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Evaluation of an Interdisciplinary Ketogenic Diet Clinic for the Treatment of Pediatric Refractory Epilepsy

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Abstract

Pediatric refractory epilepsy affects approximately 30% of all children diagnosed with epilepsy. Childhood refractory epilepsy patients pose a challenge for traditional approaches to epilepsy management due to their complex and unique needs. Refractory epilepsy negatively impacts a patient's ability to attend school or hold a job, and patients have a generally poor health status related to seizures as well as pharmaceutical side effects (Conway et al., 2016). The ketogenic diet (KD) is an alternative option for the treatment of pediatric refractory epilepsy due to established efficacy, manageable side effects, and reduced health care-associated costs due to reduced emergency department (ED) visits, and reduced inpatient admissions (Hallbook et al., 2015; Khoo et al., 2016; Lambrechts et al., 2017; Martin et al., 2016; Pasca et al., 2018; Whiting et al., 2017; Wijnen et al., 2017). When attempting to address the complex needs of a child with this chronic medical condition, interdisciplinary and multidisciplinary clinics have been shown to improve patient outcomes in various pediatric fields including refractory epilepsy, when compared to general, traditional clinics (Williams et al., 1995).

An interdisciplinary pediatric ketogenic diet clinic (KDC) was created in 2015 to provide a more coordinated approach to the management of pediatric refractory epilepsy patients on the KD. The clinic was staffed by a pediatric epileptologist, pediatric neurology nurse practitioner, registered dietician, and social worker. Through a retrospective design, data from pediatric KD patients were analyzed to determine the interdisciplinary KDC's effects on seizure frequency, seizure related hospitalizations, number of seizure medications (AEDs), and adherence to the treatment regimen by both patients and providers when compared to the management of KD patients prior to implementation of the KDC, the traditional approach. The interdisciplinary approach to the KD yielded more seizure free patients, improved adherence to KD standards of care, reduced epilepsy related inpatient admissions, and demonstrated a greater number of patients experiencing a reduction in the number of AEDs when compared to the traditional approach.

Keywords: ketogenic diet, refractory epilepsy, child, pediatric, interdisciplinary clinic

Evaluation of an Interdisciplinary Ketogenic Diet Clinic for the Treatment of Pediatric Refractory Epilepsy

Epilepsy affects up to 3% of the general population (Martin, Jackson, Levy, & Cooper, 2016). In children living in the United States, the prevalence is approximately 4.5 children for every 1,000 with an incidence of up to 82 cases/100,000 children per year (Camfield & Camfield, 2015). The most current definition of epilepsy, according to the International League against Epilepsy (ILAE), has recently been updated and defined as a disease diagnosed after a patient has experienced at least two seizures occurring at least 24-hours apart not contributed to a temporary cause (unprovoked) (Fisher et al., 2014). Additionally, the diagnosis is used to describe patients who have had one unprovoked seizure and a high probability of another unprovoked seizure in the future based on history or diagnostic testing. Furthermore, the definition also is applied to patients who have diagnostic testing revealing data associated with a specific epilepsy syndrome (Fisher et al., 2014). Traditionally, patients, including children, are treated with antiepileptic drugs (AEDs) first, before other treatment modalities are offered. The majority of patients will respond to the first appropriately chosen and dosed AED. However, up to 30% of children diagnosed with epilepsy will not respond to traditional AED treatment. The patients who do not respond to at least two appropriately chosen and trialed AEDs are classified as having drug resistant, intractable, or refractory epilepsy (Bodin et al., 2016). It is important to offer these patients treatments and services which may be more beneficial than continued traditional, pharmaceutical treatments.

Patients with refractory epilepsy have complex medical needs. Not only must seizures be managed with pharmaceutical treatments, but side-effects must be managed. Additionally, epilepsy is commonly associated with other disorders and abnormalities, which must also be managed. Health related quality of life (HRQL) is known to be adversely affected in individuals with epilepsy. Costs associated with treatment of refractory epilepsy increase as AEDs are added, side-effects are experienced, seizures continue, and the patient requires inpatient admissions and/or emergency department (ED) visits to manage seizures. Adequate and appropriate treatment of children with epilepsy addresses both seizures as well as other medical and psychosocial aspects that are associated with the diagnosis (Lach et al., 2006).

