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Self-management for people with epilepsy and a history of negative health events (SMART): A randomized controlled effectiveness trial

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Summary:

Objectives: This 2-site, 6-month randomized controlled trial of an epilepsy self-management (ESM) curriculum (SMART) vs. 6-month waitlist (WL) control assessed effects on epilepsy outcomes in 160 people with epilepsy (PWE).

Methods: PWE had at least one at least 1 negative health event (NHE) defined as a seizure, emergency department visit, hospitalization or self-harm attempt in the last 6 months. Primary outcomes were differences in proportions of PWE with reductions in NHEs from baseline to 6 months follow up and change in NHE/seizure counts between SMART and WL. Secondary outcomes included the Patient Health Questionnaire (PHQ-9), 36-Item Short Form Survey (SF-36), Quality of Life in Epilepsy (QOLIE-31), Epilepsy Self-Management Scale (ESMS), Epilepsy Stigma Scale (ESS), Multidimensional Scale of Perceived Social Support (MSPSS) and Epilepsy Self-Efficacy Scale (ESES).

Results: Mean age was 39.4 (SD 12.2), 66.9% (N=107) women, and 31% (N=50) rural. Mean PHQ-9 of 10.5 (SD 7) suggested mild/moderate depression. Seizures were the most common NHE with mean baseline past 6-month seizure count of 20.6 (SD 41.0). SMART was

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significantly associated with a 2-fold increase in odds of having at least 10-30% improvement in NHEs vs. WL ($p<0.05$). SMART was associated with significant seizure reduction ($p<0.05$), significantly improved PHQ-9 ($p=0.014$), QOLIE-31 seizure worry ($p<0.001$) and social functioning ($p=0.021$), ESES ($p=0.046$) and ESMS ($p<0.001$).

Significance: Compared to WL, SMART participants had improvement in NHEs and seizures, depressive symptoms, self-management competency and self-efficacy and selected elements of quality of life. Inclusion of effective ESMs into a comprehensive care of model for PWE may be warranted.

Keywords

epilepsy; seizures; stigma; depression; quality of life

1. Introduction

Self-management interventions have gained increasing attention for their potential benefit for people with chronic health conditions given the fact that patients with these chronic conditions have contact with their healthcare providers for only a small fraction of their time, while nearly all patient outcomes are mediated through their daily behavior [1,2]. Epilepsy Self-management (ESM) is an evidence-based approach to support people with epilepsy (PWE) that has gained increasing recognition as an important component of comprehensive, patient-centered epilepsy care [3]. In the United States, the Managing Epilepsy Well (MEW) Network has led the development, testing and scale-up of a variety of successful ESM approaches [4]. A MEW Network program called Self-management for people with epilepsy and a history of negative health events (SMART), was specifically developed to support PWE who have experienced health complications including poorly controlled seizures [5]. Featuring remote delivery by a Nurse Educator and a trained Peer Educator, a PWE trained to deliver the curriculum, SMART was demonstrated to reduce epilepsy-related complications and improve quality of life (QOL). Aligned with the operational definition of self-management interventions [1,2], SMART includes strategies to help equip PWE with skills to actively engage in the management of their epilepsy in order to function optimally through knowledge acquisition, stimulation of independent sign/symptom monitoring, medication management, enhancement of problem-solving/decision-making and promotion of healthy lifestyle elements such as good nutrition, physical activity, and avoidance of alcohol and recreational drugs [2,6].

Previous efficacy testing with the SMART intervention was conducted in a mostly urban setting in northeast Ohio and targeted community recruitment of PWE [5]. This previous efficacy trial found that PWE who participated in SMART had reduced negative health events (NHEs) such as seizures, emergency department (ED) visits, hospitalizations and self-harm attempts, as well as improved depressive symptoms and improved epilepsy self-management competency [5]. However, it was unclear if the same benefits might be seen in different populations of PWE such as those who have more complicated epilepsy due to having more frequent seizures and/or living in underserved settings. PWE in rural communities may have different challenges and those who seek treatment in epilepsy specialty treatment centers often have more difficulty with seizure control. These

populations may have unique challenges in multiple lifestyle elements that need to be managed in order to optimize health functioning.

To assess reproducibility of the original efficacy testing of SMART and to evaluate outcomes among diverse PWE, we conducted a prospective 2-site, 6-month randomized controlled trial (RCT) to assess the effects of SMART vs. a 6-month wait list (WL) control. The sample enrolled a relatively large population of PWE from rural settings and those who had poorly controlled seizures. We hypothesized that at the 6-month follow-up, SMART would be associated with reduced NHEs compared to WL. We also expected that SMART would be associated with improved depressive symptoms, better QOL, improved epilepsy self-management competency and improved epilepsy self-efficacy.

2. Methods

2.1 Overview

This 6-month prospective RCT assessed the effects of SMART vs. WL on self-reported NHEs defined as a seizure, ED visit, hospitalization or a self-harm attempt. Adults with epilepsy were enrolled at two participating sites, the University of Iowa and the Case Western Reserve University. Building on the success of a completed efficacy trial, the current RCT was an effectiveness trial which attempted to reach a diverse group of PWE, and which was delivered entirely remotely via internet or phone. The primary study outcome was change from baseline to 6-month follow-up in NHE counts. Secondary outcomes included factors relevant to PWE such as depression, epilepsy-related QOL, functional status, general health, stigma, self-efficacy, epilepsy self-management competency and social support. Assessments were conducted at screening, baseline, 13 weeks follow-up, and 6-month follow-up time-points. A detailed description of the RCT methods has been described elsewhere [7]. The study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04705441) (NCT04705441).

