 (not relevant) to 3 (highly relevant) and the content validity index (CVI) confirmed the validity of the SMI (CVI = 1.0). No revisions were made to the content of the program.

The SMI program was provided by the same researcher for all participants in the IG on an individual basis 1-hour per month for a period of three months. The IG also received the monthly routine counseling about epilepsy described above. The intervention program focused on four areas of self-management: epilepsy treatment, seizures, daily life, and emotions. The program was provided as an education and counseling program by a nurse researcher. The first month included evaluation of epilepsy treatment management (understanding of epilepsy symptoms, epilepsy treatment, and drug management) and counseling from nurse educators about any concerns the patients had about managing symptoms. The session in the second month included assessment of seizure management (the cause of seizures, seizure frequency, seizure aura, seizure treatment, and seizure frequency recording and tracking), and managing daily life events. Counseling included discussions about how to take precautions and follow medical guidelines, and the impact epilepsy was having on the patient's daily living, work, and interpersonal interactions. The third month involved emotional management assessment and education regarding psychological distress, negative experience processing, and stress coping methods. In addition to the monthly sessions, each participant received remote support and counseling twice a month, either by telephone or online via the Internet.

2.4. Ethical considerations

The study was reviewed and approved by the Institutional Review Board (No. 101-2194A3) of Chang Gung Medical Foundation. A research assistant explained the study purposes and procedures in detail. Patients were assured they were free to withdraw

from the study at any time, and for any reason, without any compromise in treatment. Written informed consent was obtained prior to filling out the questionnaires.

2.5. Data collection

Data were collected using a self-administered multi-part structured questionnaire. All participants completed the questionnaires at four time points: baseline (T0, prior to randomization), and at 1 month, 3 months, and 6 months after enrollment in the IG or CG. (T1, T2, and T3, respectively). The first part of the questionnaire collected data regarding demographic and clinical characteristics of the participants, which was only collected at baseline. Pre- and post-test measures were collected with nine self-report questionnaires, described below.

2.5.1. The Pittsburgh Sleep Quality Index (PSQI)

Sleep quality was assessed with the 9-item PSQI developed by Buysse et al. [27], which assesses sleep quality over 30 days. Items are scored on a 4-point Likert scale, ranging from 0 (never a problem) to 3 (always a problem). Total global summary scores range from 0 to 21; a score >5 indicates poor sleep quality. We used a Chinese version of the scale, which was translated and validated by Tseng [28]. The scale has been shown to be a valid measure of sleep quality of older adults in Taiwan, with a Cronbach's alpha for internal consistency reliability of 0.8, with an intraclass correlation coefficient (ICC) for 4-week test-retest reliability of 0.9, and a relative CVI of 0.96. In this study, Cronbach's alpha was 0.82.

2.5.2. The Liverpool Adverse Events Profile (LAEP)

The LAEP measures adverse effects of AEDs and contains 22 items related to symptoms of depression or anxiety experienced over the last 4 weeks [29]. Items are scored on a 4-point Likert scale, ranging from 1 (never a problem) to 4 (always a problem). Total scores ranging from 22 to 88 is calculated; higher scores are indicating a greater burden from the effects of AEDs. This study used a Chinese version of the LAEP, which was demonstrated to be a valid instrument for individuals with epilepsy in Taiwan with Cronbach's alpha of 0.92, ICC for 4-week test-retest reliability of 0.83, and a relative CVI of 1.0 [30]. The scale has been shown to be a valid instrument. In this study Cronbach's alpha was 0.93.

2.5.3. The Hospital Anxiety and Depression Scale (HADS)

The HADS self-report instrument developed by Zigmond and Snaith [31] measures anxiety and depression in an outpatient setting. The HADS is comprised of 14 items, which are divided into two 7-item subscales: HADS-A for anxiety and HADS-D for depression. Participants rate each item on a 4-point Likert scale ranging from 0 (never a problem) to 3 (always a problem); five items are reverse coded. The total subscale scores range from 0 to 21. Higher scores indicate greater levels of anxiety and depression. The total HADS score is used as a global measure of psychological distress. This study used the Chinese version of the HADS [32]. The scale has been shown to be a valid instrument with Cronbach's alpha of 0.8, ICC for 4-week test-retest reliability of 0.77, and CVI of 0.93. In this study, Cronbach's alpha was 0.84.

2.5.4. The Compliant Behavior Scale (CBS)

The 10-item CBS is a self-report questionnaire developed by Hu et al. [33] to measure medication compliance for patients with hypertension in Taiwan. Items are scored on a 5-point Likert scale, ranging from 1 (often happens) to 5 (never happens). Total scores range from 10 to 50; higher scores indicate a higher level of medication compliance. The scale has been shown to be a valid instrument with Cronbach's alpha of 0.73, ICC for 4-week test-retest

reliability of 0.97, and CVI of 0.86. In this study, Cronbach's alpha was 0.98.