Refractory Epilepsy

Uncontrolled, refractory epilepsy in children can have a catastrophic impact on a child's life. Refractory epilepsy increases a patient's seizure burden which includes, but is not limited to, seizure frequency, duration, and intensity. Refractory epilepsy, in an otherwise healthy child, is associated with learning and cognitive difficulties (Mula & Cock, 2015). However, Mula and Cock (2015) speculate many children with refractory epilepsy have comorbidities also associated with such delays, precipitating a unique conundrum for providers. Not only does seizure burden impact cognition, learning, and speech, but it also has a dramatic impact on the patient's and family's quality of life. One controlled, experimental study published in 2003, suggests the QOL of epileptic children is poorer than reported in healthy children in both physical and psychosocial domains (Miller, Palermo, & Grewe, 2003). Miller, Palermo, & Grewe go on to associate poorly controlled epilepsy and more AEDs with an inverse relationship to QOL scores (2003). Uncontrolled epilepsy places a burden on the patient and his or her family and community as medical treatments, procedures, hospital admissions, and costs are required throughout the patient's lifespan. Along with the direct impact that the seizures themselves have, the outcomes of the disease impact a patient's and family's quality of life (QOL) (Talarska, 2007).

Comorbidities associated with refractory epilepsy contribute to diminished QOL. In fact, Selassie et al., postulate comorbidities associated with epilepsy impact QOL more than seizures and AEDs (2014). Selassie (2014), noted comorbidities associated with people of all ages who had epilepsy and compared these prevalence rates to subjects who had migraines and to subjects who were healthy. Commonly associated comorbidities with epilepsy include, but are not limited to, stroke, migraine headaches, depression, anxiety, autism, and attention deficit disorder with hyperactivity (Selassie et al., 2014). Furthermore, comorbidities are predictive of poorer QOL reports, especially comorbidities associated with other neurologic abnormalities such as developmental delay, autism, or diminished cognitive abilities (Miller, Palermo, & Grewe, 2003).

Not only does seizure severity reduce QOL, but number of AEDs, caregiver unemployment, lower socioeconomic status, depression, anxiety, lower patient intelligence quotient (IQ) scores, and increased family demands also play a role (Conway et al., 2016). Compounding the issue with AEDs is the known issue of patients with refractory epilepsy not likely to respond to additional, traditional AEDs (Perry & Duchowny, 2013). It is not uncommon for pediatric refractory epilepsy patients to be managed on 5 to 7 different AEDs, each with associated side effects. Therefore, other treatment modalities have been implemented to reduce patients' seizure burdens while simultaneously improving the patients' QOL. Alternative treatment modalities include, but are not limited to, the ketogenic diet and other variations of the diet, implantation with a neurostimulator known as a vagus nerve stimulator (VNS), and resective epilepsy surgery. However, these alternative treatment modalities are not suitable for every patient. Patients must be screened and assessed appropriately to ensure treatment recommendations will promote the best outcomes for each unique patient.

The Ketogenic Diet

The KD is one of several types of dietary therapies utilized for the treatment of refractory epilepsy. It is a high fat, very low carbohydrate diet, designed to alter the body's energy source from the utilization of glucose to the utilization of fats. The KD is prescribed as a ratio of grams of fats to grams of carbohydrates. It can be utilized with traditional foods as well as specialty formulas. The metabolism of fats yields ketone bodies and a state of ketosis for the patient, measured with a serum beta hydroxybutyrate level. It is not fully understood how the diet works. Although, it has been theorized that ketones are neuroprotective, offering the patient an anticonvulsant effect as long as the patient remains in a state of adequate ketosis. The KD has contraindications, is associated with side-effects, and must be strictly maintained for adequate benefit. However, the diet has historically been shown to be effective in reducing seizure burden and enhancing quality of life for appropriately chosen refractory epilepsy patients (Lambrechts et al., 2017).

