HHS Public Access

Author manuscript

Epilepsy Behav. Author manuscript; available in PMC 2020 July 20.

One-year follow-up of a remotely delivered epilepsy self-management program in high-risk people with epilepsy

Martha Sajatovic, MD[a,b], **Kari Colon-Zimmermann, MA**[a,b], **Mustafa Kahriman, MD**[c], **Edna Fuentes-Casiano, MSSA, LSW**[b], **Christopher Burant, PhD**[d], **Michelle E. Aebi, MA**[b], **Kristin A. Cassidy, MA**[a,b], **Samden Lhatoo, MD**[e], **Douglas Einstadter, MD, MPH**[f], **Peijun Chen, MD, PhD, MPH**[g]

[a]Department of Neurology, Neurological & Behavioral Outcomes Center, Case Western Reserve University School of Medicine and University Hospitals Cleveland Medical Center, Cleveland, Ohio USA

[b]Department of Psychiatry, Case Western Reserve University School of Medicine and University Hospitals Cleveland Medical Center, Cleveland, Ohio, USA

[c]Department of Neurology, Louis Stokes Cleveland VAMC, Case Western Reserve University School of Medicine, Cleveland, Ohio USA

[d]Case Western Reserve University School of Nursing, Louis Stokes Cleveland VAMC, Cleveland, Ohio USA

[e]Department of Neurology, University of Texas Houston, Houston, Texas USA

[f]Case Western Reserve University and Center for Health Care Research and Policy, MetroHealth Medical Center, Cleveland, Ohio USA

[g]Department of Psychiatry, Louis Stokes Cleveland VAMC, Case Western Reserve University School of Medicine, Cleveland, Ohio USA

Abstract

Objective: Self-management for people with epilepsy and a history of negative health events" (SMART) is a novel group-format epilepsy self-management intervention demonstrated to reduce negative health events (NHEs) such as accidents, emergency department visits, and seizures in adults with epilepsy in a 6-month prospective randomized controlled trial (RCT). SMART also reduced depressive symptoms and improved health functioning and quality of life. This report describes the longer-term (12-month) post-efficacy RCT outcomes in adults with epilepsy who received SMART.

Methods: After completing a 6-month, prospective RCT that demonstrated efficacy of SMART vs. 6-month waitlist control (WL), adults age 18 with epilepsy were followed for an additional 12 months. Individuals originally randomized to WL received the 8-week SMART intervention immediately following the conclusion of the RCT. For this long-term extension analysis, assessments were conducted at 24 weeks (the 6-month primary outcome time-point of the efficacy RCT), at 32 weeks for individuals originally randomized to WL, and at 48 weeks and 72 weeks for all individuals. Outcomes assessed included past 6-month NHE counts, depressive symptoms assessed with the 9-item Patient Health Questionnaire (PHQ-9) and Montgomery-Asberg Depression Rating Scale (MADRS), and quality of life assessed with the 10-item Quality of Life in Epilepsy (QOLIE-10).

Results: At the beginning of this long-term observational period (24-week follow-up time point for the original RCT) there were 50 individuals in the group originally randomized to SMART and 52 originally randomized to WL. Mean age was 41.4 years, 70% women (N=71), 64% (N=65) African-American, 8% Hispanic (N=8). Study attrition from week 24 to week 72 was 8% in the arm originally randomized to SMART and 17% in the arm originally randomized to WL. During the 12-month observation period (24 weeks to 72 weeks) there were a total of 44 serious adverse events and 4 deaths, none related to study participation. There was no significant change in total past 6-month NHE counts in the group originally randomized to SMART, although the group had significantly reduced 6-month seizure counts. The group originally randomized to WL, who received SMART during this observational period, had a reduction in total NHE counts. The group originally randomized to SMART had relatively stable levels on other outcome variables except for a trend for improved MADRS (p=.08). In the group originally randomized to WL, there were significant improvements in PHQ-9 (p=.01), MADRS (p=<.01), and QOLIE-10 (p=.004).

Conclusions: This post-RCT extension study suggests that adults with epilepsy who participate in the SMART intervention sustain clinical effects at 1-year follow-up and may have incremental improvements in seizure frequency and mood. Future research needs to identify opportunities for scale-up and outreach to other high-risk groups with epilepsy.

