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The Community Targeted Self-Management of Epilepsy and Mental Illness (C-TIME) initiative: A research, community and healthcare administration partnership to reduce epilepsy burden

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Abstract

Aims: Comorbid mental health conditions (MHCs) such as depression and anxiety are common in people with epilepsy. Targeted Self-Management for Epilepsy and Mental Illness (TIME) is a behavioral program that targets mood symptoms in adults with epilepsy and comorbid MHCs. Building upon positive findings of a randomized, controlled study to establish the efficacy of TIME, the Community-TIME (C-TIME) initiative assessed the implementation feasibility and pre/post outcomes of this new evidence-based epilepsy self-management intervention in a community setting and in collaboration with key stakeholders.

Methods: C-TIME is a group-format, curriculum-based intervention delivered in eight 60–90 sessions over the course of 12 weeks. The C-TIME initiative used research staff to guide intervention performance evaluation, staff of a regional epilepsy advocacy agency to assist with community engagement and a county mental health services agency to support the transition from science to service. Process evaluations included outreach and engagement efforts needed to reach people with epilepsy and MHCs, the barriers and facilitators to roll-out, and participant retention and satisfaction. The primary intervention participant outcome was depressive symptom severity at 4-month follow-up.

Results: Referrals came from a variety of sources and approximately 1 in 3 referrals resulted in a enrollment. Thirty individuals were enrolled in 3 “cohorts” of 10. The most common reason for

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*This work is dedicated in memory of Valeria Harper, a tireless and devoted champion of the most vulnerable members of our community. Ms. Harper passed away in early 2018 and will be greatly missed.

not being enrolled post- screening was that individuals did not show up for the baseline evaluation. Mean age of participants was 49.1 (12.8) years, 50% (N=15) female, 55. 2% (N=16) white, 34.5% (N=10) African-American. With respect to participation, 2/3 of the enrolled sample attended at least 7 out of the maximum 10 C-TIME sessions. Mean number of C-TIME sessions attended was 6.9 (4.1). Five participants (17%) had family members attend the C-TIME sessions, although family members were encouraged to play a supportive rather than primary role. Four-month follow-up outcome evaluation was available for 66% of the enrolled group. There was a significant reduction in depression severity and patient satisfaction was over 90%.

Conclusions: The C-TIME program can be successfully implemented in the community and is associated with improved outcomes in adults with epilepsy and comorbid MHCs. Continued and broader scale-up of C-TIME and similar approaches could reach larger groups of adults with epilepsy and improve the health of our communities.

Keywords

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

1. Introduction:

Epilepsy is one of the most common chronic neurological conditions, affecting approximately 3 million Americans and causing substantial disability, reduced quality of life, stigma, and early mortality.[1] Adults living with epilepsy often have psychological comorbidity and published reports suggest 20–30% have serious mental health conditions (MHCs), such as schizophrenia, bipolar disorder or severe depression.[2–6]

Since 2009, the Centers for Disease Control and Prevention (CDC) Prevention Research Centers' Managing Epilepsy Well (MEW) Network has focused on development, testing and dissemination of evidence-based practices to improve epilepsy self-management.[7, 8] One of the MEW Network interventions, Targeted Self-Management for Epilepsy and Mental Illness (TIME) targets individuals with epilepsy and comorbid MHCs, and has been demonstrated to improve depression outcomes compared to treatment as usual.[9] Building upon positive efficacy findings for TIME, the Community-TIME (C-TIME) initiative assessed the implementation feasibility and pre/post outcomes of this new evidence-based epilepsy self-management intervention in a community setting (offices of a regional epilepsy advocacy organization) and in collaboration with key stakeholders. We hypothesized that partnering with stakeholders would facilitate implementation and that C-TIME participants would have a reduction in depressive symptom severity.

2. Materials and Methods:

Overall methods:

The C-TIME initiative used stakeholder input to inform refinements of the TIME curriculum in order to optimize community implementation. Research staff guided intervention performance evaluation, advocacy staff assisted with participant outreach and engagement and a county addiction and mental health services agency support the transition from science to service. Process evaluations of implementation were outreach and engagement efforts

needed to reach people with epilepsy with comorbid MHCs, barriers and facilitators to program roll-out and participant retention and satisfaction. The primary intervention participant outcome was depressive symptom severity measured with a standardized scale.