2.2 Sample

Study inclusion criteria included a self-reported diagnosis of epilepsy and age ≥ 18 years with at least 1 NHE within the previous 6 months. Given the effectiveness focus, there were only a limited number of study exclusion criteria, which included being at immediate risk of self-harm, dementia, pregnancy, or those unable to read/understand English. The study team prioritized engagement and enrollment of PWE with complex illness due to their living in rural settings and/or having poorly controlled seizures. Participants were recruited using a variety of outreach efforts including reaching out to clinicians at epilepsy centers and soliciting referrals of their patients who might benefit from SMART, solicitation of referrals from local/regional epilepsy social service agencies, outreach via free or paid advertising such as Research Match [6], querying the electronic health records (EHRs) of two medical health systems, use of IRB-approved advertising and in-person outreach. We attempted to oversample PWE who resided in rural settings by filtering EHRs for ZIP codes that aligned with more rural locations on the Rural Urban Continuum Code (RUCC), developed by the U.S. Department of Agriculture classification scheme that distinguishes metropolitan counties by the population size of their metro area, and nonmetropolitan counties by degree of urbanization and adjacency to a metro area [8]. Each county in the U.S. is assigned one

of the nine codes with 1 being most urban and 9 being most rural. Clinicians from epilepsy centers tended to refer people who had more frequent seizures and might potentially benefit from SMART. The study was approved by the local institutional review board (IRB) and all individuals provided written informed consent.

2.3 Randomization and blinding

Participants were randomly assigned, on a 1:1 basis, to receive either SMART ($N = 80$) or WL ($N = 80$) using a computer-generated random number generator. The randomization scheme was unavailable to study staff interacting with participants. While participants and SMART interventionists were not blinded (due to the nature of the intervention), data analysts had no interaction with participants or interventionists. Participants were enrolled in 10 sequential “cohorts” such that once 16 individuals were enrolled (about half randomized to SMART vs. WL) the individuals allocated to SMART in that cohort began their SMART group sessions.

3. Interventions

3.1 SMART

The experimental arm of this RCT delivered the SMART curriculum, divided into 2 phases. Phase 1 comprised 8 group-format 45-60-minute sessions with 5-10 PWE in each group and occurred over a period of 8-12 weeks. Phase 2 comprised a short series of follow-up phone calls. The SMART intervention is an adjunct to standard epilepsy management, including use of antiseizure medications as prescribed by the participant’s regular (non-research) epilepsy care clinician.

Each of the Phase 1 SMART group sessions was jointly delivered by a Nurse Educator and a Peer Educator. Nurse Educators ($N=6$, 5 women, 1 man) were individuals who were already participating in clinical research at the participating sites, but did not need to have any previous experience in epilepsy care. The Peer Educators ($N=6$, 2 women, 4 men) were referred by site clinicians or by epilepsy-service organizations. Some PWE were self-referred based on previous experience serving as a SMART Peer Educator. Nurse and Peer Educators participated in an initial 2-day virtual training supplemented with online and written materials.

Phase 1 of SMART was delivered remotely using secure videoconferencing. Telephone call-in was available for those without internet access. SMART group participants received e-mail and phone/text reminders of upcoming sessions, and make-up sessions were available. SMART Phase 2 phone follow-up consisted of 3 brief (no more than 15 minutes) monthly telephone sessions conducted by the Nurse Educator to address ongoing issues of ESM. The nurse also served as a facilitator of linkage between the PWE’s epilepsy care clinicians by providing SMART program status updates to providers.

Attendance of SMART sessions was recorded, and acceptability was assessed at the end of each group series by a brief self-rated survey. Following Fraser [9], and to help ensure fidelity, non-interventionist research staff monitored and randomly assessed 25% of group sessions, with each fidelity dimension rated on a 1-10 scale.

3.2 WL

Individuals randomized to WL received standard epilepsy management, including use of antiseizure medications as prescribed by the participant's regular (non-research) epilepsy care clinician. After they completed their 13-week and 6-month assessments, which were identical to the SMART group assessments, individuals randomized to WL then received the SMART intervention (data not presented here).

3.3 Measures

Research assessments were conducted remotely using REDCap (Research Electronic Data Capture), a secure web application for building and managing online surveys and databases [10]. We collected sociodemographic information, select clinical variables (epilepsy age of onset/duration, type of epilepsy, somatic comorbidity) and standardized measures of epilepsy outcomes. Health literacy was evaluated using the Rapid Estimate of Adult Literacy in Medicine-Revised (REALM-R) [11,12]. Individuals unable or unwilling to complete REDCap surveys could complete assessments by phone. Individuals were assessed at study screening, baseline, 13-week and 6-month timepoints.

3.4 Primary outcomes

The primary outcome was differences in proportions of PWE with reductions in NHEs from baseline to 6 months follow up (SMART vs. WL), defined as any improvement, $\geq 10\%$, $\geq 20\%$, $\geq 30\%$, $\geq 40\%$, and $\geq 50\%$ improvement. NHEs were defined as seizures, ED visits, hospitalizations, and self-harm attempts identified via self-report. In addition, we assessed counts of NHEs in each category, including seizure frequency, and length of stay in days for hospitalization NHEs. As an *a priori* validation of self-reported NHEs, we counted ED visit and hospitalization encounters documented in the EHRs of individuals in the primary enrolling site in Iowa (32 out of 108 = 33% total enrolled at this site).