Keywords

epilepsy; seizures; self-management; depression; quality of life

Introduction

In spite of advances in biological therapies for epilepsy such as antiepileptic drugs (AEDs), many people with epilepsy have negative health events (NHEs) such as accidents, emergency room (ER) visits, and poor quality of life [[1–4]. For the past decade, the Centers for Disease Control and Prevention (CDC) Prevention Research Centers' Managing Epilepsy Well (MEW) Network has focused on the development and testing of evidence-based epilepsy self-management interventions [[5]. SMART "Self-management for people with epilepsy and a history of negative health events" (SMART), developed as part of the MEW Network effort, is a group-format, remotely delivered, self-management intervention designed to assist vulnerable subgroups with epilepsy, including those with recent seizures and other health complications. In a prospective 6-month efficacy randomized controlled trial (RCT), individuals randomized to SMART had greater reduction in the total NHE

counts from baseline compared to 6-month waitlist (WL) control (p=.04). [[6] In the 6-month RCT, there were no significant differences in sub-categories of NHE counts between the SMART and WL arms. [[6] In addition to reducing health complications, compared to WL, SMART was also associated with improved self-rated depressive symptom severity (p=.032), rater-assessed depressive symptom severity (p= .002), quality of life (p<.001) and global physical (p=.015) and mental health (p=.003) [[6]

A recent systematic literature review of group-format self-management interventions for adults with epilepsy generally suggested promise in improving quality of life and selected other outcomes [[7]. However, the existing evidence is predominantly from pilot studies with small sample sizes and short follow-up durations. This report describes the longer-term outcomes (12-month follow-up) in adults with epilepsy who participated in the original 6-month SMART efficacy RCT. Examination of the potential sustainability of effects and outcomes of self-management interventions is critical to inform future efforts to embed evidence-based epilepsy self-management programs into standard models of epilepsy care.

Methods

Overview:

The overall research project had three design components: (1) a community participatory approach that informed the development of the intervention, (2) a prospective 6-month efficacy RCT of SMART vs WL, and (3) follow-up evaluation of both SMART and WL study arms to evaluate longer-term post-RCT outcomes. This report describes the 12-month longer-term outcomes after the original RCT. The earlier parts of the study, described in detail elsewhere [[6], demonstrated that compared to WL, participants in SMART had significant reductions in total NHE counts, the primary RCT outcome, as well as improvements in mood, quality of life, and functioning. For the analysis presented here, participants were assessed three times in the group originally randomized to SMART: at the 24-week follow-up time-point in the original RCT, at 48 weeks, and at 72 weeks. For the group originally randomized to WL, participants were assessed four times: at the 24-week follow-up time-point in the original RCT, at 32 weeks (immediately after they completed the SMART program), at 48 weeks, and at 72 weeks.

Study participants:

Study participants were drawn from the community and from clinical settings. Study inclusion criteria included a self-reported diagnosis of epilepsy, age 18, having at least one NHE within the past 6 months, and being able to provide written informed consent and participate in study procedures. NHEs were defined as self-reported seizures, accidents or traumatic injury, self-harm attempts, ER visits, and hospitalizations. The total NHE count is a summation of each of the sub-categories of NHEs in the past 6 months. Participants were excluded if they were at immediate risk of self-harm, had dementia, were pregnant, or were unable to read/understand English. All participants provided written informed consent, and the study was approved by the institutional review board (IRB) of University Hospitals of Cleveland Medical Center. Table 1 shows selected demographics (generally similar between individualized originally to SMART vs WL) at the beginning of this long-term extension

observation period (24-week follow-up in the original RCT). A more detailed description of baseline demographic and clinical variables in the original SMART RCT is provided elsewhere. [[6]

SMART intervention:

SMART is operationalized in two steps. Step 1 consists of one group-format, in-person 60–90 minute session (up to 10 participants), collaboratively delivered by a Nurse Educator-Peer Educator dyad. Peer Educators are adults with epilepsy who have been trained to deliver the SMART curriculum. Following the initial in-person session, there are 7 group-format sessions delivered via Internet on personal computer tablets. A study team member participated in the session as an external observer and identified and recorded individuals who logged onto the group sessions on-line as well as those that participated via audioconference phone line. Step 2, following completion of the group sessions, consists of six telephone maintenance sessions (spaced approximately 2 weeks apart) with the Peer Educator and the Nurse Educator alternating calls. In this post-RCT observation period, individuals originally randomized to SMART had no treatment/intervention.

WL control:

In this post-RCT observation period, individuals' original randomized to WL received the SMART intervention over a period of approximately 8 weeks. Outcomes were assessed at 32-week follow-up in this group. Procedures administered after 32 weeks were then identical to those described above for the original SMART group.

Outcomes:

Evaluation in this long-term post-RCT included past 6-month NHEs, counted independently and calculating a total NHE count that was derived by summing NHE numbers in each category (seizures, ER visits, hospitalizations (for any cause), self-harm attempts, and accidents/traumatic injuries). Additional outcomes included depressive symptoms, quality of life, functioning, seizure severity, self-efficacy, social support, epilepsy self-management competency, and epilepsy stigma.

Standardized rating scales:

Depressive symptoms were assessed using the nine-item Patient Health Questionnaire (PHQ-9), a validated self-rated depression scale [8]. Scores range from 0–27 with higher scores indicating worse depression severity. Depressive symptom severity was also assessed with the Montgomery-Asberg Depression rating scale (MADRS), a 10-item rater-administered questionnaire with scores ranging from 0–60 [9]. Higher scores indicate worse depressive symptom severity.