A recent review of the literature reveals at least 30% of all patients with all types of refractory epilepsy on the KD experienced at least a 50% reduction in seizure frequency from baseline (Hallbook et al., 2015; Khoo et al., 2016; Lambrechts et al., 2017; Martin et al., 2016; Pasca et al., 2018). Not unlike traditional, medical management, the patients studied on the KD also exhibited side-effects, with gastrointestinal side-effects most often reported. Compliancy issues and discontinuation of the diet were noted in all studies, although listed as a primary outcome in the Wijnen et al. study from 2017. Ultimately, all patients with refractory epilepsy should be introduced to the KD as an option for treatment due to established efficacy with side effects monitored and health care associated costs likely reduced if inpatient initiation costs, ED visits, and inpatient admissions are reduced (Hallbook et al., 2015; Khoo et al., 2016; Lambrechts et al., 2017; Martin et al., 2016; Pasca et al., 2018; Whiting et al., 2017; Wijnen et al., 2017). The unique and complex needs of pediatric refractory epilepsy patients necessitate a comprehensive and coordinated approach to optimize seizure treatments, specifically, the KD. A team based, interdisciplinary approach to manage the KD as a treatment for pediatric refractory epilepsy offers patients and families the expertise and support to optimize medical management (Conway et al., 2016).

Interdisciplinary and Multidisciplinary Clinics

Interdisciplinary clinics (IDC) and multi-disciplinary clinics (MDC) have demonstrated effectiveness in the management of complex health needs. Each clinic approach brings together specialists in various fields to work together with the patient, who is central to the team. The goal of both approaches is to achieve better patient outcomes. Although the terms are often used interchangeably, there are differences between the two approaches, as depicted in Figure 1. An MDC involves a patient seeing various team members, in a separate and coordinated manner, with patients typically seeing all specialists involved in their care on the same day. An IDC consists of one patient visit with all team members present in the same room, together with the patient, making treatment decisions (Korner, 2010). An IDC focuses on team work and collaboration to achieve optimal patient outcomes rather than the coordination of ideas and decisions (Korner, 2010). In the MDC model, the providers are independently making decisions while communicating their decisions to other team members, often through a single coordinator. Team make-up may be directed by billing or the facility in which the team is functioning. For example, when billing Medicare for a multidisciplinary or interdisciplinary visit, the team must include one physician, and a minimum of two other individuals from different disciplines, excluding nursing. Other multidisciplinary or interdisciplinary teams utilize a broader definition and include two or more health professionals from different disciplines who either diagnose, treat, manage, or support the patient (Parman, 2018). Although both IDCs and MDCs are used to manage complex health conditions and improve patient outcomes, the IDC approach may yield better efficacy due to a stronger emphasis on collaboration than MDCs (Korner, 2010). However, both approaches are known to produce better patient outcomes when compared to the traditional approach (Korner, 2010).

There are more studies published about MDCs than IDCs. MDCs have been reported in the management of pediatric asthma, neurocritical care follow-up, functional constipation, kidney disease, oncology, chronic headaches, Prader-Willi syndrome, and orthopedics (Ajarmeh et al., 2012; Cantrell & Rubel, 2011; Cook et al., 2017; Duis et al., 2019; Moe et al., 2016; Poenaru et al., 1997; Rabner et al, 2015; Wainwright et al., 2014). MDCs report better outcomes for patients with complex medical problems when compared to traditional approaches to patient management (Cook et al., 2017). Cook et al., assert an MDC is capable of adequately assessing and addressing complex modifiable issues in children (2017). Many characteristics, such as depression, anxiety, seizure burden, and so forth, are noted to decrease a patient’s QOL and are considered modifiable factors associated with childhood refractory epilepsy. Other MDCs have noted an improvement in patient satisfaction after implementing the clinics, compared to independent visits with each healthcare provider (Moe et al., 2016). Still, other practices implementing MDCs note a reduction in gaps in care, specifically, a reduction in the number of required referrals and visits to other specialties (Williams, Kirby, & Piantino, 2017). When used with pediatric chronic kidney disease patients, an MDC led to increased medication adherence, improved disease progression, improved nutrition, and generally, improved outcomes (Ajarmeh, Er, Brin, Djurdjev, & Dionne, 2012).

