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## The Feasibility and Impact of the EMOVE Intervention on Self-Efficacy and Outcome Expectations for Exercise in Epilepsy

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### Abstract

The purpose of this pilot study was to evaluate the feasibility of the self-efficacy based EMOVE intervention and report on the preliminary efficacy of this intervention aimed at improving exercise behaviors in adults with epilepsy.

**Methods:** A single-group repeated measures design was used in 30 outpatients. Data were collected at baseline and 12 weeks following the intervention. Participant outcomes included Self-Efficacy (SEE-E) and Outcome Expectations for Exercise in Epilepsy (OEE-E), Beck Depression Inventory – II (BDI-II), Quality of Life in Epilepsy – 31 (QOLIE-31), seizure frequency, average daily steps, and body mass index (BMI). Daily number of steps were measured using a wrist-worn

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activity monitor. Feasibility data was assessed using evidence of treatment fidelity including intervention delivery, receipt and enactment.

**Results:** Participants were single (63%), White (53%), female (63%) with mean age 46.7 years (SD=13), range 26 – 68, had low levels of self-efficacy (M=5.10, range 0 – 10), high outcome expectations (M=3.90, range 0 – 5), took under the recommended 10,000 steps per day (M=5107) and had an average six seizures per month. Post intervention testing showed statistical improvement in depressive symptoms (M=9.95, SD=9.47, p<0.05). There were no significant differences found for the other study outcomes.

Our study showed the EMOVE intervention was feasible. Study participants had improved depressive symptoms. Future research should focus on increasing the sample size, improving exercise performance through group or individualized exercise sessions, and adding a control group to better evaluate the relationship between the intervention and improved depressive symptoms.

Epilepsy is a serious disease affecting at least 65 million people worldwide.<sup>1</sup> Regular exercise may help the common co-morbidities seen in persons with epilepsy (PWE), including obesity, osteoporosis (due to medication side-effects and sedentary lifestyle), depression, and decreased quality of life.<sup>1</sup> After, even a few weeks of regular exercise, mood, blood pressure, strength and cardiorespiratory fitness improve, yet only about half of Americans exercise regularly and PWE exercise even less than the general population.<sup>2, 3</sup> Besides common barriers to exercise faced by the general population (lack of time, resources, limited belief in benefits, and low levels of motivation)<sup>2</sup>, PWE face additional challenges, including unsubstantiated fear that exercise may provoke seizures, and lack of health care provider encouragement.<sup>4</sup> Additionally, anti-epileptic drug (AED) side-effects such as drowsiness, fatigue, and mood alterations may also interfere with exercise engagement.<sup>5</sup> Addressing motivational issues related to regular exercise may improve participation by PWE, promoting its health benefits.

Bandura's theory of self-efficacy states the stronger one believes in their ability to engage in a behavior (self-efficacy expectations) and in the benefits to performing the behavior (outcome expectations), the more likely they will initiate and adhere to that behavior.<sup>6,7</sup> These beliefs are reinforced by four sources of inputs: (1) performance of the behavior; (2) verbal encouragement; (3) role modeling; and (4) elimination of unpleasant sensations, such as pain, fatigue, or anxiety associated with an activity. Using these sources of information, self-efficacy based interventions have been effective at increasing regular exercise among individuals with chronic disease such as pre-diabetes, heart disease, arthritis, multiple sclerosis, and among older adults.<sup>8</sup> Thus, using a self-efficacy based approach to increase regular physical exercise in persons with epilepsy is worthy of investigation. Interventions that use multiple sources of self-efficacy information and according to self-efficacy theory, will build the most confidence enhancing self-efficacy for exercise and resulting in increased exercise behaviors.<sup>6,7</sup>

Using these postulates, prior research, and practical experience with epilepsy patients, the Epilepsy-Motivate and Outcome Expectations for Vigorous Exercise (E-MOVE) intervention was developed. The overall goal of EMOVE was to encourage individuals with

epilepsy to achieve 30 minutes or more of moderate-intensity exercise at least 5 days per week, by using a blended approach of self-efficacy information sources, including face-to-face education and counseling, goal setting, activity monitors, and telephone support.