2.1 Implementation stakeholders:

- a. **Academic personnel:** Researchers from the Case Western Reserve University (CWRU), with funding from the Centers for Disease Control and Prevention (CDC) awarded to the CWRU Prevention Research Center (PRCHN), and in collaboration with community stakeholders including the Epilepsy Association in Cleveland, Ohio, developed TIME (Targeted Self-Management for Epilepsy and Mental Illness) a behavioral program intended to empower people living with epilepsy and MHCs.[9]
- b. **Epilepsy advocacy:** The Epilepsy Association (EA) is a community-based agency providing services to those with epilepsy through a menu of resources that includes information and referral services, a children's and family program, community-based education, support groups and an adult mental health case management program.
- c. **Public health provision:** The Alcohol, Drug Addiction and Mental Health Services (ADAMHS) Board of Cuyahoga County is responsible for the planning, funding and monitoring of public mental health and addiction treatment and recovery services delivered to the residents of Cuyahoga County in Cleveland, Ohio, U.S.A.. Under Ohio law, the ADAMHS Board is one of 50 Boards coordinating the public mental health and addiction treatment and recovery system in Ohio. The Board is a quasi-independent part of county government, governed by a volunteer Board of Directors. The EA has been a contract agency of the ADAMHS Board since 1991. ADAMHS provided modest funding for recruitment effort, interventionist time and performance evaluation effort.

2.2 Intervention description:

The original TIME intervention is a group-format, curriculum-based intervention implemented in 12 weekly 60–90 minute sessions delivered over 12 weeks. Details of the TIME intervention are described in greater detail elsewhere. [9] A key feature of TIME is peer educators (adults with epilepsy) who serve as experiential guides to support intervention participants. [9] EA and CWRU, in collaboration with peer and nurse educators from the original TIME efficacy trial, made minor modifications to the TIME curriculum in order to optimize community implementation and future generalizability (Table 1). The detailed curriculum provides instructions for C-TIME interventionists and hand-out materials and resources for participants. The C-TIME curriculum also reinforces all elements identified within the Eight Dimensions of Wellness identified by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA).[10] Following completion of the 10 group sessions, the nurse followed up with participations via 2 phone calls spaced approximately 2 weeks apart. Phone calls were brief (no more than 10–15 minutes) and followed a semi-scripted structure in which the nurse asked participants how they were doing with attempting to accomplish personal care plans (established during the

group sessions). Nurses did not introduce new materials, but rather reinforced messages from C-TIME that might help participants meet their goals.

2.3 C-TIME participants:

Participants were adults with self-reported epilepsy and MHCs including depression, anxiety, bipolar disorder, post-traumatic stress disorder or schizophrenia. To broaden acceptability, enrollees were not required to have epilepsy or MHC diagnoses confirmed via record review or formal diagnostic assessment. Participants were recruited from the community, self-referred in response to Institutional Review Board (IRB) approved flyers placed in community and clinical settings and via electronic health record identification of adults with epilepsy and follow-up program invitation letters. The academic and advocacy team collaborated on outreach and raising awareness of the program. EA pushed out information through social media, their website, email and printed promotion of the program, and directed interested individuals to CWRU staff for intake. CWRU staff did outreach through community mental health centers, local flyer placement and outreach through the clinician and hospital community. All procedures were approved by the local IRB and participants provided informed consent to outcomes data collection.

2.4 Assessments:

To evaluate if C-TIME participants had similar key outcomes to participants in the TIME study, data was collected at the same 3 assessment time-points: baseline, 3 months and 4 months. Assessments used the same standardized question formats as in the TIME study including baseline demographics, past and current mental health conditions, substance use/abuse history, and epilepsy and mental health medication treatments. Standardized assessments included depressive symptom severity measured with the rater-administered Montgomery Asberg Depression Rating Scale (MADRS)[11] and the self-reported Patient Health Questionnaire 9-item version (PHQ-9).[12] Quality of life was measured with the QOLIE –10-P, which includes weighting based on patient perceived overall distress. [13] Anxiety was measured with the 7-item Generalized Anxiety Disorder (GAD-7) scale.[14] Thirty-day and past 4-month seizure frequency was based upon self-report as was client satisfaction (using a Likert scale). To try and ascertain how C-TIME might be impacting use of other available services, participants were evaluated on past history of negative health events (seizure, emergency room visits, hospitalizations, self-injury) with the same questionnaire used in other epilepsy self-management studies[15] and on use of community (EA services, counseling, occupational or other community resources) and other outpatient medical services (medical, mental health).