Quality of life was assessed with the self-rated ten-item Quality of Life in Epilepsy (QOLIE-10) [10,11]. Scores were calibrated to range from 1 to 5, with higher scores indicating worse quality of life. Functional status evaluation used the 36-item short-form health survey SF-36, which has two subcomponents: a physical component summary (PCS) and mental component summary (MCS) [12]. Scores range from 0 (worst functioning) to 100 (best functioning). Epilepsy severity (assessed only in those individuals who had

experienced a seizure within the past 30 days) was evaluated with the Liverpool Seizure Severity Scale [13]. Scores on the Liverpool range from 1 to 40, with lower scores indicating more severe seizures. The Liverpool is only scored on individuals who have had a seizure in the past 30 days.

Self-efficacy was measured using the Epilepsy Self-Efficacy Scale (ESES) with scores ranging from 0 to 330, with higher scores indicating better self-efficacy [14, 15]. Social support was measured with the Multidimensional Scale of Perceived Social Support (MSPSS), which measures perception of social support provided by family and friends as well as satisfaction with that support [16]. The MSPSS score ranges from 1 to 84, with higher scores indicating better social support. Epilepsy self-management was measured using the Epilepsy Self-Management Scale (ESMS); scores range from 1 to 190, with higher scores indicating better self-management of epilepsy [17]. Stigma for epilepsy was measured using the Epilepsy Stigma Scale (ESS) [14, 18] with scores ranging from 7 to 70 and higher numbers indicating greater stigma.

Statistical analysis:

Statistical analysis was performed using SAS 9.4 (SAS Institute, NC). Descriptive univariate analyses examined change over time in NHEs, PHQ-9, MADRS, QOLIE-10, SF-36, and Liverpool Seizure Severity Scale. For this 1-year post-RCT analysis (starting at 24 weeks after the original RCT baseline to 72 weeks post-baseline), the focus was to identify whether individuals in SMART would sustain their level clinical status and whether the WL arm might derive some additional benefit from participating in SMART after the original WL period was completed. Pre-post evaluations for each of the subgroups (those originally randomized to SMART and those originally randomized to WL) were conducted independently (not compared to each other). Pre-post evaluations were conducted using dependent paired t-tests for the characteristics of the data. For the SMART subgroup, three time-point Repeated Measures ANOVAs (RMANOVAs) were conducted to determine the trend in means over time (24, 48, and 72 week) for all additional outcomes. For the WL subgroup, four time-point RMANOVAs were conducted to determine the trend in the means over time (24, 32, 48, and 72 weeks) for all additional outcomes. A Type I error rate of 0.05 was used for all statistical tests.

Results

Retention and analyzed sample:

Figure 1 illustrates the sample, drop-out and retention of the sample by study arm (individuals originally randomized to SMART and those originally randomized to WL) from weeks 24 to 72, the longer-term follow-up observation period that is the focus of this report. At 24 weeks from baseline in the original RCT (beginning of this longer-term observational period) there were 50 individuals in the original SMART arm and 52 individuals in the original WL arm. Study attrition from week 24 to week 72 was 8% in the arm originally randomized to SMART and 17% in the arm originally randomized to WL.

Longer-term outcomes, adverse events, and SMART attendance:

There were 44 clinical trial serious adverse events (SAEs) that occurred in 35 participants during the observation period between 24 weeks and the final 72-week follow-up period. SAEs that occurred were 26 hospitalizations due to seizures (six individuals had multiple hospitalizations due to seizures), 16 hospitalizations due to medical events not related to seizures (reasons for hospitalization included fractured foot, abdominal pain, internal bleeding, exacerbation of systemic lupus erythematosus, shortness of breath/chest pain, allergic reaction to medication, migraines, asthma, pre-eclampsia, pneumonia, syncope/hypotension, osteomyelitis, respiratory infection, hypoglycemia, and psychiatric illness exacerbation) and two individuals who had serious acute suicidal thoughts or behavior (two hospitalized for this reason). There were four deaths during the observation period between 24 and 72 weeks due to one individual who had hematologic complications of intestinal surgery, one individual who had cardiac arrest (underlying cause unknown), one individual who died of homicide, and one death of unknown cause (family not willing to share this information). Of the four deaths, two were in the group originally randomized to SMART and two were in the group originally randomized to WL. No SAEs were related to study participation.

NHEs:

Seizures comprised the majority of NHEs during the 24- to 72-week observation period. Table 2 shows changes in means and medians from 24-week to 48 and 72 weeks on total NHEs and selected specific types of NHEs. There was no significant change in mean or median total past 6-month NHE counts in the group originally randomized to SMART, though 6-month seizure counts were significantly reduced at 72 weeks. The group originally randomized to WL, who received the SMART intervention during this observation period, had a reduction in mean and median total 6-month NHE counts and in 6-month seizure counts at 72 weeks.