2.5.5. The Epilepsy Knowledge Profile (EKP)

The 34-item EKP is a self-report instrument developed by Jarvie et al. to assess a patient's knowledge of the medical aspects of epilepsy [34,35]. Participants answer each item with a yes (1) or no (0) response. Higher scores indicate a higher level of knowledge of epilepsy. We used a Chinese translation of the EKP scale, which has been shown to be a valid instrument with Cronbach's alpha of 0.63, ICC for 4-week test-retest reliability of 0.78, and a CVI of 0.84 [36]. In this study, Cronbach's alpha was 0.92.

2.5.6. The Epilepsy Self-Efficacy Scale (ESES)

The 33-item ESES is a self-report instrument that assesses various aspects of daily self-management of epilepsy [37]. Each item is rated on an 11-point Likert scale from 0 (I cannot do it at all) to 10 (Sure I can do it). Total scores range from 0 to 330; higher scores indicate higher levels of self-efficacy for managing epilepsy. This study used a validated Chinese translation of the scale, which has Cronbach's alpha of 0.92, an ICC for 4-week test-retest reliability 0.8, and a CVI of 0.97 [36]. In this study, Cronbach's alpha was 0.90.

2.5.7. Jalowiec Coping Scale (JCS)

The 40-item JCS measures frequency and effectiveness of different coping behaviors consisting of affective-oriented coping (25 items) and problem-oriented coping (15 items) [38,39]. Participants respond to each item on a 4-point Likert scale from 0 (never used) to 3 (often used). Total scores range from 1 to 120; higher scores indicate better coping skills. Cronbach's alpha for the total scale is 0.86. In this study, we used a validated Chinese translation of the scale, which has Cronbach's alpha of 0.89, and an ICC for 4-week test-retest reliability of 0.77, and a relative CVI of 1.0.

2.5.8. Inventory of Socially Supportive Behaviors (ISSB)

The 15-item ISSB scale is a self-report measure of perceived social support during the preceding month [40,41]. Items include support in the form of goods and services (tangible) and support in the forms of guidance and encouragement (intangible), which are rated on a 5-point Likert scale from 0 (not at all) to 4 (about every day). Total scores range from 0 to 60; higher scores indicate greater perceived social support. We used a Chinese translation of the scale for this study, which has been demonstrated to be valid for adults in Taiwan, with Cronbach's alpha of 0.93, an ICC for 4-week test-retest reliability of 0.75, and a relative CVI was 1.0 [36]. In this study Cronbach's alpha was 0.95.

2.5.9. Quality of Life in Epilepsy-31 (QOLIE-31)

The 31-item QOLIE-31 instrument was developed as a measure of HRQoL for adults with epilepsy [42]. The QOLIE-31 self-report is comprised of questions about a patient's health and daily activities. The summary score of this scale ranges from 0 to 100. A higher total score indicates a better QOL for adults with epilepsy. We used the Taiwanese version of the QOLIE-31, which has been demonstrated to be a valid scale for persons with epilepsy in Taiwan, which Cronbach's alpha of 0.93, an ICC for 4-week test-retest reliability of 0.86, and a relative CVI of 1.0 [36]. In this study, Cronbach's alpha was 0.93.

2.6. Statistical analysis

All questionnaires were encoded to comply with confidentiality. Statistical analysis was performed using the software package SPSS 21.0 for Windows. Univariate analyses of baseline demographic and clinical data for all participants and the CGs and IGs were conducted using chi-square tests and independent *t*-tests for

frequency (*n*, %), mean, and standard deviation (SD). Analysis of baseline scores on the multi-part self-management questionnaire were conducted using one-way ANOVA and Pearson's correlation. We then performed bivariate analyses with generalized estimating equations (GEE) to examine changes in scores from baseline at T1, T2, and T3. All statistical tests were two-tailed, and the significance level was set to a standard of $\alpha < 0.05$.

3. Results

3.1. Participants and characteristics

A total of 216 patients agreed to participate. However, only 210 participants returned for baseline evaluations. These participants were then randomized to the IG (*n* = 105) or CG (*n* = 105). An additional 30 participants in the IG and 25 in the CG were not included in the final analysis due to withdrawal from the study (IG, *n* = 14; CG, *n* = 7), a missed outpatient follow-up (IG, *n* = 2; CG, *n* = 3), or not all intervention or phone support sessions were completed (IG, *n* = 14; CG, *n* = 15). Data from 155 valid questionnaires were analyzed: 75 participants from the IG and 80 participants in the CG. The flowchart for the participants is shown in Fig. 1.