2.5 Data analysis:

Statistical analysis was performed using SAS 9.4 (SAS Institute, NC). Descriptive analyses examined change over time in MADRS as well as secondary outcomes. T-tests comparing differences from baseline to 4-months were used, but we also considered nonparametric tests as appropriate. Of primary interest was the difference in depressive symptoms measured via MADRS from baseline to the 16-week endpoint, but the 12-week difference was analyzed as well. Repeated measures ANOVA were used to analyze change in depressive symptoms (MADRS, PHQ-9), anxiety symptoms (GAD-7) and quality of life (QOLIE-10) over time.

The Wilcoxon signed-rank test evaluated change in negative health even and resource use counts over time. A Type I error rate of 0.05 was used for all tests.

3. Results:

3.1 Feasibility, barriers to recruitment:

In spite of the collective effort, recruitment and implementation of the program was challenging due to logistic and other barriers. Many individuals with epilepsy and MHCs do not openly seek care and are isolated and socially marginalized. The CWRU team included staff with MHC expertise, a helpful factor to overcoming stigma barriers to recruitment. Referrals came from a variety of sources including the EA, clinical referrals and from the research team. Approximately 1 in 3 referrals resulted in a C-TIME enrollment.

3.2 Sample:

There were 30 individuals enrolled, with 3 group “cohorts” of ten individuals. The first cohort began group sessions in September 2017 and the last outcome data collection for the third/final cohort was completed in May of 2018. Enrollment flow is shown in Figure 2. The most common reason for not being enrolled once screening was begun is that individuals did not show up for the baseline evaluation. As noted in Table 1, mean age of participants was 49.1 (SD 12.8) years, 50% (N=15) female, 55 % (N=16) white, 35% (N=10) African-American. Depression was the most common mental health condition (N=23, 77%) and half of individuals (N=15) had an anxiety disorder. Individuals had, on average, between 1–2 seizures in the last month and were prescribed a mean of 2.1 (SD 0.9) mental health medications and 1.4 (2.4) medications for epilepsy.

3.3. Barriers to engagement, retention:

A number of potential participants faced transportation barriers due not being able to drive. C-TIME participants were not financially compensated, however, they were provided a modest stipend for transportation costs or bus passes for each in-person session attended (U.S. \$5). To help participants plan their schedules, C-TIME sessions were held on the same day of the week at the same time for a given cohort. Since classes were conducted at the EA offices and included EA agency staff, some C-TIME participants used this as an opportunity learn about and access other community services. CWRU team members coordinated the C-TIME group sessions and trained interventionists. EA was an active part of training and EA staff gained skills intended to be helpful for future broader scale-up.

With respect to C-TIME group session participation, 2/3 of the enrolled sample attended at least 7 out of the maximum 10 C-TIME sessions. Only 4/30 (13%) did not attend a single session. Mean number of C-TIME sessions attended was 6.9 (4.1). Five participants (17%) had family members attend the C-TIME sessions along with them, although it was emphasized in the curriculum that the primary focus of C-TIME is self-management/self-empowerment and family members were encouraged to play a supportive rather than primary role. There was 1 individual who withdrew from the program.

3.4 Intervention participant outcomes:

Follow-up outcome evaluation was available for 66% of the enrolled group. T-tests comparing baseline to 4-month outcomes for both the MADRS and PHQ-9 were statistically significant ($p=.043$ and $.035$ respectively). As noted in Table 2, using repeated measures ANOVA, there was a significant reduction in the MADRS ($p=.018$), the primary outcome. The PHQ-9 showed a trend for improvement ($p=.06$). Other outcomes did not show a statistically significant change except for mental health services use (which showed a modest reduction).

3.5 Participant Satisfaction:

There were 18 out of the 20 individuals who completed the 4-month follow-up evaluation who provided information on perceived satisfaction. Of these, 17/18 (94%) agreed or strongly agreed that C-TIME was useful, that it covered all/most of the important issues relevant to their situation, and that they would recommend it to other people with epilepsy. Sixteen out of 18 (89%) strongly agreed or agreed that the benefit of C-TIME exceeds the burden or hassle of attending sessions.