3.5 Secondary outcomes

Additional key assessments included evaluation of depression, functioning, epilepsy-related QOL, ESM competence, epilepsy stigma, social support and epilepsy self-efficacy. Depressive symptom severity was assessed using the 9-item Patient Health Questionnaire (PHQ-9), a widely used and validated self-rated depression scale [13]. On the PHQ-9, scores range from 0-27, with higher scores indicating worse depression severity. Functional health status was assessed using the 36-Item Short Form Survey (SF-36), a multi-purpose, short-form health survey that yields two psychometrically-based components: a physical component summary and mental component summary [14]. On each component of the SF-36, scores range from 0 (worst functioning) to 100 (best functioning). Epilepsy-related QOL was assessed with the Quality of Life in Epilepsy (QOLIE-31), a self-rated instrument which contains 7 sub-components including seizure worry, overall QOL, emotional well-being, energy-fatigue, cognitive functioning, medication effect, and social function, each with a range of 0 (lower QOL) to 100 (higher QOL) [15,16]. QOLIE-31 total score can be converted to a T-score with a range from 11 (lower QOL) to 73 (higher QOL).

ESM competency was measured with the Epilepsy Self-Management Scale (ESMS); scores range from 1-190 with higher scores indicating better self-management of epilepsy [13].

Stigma in PWE was measured using the Epilepsy Stigma Scale (ESS) [17,18]. In the ESS, scores range from 7-70; each item is rated on a 7-point scale from strongly disagree to strongly agree, with higher numbers indicating greater perceived stigma. Social support was measured with the 12-item Multidimensional Scale of Perceived Social Support (MSPSS), that measures perception of social support provided by family and friends, as well as satisfaction with that support [19]. The MSPSS score ranges from 1-84 with higher scores indicating better social support. Self-efficacy was measured using the 33-item Epilepsy Self-Efficacy Scale (ESES) with scores ranging from 0-330 and higher scores indicating better self-efficacy [17-21].

3.6 Process measures

To help inform future efforts in scale-up and implementation [22], the study team conducted process evaluations in two main areas: 1) PWE's perception of the SMART program, and 2) "Reach" among referral partners. PWE perceptions were assessed via a set of open-ended questions regarding their satisfaction with the program, comprising Likert-style questions assessing positive/negative/neutral components of the program and whether they would recommend participation in SMART to a family member or friend with epilepsy. To assess reach, referral sources were tracked for all study screens as well as successful enrollments.

3.7 Data analysis

Statistical analyses were performed using STATA v17.0 (StataCorp, TX). Descriptive analyses compared individuals assigned to SMART or WL using Fisher's exact test and non-parametric Wilcoxon-Mann-Whitney tests when appropriate. Analyses were performed for the intention-to-treat population (ITT, all participants enrolled to receive the SMART trial; N=160) and in a per-protocol (PP) sample.

Because of study disruptions and delays due to the COVID-19 pandemic, which began shortly after this study began, there was substantial variability in the time lag between study baseline and when each cohort of individuals (group of 16 PWE with half randomized to SMART and half randomized to WL) began their SMART group sessions. The pandemic also impacted scheduling of follow-up visits. To account for this variable observation period at follow-up, in the ITT sample, NHEs and seizure counts were pro-rated by calculating NHE and seizure counts over each participant's observation period and re-scaled to derive NHE and seizures counts over the prior 6 months. The primary outcome to assess SMART vs. WL differences in proportions of PWE with NHE reductions from baseline to 6 months follow-up was defined as: 1) any improvement, 2) improvement that reached each the clinically relevant thresholds of $\geq 10\%$, $\geq 20\%$, $\geq 30\%$, $\geq 40\%$, and $\geq 50\%$, and 3) change in NHEs and seizures over 6 months. Logistic regression models with the binary dependent variable of any improvement or improvement at specific thresholds at 6 months and the intervention as the independent variable, used a clustered sandwich estimator for the variance-covariance matrix allowing for intragroup correlations by RUCC category, and were restricted to those reporting < 500 NHEs or seizures at baseline and at 6-month follow up. Change in NHEs and seizures over 6 months were inverse rank normalized, and the effect of SMART was evaluated using linear regression models allowing for intragroup

correlations by RUCC category and restricted to those with <180 NHEs or seizures at baseline and at 6-month follow up (those averaging at most 1 event per day).

All comparisons were repeated restricting to a PP sample which was defined as those who received the intervention within 2 months of baseline visit (+1 week for anticipated normal scheduling variability) and subsequently SMART and WL participants completing the 6-month follow-up visit within 180 days (+2 weeks for anticipated normal scheduling variability). This sample included 58 participants (20 SMART, 38 WL).

For secondary outcomes, longitudinal linear mixed models with a subject-level random effect, and an intervention-by-time (days from baseline) interaction spanning baseline, week 13, and 6-month observations for PHQ-9, QOLIE-31 T-score, 7 QOLIE-31 sub-scores, SF-36 physical and mental component summaries, ESMS, ESS, ESES, and MSPSS, similarly inverse rank normalizing each outcome and adjusting the variance-covariance matrix to allow for intragroup correlations for RUCC levels.

Amongst those receiving SMART, we also assessed if number of sessions attended were associated with primary and secondary outcomes using similar models described above. A two-sided, Type I error rate of 5% was used for all tests.

4. Results

4.1 Study enrollment and flow

Figure 1 illustrates overall study flow. There were 176 PWE screened and 160 randomized. For the 6-month follow-up outcome there were a total of 65 PWE in the analyzable SMART sample (81.0% of original randomized allocation) and 63 in the analyzable WL sample (79.0%). Six-month study attrition was 20.0% overall (N=32 lost to follow-up or withdrew consent). Individuals lost to follow up were unable to be contacted by study staff and thus the reason for drop out is not known. Reasons for study withdrawal when this was available (N= 6, 3.75 % of the overall sample) included three individuals reporting no longer having time to participate and three individuals reporting they were no longer interested in participating. Baseline characteristics including age, gender, race, education, employment level, health literacy, epilepsy age of onset, epilepsy duration, past 6- month NHE counts and depression severity between those retained in the analysis and those who dropped out showed no significant differences, suggesting a low likelihood of substantial selection bias.