Other outcomes:

Table 3 notes changes in depressive symptom severity, quality of life, functional status, self-efficacy, social support, epilepsy self-management, and epilepsy stigma. The group originally randomized to SMART appeared to have relatively stable levels on all of these variables except for a non-statistically significant trend for continued improvement in depression as measured by the MADRS (p=.08). In the group originally randomized to WL, there were significant improvements in both self-rated and observer-rated depressive symptoms as measured with the PHQ-9 (p=.01 between 24 and 32 weeks) and with the MADRS (p=<.01) respectively. There was also significant improvement in quality of life (QOLIE-10 p=.004 significant between 24 and 48 weeks), self-efficacy (ESES p=.01 significant between 24 and 72 weeks), epilepsy self-management (ESMS p<.01 significant between 24 and 32 weeks and 24 and 72 weeks), social support (MSPSS p=.01, significant between 48 and 72 weeks and epilepsy stigma (ESS p=.01, significant between 24 weeks and 32 weeks, 24 weeks and 48 weeks, and 24 weeks and 72 weeks (LSD correction).

Discussion

Epilepsy self-management has been demonstrated to improve a variety of outcomes among people with epilepsy [7]. However, many published trials have not included longer-term follow-up [7]. Since epilepsy is a chronic health condition, it is important to understand how evidence-based epilepsy self-management may impact people with epilepsy over a longer period. The original SMART RCT demonstrated a significant improvement in total NHE counts over 6 months vs. WL control, although sub-categories of NHEs (including seizure frequency, hospitalizations and ER visits) were not significantly different between study arms. This 12-month observational period conducted after a 6-month RCT testing the SMART program vs 6-month WL controls suggested that individuals originally randomized to SMART for the most part did not change their health status, and that total NHE counts did not change, however there were continued improvements in past 6-month seizure frequency and depressive symptoms over time. The group originally randomized to WL who received SMART during the observational 12-month time-period, had a reduction in total number of NHEs and improvements in seizure frequency over time. The WL group also had improvement in depressive symptoms, quality of life, self-efficacy, epilepsy self-management competency, and social support. The changes in secondary outcomes in the group originally randomized to WL are mostly consistent with findings seen in the original efficacy RCT, though original SMART RCT participants also had improved physical and mental health functioning as assessed with the SF-36 [6].

Several of our study findings have potentially important clinical implications. First, this sample is one considered "high-risk" in that the participants were required to have had recent seizures or epilepsy-related complications pre-enrollment. Sadly, during the 18-months that comprised the original 6-month RCT plus the 12-month post-RCT extension study, four individuals died (4/120, 3.3 %, two in the group originally randomized to SMART, two in the group originally randomized to WL). While one would require longer than 18 months to see if epilepsy self-management might have potential downstream impact on the premature mortality that has been documented among people with epilepsy [19, 20], this area is one that needs further study. It is possible that better physical and emotional health functioning as was seen in the original SMART RCT could eventually contribute to improved survival among people with epilepsy.

The majority of the sample consisted of racial or ethnic minorities (64% African American, 8% Hispanic) both being a subpopulation of individuals with epilepsy who may be particularly likely to experience health disparities. African Americans with epilepsy are more likely to receive care in crisis settings like the emergency room emergency [21] and mortality rates are greater for African Americans with epilepsy compared to individuals with epilepsy from other racial and ethnic group [22]. Some Hispanics with epilepsy may also experience health disparities, particularly if they are less acculturated immigrants to the US [23, 24]. Given the potential for higher rates of epilepsy complications among both African Americans and Hispanics with epilepsy, self-management programs like SMART may be an approach that helps to reduce health disparities for these groups.

An additional point worth noting is the fact that this relatively brief intervention (one hour-long in-person session, seven hour-long web-delivered sessions, and six brief phone calls) appears to have sustained positive effects among people who have had epilepsy for an average of 2 decades. It is possible that implementing SMART earlier in the course of illness, perhaps shortly after the initial diagnosis and as part of a comprehensive package of care in epilepsy, could reduce some of the overall burden that people with epilepsy typically experience, such as social isolation and unemployment or under-employment [25].

This study has several limitations including a single geographic location, reliance on self-report for NHEs, and non-blinded research assessments. Individuals with epilepsy who volunteer for a research study may not represent the full spectrum of individuals with epilepsy, and the 1-year observational period analyzed here is still a relatively short period of time considering the long duration for which most individuals live with epilepsy. The fact that the group originally assigned to WL control received a new treatment at 24 weeks presents some inherent limitations in being able to compare long-term findings between the 2 groups. Although we can't conclude why some of the differences in longer-term follow up between study arms occurred, it is possible that it could have been related to the interventions that individuals received and/ or reasons for attrition between arms. Individuals in the study arm originally randomized to SMART were in an observation-only phase and the relative reduction in support could have limited their ability to continue to improve. It is also possible that individuals who are the least motivated to engage in self-care might be particularly likely to drop out of study at the time when they are asked to participate in the group sessions (months 1–6 in the group originally randomized to SMART and months 6–12 in the group originally randomized to WL).