MDCs have been used in the treatment of complex pediatric neurologic issues as well. For example, pediatric migraine patients were noted to have less school absences and higher functional performance after implementation of a pediatric headache MDC (Rabner, Gottlieb, Lazdowsky, & LeBel, 2015). Williams et al. reported outcomes associated with a pediatric refractory epilepsy clinic in 1995. The authors noted a higher success rate in reducing seizure frequency than was expected with a traditional approach. QOL indicators were not specifically studied by Williams et al. (1995). Reducing seizure frequency, however, is known to improve QOL in refractory epilepsy patients, as noted by Mula (2014). Furthermore, Williams et al., demonstrated patient and family satisfaction improved with a multidisciplinary team approach (1995). MDCs are known to be the “gold standard” of care for pediatric neuromuscular diseases due to their ability to reduce barriers to providers and resources. Additionally, Paganoni et al., noted greater adherence to clinical practice guidelines, reduced hospital admissions, and improved patient advocacy with a pediatric neuromuscular MDC (2017). Costs associated with the neuromuscular clinic, however, were high although the clinic was considered “cost-effective” (Paganoni et al., 2017).

Pediatric refractory epilepsy is a complex medical condition with several treatment modalities. The KD is an effective treatment for these patients to decrease seizure burden (Hallbook et al., 2015; Khoo et al., 2016; Lambrechts et al., 2017; Martin et al., 2016; Pasca et al., 2018). However, compliance and side-effects must be monitored and managed adequately (Wijnen et al., 2017). MDCs and IDCs are known to promote positive outcomes when utilized to address complex medical diseases in other pediatric specialties (Ajarmeh et al., 2012; Cantrell & Rubel, 2011; Cook et al., 2017; Moe et al., 2016; Poenaru et al., 1997; Rabner et al, 2015; Wainwright et al., 2014). However, IDCs may foster more collaboration and team efficacy. Therefore, an interdisciplinary, pediatric, ketogenic diet clinic (KDC) can be utilized to deliver and manage care of pediatric refractory epilepsy patients initiating or maintaining the KD

Theoretical Framework

A theory can help guide or validate the framework of a program in conjunction with evidenced based practices. The Model for Effective Chronic Illness Care validates the creation of an interdisciplinary team (Wagner, Davis, Schaefer, & Von Korff, 2002). The Model for Effective Chronic Illness Care was first published in 1996 with an adaptation in 1999 and reprint in 2002 (Figure 2). It attempts to describe how chronic illness can be best managed through a concerted effort between the patient, provider(s), and the system (health care organization and community) (Wagner et al., 2002). Features of the model include practice change to accommodate the complex needs of patients with chronic medical conditions. Additionally, patients are a key element and must be empowered to take an active role in the management of their healthcare needs. Wagner et al. theorize encouraging self-management can be accomplished through education and psychosocial support (2002). The final two elements of the model note medical providers who must manage patients according to best practice, and information dissemination through reminders, feedback, and formal care planning. The five key elements of the model are then organized into an interactive model where the health system consists of the practice providing appropriate clinic visits for which health professionals make research-based decisions and support their invested patients with information and resources available in the community. Consequently, the model facilitates interactions between collaborative and informed health team members and an informed and proactive patient to achieve the best functional and clinical outcomes possible for a patient with a chronic illness (Wagner et al., 2002). The model's collaborative, evidenced based management of care with a patient at its core confirms the need for an interdisciplinary clinic to best manage the complex health needs of a pediatric refractory epilepsy patient on the ketogenic diet.