The mean age of the 155 participants was 39.6 years (SD = 10.9); 56% were male; and most (78%) had at least a college or university education. Seizure frequency ranged from one per month (14.8%) to ≥ 1 per year (59.4%); 58% had a combined seizure type. There was no significant difference between groups for demographic or clinical variables (Table 1).

Baseline scores for the nine self-report questionnaires used as outcome variables are shown in Table 2. Only the score for epilepsy knowledge (EKP scale) differed between groups. The score for all participants was 27.64 (SD = 6.60). The CG had a significantly higher baseline score than the IG (32.28, SD = 3.92 vs. 23.01, SD = 2.79, respectively ($p < 0.001$)). The test for homogeneity showed no significant differences for any other variables.

3.2. Effects of the SMI

GEE analysis demonstrated significant differences in outcome variables between participants who received the SMI and the CG. In the IG, the 6-month SMI significantly increased medication compliance ($p < 0.001$) and epilepsy knowledge ($p < 0.001$). In the CG, adverse events increased ($p < 0.001$), whereas knowledge of epilepsy and QOL decreased ($p < 0.001$ and $p = 0.04$, respectively).

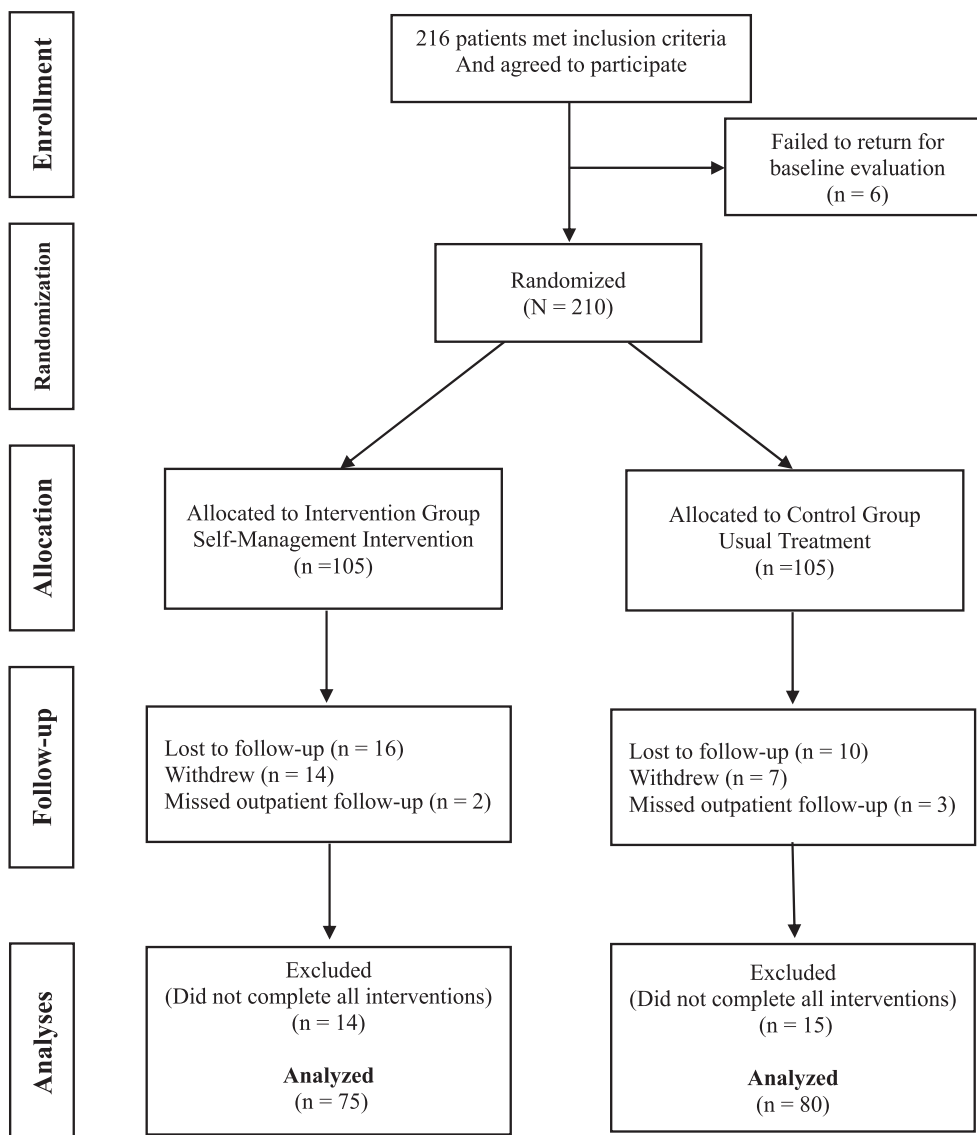


Fig. 1. Flow chart of participants in the study.