4. Discussion:

The C-TIME epilepsy self-management program intended for people with epilepsy and comorbid MHCs was evaluated for implementation feasibility and intervention participant outcomes in a community setting via a productive partnership between researchers, an epilepsy community support agency and a county alcohol, drug addiction and mental health services board. In spite of numerous recruitment challenges the stakeholder team recruited 30 adults with epilepsy over a time-period of approximately 6 months. A clear “lesson learned” is that multiple sources of referrals are needed and that having staff with both epilepsy and MHC expertise conduct community outreach may help engage those who are challenged with 2 stigmatizing brain disorders. Logistic and transportation support is key to helping individuals who may have limitations on travel due to frequent seizures. As expected, attrition over time was somewhat higher in the C-TIME initiative (33%) vs. the TIME efficacy trial (20%). This may have occurred because the intensive outreach and support procedures used in a standard research study were not used in this real-world scale-up of an epilepsy self-management program. It is possible that additional modifications to C-TIME could enhance participant retention such as reducing the number of sessions or more intensively working with family members to assist with transportation and attendance. Some studies have demonstrated that remotely-delivered programs (web-based, phone) can be readily accessed by people with epilepsy and this may be one way to overcome logistic or transportation barriers to retention. [15, 16]

A notable finding is that in spite of the small sample size, our hypothesis on expected change in depressive symptom severity was confirmed with the significant reduction in depression scores. Thus, the C-TIME results were in-line with results of the efficacy research clinical trial. [9] Participant satisfaction with the C-TIME program was high and over 90% felt that they would recommend the program to other people with epilepsy.

The findings of this report have several important clinical implications. Since C-TIME is an add-on to whatever care that adults with epilepsy and MHCs are already receiving, the program could be implemented in medical or non-medical settings. Ideally, C-TIME could be a useful complement to medical management of epilepsy, and might help patients engage more in their overall care. The resource requirements to deliver C-TIME are modest and mainly for supporting training of peers (people with epilepsy who serve as educators) and nurses (who are generally compensated at a reasonable hourly rate). Accountable Care Organizations (ACOs) or similar value-based health entities might find this a practical approach to advancing the care of covered individuals with relatively small effort.

There are a number of limitations to this project including the small number of adults with epilepsy enrolled, a single-site partnership with one community agency and one government agency and the fact that even with collaboration, it is likely that individuals who are too isolated to agree to participate in a community-based program were not included. Additionally, the short time interval between follow-up assessments does not really allow for a long-term view of whether people with epilepsy sustain observed improvement. However, in spite of these limitations, the C-TIME initiative experience and outcomes may serve as a model for other stakeholders planning to implement epilepsy self-management in a community setting. The MEW Network has previously partnered with the Epilepsy Foundation and other groups to train staff in epilepsy self-management and assist with the implementation of other evidence-based epilepsy self-management interventions.[7, 8]

A key consideration going forward is sustainability of C-TIME in community settings. The C-TIME curriculum and materials will be available in the future to members of the general public as part of the CDC-funded MEW Network.[7, 8] While costs are relatively modest (especially if no performance evaluation is included), stipends for nurse and peer educators are essential as is space that is private and sufficiently large to include a group of 12– 15 individuals on a weekly basis for 10 weeks. Dissemination of evidence-based interventions is a current focus of the MEW Network, but it is likely that there will be no “one-size-fits-all” solution to sustainability and broader scale-up.

In conclusion, the C-TIME program for epilepsy self-management can be successfully implemented in the community, is highly satisfactory to participants and is associated with improved outcomes in individuals with epilepsy and comorbid MHCs. Continued and broader scale-up of C-TIME and similar approaches could reach larger groups of individuals with epilepsy and improve the health of our communities.