The Interdisciplinary Ketogenic Diet Clinic Design

An interdisciplinary pediatric KDC was created in October, 2015 based on best practices and published experiences with IDCs and MDCs utilized in other specialty areas. The KDC is within an outpatient child neurology clinic (CNC) in Louisville, Kentucky. The outpatient clinic specializes in the care of patients with many neurologic conditions including, but not limited to, epilepsy, cerebral palsy, muscular dystrophy, autism, developmental delay, tuberous sclerosis, multiple sclerosis, neurodegenerative diseases, and migraines. The CNC employs multiple child neurologists, nurse practitioners, nurses, a social worker, and psychologist to care for the unique needs of pediatric neurology patients. Approximately 3000 unique pediatric patients with epilepsy are seen in the clinic each year, accounting for nearly 5000 outpatient appointments. Of these patients, approximately 900 have refractory epilepsy. The CNC has a working relationship with the local children's hospital. The children's hospital has approximately 4000 admissions/year due to epilepsy, 1200 of which can be attributed to refractory epilepsy. Patients with refractory epilepsy are responsible for the majority of multiple admissions or readmissions secondary to seizures. Furthermore, the CNC collaborates with members of other disciplines from the local children's hospital, such as dieticians and pharmacists. The KD has been a treatment modality offered jointly by the CNC and children's hospital since prior to 2009.

Prior to 2015, all patients on the KD returned to their primary neurology provider who managed all KD care. The independent manner in which providers managed KD care without use of an IDC, created situations where a KD patient may or may not have KD adjustments, adequate monitoring of side-effects, or appropriate withdrawal of AEDs. Accompanying side effects and continued seizures could result in premature discontinuation of the diet, poor compliance, and increases in hospitalizations. With traditional care, outcomes and adherence to the KD recommendations could vary by provider. However, recommended standard care for patients on the KD has remained consistent since 2009 at the CNC and includes follow-up appointments at the recommended intervals of 0-3-months post-diet initiation, 4-6-months post-initiation, 7-9 months post-initiation, and 10-15-months post-initiation (Kossoff et al., 2018). Moreover, recommendations for ketogenic modifications, supplements, and laboratory testing have remained consistent, as well. Since 2009, standard care at the CNC included AED levels and serum ketone levels (beta-hydroxybutyrate) drawn prior to every follow-up appointment. Therefore, implementation of the KDC resulted in no change to established standards of care, but altered the coordination and delivery of care.

The interdisciplinary KDC is staffed by a team comprised of a primary neurologist responsible for AED adjustments, a dietician trained in the ketogenic diet and whom is responsible for making diet modifications, a social worker responsible for identifying needs and resources of the patient and family, and a pediatric neurology nurse practitioner responsible for managing both diet modifications and AED changes, as well as family education and communication. The purpose of this evaluation is to determine if participation in an interdisciplinary KDC yields improvements in epilepsy related outcomes of parent reported seizure frequency, inpatient hospitalizations, and the number of prescribed seizure medications, as well as clinic outcomes of adherence by both patients and providers to the recommended treatment regimen (patient compliance) and discontinuation rates when compared to patients on the KD who received care as usual (no participation in an interdisciplinary clinic) .

Methods

The interdisciplinary pediatric KDC was confirmed as best practice based on published experiences with IDCs and MDCs utilized in other specialty areas. A literature review of IDCs and MDCs was conducted using EBSCOhost. Within EBSCOhost, Academic Search Complete, CINAHL, and Medline, databases were utilized. Search terms included "child", "pediatric", "refractory epilepsy", "intractable epilepsy", "multidisciplinary clinic", and "interdisciplinary clinic". All articles utilized were in English. Articles were not excluded based on date, with one article included, specific to pediatric refractory epilepsy, published in 1995. However, preference for inclusion in the literature review included dates after January 1, 2010. Identified outcomes were adapted from outcomes observed in the review of current literature based on refractory epilepsy treatment and outcomes observed in MDC/IDCs from other fields.