In conclusion, this post-RCT extension study suggests that adults with epilepsy who participate in the SMART intervention appear to have incremental improvements, particularly in seizure frequency and mood. Future research needs to identify and test opportunities for scale-up and outreach to other groups of people with epilepsy who may benefit from an evidence-based epilepsy self-management program.

Acknowledgements

References

[1]. Chong J, Kudrimoti HS, Lopez DCW, Labiner DM. Behavioral risk factors among Arizonans with epilepsy: Behavioral Risk Factor Surveillance System 2005/2006. Epilepsy & Behavior 2010;17: 511–519. [PubMed: 20215042]

[2]. Hesdorffer DC, Begley CE. Surveillance of epilepsy and prevention of epilepsy and its sequelae: lessons from the Institute of Medicine report. Current Opinion in Neurology 2013;26: 168–173. [PubMed: 23406912]

[3]. Ferguson PL, Chiprich J, Smith G, Dong B, Wannamaker BB, Kobau R, Thurman DJ, Selassie AW. Prevalence of self-reported epilepsy, health care access, and health behaviors among adults in South Carolina. Epilepsy & Behavior 2008;13: 529–534. [PubMed: 18585962]

[4]. Begley C, Basu R, Lairson D, Reynolds T, Dubinsky S, Newmark M, Barnwell F, Hauser A, Hesdorffer D. Socioeconomic status, health care use, and outcomes: Persistence of disparities over time. Epilepsia 2011;52: 957–964. [PubMed: 21320113]

[5]. Sajatovic M, Jobst BC, Shegog R, Bamps YA, Begley CE, Fraser RT, Johnson EK, Pandey DK, Quarells RC, Scal P, Spruill TM, Thompson NJ, Kobau R. The Managing Epilepsy Well Network: Advancing Epilepsy Self-Management. American Journal of Preventive Medicine 2017;52: S241–S245. [PubMed: 28215372]

[6]. Sajatovic M, Colon-Zimmermann K, Kahriman M, Fuentes-Casiano E, Liu H, Tatsuoka C, Cassidy KA, Lhatoo S, Einstadter D, Chen P. A 6-month prospective randomized controlled trial of remotely delivered group format epilepsy self-management versus waitlist control for high-risk people with epilepsy. Epilepsia 2018;59: 1684–1695. [PubMed: 30098003]

[7]. Smith A, McKinlay A, Wojewodka G, Ridsdale L. A systematic review and narrative synthesis of group self-management interventions for adults with epilepsy. BMC Neurol 2017;17: 114. [PubMed: 28623909]

[8]. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16: 606–13. [PubMed: 11556941]

[9]. Montgomery SA, Asberg M. A new depression scale designed to be sensitive to change. Br J Psychiatry 1979;134: 382–9. [PubMed: 444788]

[10]. Cramer JA, Perrine K, Devinsky O, Meador K. A brief questionnaire to screen for quality of life in epilepsy: the QOLIE-10. Epilepsia 1996;37: 577–82. [PubMed: 8641236]

[11]. Cramer JA, Arrigo C, Van Hammee G, Bromfield EB. Comparison between the QOLIE-31 and derived QOLIE-10 in a clinical trial of levetiracetam. Epilepsy Res 2000;41: 29–38. [PubMed: 10924866]

[12]. Ruta D, Garratt A, Abdalla M, Buckingham K, Russell I. The SF 36 health survey questionnaire. A valid measure of health status. BMJ 1993;307: 448–9.

[13]. Baker GA, Smith DF, Jacoby A, Hayes JA, Chadwick DW. Liverpool Seizure Severity Scale revisited. Seizure 1998;7: 201–5. [PubMed: 9700832]

[14]. DiIorio C, Osborne Shafer P, Letz R, Henry T, Schomer DL, Yeager K, Project ESG. The association of stigma with self-management and perceptions of health care among adults with epilepsy. Epilepsy Behav 2003;4: 259–67. [PubMed: 12791327]

[15]. DiIorio C, Hennessy M, Manteuffel B. Epilepsy self-management: a test of a theoretical model. Nurs Res 1996;45: 211–7. [PubMed: 8700654]

[16]. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The multidimensional scale of perceived social support. Journal of Personality Assessment 1988;52: 30–41.