Table 1
Demographic and clinical characteristics of all participants (N = 155) and comparison between the Control group and Intervention group.

Variable	Group			t/ χ^2	p
	All Participants (N = 155)	Control (n = 80)	Intervention (n = 75)		
Demographic characteristic					
Age (years), mean (SD)	39.55 (10.9)	40.72 (10.46)	39.11 (10.37)	0.72	0.37
20–40 years, n (%)	87 (56.1)	43 (53.7)	43 (57.3)	0.01	0.91
41–65 years, n (%)	68 (43.9)	37 (46.3)	32 (42.7)		
Gender, n (%)					
Male	87 (56.1)	46 (57.5)	41 (54.7)	0.08	0.78
Female	68 (43.9)	34 (42.5)	34 (45.3)		
Level of education, n (%)					
Junior high school	15 (9.7)	10 (12.5)	5 (6.7)	16.55	0.60
Senior high school	19(12.3)	8 (10.0)	11 (14.7)		
College	60 (39.3)	29 (36.3)	31 (42.6)		
University or higher	61 (38.7)	33 (41.2)	27 (36.0)		
Employment, n (%)					
Employed	112 (72.3)	55 (68.8)	57 (76.0)	–1.0	0.32
Unemployed	43 (27.7)	25 (31.2)	18 (24.0)		
Clinical characteristic					
Onset of seizures (age), mean (SD)	17.65 (9.62)	18.13 (10.6)	17.15 (8.5)	0.32	0.53
Duration of seizures, mean (SD)	22.05 (11.50)	22.25 (10.7)	21.82 (12.4)	0.20	0.82
Seizure frequency, n (%)					
Once a month	23 (14.8)	12 (15.0%)	11 (14.7)	19.58	0.77
Once every 3 months	13 (8.4)	6 (7.4)	7 (9.3)		
Once every 6 months	13 (8.4)	7 (8.8)	6 (8.0)		
Once a 1 year	14 (9.0)	7 (8.8)	7 (9.3)		
Over >once a year	92 (59.4)	48 (60.0)	44 (58.7)		
Number of AEDs per day, n (%)					
1	68 (43.9)	31 (38.8)	37 (49.3)	3.92	0.92
2	47 (30.3)	20 (25.0)	27 (36.0)		
≥3	40 (25.8)	29 (36.2)	11 (14.7)		
Seizure type					
Partial	32 (20.7)	20 (25.0)	12 (16.0)	2.61	0.63
Generalized	33 (21.3)	15 (18.8)	18 (24.0)		
Combined	90 (58.0)	45 (56.2)	45 (60.0)		

Abbreviation: SD = standard deviation; AED = antiepileptic drugs.

Table 2
Baseline scale scores (T0) on self-report questionnaires for all participants and comparison between the Control and Intervention group.

Questionnaire	All participants (N = 155)		Control group (n = 80)		Intervention group (n = 75)		t/r	p
	Mean ± SD	n (%)	M ± SD	n (%)	Mean ± SD	n (%)		
The Pittsburgh Sleep Quality Index	8.79 ± 2.69		8.95 ± 2.50		8.75 ± 2.89		0.15	0.86
Good (≤5)		21 (13.5)		9 (11.3)		12 (16.0)	1.71	0.19
Poor (>5)		134 (86.5)		71 (88.8)		63 (84.0)		
The Liverpool Adverse Events Profile	38.72 ± 13.10		38.95 ± 13.89		38.47 ± 12.3		0.23	0.82
HADS-Anxiety	6.27 ± 4.15		6.83 ± 4.53		5.71 ± 3.67		0.06	0.19
≤7		84 (54.2)		39(48.7)		45 (60.0)	4.93	0.30
8–10		48 (31.0)		26(32.5)		22 (29.3)		
≥11		23 (14.8)		15(18.8)		8 (10.7)		
HADS-Depression	5.34 ± 3.80		5.49 ± 3.99		5.19 ± 3.61		0.68	0.73
≤7		103 (66.5)		53(66.3)		50 (66.6)	1.02	0.91
8–10		35 (22.5)		18(22.5)		17 (22.7)		
≥11		17 (11.0)		9(11.3)		8 (10.7)		
Compliant Behavior Scale	36.21 ± 2.96		36.48 ± 2.96		35.95 ± 2.97		0.90	0.29
Epilepsy Knowledge Profile	27.64 ± 6.60		32.28 ± 3.92		23.01 ± 2.79		17.32	<0.001
Epilepsy Self-Efficacy Scale	277.47 ± 41.33		273.64 ± 41.29		281.29 ± 41.37		–1.00	0.32
Jalowiec Coping Scale	50.90 ± 14.76		51.41 ± 14.7		50.41 ± 14.85		0.66	0.69
Inventory Social Support Behavior	13.13 ± 2.50		13.08 ± 1.95		13.19 ± 2.99		–0.03	0.98
Quality of Life in Epilepsy-31	60.51 ± 16.54		59.54 ± 18.45		61.48 ± 14.24		–0.95	0.34