Design

The KD treatment option has been utilized since prior to 2009 with little variation to management. Recommended follow-up time intervals, laboratory testing, supplements, and methods of diet adjustments have remained consistent since this time. Therefore, the project's primary design was conducted through a retrospective chart review, with data collection and analysis completed to compare outcomes of patients started on the KD prior to and after creation of the KDC for 4 outpatient visits or a maximum of 15-months, beginning with the KD inpatient admission. When patients were initiated on the KD during the inpatient hospital admission, an order-set was used. Therefore, all patients who had a KD initiation order-set in the current electronic medical record (EMR) at the local children's hospital were initially identified. The initial query identified 80 patients who had a KD initiation order-set from May, 2012 (start of current EMR, EPIC) through November, 2019. The initial inquiry of patients was cross referenced with the EMR from the CNC (Allscripts) and screened for inclusion criteria. General inclusion criteria included patients from birth to 18-years of age with a known diagnosis of refractory epilepsy (failure of two or more AEDs as determined by the patient's primary neurology provider). Additionally, inclusion criteria were set for each group. The pre-intervention group included children who had at least one documented outpatient neurology follow-up after initiation of the KD and who were initiated on the diet from May, 2012 through October, 2014 with all outpatient visits occurring prior to creation of the KDC. The post-intervention group included children who had at least one outpatient visit with the KDC and were initiated on the diet beginning in October, 2015 through May, 2018 with all outpatient KD visits occurring within the KDC. Ultimately, 20 patients met all inclusion criteria with 30 patients excluded due to lack of follow-up care, discontinuation of the KD prior to follow-up appointments, follow-up visits occurred prior to and within the KDC, or the patient had not completed 4 outpatient visits or 15-months of treatment on the KD. Study data were collected and managed using REDCap electronic data capture tools hosted at The University of Louisville (Harris et al., 2009). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

Outcomes and Analysis

Data were evaluated by comparing outcomes in the pre-intervention group to outcomes in the post-intervention group. SPSS software was used for descriptive statistics and statistical analyses. The evaluation utilized descriptive data to determine information about patient demographics (age, gender, and race), as well as types of epilepsy (focal, generalized, or multi-focal), MRI results (lesion identified or no lesion identified), and insurance provider (private or Medicaid). Additionally, descriptive data were collected and reported regarding the number of AEDs the patient was taking at the time of diet initiation.

Epilepsy Related Outcomes

Epilepsy related outcomes included seizure frequency, number of AEDs, and the number of epilepsy related inpatient admissions (as noted in the history and physical, consultation note, or daily progress notes), as noted in Table 1. Seizure frequency was defined as status epilepticus, daily seizures, weekly seizures, monthly seizures, < monthly seizures, and no seizures. Descriptive statistics were used to compare seizure frequency and number of AEDs at recommended follow-up appointment interval encounters. Analysis included available data with patients at each interval with missing data being omitted case-wise. Consequently, the sample size fluctuated at each encounter interval. Descriptive statistics were also used to compare the number of epilepsy-related inpatient admissions occurring within the study period for both groups. Additionally, the number of patients who experienced reductions in seizure frequency and AEDs as well as the number of patients who experienced inpatient admissions were analyzed utilizing a 2-sided Fishers Exact Tests.

Clinic Outcomes

Patient compliance, adherence to recommended KD follow-up intervals, and discontinuation rates were analyzed to compare process and guidelines outcomes both pre-implementation and post-implementation of the KDC (Table 1). Patient compliance was defined as; patients with no more than one "no show", serum beta-hydroxybutyrate (BOH) levels ≥ 2mmol/L, and therapeutic AED levels. Data were collected at each follow-up appointment, but reported once, at the end of the 15-month data collection for all study participants. Follow-up schedule adherence, patient compliance, and number of discontinuations were analyzed with 2-sided Fisher's Exact Tests to determine if there was an association between clinical outcomes and care model.