The purpose of this pilot study was to test feasibility, based on evidence of treatment fidelity including intervention delivery, receipt, and enactment.<sup>9</sup> We hypothesized that those exposed to EMOVE would demonstrate increased self-efficacy and outcome expectations associated with exercise behavior, increased time exercising, improved quality of life, decreased seizure frequency, decreased depressive symptoms and decreased body mass index.

#### Methods

We used a single-group repeated measures design. Community dwelling PWE were eligible to participate if they were: (1) age 18 years or older, (2) able to speak English, (3) able to provide informed consent, (4) diagnosed with epilepsy based on standard clinical criteria (two or more unprovoked seizures separated by at least 24 hours)<sup>10</sup>, and (5) able to complete seizure calendars. Individuals were excluded if they did not have health care provider clearance to participate in an exercise program. The study was approved by both a university and federal Institutional Review Board (IRB).

Participants were recruited using study flyers and referrals from clinical staff within an outpatient epilepsy clinic. The epilepsy clinic provided care to a total of approximately one hundred-twenty-seven adults per year with epilepsy. Of these, 47 (37%) were deemed eligible and invited to participate: 30 (64%) consented, 4 (8%) were unable to complete the consent in English and 13 (28%) declined to participate, leaving a net sample of 30 individuals. All 30 enrollees completed baseline measures. Two (7%) withdrew after baseline because they no longer wanted to participate, one (3%) was unable to continue due to acute illness, and three (10%) were lost to follow-up; for a final sample of 24. Descriptive information included age, gender, race, marital status, years living with seizures, number of anti-epileptic drugs prescribed, and medical co-morbidities obtained via participant interview and chart review. Research participants were predominantly single (63%), White (53%), female (63%) with a mean age of 46.7 (SD=13), range 26 – 68, and a mean BMI of 28.8 (SD=7.1), range 21.2 – 48.1 (Table 1). The mean number of years living with seizures was 30 (SD=17.6), range 2 - 60. The most common co-morbidity was depression (40%) or depression plus one or more other conditions (26.7%), such as obesity, diabetes, and hypertension. No significant relationship was found between number of AEDs, comorbidities, number of seizures, and depression

#### **Educational Intervention**

The EMOVE intervention had 4 components (See Table, Supplemental Digital Content 1, description of intervention) including education about and a return demonstration of the exercise program, individualized goal setting, exercise self-modeling and on-going verbal encouragement. The education included providing participants with the Epilepsy Foundation's Physical Fitness and Seizure Safety standards<sup>11</sup> and Centers for Disease Control Physical Activity Recommendations for exercise for all adults.<sup>12</sup> Copies of these

materials were provided to participants for reference. Participants were then asked to provide a return demonstration of one or more exercises, such as squats or a timed plank during the educational session (See Table, Supplemental Digital Content 2, shows demonstration of sample exercises). Each participant established 2 - 4 individualized exercise goals and were evaluated using the goal attainment scale (GAS).<sup>13</sup> At the conclusion of the educational session, participants were provided with a copy of their goals and dates for weekly phone calls. Participants were contacted once per week for 12-weeks for on-going verbal encouragement using scripted coaching (See Table, Supplemental Digital Content 3, showing sample telephone script) to facilitate goal attainment. Exercise self-modeling was provided by downloading results from the wrist-worn activity monitor and reviewing their average daily step counts following the baseline assessment.

The baseline interview was scheduled at a time convenient for participants in a private clinic room. Participants then completed surveys to explore study outcomes related to self-efficacy for exercise, outcome expectations for exercise, knowledge of exercise and epilepsy, mood, and quality of life. At the conclusion of the 12-week intervention period, participants returned to the outpatient clinic for final face-to-face visits, completed surveys, reviewed activity monitor recordings, and evaluated progress towards goal attainment. Goals were individualized based on the participants current level of activity and interests. Examples of individualized goals are achieving a targeted step count for the day, losing weight, and lowering blood pressure.