Acknowledgments

Declarations of interest:

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- Facts and myths about mental illness and epilepsy
- General mental health and epilepsy management principles: relationships of mental illness and of epilepsy symptoms and functioning in response to stress; introduction to goal setting
- Treatments for epilepsy; complications of epilepsy; minimizing epilepsy complications;
- Personal mental illness profile (what does worsening illness look like for you); triggers of mental illness relapse; personal action plan for coping with mental illness relapse;
- Problem solving skills and the IDEA approach (Identify the problem, Define possible solutions, Evaluate the solutions, Act on the best solution); talking with your healthcare providers;
- Stigma and “double stigma”, strategies to cope with stigma, nutrition for best physical and emotional health
- Substance abuse and its effects on mental illness and on epilepsy specific stress management approaches
- Effects of exercise and being outdoors on physical and emotional health; the importance of daily routine and good sleep habits and medication routines
- Medications and psychological treatments for mental illness; a personal care plan to take care of the mind and the body
- Social supports and using your available supports; advocacy groups for epilepsy and for mental illness
- Normalizing your life in spite of having a chronic but unpredictable condition; prioritizing medication side effects and discussing it with your clinician
- Self-management as a lifestyle; acknowledgement of group progress, setting the stage for ongoing illness management and recovery

Figure 1:
The C-TIME program curriculum topics:

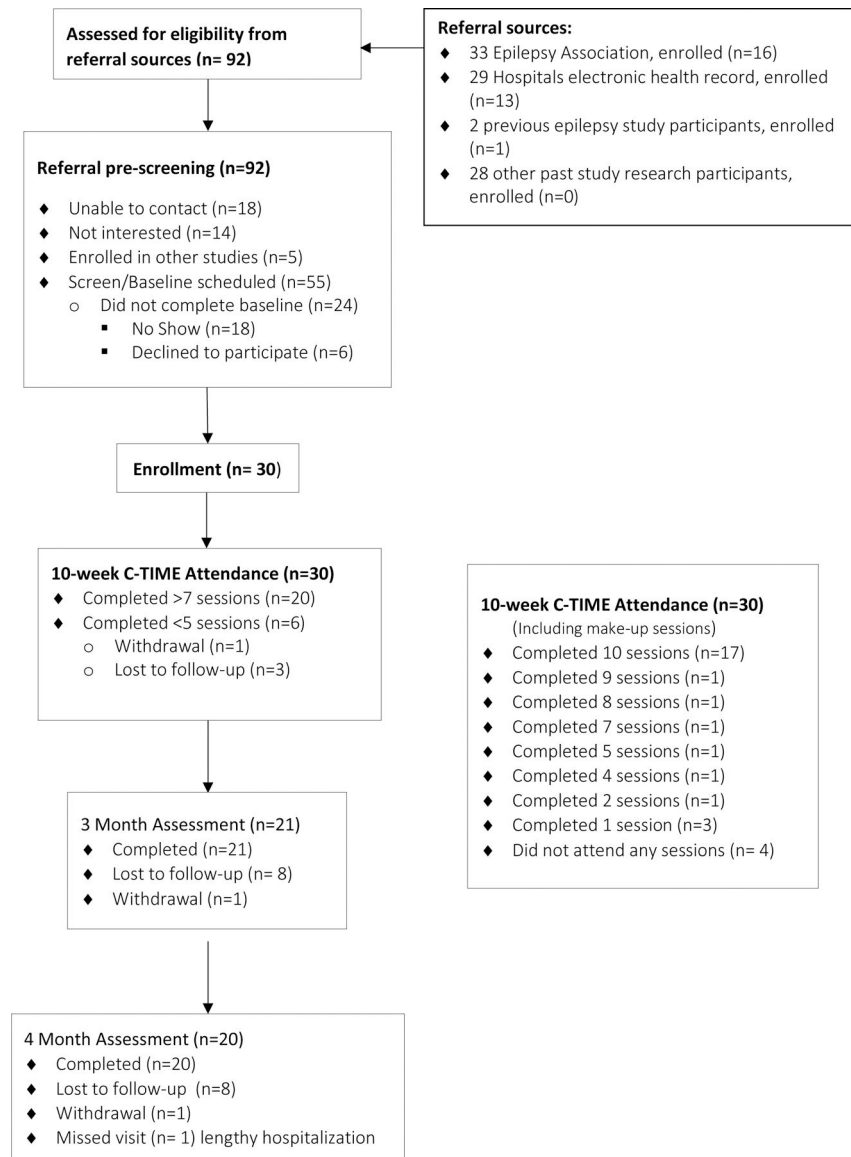


Figure 2:
C-TIME Consort Flow

Table 1:

Key elements of TIME vs. C-TIME epilepsy self-management interventions

TIME	C-TIME
Group-format, curriculum-based, in-person epilepsy self-management support	Group format, curriculum-based, in-person epilepsy self-management support
Co-delivered by nurse educator and trained peer educator (adult with epilepsy)	Co-delivered by nurse educator and trained peer educator (adult with epilepsy)
Up to 10 individuals per group	Up to 10 individuals per group
12-sessions, 60–90 minutes each. Sessions spaced out weekly over the course of 12 weeks	10-session, 60–90 minutes each Sessions spaced out every 1–2 weeks over the course of 12 weeks
Group sessions held at academic medical center	Group sessions held at community Epilepsy Association
Follow-up telephone calls over a 4-week time-period initiated by nurse educator and peer educator in alternating fashion	Follow-up telephone calls over a 4 week time-period initiated by nurse educator

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Table 2:

C-TIME program outcomes

Variable	Baseline Mean (SD) N=30	3-month Mean (SD) N=21	4-month Mean (SD) N=20	statistic
Age	49.1 (12.8)			
Gender				
Male	15, 50.0%			
Female	15, 50.0%			
Race				
Caucasian	16, 55.2%			
African American	10, 34.5%			
Other	3, 10.3%			
Ethnicity				
Hispanic	0, 0%			
Not Hispanic	29, 96.7%			
Other	1, 3.3%			
Marital Status				
Single, Never married	17, 56.7%			
Married	2, 6.7%			
Separated/Divorced/ Widowed	11, 36.7%			
Number of epilepsy medications Mean (SD)	1.9, 1.0			
Mental health conditions Mean number (SD)	2.2, 1.4			
Depression (N, %)	23, 76.7%			
Anxiety	15, 50%			
Bipolar	5, 16.7%			
Panic Disorder	5, 16.7%			
Schizophrenia	2, 6.7%			
Obsessive Compulsive Disorder	2, 6.7%			
ADHD	1, 3.3%			
PTSD	7, 23.3%			
Other	6, 20%			
Number of mental health medications Mean (SD)	2.1, 0.9			
MADRS ^a total Mean (SD)	12.3, 10.2	9.5, 6.6	9.8, 7.5	.0178 ^f
PHQ-9 ^b total Mean (SD)	9.6, 6.6	9.0, 4.6	8.9, 5.0	.0618 ^f
QOLIE-10-P ^c total Mean (SD)	30.8, 20.0	29.0, 15.9	26.8, 14.8	0.3398 ^f

Variable	Baseline Mean (SD) N=30	3-month Mean (SD) N=21	4-month Mean (SD) N=20	statistic
GAD-7 ^d total Mean (SD)	7.8, 5.1	7.3, 5.8	7.4, 4.4	.1195 ^f
Number of seizures in past 30 days Mean (SD)	1.4, 2.4	-	1.1, 1.4	.6680 ^g
Number of seizures in past 4 months Mean (SD)	7.2, 14.8	-	2.9, 3.4	.6385 ^g
Number of negative health events in past 4 months ^e Mean (SD)	7.9, 14.8	-	3.0, 3.4	.5640 ^g
Community services use count Mean (SD)	3.1, 5.8	-	3.0, 4.0	.6875 ^g
Health services use count Mean (SD)	7.8, 9.1	-	7.0, 3.8	.9108 ^g
Medical	5.6, 7.4		4.4, 2.0	.3145 ^g
Mental health	3.8, 3.7		3.2, 2.7	.0098 ^g

SD= Standard Deviation

^aMADRS: Montgomery Asberg Depression Rating Scale: total score ranges from 0–60, with higher scores corresponding to more depressive symptoms.

^bPHQ-9: Patient Health Questionnaire--total score ranges from 0–27 with higher scores corresponding to more severe depression

^cQOLIE-10-P: Patient weighted Quality of Life in Epilepsy. Total score ranges from 0–100, Total score includes weighting for patient perceived disability. Higher scores indicate better quality of life

^dGAD-7: Total score ranges from 0–21, with higher scores indicating more severe anxiety.

^eNegative health events: seizure, emergency room visits, hospitalizations, self-injury

^fRepeated measures ANOVA.

^gWilcoxon signed-rank test.