Results

Twenty patients were included in the evaluation (*N* = 20). Seven patients were included in the pre-intervention group (*n* = 7) and 13 patients were included in the post-intervention group (*n* = 13). Demographics of the samples are noted in Table 2. The majority of patients in the pre-intervention group were female (57.1%) compared to a majority of males in the post-intervention group (61.5%). The mean age of the patients included in the pre-intervention group was 1.72 years (*SD* = 1.52) compared to 6.56 years (*SD* = 5.80) in the post-intervention group. The predominant race and ethnicity of both groups was white, Caucasian. Patients on Medicaid accounted for 42.9% of the pre-intervention group and 84.6% (11) of the post-intervention group. The remaining patients in each group had private insurance.

Additionally, epilepsy characteristics were identified for each group (Table 3). Focal epilepsy was the most frequent type of epilepsy in both groups (42.9% in in pre-intervention and 38.5% in the post-intervention group). Furthermore, 28.6% of the pre-intervention group exhibited generalized epilepsy and 28.6% of patients exhibited multifocal epilepsy. Generalized, multi- focal, and focal epilepsy were almost equally represented in the post-intervention group, with 30.8%, 30.8%, and 38.5%, respectively. MRI findings were different between the 2 groups with brain lesions identified in 28.6% of patients in the pre-intervention group and 69.2% of patients in the post-intervention group.

Lastly, the number of AEDs and seizure frequency at the time of KD initiation were identified for the 2 groups (Table 3). In both groups, daily seizures was the most common frequency with 71.4% (5) of the pre-intervention group and 53.8% in the post-intervention group. There were 3 (23.1%) KD initiations for refractory status epilepticus in the post-intervention group and none noted in the pre-intervention group, although there was no significant association between status epilepticus and care model when analyzed with a 2-sided Fisher's Exact Test (*n* = 20), *p* = .52. One patient in the post-intervention group had no reported seizures at the time of initiation. The average number of AEDs was greater in the post-intervention group (*M* = 3.38, *SD* = 1.50) compared to the pre-intervention group (*M* = 2.71, *SD* = 1.38).

Epilepsy Related Outcomes

Epilepsy related outcomes were analyzed in both groups with number of AEDs and seizure frequency analyzed at each follow-up appointment interval. Although the initial sample size at KD initiation was 7 in the pre-intervention group and 13 in the post-intervention group, sample sizes fluctuated at each follow-up interval. Seizure frequency was documented at each recommended follow-up interval based on parental report. Figure 3 and Table 4 demonstrate that both care model groups included patients who achieved seizure freedom. The first follow-up appointment included 3 patients from each group who achieved seizure freedom. At the time of the fourth follow-up appointment, the post-intervention group was the only group noted to have patients who had achieved seizure freedom. The number of patients exhibiting daily, weekly, monthly, and less than monthly seizures fluctuated throughout the 15-months of data collection. However, all follow-up appointments included patients experiencing a reduction in seizure frequency as depicted in Figure 4. The percent of patients experiencing a decrease in seizure frequency ranged from 50% - 66.7% in the pre-intervention group and 22.22% - 63.64% in the post-intervention group, with the exclusion of the patient who initiated the diet without current seizures. A 2-sided Fisher's Exact Test showed no significant associations between the number of patients experiencing a reduction in seizure frequency and the care model at the first follow-up interval (n = 17), p = .16, the second follow-up interval (n = 16), p = 1, the third follow-up interval (n = 12) p = .236, or the fourth follow-up interval (n = 12), p = 1.

The number of AEDs changed throughout the 15-month period for both groups as noted in Table 5 and Figure 5. Both groups experienced a reduction in AEDs at the first follow-up appointment with the pre-intervention taking a mean of 2.17 (*SD* = 1.38) AEDs and the post-intervention group taking 3.38 (*SD* = 1.50) AEDs. The percent of patients able to decrease the number of AEDs at a follow-up encounter ranged from 16.7% - 40% in the pre-intervention group and 33% - 50% in the post-intervention group as noted in Figure 6. Utilizing a 2-sided Fisher's Exact Test, no significant associations were found between the number of patients experiencing a reduction in AEDs and the care model at the first follow-up interval (n = 17), p = .33, the second follow-up interval (n = 16, p = 1), the third follow-up interval (n = 12), p = 1, or the fourth follow-up interval (n = 12), p = .58.