Abbreviations: SD = standard deviation; HADS = Hospital Anxiety and Depression Scale. P-values in bold indicate significance <0.05.

However, there was no significant difference between two IG and CG in sleep quality, anxiety, depression, self-efficacy, coping or social support (see Table 3).

3.3. Effects of the SMI by gender and seizure frequency

GEE analysis demonstrated significant differences in changes from baseline to 6 months (T3) for outcome variables between

male and female participants who received the SMI (Table 4). Although both males and females had significant changes in medication compliance and epilepsy knowledge, the change in medication compliance was significantly greater for females compared with males (p < 0.001), while the increase in epilepsy knowledge was greater for males (p < 0.001). Only male participants in the IG had a significant change from baseline for adverse events, anxiety, and epilepsy self-efficacy (all p < 0.05).

Table 3
GEE analysis of change in scores on self-report questionnaires at 1 month (T1), 3 months (T2) and 6 months (T3) compared with baseline (T0) for the Intervention group (n = 75) and Control group (n = 80).

Questionnaire	Group	T0	T1	T2	T3	P-value	Group p/Wald χ^2	Time p/Wald χ^2	Group \times time p/Wald χ^2
		M \pm SEM	M \pm SEM	M \pm SEM	M \pm SEM				
Sleep quality	Control	8.95 \pm 0.28	9.40 \pm 0.26	9.16 \pm 0.32	9.52 \pm 0.30	0.05	0.29/1.10	0.50/1.40	0.47/4.55
	Intervention	8.75 \pm 0.33	8.73 \pm 0.32	8.85 \pm 0.33	8.75 \pm 0.40	0.10			
Adverse events	Control	39.26 \pm 1.6	43.71 \pm 1.63	43.07 \pm 1.68	45.75 \pm 1.60	<0.001	0.23/1.42	0.001/14.71	<0.001/23.61
	Intervention	38.47 \pm 1.4	39.43 \pm 1.32	41.40 \pm 1.40	42.19 \pm 1.30	0.07			
Anxiety	Control	6.83 \pm 0.5	6.66 \pm 0.47	6.31 \pm 0.48	6.33 \pm 0.50	0.29	0.06/3.67	0.38/1.94	0.27/6.35
	Intervention	5.71 \pm 0.4	5.32 \pm 0.42	5.48 \pm 0.45	6.11 \pm 0.50	0.21			
Depression	Control	5.49 \pm 0.4	5.54 \pm 0.48	5.71 \pm 0.38	5.33 \pm 0.40	0.71	0.22/1.52	0.63/0.94	0.66/3.28
	Intervention	5.19 \pm 0.4	4.65 \pm 0.46	5.17 \pm 0.41	5.21 \pm 0.50	0.95			
Medication compliance	Control	36.48 \pm 0.3	36.20 \pm 0.25	37.47 \pm 0.40	37.09 \pm 0.40	0.17	0.56/0.34	<0.001/23.94	<0.001/28.17
	Intervention	35.95 \pm 0.3	36.70 \pm 0.45	38.12 \pm 0.43	38.27 \pm 0.50	<0.001			
Epilepsy knowledge	Control	32.28 \pm 0.6	33.79 \pm 0.48	24.22 \pm 0.34	24.44 \pm 0.30	<0.001	<0.001/171.76	<0.001/181.17	<0.001/481.11
	Intervention	23.01 \pm 0.4	24.53 \pm 0.46	24.79 \pm 0.35	25.61 \pm 0.40	<0.001			
Epilepsy Self-efficacy	Control	273.64 \pm 4.6	274.83 \pm 5.16	278.22 \pm 5.59	272.12 \pm 5.30	0.70	0.23/1.43	0.48/1.46	0.52/4.19
	Intervention	281.29 \pm 4.6	284.61 \pm 4.93	283.27 \pm 4.76	286.66 \pm 4.60	0.13			
Coping behaviors	Control	51.41 \pm 1.6	52.05 \pm 1.75	52.14 \pm 1.61	53.33 \pm 1.50	0.10	0.86/0.03	0.36/2.02	0.83/2.16
	Intervention	50.41 \pm 1.7	51.59 \pm 1.53	52.58 \pm 1.27	53.19 \pm 1.70	0.12			
Social support	Control	13.08 \pm 0.3	13.06 \pm 0.34	13.55 \pm 0.32	13.54 \pm 0.30	0.22	0.79/0.07	0.59/1.04	0.16/7.88
	Intervention	13.19 \pm 0.3	13.61 \pm 0.33	13.21 \pm 0.36	13.64 \pm 0.30	0.20			
Quality of life	Control	59.54 \pm 1.9	56.17 \pm 1.82	58.36 \pm 1.70	58.96 \pm 2.26	0.04	0.36/0.86	<0.001/17.01	0.001/20.77
	Intervention	61.30 \pm 1.6	59.20 \pm 1.65	59.71 \pm 1.66	59.16 \pm 1.70	0.06			