#### Assessments

The **Self-Efficacy for Exercise in Epilepsy** (SEE-E) was developed from the self-efficacy for exercise (SEE) scale and includes 10 items focused on overcoming challenges to exercise among PWE. The response format for all items ranged from (0) not confident to (10) very confident. The SEE was scored by summing self-efficacy numerical ratings for each response and dividing by number of responses. This score represented exercise self-efficacy strength. Scores ranged from 0 to 10 with higher scores indicating stronger exercise self-efficacy. Reliability and validity of the SEE-E was tested and documented in a different manuscript.<sup>14</sup>

The **Outcome Expectations for Exercise in Epilepsy** (OEE-E) is a 15-item measure with 12 positive items and 3 negative items. The twelve positive items (items 1-12) were reverse coded and summed with the three negative outcome expectation items (items 13-15) and then divided by the number of responses. Scores ranged from 0 to 5 with higher scores indicating stronger outcome expectations. As with the SEE-E reliability and validity of the OEE-E was tested and documented in a different manuscript.<sup>14</sup>

**Average daily step counts** were obtained using Jawbone UP (Jawbone, San Francisco, CA), a wrist-worn accelerometer. The Jawbone was worn on the wrist during waking hours. The first consecutive seven days of baseline period recording and the last seven days of the 12-weeks post intervention were collected. Data were included in analysis if there were at least 3 full days of recorded activity during each recording period. Evidence of validity was based on significant correlations between the step counts obtained using the Jawbone UP relative

to research-grade accelerometers.<sup>15</sup> Following baseline measures, the Jawbone idle alert was set to vibrate after one hour of inactivity. This reminded participants they had been inactive for one hour and were encouraged to move when they felt this vibration.

**Seizure frequency** was measured by counting the number of seizures over a set period of time and is a standard measure for AED efficacy and seizure intractability. Study participants recorded weekly seizure counts with pencil and paper calendars or electronic calendars.

**Quality of Life in Epilepsy Inventory** – **31** (QOLIE-31) is a disease specific tool used to assess quality of life in epilepsy populations. QOLIE-31 is the short-form version of the original long-form QOLIE-89. The instrument provided a scale from 0 - 10, with 10 representing the best possible quality of life and 0 representing the worst possible quality of life.

The **Beck Depression Inventory - Version 2** (BDI-II) includes 21-items that reflect symptoms of depression over the past two weeks and was scored by summing the ratings given to each of the items. Total possible scores on the BDI-II range from 0 - 63. Higher scores indicate increased severity of reported depressive symptoms.

**Body mass index** (BMI) was calculated using the following calculation: BMI (lbs./inches) = weight (lb.) / [height (in)]<sup>2</sup> × 703 Scores were interpreted based on the following CDC guidelines: below 18.5 = underweight; 18.5 - 24.9 = normal; 25.0 - 29.9 = overweight; > 30 = obesity.<sup>2</sup>

#### **Feasibility Data**

Feasibility assessment of the EMOVE intervention was based on evidence of treatment fidelity including intervention delivery, receipt and enactment.<sup>9</sup> Delivery of the intervention was focused on the ability to implement all aspects of the intended intervention and monitored through scripts for implementing the intervention and a single provider to consistently administer the intervention. Receipt of the intervention by the study participants was measured by increased knowledge scores among participants using the Knowledge of Exercise and Epilepsy Survey (KEES). This survey was administered at baseline and then again following the EMOVE intervention. This survey included 7 multiple-choice questions and 4 true or false questions about the benefits of exercise and seizure safety and exercise. Enactment of the intervention was measured through performance of exercise via the Jawbone activity monitor and attainment of goals as measured by the Goal Attainment Scale (GAS). The GAS involved having participants articulate 2-4 goals and then measuring their perception of goal attainment over the course of the intervention period. Using the goals identified at baseline, participants were asked to evaluate their perception of goal achievement at the final follow up, 12-weeks post implementation of the intervention. Scoring was done for each goal by having the individual rate achievement as either: achieved more than expected (+2); somewhat better than expected (+1); meeting program goal (0); somewhat less than expected (-1); much less than expected (-2). A score of 0 was indicative