[17]. DiIorio C, Shafer PO, Letz R, Henry TR, Schomer DL, Yeager K, Project Esg. Project EASE: a study to test a psychosocial model of epilepsy medication managment. Epilepsy Behav 2004;5: 926–36. [PubMed: 15624235]

[18]. Austin J, Dunn D, Huster G, Rose D. Development of scales to measure psychosocial care needs of children with seizures and their parents. 1. J Neurosci Nurs 1998;30: 155–60. [PubMed: 9689606]

[19]. Thurman DJ, Logroscino G, Beghi E, Hauser WA, Hesdorffer DC, Newton CR, Scorza FA, Sander JW, Tomson T, Epidemiology Commission of the International League Against E. The burden of premature mortality of epilepsy in high-income countries: A systematic review from the Mortality Task Force of the International League Against Epilepsy. Epilepsia 2017;58: 17–26. [PubMed: 27888514]

[20]. Beghi E Addressing the burden of epilepsy: Many unmet needs. Pharmacol Res 2016;107: 79–84. [PubMed: 26952026]

[21]. Saadi A, Himmelstein DU, Woolhandler S, Mejia NI. Racial disparities in neurologic health care access and utilization in the United States. Neurology 2017;88: 2268–2275. [PubMed: 28515272]

[22]. Greenlund SF, Croft JB, Kobau R. Epilepsy by the Numbers: Epilepsy deaths by age, race/ethnicity, and gender in the United States significantly increased from 2005 to 2014. Epilepsy Behav 2017;69: 28–30. [PubMed: 28219043]

[23]. Pallin DJ, Goldstein JN, Moussally JS, Pelletier AJ, Green AR, Camargo CA Jr. Seizure visits in US emergency departments: epidemiology and potential disparities in care. Int J Emerg Med 2008;1: 97–105. [PubMed: 19384659]

[24]. Myers L, Lancman M, Vazquez-Casals G, Bonafina M, Perrine K, Sabri J. Depression and quality of life in Spanish-speaking immigrant persons with epilepsy compared with those in English-speaking US-born persons with epilepsy. Epilepsy Behav 2015;51: 146–51. [PubMed: 26277451]

[25]. Jennum P, Sabers A, Christensen J, Ibsen R, Kjellberg J. Welfare consequences for people with epilepsy and their partners: A matched nationwide study in Denmark. Seizure 2017;49: 17–24. [PubMed: 28531819]
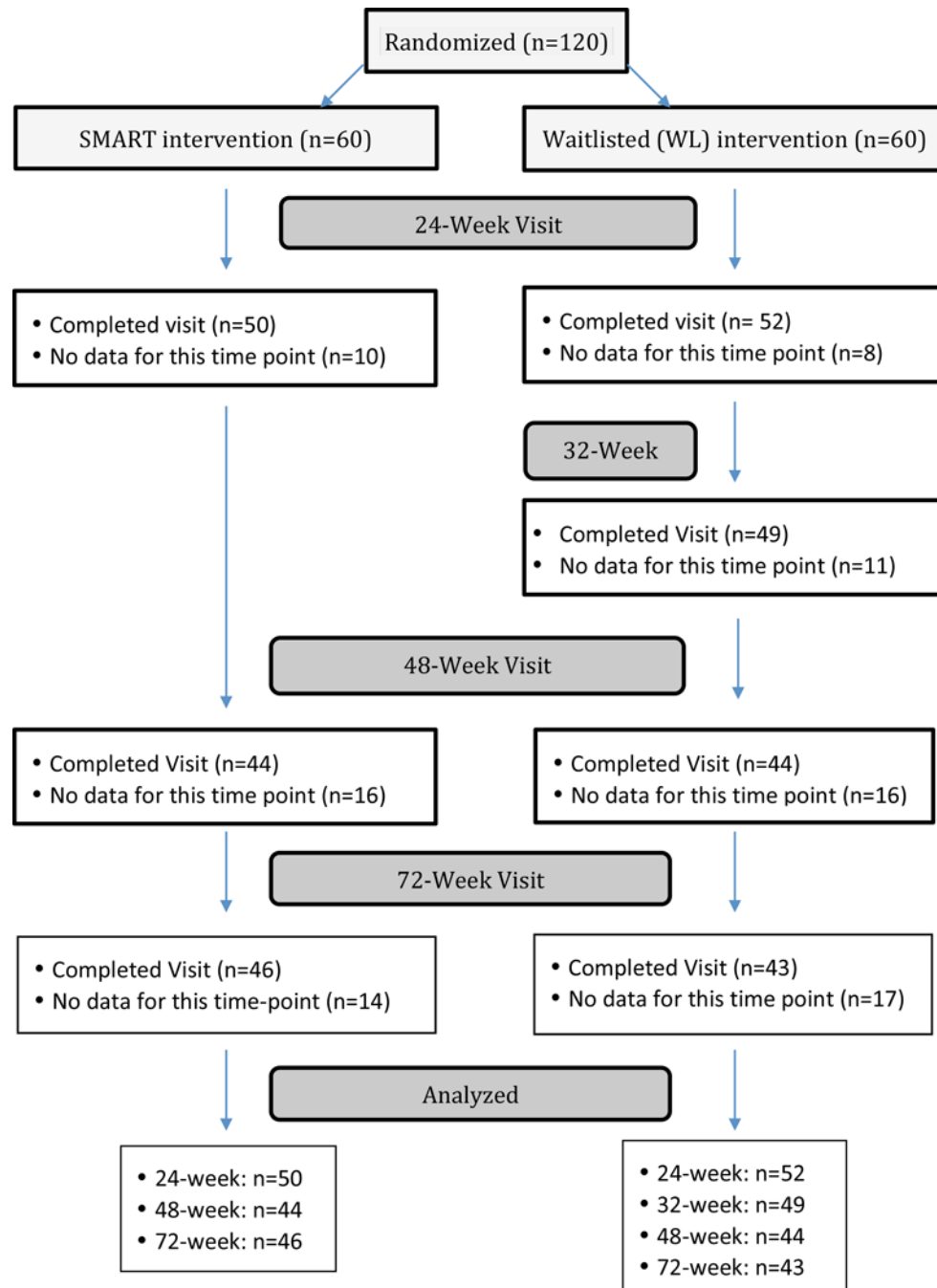
Figure 1:
SMART Long-term Outcomes Consort Flow Diagram