Abbreviations: M \pm SEM = Estimated marginal mean \pm standard error of the mean; GEE = general estimating equation. P-values in bold indicate significance <0.05.

Table 4
GEE analysis of change in scores from baseline (T0) at 6 months (T3) in the intervention group by gender.

Questionnaire	Male (n = 41)			Female (n = 34)			Group p/Wald χ^2	Time p/Wald χ^2	Group \times time p/Wald χ^2
	T0	T3	P-value	T0	T3	P-value			
	M \pm SEM	M \pm SEM		M \pm SEM	M \pm SEM				
Sleep quality	8.66 \pm 0.4	8.74 \pm 0.5	0.85	8.85 \pm 0.33	8.47 \pm 0.5	0.47	0.15/2.08	0.87/0.73	0.85/3.40
Adverse events	36.78 \pm 1.6	40.66 \pm 1.8	0.01	42.71 \pm 2.3	43.89 \pm 1.8	0.67	<0.001/35.97	0.03/8.74	<0.001/46.10
Anxiety	5.0 \pm 0.5	5.92 \pm 0.7	0.03	6.56 \pm 0.6	6.16 \pm 0.7	0.50	<0.01/7.83	0.85/0.80	0.02/16.86
Depression	5.51 \pm 0.5	5.32 \pm 0.6	0.63	4.79 \pm 0.6	5.1 \pm 0.7	0.65	0.58/0.30	0.90/0.60	0.96/2.05
Medication Compliance	35.54 \pm 0.5	37.16 \pm 0.7	0.04	36.44 \pm 0.5	39.57 \pm 0.7	<0.001	0.24/1.38	<0.001/28.87	<0.001/33.81
Epilepsy knowledge	22.61 \pm 0.7	25.58 \pm 0.6	<0.001	23.50 \pm 0.4	25.70 \pm 0.7	0.002	0.63/0.24	<0.001/49.9	<0.001/152.9
Epilepsy Self-efficacy	279.93 \pm 6.3	289.08 \pm 6.0	0.04	282.94 \pm 7.2	279.93 \pm 7.2	0.59	0.68/0.17	0.92/0.48	0.99/1.10
Coping behaviors	49.59 \pm 2.5	54.00 \pm 1.9	0.06	51.41 \pm 1.7	50.90 \pm 2.9	0.85	0.64/0.22	0.58/1.97	0.75/4.22
Social support	13.12 \pm 0.4	13.26 \pm 0.5	0.70	13.26 \pm 0.6	13.87 \pm 0.5	0.37	0.34/0.91	0.73/1.31	0.86/3.22
Quality of life	63.70 \pm 1.9	62.04 \pm 2.4	0.20	58.79 \pm 2.3	56.59 \pm 2.6	0.12	<0.001/29.93	<0.01/3.66	<0.001/33.88

Abbreviations: M \pm SEM = Estimated marginal mean \pm standard error of the mean; GEE = general estimating equation. P-values in bold indicate significance <0.05.

Table 5
GEE analysis of change in scores from baseline (T0) at 6 months (T3) in the intervention group by seizure frequency.