4.2 Overall description of sample

Demographic and clinical characteristics, shown in Table 1, had a mean age of 39.4 (SD 12.2) years, 66.9% (N=107) women and 82.5% (N=132) white. A slight majority (N=83, 51.9%) had publicly funded health insurance (Medicaid, Medicare, VA). Just over 31% (N=50) were from more rural regions (RUCC of 4-9), 56.9% unemployed, and 40.3% with yearly incomes of less than \$25,000 US dollars. Mean depression scores were in mild/moderate severity range with a mean PHQ-9 of 10.5 (SD 7). Participants had epilepsy for a mean duration of 15.5 (SD 13.8) years. The most common seizure type was bilateral tonic-clonic, reported by 49.8% of individuals.

The overwhelming proportion of NHEs were seizures. Given that recall of exact seizure counts among those with very seizure recurrence might not be reliable, those with seizure counts > 500 in the prior 6 months were not included in seizure or NHE count ITT analyses. Of 152 PWE with analyzable seizure data (not missing or not above 500), the mean seizure count in the 6 months prior to baseline was 20.6 (SD 41.0). It is notable that the range of past seizure counts was particularly broad in the WL arm (0-375) although this was not statistically significant compared to SMART (0-180). While 41.3% (N=66) of the sample had at least one ED visit and 23.1% (N=37) had at least 1 hospitalization in the 6 months prior to study enrollment and the mean number of hospitalization NHEs was 0.34 (SD 0.96); overall, non-seizure NHEs were relatively rare events.

4.3 SMART attendance and safety

For individuals in SMART, the average number of group sessions attended (out of a possible maximum of 8) was 5.9 (SD 2.8). Of the 80 individuals randomized to SMART, 9 (11.3%) attended no sessions. There were no adverse events related to study participation.

4.4 Primary outcome

In unadjusted comparisons of SMART vs. WL, there was no significant difference between rates of any improvement in NHE and non-significant trends for SMART participants to have selected thresholds for improvement in NHEs compared to WL (Table 2). From the logistic regression models that allowed for intraclass correlation by RUCC category of residence (Table 2), SMART was significantly associated with 2-fold increased odds of having at least 10-30% improvement in the number of NHEs compared to WL ($p<0.05$). An examination of PWE who averaged having NHEs or seizures of not more than about once/day (mean of 180 NHEs or 180 seizures at baseline and at 6 months follow-up) found that individuals in SMART had significantly less seizures ($p<0.05$) and a trend for fewer NHEs ($p=0.054$) compared to WL. Figure 2 notes NHE frequency distributions for SMART at baseline and at 6 months (A) and for WL at baseline and at 6 months (B).

There was no significant difference between SMART and WL in non-seizure NHEs including hospital length of stay in days (data not shown). In the modestly sized PP analyses (20 SMART, 38 WL), there was no evidence for associations with any of these outcomes (data not shown). Number of SMART sessions attended was also not associated with these outcomes. With respect to accuracy (percent agreement) of self-report vs. health record hospital-based NHE documentation, baseline ED visit accuracy was 78% and baseline hospitalization accuracy was 91% while 6-month ED visit accuracy was 82% and 6-month hospitalization accuracy was 97%.

When restricting to those who attended at 8 session and comparing to WL, similar significant results were obtained for 10% and 20% improvement ($p<0.05$) and trending association for decreases in NHEs and seizures ($p<0.1$) (Supplementary Table 1). When comparing those who attended 5 or fewer sessions to WL, there were significant 10-40% improvements ($p<0.05$) with non-significant trends for decreases in NHEs and seizure counts ($p<0.15$) (Supplementary Table 2).

4.5 Secondary and exploratory outcomes

Table 3 shows changes from baseline to 13 weeks and 6 months in depressive symptoms severity (PHQ-9), epilepsy-related QOL (QOLIE-31 T-score (composite measure/T-score and 7 sub-scales)), functional health status (SF-36, physical and mental health components), epilepsy self-management competency (ESMS), epilepsy stigma (ESS), social support (MSPSS) and epilepsy self-efficacy (ESES). In the ITT sample, SMART was associated with significantly improved PHQ-9 ($p=0.014$), QOLIE-31 seizure worry ($p<0.001$) and social functioning ($p=0.021$), ESES ($p=0.046$) and ESMS ($p<0.001$). In the PP sample SMART was associated with significantly improved QOLIE-31 T-score ($p=0.011$) and social functioning ($p=0.007$), ESS ($p=0.04$), ESES ($p=0.01$), ESMS ($p=0.006$) and SF-36 mental health component ($p=0.014$). There were no significant differences between SMART and WL on other variables. Change in any of the secondary variables was not significantly associated with SMART session attendance.

4.6 Study referrals and SMART participant satisfaction

As noted in Table 4, the majority of PWE enrolled (approximately 59% for both screen and randomized participants) were referred from clinicians. Epilepsy-specific social support entities such as the Epilepsy Foundation referred approximately 30%. In the group that was randomized to SMART, 31 participants responded to the acceptability survey. Of those that completed the acceptability survey, the majority, 23 (74.2%) strongly agreed or agreed that SMART covered most of the important issues and 21 (68.0%) strongly agreed or agreed that SMART addressed issues important to their particular situation. A majority, 19 (61.3%) strongly agreed or agreed that the benefit of SMART exceeded the burden or hassle of attending. Additionally, 22 (71.0%) felt that the number of sessions was about right, while 25 (81.0%) felt that the length of each SMART session was about right.