Table 1:

Demographic and clinical characteristics of a sample with epilepsy at the beginning of a long-term observation period[†]

Variable	Total sample N = 102
Age – Mean, SD	41.39 (11.62), n = 101
Gender- N (%)	
Female	71 (69.6)
Male	31 (30.4)
Race - N (%)	
African American	65 (63.7)
White	29 (28.4)
Ethnicity- N (%)	
Hispanic	8 (7.8)
Duration of epilepsy in years (mean, SD)	20.22 (15.45), n = 97
Number of prescribed AEDs [a] (mean, SD)	1.68 (0.85), n = 101
Past 30-day seizure count (mean, SD)	1.47 (5.20) median = 0.00
Total past 6-month NHE [b] count (mean, SD)	7.57 (14.30) median = 3.00
Total past 6-month seizure count (mean, SD)	9.03 (23.35) median = 2.00
Total past 6-month ER visits and hospitalizations (mean, SD)	0.49 (1.46)median = 0.00

[†]Beginning of observation period is 24 weeks after the initial baseline time-point in the original randomized controlled trial (RCT).

[a]Antiepileptic drug (assessed at baseline)

[b]NHE = Negative Health Event defined as a seizure, accident or traumatic injury, self-harm attempt, ER visit, or hospitalization

Table 2:

Mean and median number of negative health events (NHEs) in groups originally randomized to SMART and to WL at 24-, 48-, and 72-week follow-up

Variable	SMART (Mean, SD, Median, N)	p-value *	WL (Mean, SD, Median, N)	p-value *
Total past 6-month NHEs:				
24 week	8.17 (16.89), 2.50, 50		6.94 (11.13), 3.00, 50	
48 week	9.00 (18.38), 1.50, 44	0.92 **	6.90 (11.39), 3.00, 41	0.77 **
72 week	7.89 (27.67), 1.00, 44	0.09 ***	3.68 (5.21), 1.00, 44	<0.05 ***
NHE sub-types:				
Past 30-day seizure count				
24 week	2.14 (7.24), 0.00, 50		0.81 (1.34), 0.00, 52	
48 week	2.21 (5.03), 0.50, 42	0.82 **	1.38 (2.79), 0.00, 42	0.09 **
72 week	1.61 (4.84), 0.00, 44	0.74 ***	0.89 (1.48), 0.00, 44	0.58 ***
Past 6-month seizure count				
24 week	11.07 (30.73), 2.00, 50		6.94 (11.53), 3.00, 52	
48 week	8.52 (18.30), 1.00, 44	0.37 **	5.63 (10.24), 2.00, 41	0.55 **
72 week	7.07 (27.64), 1.00, 44	0.04 ***	2.77 (4.97), 1.00, 43	0.04 ***
Past 6-month ER and hospitalization count				
24 week	0.36 (0.74), 0.00, 50		0.62 (1.93), 0.00, 52	
48 week	0.45 (0.76), 0.00, 44	0.78 **	0.93 (1.86), 0.00, 41	0.10 **
72 week	0.38 (0.78), 0.00, 45	0.50 ***	0.89 (2.28), 0.00, 43	0.27 ***

*
Change from 24-week to 48-week and from 24-week to 72-week

P-value is based on mean difference (paired t-test)

**
test between 24 and 48 weeks

***
test between 24 and 72 weeks

NHE = Negative Health Event defined as a seizure, accident or traumatic injury, self-harm attempt, ER visit, or hospitalization

Table 3:

Change in other outcomes in groups originally randomized to SMART and to WL at 24, 32, 48, and 72-week follow-up