Questionnaire	<1/year (n = 31)			\geq 1/year (n = 44)			Group p/Wald χ^2	Time p/Wald χ^2	Group \times time p/Wald χ^2
	T0	T3	P-value	T0	T3	P-value			
	M \pm SEM	M \pm SEM		M \pm SEM	M \pm SEM				
Sleep quality	8.75 \pm 0.6	9.23 \pm 0.8	0.47	7.38 \pm 0.8	8.38 \pm 0.6	0.17	0.05/3.77	0.87/0.71	0.69/4.76
Adverse events	44.83 \pm 2.6	45.82 \pm 2.1	0.69	34.0 \pm 3.6	40.13 \pm 3.5	0.27	<0.001/39.19	0.03/8.84	<0.001/48.55
Anxiety	6.46 \pm 0.7	7.23 \pm 0.8	0.29	6.5 \pm 1.3	6.63 \pm 1.1	0.9	<0.001/18.86	0.77/1.14	<0.01/21.34
Depression	6.33 \pm 0.7	6.77 \pm 0.7	0.47	5.75 \pm 0.6	5.75 \pm 1.6	1.0	<0.001/29.78	0.74/1.26	<0.001/35.34
Compliant behavior	35.04 \pm 0.8	37.14 \pm 0.9	0.07	36.63 \pm 0.4	37.88 \pm 1.0	0.13	<0.001/17.88	<0.001/24.31	<0.001/49.77
Epilepsy knowledge	23.71 \pm 0.5	25.36 \pm 0.6	0.006	22.88 \pm 0.9	25.50 \pm 0.8	<0.001	0.18/1.81	<0.001/143.5	<0.001/157.4
Epilepsy Self-efficacy	268.71 \pm 8.2	277.09 \pm 7.7	0.27	287.0 \pm 13.3	287.5 \pm 14.8	0.97	<0.001/16.69	0.84/0.83	0.01/17.57
Coping behaviors	52.42 \pm 3.1	52.77 \pm 2.8	0.86	45.63 \pm 7.2	52.13 \pm 7.3	0.42	0.12/2.37	0.6/1.89	0.47/6.65
Social support	13.42 \pm 0.5	14.0 \pm 0.4	0.22	12.88 \pm 0.9	12.5 \pm 1.7	0.68	0.69/1.45	0.01/6.66	0.3/8.43
Quality of life	55.05 \pm 2.2	52.06 \pm 2.7	0.49	62.08 \pm 3.7	60.47 \pm 6.0	0.72	<0.001/56.72	0.42/2.83	<0.001/61.82

Abbreviations: M \pm SEM = Estimated marginal mean \pm standard error of the mean. P-values in bold indicate significance <0.05.

We also compared outcomes for participants in the IG by seizure frequency of <1 and \geq 1 seizure per year (Table 5). Participants in both groups showed significant increases in epilepsy knowledge

at T3 compared with baseline (<1 per year, $p < 0.01$; \geq 1 per year, $p < 0.001$). The increase was significantly greater for participants with \geq 1 seizure per year compared with participants who

experienced <1 seizure per year. Although changes in scores from T0 to T3 differed between groups, there were no significant increases for any other outcome variables.

4. Discussion

4.1. Characteristics of participants

We examined and baseline measures on self-report questionnaires for participants randomized to the SMI program compared with those who received usual care. There were no differences in demographic or clinical characteristics between the IGs and CGs and, with the exception of epilepsy knowledge, baseline measures of the nine outcome variables were not significantly different. The mean age for participants of 39.55 years is similar to the mean age of persons with epilepsy in other countries [5,21,43]. Although there were more males than females in both groups, the difference was not significant, which reflects the distribution in other studies [4,23,44]. The mean total score for the QOLIE-31 scale for all participants was 60.5 ± 16.5 , which is similar to other reports for patients with epilepsy in the Netherlands, Germany, and the UK [5,12,23], although higher than reported for patients in Iran (48.6 ± 15.04) [45] and the United States (52 ± 9.4) [2].

4.2. Effect of the SMI on medication compliance

Medication compliance scores increased significantly in IG compared with the CG at 6 months. Our finding is similar to a study showing a SMI for patients with poor epilepsy control and poor medication compliance improved medication compliance [22]. Self-management programs are effective at helping patients with poor seizure control learn how to manage epilepsy, which includes increasing self-management of medication compliance [46]. We also found female and male participants in the IG had significant improvements at 6 months in medication compliance. The improvement was significantly greater for females compared with males ($p < 0.001$). Our findings are similar to previous studies demonstrating medication compliance is lower for males than females [47,48]. We suggest that SMI programs might need to be modified for males, in order to target factors that might help facilitate medication compliance.