of expected achievement. Prior work has established the inter-rater reliability (r=0.93) and validity based on a GAS score correlating (r >0.50) with standardized functional measures.<sup>16</sup>

#### Statistical Analysis

Statistical analyses were performed using the Statistical Packages for Social Sciences (SPSS) statistical software, version 20 (SPSS, Chicago, IL). Descriptive statistics and MANOVA were performed to assess trends and evaluate changes over time. A Pearson product-moment correlation coefficient was computed to assess the relationship between number of AEDs taken, number of co-morbidities, number of seizures, and depression scores. A repeated-measures analyses of variance was done to evaluate changes over time on outcome variables. Significance was determined using Pillai's Trace test and p<.05 was used to establish significance.

#### Results

Baseline mean SEE-E scores were 4.74 (SD=2.3) and OEE-E 3.91 (SD=0.67). At baseline participants had under the recommended 10,000 average daily steps (M=5107, SD=3434), averaged 5.4 seizures per month (M=5.4, SD=7.7), had mild symptoms of depression (M=14.4, SD= 10.6), and poor QOL (M=45.2, SD=13.6). Post intervention there was significant improvement in depression symptoms (M=9.95, SD=9.47, p<0.05) (Table 2). There was no significant difference between baseline and 12-weeks for self-efficacy or outcome expectations for exercise, number of steps, seizure frequency, quality of life, or BMI.

Analysis of feasibility data demonstrated the initial face-to-face educational aspect of the intervention was both delivered and received, as intended. The use of scripts to implement the intervention and a single provider to consistently deliver the intervention suggested that the intervention was delivered as intended, while the knowledge test suggested evidence of receipt of the intervention educational component. The baseline KEES score was 6.9 (SD=1.92) and at 12-weeks scores increased to 8.9 (SD=1.54) (p< 0.01). In addition, all participants established 2 to 4 personal exercise goals. Enactment of E-MOVE was supported based on scores from the GAS and evidence of walking based on activity monitor data. The majority of participants (67%) met or exceeded their exercise goals. Participants showed an average of 5107 (SD=3434, range 528 – 12358) daily steps at baseline and this increased to 6350 (SD=3547, range 1392 - 15982) at 12-weeks. The increase in number of steps daily and having the majority of participants achieve their personal goals was indicative that participants engaged in the exercise behavior recommended within the study intervention. Lastly, participants provided feedback during the intervention activities that reflected their engagement in the intervention related activities (See Table, Supplemental Digital Content 4, showing participant comments about being in the study).

#### Discussion

We tested feasibility and preliminary efficacy of a self-efficacy-based intervention to increase exercise behaviors in PWE. The results showed positive feasibility: study

participants were willing to participate; receptive to the intervention; and expressed the desire for on-going weekly encouragement. Further, the majority of participants achieved stated goals and tended to increase the number of steps taken per day.

Only depressive symptoms improved significantly. Several factors have been documented as contributing to depression in people with epilepsy, including side effects from anti-epileptic drugs, social and psychological stresses, as well as biological factors such as the location of the seizure focus and decreased serotonergic function.<sup>17,18</sup> This was a clinically meaningful change in that baseline depression scores were indicative of mild depression and the 12-week follow-up scores declined into the minimal to no depression range.<sup>19</sup> While exercise has been shown to decrease depression in other chronic diseases<sup>20</sup>, there are several factors not studied that may have contributed to a decrease in depressive symptoms reported in this study, such as being included in the study, meeting personal goals, or the attention given by the interventionist. There are other variables that were not assessed that may have contributed to this improvement such as medication compliance. Using a control group would have provided some insight into how these other variables may have contributed to the improvement in depression scores.