5.0 Discussion

Intended to test the reproducibility of a previous SMART efficacy RCT, this 2-site, 6-month RCT assessed the effects of SMART vs. a 6-month WL control in a diverse sample with epilepsy including rural PWE and individuals with poorly controlled epilepsy receiving care within an epilepsy specialty care center. Our original hypotheses with respect to NHEs/epilepsy complications were partially confirmed. While the overall average number of NHE counts did not differ between study arms, adult PWE randomized to SMART had 2-fold increased odds of having at least 10-30% improvement in the number of NHEs and a significant reduction in seizure count. Aligned with the effects of our original SMART efficacy RCT and confirming our secondary hypotheses, we also found improved depressive symptoms, ESM competency and epilepsy self-efficacy. Only partially confirming our hypotheses on QOL change, we found improvement in selected QOL domains, but no statistical difference in the QOLIE-31 composite score.

It is worth noting that our PWE sample only included those with a recent NHE, and many participants may have faced additional difficulties and barriers to treatment due to rural residence or because they were determined by their referring epilepsy care clinician as someone who might be in particular need of an ESM such as SMART. Perhaps not

surprisingly given our solicitation of referrals from a tertiary care epilepsy center, our sample had a relatively high seizure frequency prior to enrollment. While study methods do not allow for a determination of those who might have drug-resistant epilepsy vs. those who had poorly controlled seizures due to adherence or lifestyle issues, it is possible that some PWE, especially those with extremely high seizure counts to begin with, had epilepsy that was truly drug-resistant and the potential for improvement with SMART was thus potentially limited. Our analysis of individuals who averaged less than a seizure a day (mean of < 180 NHEs or seizures during a 6-month period) found that PWE randomized to SMART had significantly reduced seizure frequency and a trend for NHE reduction compared to WL. It is possible that factors unique to SMART could have affected seizure management, particularly the use of PWE trained to deliver the SMART curriculum. Similar models of care can be found with community health workers, individuals who are culturally competent and uniquely situated to provide ongoing behavioral support to patients in conjunction with the broader health care team [23].

A recent overview of ESM study reviews by Goh and colleagues suggested inconsistent outcomes for some ESM studies [3]. The outcome that had the most robust effects in the review by Goh and colleagues was health-related QOL [3], most often measured with the 31-item QOLIE scale [15,16]. The study reported here also used the QOLIE-31 and found that while composite QOLIE-31 did not differ between study arms, there were selected QOLIE-31 domain improvements seen in SMART vs. WL, namely seizure worry and social functioning. The review by Goh and colleagues also noted no clear effects on seizure status in ESM studies, which differs from our primary finding of improvements in clinically relevant change in the proportion of NHEs.

Consistent with the review summary by Goh and colleagues, we observed improvement in depressive symptom severity among PWE who participated in SMART vs. WL. Individuals in SMART had PHQ-9 score mean of 11.2 (7.1) at baseline and 8.5 (5.5) at 6-month follow-up as compared to a baseline score of 9.7 (6.9) and 10.0 (6.4) at 24 weeks in the WL arm ($p=0.01$). It must be noted that overall depression severity was generally in the low/moderate range in this sample given that PHQ-9 scores of 5, 10, 15, and 20 represent the severity categories of mild, moderate, moderately severe, and severe depression, respectively [13]. While the PHQ-9, a general measure of depression, was used to assess depressive symptom severity in our previous SMART RCT, it is also possible that the effects of SMART on depressive symptoms in PWE might not be ideally assessed with the PHQ-9. Future studies might use an epilepsy-specific instrument such as the Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) [24].

An additional secondary outcome relevant to prognosis and a better understanding of posited mechanism of action for SMART and similar ESMs is our finding that SMART was significantly associated with improvements in ESM competency and epilepsy-related self-efficacy. Follow-up beyond 6 months is currently being analyzed in a post-RCT extension phase of this study and a key point of interest will be to assess whether higher scores on these two relevant domains might predict health trajectory at 18-month follow-up. In addition to the need for more information on longer-term sustainability, more work needs to be done to establish feasibility, scale-up and cost-effectiveness of ESMs such as

SMART in routine clinical settings. However, recent experience with building in electronic health record prompts for epilepsy care clinicians to identify and refer PWE to SMART programming appears promising and an efficient use of resources [25].

While this RCT had several important findings that have substantial clinical relevance, generalizability is limited by a relatively small baseline sample, reliance on self-report for NHEs (including seizure count and seizure type) and the fact that it was not possible to blind participants to study arm assignment. The study team was not routinely appraised of and did not collect data on medication changes that may have occurred during the course of the trial. While the randomized allocation might be expected to minimize any bias for either group getting medication adjustments prescribed by their regular epilepsy care clinician, this possibility, which could affect study outcomes, cannot be entirely ruled out and this is a limitation of the study. Findings from this U.S. sample may not generalize to PWE outside of the U.S. The individuals in this study also volunteered for a research study and likely do not represent the full spectrum of PWE. Also, loss-to-follow-up has the potential to introduce selection bias, fortunately, there were no significant differences in baseline attributes for those retained versus excluded from final comparisons. Finally, this 6-month RCT does not provide information on possible longer-term sustainability of the SMART intervention. As described in a previously published description of the overall study methods [7], the study team is currently analyzing longer-term post RCT data and hopes to be able to share this with the epilepsy care community in the near future.