Variable	24 weeks		32 weeks		48 weeks		72 weeks		p*	Post-hoc
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
PHQ-9 [a]										
SMART n=38	6.47	6.63	---	---	5.50	5.44	6.34	5.30	$F_{(2,74)}$=0.83, p=0.44	---
WL n=36	10.28	6.84	7.22	5.02	8.06	5.91	7.69	5.55	**$F_{(3,105)}$=3.99, p=0.01**	24 week > 32 week
MADRS [b]										
SMART n=41	10.49	12.33	---	---	7.05	8.88	8.73	9.40	$F_{(2,80)}$=2.57, p=0.08	---
WL n=39	17.49	11.07	13.31	9.88	11.85	9.38	13.44	11.04	**$F_{(2.6,97.3)}$=4.54, p< 0.01** [**]	24 week > 48 week
QOLIE-10 [c]										
SMART n=38	2.39	0.98	---	---	2.39	0.88	2.35	0.90	$F_{(2,74)}$=0.06, p= 0.94	---
WL n=35	2.86	0.85	2.63	0.81	2.55	0.79	2.57	0.85	**$F_{(2.6,86.7)}$=3.07, p=0.04** [**]	24 week > 48 week
SF-36 [d]										
PCS										
SMART n=38	44.76	12.03	---	---	43.69	10.46	45.13	11.77	$F_{(2,74)}$=0.60, p=0.55	---
WL n=36	42.77	10.80	44.05	11.41	43.83	10.45	45.43	10.81	$F_{(3,105)}$=1.45, p=0.23	---
MCS										
SMART n=38	46.77	15.11	---	---	49.80	12.73	47.10	13.48	$F_{(2,74)}$=1.32, p=0.27	---
WL n=36	41.25	11.95	43.95	13.20	43.27	11.42	43.53	12.62	$F_{(2.5, 88.8)}$=0.88, p=0.44	---
ESES [e]										
SMART N=37	275.03	59.66	---	---	281.05	60.17	282.24	44.23	$F_{(1.4,51.5)}$=0.36, p=0.63	---
WL n=35	256.14	64.99	269.83	53.57	266.60	54.50	276.23	50.74	**$F_{(3,102)}$=3.88, p=0.01**	24 week < 72 week
MSPSS [f]										
SMART n=37	5.72	1.41	---	---	5.77	1.29	5.92	1.28	$F_{(1.6, 27.2)}$=0.47, p=0.63	---
WL n=35	5.31	1.32	5.45	1.41	5.30	1.36	5.76	1.15	**$F_{(3,102)}$=3.76, p=0.01**	48 week < 72 week
ESMS [g]										

Variable	24 weeks		32 weeks		48 weeks		72 weeks		p*	Post-hoc
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
SMART N=38	152.39	16.84	---	---	153.18	16.82	153.18	18.73	$F_{(2,74)}=0.13$, p=0.88	---
WL n=36	141.00	17.37	148.56	16.81	147.11	17.07	147.75	17.87	**$F_{(3,105)}=5.35$, p<0.01**	24 week < 32 week, 72 week
ESS[h]										
SMART n=37	33.68	18.08	---	---	32.81	15.79	32.05	19.08	$F_{(2,72)}=0.30$, p=0.74	---
WL n=34	37.32	18.03	31.56	15.10	30.71	15.70	31.06	16.40	**$F_{(3,99)}=4.03$, p=0.01**	24 week > 32 week, 48 week, 72 week (LSD)
Liverpool[i]										
SMART n=37	22.77	33.63	---	---	27.03	30.80	18.78	29.30	$F_{(2,72)}=1.19$, p=0.31	---
WL n=37	22.36	29.89	24.66	31.09	18.65	28.19	15.74	26.31	$F_{(3,108)}=1.32$, p=0.27	---

*
One-way Repeated Measures ANOVA using Bonferroni correction

**
Adjusted with Greenhouse-Geisser to account for non-sphericity

[a]PHQ-9 (Patient Health Questionnaire-9): Total scores range from 0 to 27, with higher scores indicating higher degree of depression severity.

[b]MADRS (Montgomery-Asberg Depression Rating Scale): Total scores range from 0 to 50 with higher scores indicating more severe depression.

[c]QOLIE-10 (Quality of Life in Epilepsy-10): Mean total scores calibrated to range from 1 to 5 with lower scores indicating better quality of life.

[d]SF-36 (Short-Form 36): There are 2 sub-scales, the physical component summary (PCS) and mental component summary (MCS). Each subscale ranges from 0 to 100 with higher scores indicating lower disability.

[e]ESES (Epilepsy Self-Efficacy Scale): Total scores range from 0 to 330 with higher scores showing better efficacy in the self-management of epilepsy.

[f]MSPSS (Multidimensional Scale of Perceived Social Support): Mean total scores range from 1–7 with higher scores indicating higher perceived social support.

[g]ESMS (Epilepsy Self-Management Scale): Total scores range from 38–190 with higher scores indicating more competency with self-management.

[h]ESS (Epilepsy Stigma Scale): Total scores range from 7–49 with higher scores indicating a higher belief that epilepsy is perceived as negative and interferes with relationships with others.

[i]Liverpool (Liverpool Seizure Severity Scale): The severity score ranges from 0 (no seizures) to 100 (most severe possible).