4.3. Effect of the SMI on epilepsy knowledge and seizure frequency

Epilepsy knowledge scores significantly decreased for the CG and increased for the IG at 6 months compared with baseline scores. We can only speculate about why knowledge decreased in the CG and increased in the IG. One possible explanation is the intervention was effective at providing participants with knowledge that allowed them to make changes in their behaviors. A literature review by Kim suggested knowledge about an area can help individuals take effective actions that can help them make cognitive and behavioral changes [49]. In addition, the intervention involved continuous reinforcement of skills, similar to what Baldwin and Ford describe as transfer of training, which can help maintain skills learned during initial training [50]. In contrast, usual care for participants in the CG was only routine monthly counseling, without continuous reinforcement of self-management behaviors. The significant increase in epilepsy knowledge at 6-months for the IG suggests knowledge was sustained following completion of the SMI. The participants in the IG may also have been more motivated due to frequent encouragement received via telephone support as a means of transfer of training [50].

We examined whether there were differences in outcomes for the IG at 6 months based on seizure frequency. Participants with

a frequency of ≥ 1 per year and those with <1 per year showed significant improvements compared with baseline scores for epilepsy knowledge. Studies have demonstrated that a SMI can help patients with poor epilepsy control to learn how to manage epilepsy treatment by including activities and information that improve knowledge of epilepsy and side effects of medications [16,46], strengthen information regarding epilepsy treatments, and self-management of daily living [16,17].

4.4. Effect of the SMI on self-efficacy

The SMI had no effect on scores for self-efficacy for either the CG or IG at any time point. Our findings are in contrast to studies showing significant improvements in self-efficacy for patients with epilepsy following participation in a SMI [14–17]. However, when we examined scores for males and females in the IG at 6 months, compared with baseline, there was a modest, but significant increase for males, and changes in scores from baseline were significantly greater for males compared with females. The difference in self-efficacy between genders is in agreement with one study showing male patients with epilepsy had higher self-efficacy scores for managing daily activities and social interactions than females [51].

4.5. There was no effect of the SMI on HRQoL and other outcome variables

Participation in the SMI program did not result in significant improvements in HRQoL compared with participants in the CG, as measured by the QOLIE-31, which is contrast to other studies [11,16,52]. We also saw no significant improvement for HRQoL when participants who received the SMI were grouped by gender or seizure frequency, which is in contrast to studies showing females have lower HRQoL than males [21,36,53] and those with higher seizure frequency have poorer HRQoL [21,53]. One explanation for a lack of significant improvement may be that seizure frequency for most participants in our study (60%) was less than once per year. Control of seizures was relatively stable, therefore making it less likely of detecting a change in HRQoL for participants. A second explanation could be the SMI may need a longer period of time for behavior changes to have a significant impact on HRQoL. The factors that affect QoL are diverse and complex. Therefore, not only intervention measures can be improved but also multiple factors need to be considered.

Finally, the SMI had no significant effect on changes from baseline in scores for sleep quality, anxiety, depression, coping skills, or social support compared with controls. Our findings are similar to studies showing these variables did not differ between patients with epilepsy in a self-management program and those receiving using care [5,21].

4.6. Study limitations

Our findings might be limited by the design of the SMI. Although the SMI was based on previous interventions for patients with epilepsy, the patient-intervener contact was less frequent than other SMIs. Studies have provided nurse consultations by telephone once-per-week for 8 weeks [2], four contacts once every 3 weeks [18], or every 3 months for 2 years [24]. Funding constraints required that a compromise be made on the number of consultations, and therefore phone/Internet support for the SMI intervention occurred twice a month for 3 months. This 3-month period might also be too short for participants to make significant improvements in outcome variables. Further research conducted over a longer period, with more frequent consultations are

recommended in order to adequately examine the impact of the SMI for patients with epilepsy.

5. Conclusions

The SMI was a holistic program that provided patients with epilepsy the skills to help manage seizures, medications, daily life events, and emotions by assessing abilities, epilepsy knowledge, self-confidence, and coping. Although the overall goal was improvement in QOL for patients with epilepsy, the SMI program did not significantly improve HRQoL. This might suggest this QOL is a variable that is difficult to alter or requires more time to change behaviors that impact QOL for patients with epilepsy. Additional research on patients with epilepsy should focus on variables associated with medication compliance, epilepsy knowledge, medicine symptom distress, self-efficacy, anxiety, and QOL.

Individualized SMI programs are a means of enhancing the ability of patients with epilepsy to manage this disorder. We suggest future research examine whether further enhancements could be made in the application of medical Internet technology. An online, iCloud-based computing network could facilitate communication between healthcare providers and patients with epilepsy as well as improve patient evaluations and data collection. This form of remote healthcare could allow the medical team to help patients with epilepsy obtain immediate care that is also cost-effective, while simultaneously providing information about epilepsy knowledge, seizure treatment, and emotional support.

6. Disclosure

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Declaration of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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