In conclusion, this RCT testing the SMART ESM intervention vs. WL mostly replicated findings of previous work and suggests that SMART is one of several known effective epilepsy self-management approaches [4]. Adult PWE who engage with SMART might expect to have a proportion of epilepsy complications, fewer seizures, selected improved elements of QOL, improved depression severity and better ability to self-manage their epilepsy. Given the high acceptability and relatively low-cost of evidence-based ESMs, inclusion of approaches such as SMART into a comprehensive care model for PWE seems warranted.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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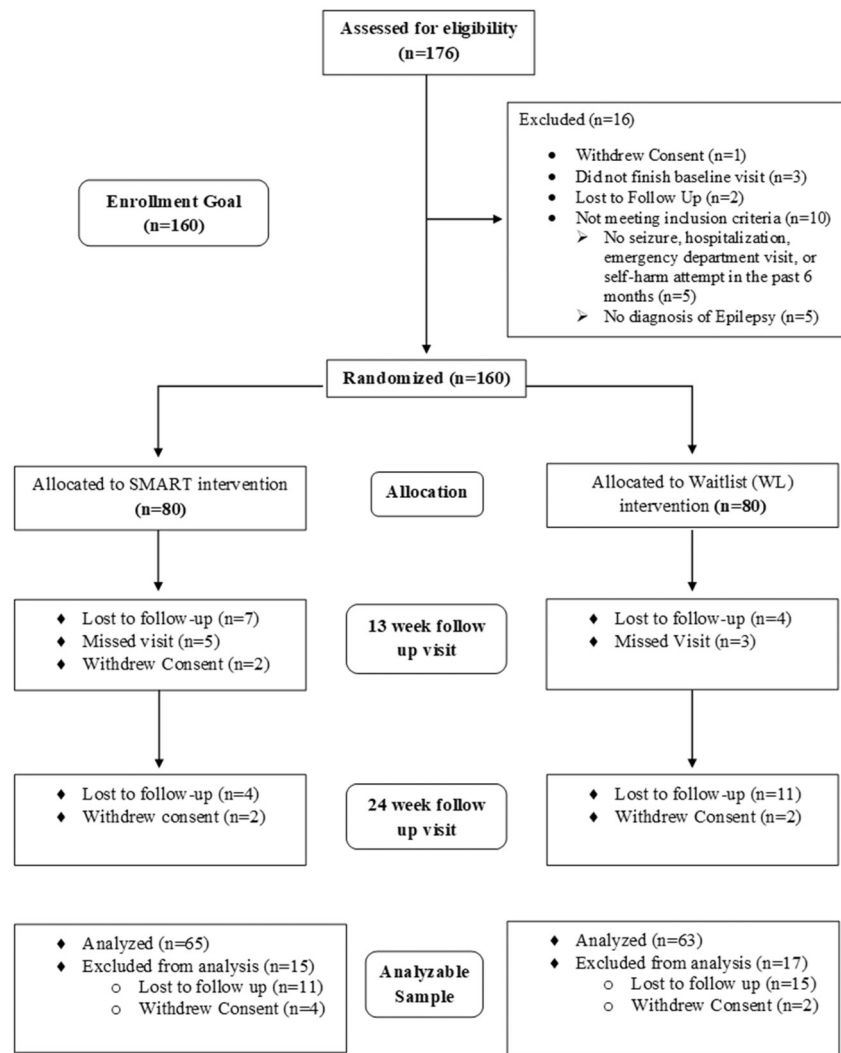


Figure 1:
CONSORT diagram for participation of (N=160) of PWE participating in an RCT of SMART vs. 6-month waitlist control (WL)

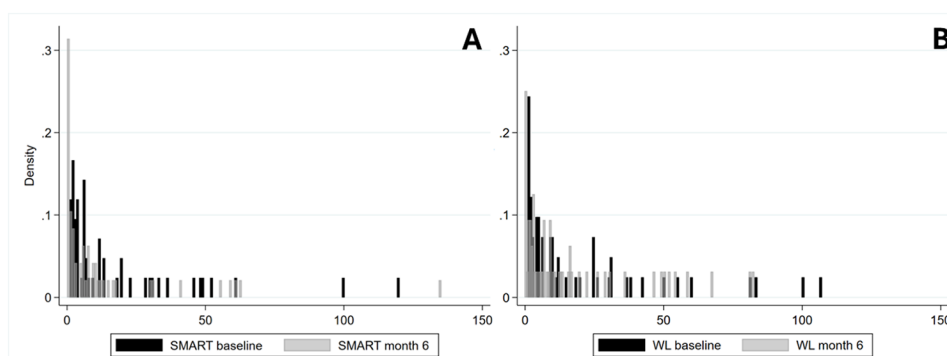


Figure 2. Distribution of NHEs at baseline and at month 6 in the intervention SMART arm (A) and in the WL arm (B).

Table 1. Baseline Characteristics of PWE in an RCT of SMART vs. 6-month waitlist control (WL)

Sociodemographic Characteristics	Total sample Mean (SD) or N (%) N=160	SMART N=80	WL N=80	P
Age	39.4 (12.2) range 19-77	38.7 (11.7) range 19-63	40.1 (12.6) range 19-77	0.50
Gender				
Male	52 (32.5%)	24 (30.0%)	28 (35.0%)	0.50
Female	107 (66.9%)	56 (70.0%)	51 (63.7%)	
Race				
Non-White	20 (12.5%)	9 (11.3%)	11 (13.8%)	0.09
White	132 (82.5%)	64 (80.0%)	68 (85.0%)	
Ethnicity				
Hispanic	11 (6.9%)	8 (10.0%)	3 (3.8%)	0.21
Marital Status				
Married or cohabitating	84 (52.5%)	46 (57.5%)	38 (47.5%)	0.27
Other	76 (47.5%)	34 (42.5%)	42 (52.5%)	
Education Level				
More than high school	124 (77.5%)	58 (72.5%)	66 (82.5%)	0.19
High school or less	36 (22.5%)	22 (27.5%)	14 (17.5%)	
Employment Status				
Employed	69 (43.1%)	33 (41.3%)	36 (45%)	0.75
Unemployed	91 (56.9%)	47 (58.7%)	44 (55%)	
Income				
>\$25,000	96 (60%)	52 (65%)	44 (55.0%)	0.26
<\$25,000	64 (40%)	28 (35.0%)	36 (45.0%)	
RUCC				
1	31 (19.4%)	18 (22.5%)	13 (16.3%)	0.88
2	41 (25.6%)	22 (27.5%)	19 (23.8%)	
3	38 (23.8%)	16 (20%)	22 (27.5%)	
4	16 (10.0%)	6 (7.5%)	10 (12.5%)	
5	5 (3.1%)	2 (2.5%)	3 (3.8%)	