Self-efficacy for exercise was generally low suggesting that our patients did not have confidence in their ability to exercise regularly. Performance accomplishments, based on personal experience, may be the most influential source of self-efficacy beliefs.<sup>6</sup> Because PWE have historically been discouraged from exercise from childhood, they may not have experience with exercise prior to participating in our study.<sup>6</sup>

To assess efficacy of the study intervention, the EMOVE participants were asked to provide a return demonstration of one or more exercises, such as sit-ups, squats, or a timed plank during the educational session as a source of performance accomplishment. Interestingly, many participants did not know how to do these basic exercises. A recommendation for future work would be to include supervised exercise sessions. This would ensure the individual's experience with exercise that is needed to provide information and feedback which influences and increases self-efficacy for future exercise behavior.<sup>6</sup>

Participants did not meet the American Heart Association (AHA) recommendations of 10,000 steps per day.<sup>21</sup> The intervention may not have been specific enough to help them increase activity to the level needed. Participants were enthusiastic about the activity monitor, learned how to use it, and monitored their progress using the Jawbone UP application. We used one of the first- generation Jawbone activity monitors. Improved versions allow viewing live step counts and wireless data download to a smart phone or computer. These features would help obtain real-time step counts, potentially serving as additional motivators for increasing exercise.

#### Study Strengths and Limitations

Our results indicate that the EMOVE intervention was feasible. During study participation, depressive symptoms significantly improved. While this study included using a variety of sources of self-efficacy-based information, the study design does not allow for determining

the precise cause of improved depressive symptoms. The study does have the practical value of the intervention being easily incorporated into a routine clinical visit. This study was limited by a small convenience sample and self-reported measures, but it addresses the critically important need to increase exercise behaviors in an often-neglected patient population. Building off of the findings from this pilot study, future research should focus on increasing the sample size, improving exercise performance through group or individualized exercise sessions, and adding a control group to better evaluate the relationship between the intervention and improved depressive symptoms. Engaging these patients in regular exercise has the potential to substantially influence health outcomes.

#### **Supplementary Material**

Refer to Web version on PubMed Central for supplementary material.

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#### Table 1

Descriptive Statistics of the Baseline Sample (N=30)

Variable	Mean	SD	Frequency (%)
Self-Efficacy for Exercise	4.7	2.3	
Outcome Expectations for	3.9	.67	
Average Daily Steps	5107	3434	
Age	46.7	13.0	
Gender			
Males			11(37%)
Females			19(63%)
Race			
Caucasian			16(53%)
African American			8(27%)
Hispanic			6(20%)
Marital Status			
Single			19(63%)
Married			8(27%)
Divorced			2(7%)
Widowed			1(3%)
Number of Seizures			
Seizure free			4(13%)
1 /month			5(17%)
2-3/month			7(23%)
> 3/month			14(47%)

#### Table 2

Within-subjects effects at baseline and 12-weeks after EMOVE

	<b>Pre-Intervention</b>		Post-Intervention			
Variable	Mean	SD	Mean	SD	F	p-value
SEE-E	4.74	2.3	5.40	2.6	.006	0.80
OEE-E	3.91	0.6	2.28	0.45	1.52	0.23
Exercise Behavior	5107	3434	6520	3670	3.77	0.06
Seizure Frequency	5.40	7.6	3.65	5.9	0.04	0.85
Depression	14.4	10.6	9.95	9.47	4.61	0.04 *
QoL	45.2	13.6	48.3	12.4	2.67	0.12
BMI	29.0	7.8	28.3	6.94	0.35	0.56

\* Repeated Measures p < 0.05