Sociodemographic Characteristics	Total sample Mean (SD) or N (%) N=160	SMART N=80	WL N=80	P
6	14 (8.8%)	8 (10.0%)	6 (7.5%)	
7	10 (6.3%)	5 (6.3%)	5 (6.3%)	
8	3 (1.9%)	2 (2.5%)	1 (1.3%)	
9	2 (1.3%)	1 (1.3%)	1 (1.3%)	
RUCC				
Population 20,000+	131 (81.9%)	64 (80.0%)	67 (83.8%)	0.68
Population <20,000	29 (18.1%)	16 (20.0%)	13 (16.3%)	
Health Insurance Coverage				
Private	73 (45.6%)	38 (47.5%)	35 (43.8%)	0.90
Public	83 (51.9%)	40 (50.0%)	43 (53.8%)	
No coverage	4 (2.5%)	2 (2.5%)	2 (2.5%)	
Epilepsy/health-related variables				
Age of epilepsy onset, years	23.9 (14.0)	24.5 (14.6)	23.3 (13.4)	0.57
Epilepsy duration, years	15.5 (13.8)	14.2 (12.7)	16.8 (14.8)	0.37
Seizure type				
Bilateral tonic-clonic	103 (49.8%)	50 (50%)	53 (49.5%)	0.74
Other seizure types	104 (50.2%)	50 (50%)	54 (50.5%)	0.62
Number of seizures in the prior 6 months (N=152) *	20.6 (41.0), range 0-375	20.8 (35.0), range 0-180	20.5 (46.2), range 0-375	0.57
Number of seizures in the prior 30 days (N=157) *	6.4 (21.2) range 0-240	6.2 (12.8) range 0-90	6.6 (27.1) range 0-240	0.69
Number with a seizure in prior 30 days (N=159)	110 (69.2%)	55 (68.8%)	55 (69.6%)	1.0
Number of CCI categories	1.0 (1.6)	1.1 (1.6)	0.9 (1.6)	0.32
REALM-R (N=158)	7.4 (1.2)	7.3 (1.4)	7.5 (1.1)	0.52
ED visit in prior 6 months	66 (41.3%)	32 (40.0%)	34 (42.5%)	0.87
Hospitalization in prior 6 months	37 (23.1%)	18 (22.5%)	19 (23.85)	1.0
Number of hospitalizations in the prior 6 months (N=159)	0.34 (0.96) range 0-7	0.38 (1.11) range 0-7	0.31 (0.79) range 0-6	0.84
Self-harm attempt in prior 6 months	5 (3.1%)	1 (1.3%)	4 (5.0%)	0.37
Depression severity score (PHQ-9) (N=159)	10.5 (7.0) range 0-27	11.2 (7.1) range 0-27	9.7 (6.9) range 0-27	0.20

* Samples with <500 seizures

RUCC= Rural-urban continuum code, ED=Emergency Department, CCI= Self-reported Charlson Comorbidity Index, REALM-R= Rapid Estimate of Adult Literacy in Medicine-Revised

Table 2: Change in negative health events (NHEs) in SMART vs. WL between baseline and 6-month follow-up *

Variable	Total sample	SMART	WL	p **	OR/ β (95% CI) ***	p ***
Any change in NHE total	64.0%	69.1%	59.3%	0.33	1.53 (0.83, 2.83)	0.17
At least 10% improvement	57.0%	65.5%	49.2%	0.091	1.96 (1.23, 3.13)	0.005
At least 20% improvement	54.4%	63.6%	45.8%	0.063	2.07 (1.36, 3.16)	0.001
At least 30% improvement	50.0%	58.2%	42.4%	0.13	1.89 (1.04, 3.46)	0.038
At least 40% improvement	46.5%	52.7%	40.7%	0.26	1.63 (0.94, 2.82)	0.084
At least 50% improvement	41.2%	43.6%	39.0%	0.70	1.21 (0.65, 2.24)	0.54
Change in NHEs among those with < 180 seizures at 6-month baseline lookback and at 6- month follow-up from baseline ⁺	-4.22 (2.33)	-6.49 (3.32)	-2.18 (3.27)	0.19	-0.200 (-0.405, 0.004)	0.054
Change in seizures among those with < 180 seizures at 6-month baseline lookback and at 6- month follow-up from baseline ⁺	-4.13 (2.31)	-6.29 (3.32)	-2.21 (3.23)	0.16	-0.232 (-0.445, -0.018)	0.037

* Samples with <500 NHEs/seizures at baseline and at week 24; N=114 (55 SMART, 59 WL)

⁺ Samples with <180 NHEs/seizures at baseline and at week 24; N=110 (52 SMART, 58 WL)

** Statistical significance from unadjusted Fisher's exact test for binary variables and non-parametric Wilcoxon rank-sum test for the continuous variable.

*** For binary variables, associations are from logistic regression models for SMART vs WL, with the variance-covariance matrix allowing for correlations by RUCC status. For continuous variables, they were inverse rank normalized, and the associations are from linear regression models for SMART vs WL, with the variance-covariance matrix allowing for correlations by RUCC status.

Table 3:
Secondary outcomes for SMART vs. WL over 13 weeks and 6-months follow-up

		Baseline	Week 13	Week 24	p ^a	p ^b
PHQ-9	SMART	11.2 (7.1)	9.4 (6.6)	8.5 (5.5)	0.014	0.086
	WL	9.7 (6.9)	9.7 (5.8)	10.0 (6.4)		
QOLIE-31 T-score^{**}	SMART	39.2 (11.8)	43.1 (11.5)	44.2 (11.3)	0.23	0.011
	WL	40.7 (11.9)	41.5 (11.0)	42.1 (11.2)		
QOLIE-31 Seizure Worry	SMART	35.7 (27.0)	44.4 (29.6)	49.0 (29.8)	0.001	0.15
	WL	41.8 (29.9)	40.8 (26.8)	43.1 (29.2)		
QOLIE-31 Overall QOL	SMART	55.7 (18.8)	59.8 (19.7)	58.4 (20.5)	0.71	0.55
	WL	56.2 (20.8)	57.4 (20.1)	48.3 (20.1)		
QOLIE-31 Emotional Wellbeing	SMART	53. (23.6)	60.4 (22.2)	60.6 (20.3)	0.27	0.081
	WL	55.3 (24.7)	57.4 (21.3)	55.8 (22.3)		
QOLIE-31 Energy	SMART	38.1 (21.2)	43.7 (22.7)	43.8 (21.6)	0.16	0.17
	WL	41.7 (24.4)	40.4 (21.7)	41.2 (24.4)		
QOLIE-31 Cognition	SMART	43.7 (25.1)	45.8 (24.7)	50.5 (24.9)	0.90	0.30
	WL	44.7 (26.7)	45.3 (25.5)	47.4 (25.1)		
QOLIE-31 Medication Effects	SMART	46.0 (28.4)	49.6 (31.0)	52.9 (31.6)	0.076	0.12
	WL	46.4 (28.1)	47.2 (28.1)	47.4 (26.0)		
QOLIE-31 Social Functioning	SMART	43.0 (27.3)	50.5 (26.4)	54.5 (27.4)	0.021	0.007
	WL	46.4 (26.4)	47.4 (26.4)	49.9 (27.1)		
ESS	SMART	42.0 (16.4)	39.1 (15.8)	38.3 (14.8)	0.74	0.040
	WL	42.7 (12.8)	42.0 (12.3)	42.1 (12.9)		
ESES	SMART	241.7 (48.9)	258.9 (43.5)	254.1 (38.2)	0.046	0.010
	WL	244.8 (53.5)	243.7 (48.2)	249.7 (52.5)		
ESMS	SMART	141.3 (14.6)	148.9 (14.5)	148.9 (13.1)	0.009	0.006
	WL	143.8 (16.3)	146.8 (16.1)	149.3 (16.1)		
MSPSS	SMART	62.8 (16.6)	66.2 (16.0)	64.2 (16.6)	0.49	0.50
	WL					

		Baseline	Week 13	Week 24	p ^a	p ^b
	WL	61.6 (17.5)	60.0 (16.7)	62.1 (15.7)		
SF-36 PCS						
	SMART	46.8 (10.9)	46.7 (9.8)	47.6 (9.7)	0.40	0.47
	WL	46.2 (9.5)	46.2 (9.4)	48.0 (9.7)		
SF-36 MCS						
	SMART	37.1 (13.5)	41.0 (13.5)	41.5 (11.3)	0.17	0.014
	WL	39.5 (13.1)	38.6 (13.2)	38.2 (11.7)		

***.

T-score is a total QOLIE-31 score and provides relative comparison to standard epilepsy cohorts (mean of 50)

^a Group x time interaction p-value from intent-to-treat model, calculated by longitudinal linear mixed-effects regression models with the variance-covariance matrix allowing for correlations by RUCC status. Outcomes were inverse rank normalized.

^b Group x time interaction p-value from per-protocol model, calculated by longitudinal linear mixed-effects regression models with the variance-covariance matrix allowing for correlations by RUCC status. Outcomes were inverse rank normalized.

WL= Waitlist control, PHQ-9= 9-item Patient Health Questionnaire for Depression, , QOLIE-31= Quality of Life in Epilepsy, 31-item version, SF-36= Short-form 36 item functional health index, ESMS= Epilepsy Self-Management Scale , ESS= Epilepsy Stigma Scale , MSPSS= Multidimensional Scale of Perceived Social Support, ESES= Epilepsy Self-Efficacy Scale

Table 4:**Study Referral Sources**

Referral sources	Screening N (%)	Randomized N (%)
Clinician referral	100 (59.2%)	94 (59.0%)
Epilepsy social service agency/MEW Network	14 (8.3%)	14 (8.8%)
Social media	8 (4.7%)	5 (3.1%)
University of Cincinnati site	5 (3.0%)	5 (3.1%)
Summa Health site	5 (3.0%)	5 (3.1%)
Josh Provides (on-line epilepsy support community)	8 (4.7%)	8 (5%)
Electronic Health Record Query	8 (4.7%)	8 (5%)
Research Match	15 (8.9%)	15 (9.4%)
Self-response to advertisement	2 (1.2%)	2 (1.3%)
Word of mouth	2 (1.2%)	2 (1.3%)
Study flyer	1 (0.6%)	1 (0.45%)
Other	1 (0.6%)	1 (0.45%)
Total	169 * (100%)	160 (100%)

* 7 of the 176 total screened participants did not have referral source data

Managing Epilepsy Well (MEW) Network