Lastly, the number of epilepsy-related inpatient admissions were analyzed for both groups. The pre-intervention group had a mean of 1.71 (*SD* = 2.56) admissions per patient for the 15-months of data collection. The post-intervention group had a mean of 0.54 (*SD* = 0.66) admissions per patient. The pre-intervention group had 57% of patients admitted and the post-intervention group had 38% of patients admitted in 15-months. Utilizing a 2-sided Fisher's Exact Test, no significant association was found between the number of patients requiring an epilepsy related admission and the care model (n = 20), p = .64.

Clinic Outcomes

Patient compliance is a multi-faceted outcome looking at “no show” rates as well as therapeutic levels of drugs and serum ketones (beta-hydroxybutyrate). There were no “no shows” in the pre-intervention group, and two (15.4%) in the post-intervention group. A 2-sided Fisher’s Exact Test indicated no significant association between “no shows” and the care model, (n = 20), p = .52. Serum BOH levels ≥ 2mmol/L indicate a patient is in adequate ketosis. Four patients (57.14%) in the pre-intervention group had a total of five BOH levels drawn and monitored within the 15 months studied, of which, four (80%) were therapeutic. The post-intervention group included 10 patients (76.92%) who had a total of 33, BOH levels drawn and monitored, of which 24 (72.73%), were therapeutic. A 2-sided Fisher’s Exact Test indicated no significant association between BOH levels ≥ 2mmol/L and care model, (n = 38), p = 1. Likewise, therapeutic AED levels can indicate if a patient is taking his or her medications. AED levels were drawn seven times, within the 15-months for three patients (42.86%) in the pre-intervention group with three (42.86%) levels noted to be therapeutic. Six patients in the post-intervention group had AED levels drawn a total of 25 times within the 15-months, of which 18 (72%) were therapeutic. A 2-sided Fisher’s Exact Test indicated no significant association between number of therapeutic AED levels and study group, (n = 32), p = .19.

Adherence to the recommended follow-up schedule and discontinuation rates were also analyzed to determine alterations based on care model. Four patients (57.1%) adhered to the entire follow-up schedule in the pre-intervention group six patients (46.2%) in the post-intervention group. A 2-sided Fisher’s Exact Test indicated no significant association between adherence to the entire recommended follow-up schedule and study group, (N = 20), p = 1. Finally, discontinuation rates were noted during the 15-month study period. Two patients (28.6%) in the pre-intervention group discontinued the diet within 15-months while three (23.1%) discontinued the diet in the post-intervention group. Again, a 2-sided Fisher’s Exact Test indicated no significant association between discontinuing the diet and study group, (N = 20), p = 1. Discontinuation reasons cited in the pre-intervention group included side-effects (1) and lack of efficacy (1). One patient in the post-intervention group discontinued the KD due to side effects, another due to parental choice, and a third patient discontinued for unknown reasons.

Discussion

Analysis of the interdisciplinary KDC is an evaluation of a program created in October, 2015. However, outcomes of the program had not been analyzed. Due to a lack of benchmarks, data from the KDC were compared to data from similar patients who did not participate in the interdisciplinary clinic. The sample size was 20, limiting statistical analysis. However, by comparing raw data and non-parametric tests, the outcomes of the KDC can still useful when trying to translate the utilization and benefits of an IDC for the treatment of pediatric refractory epilepsy with the KD.

All patients included in the study had a diagnosis of refractory epilepsy, although one patient was seizure free at the time of KD initiation. Parents of this seizure free patient elected to start the diet due to the patient's regimen of multiple AEDs with prior seizures occurring over one-year before the KD was initiated. Other similar features between the 2 groups included the type of epilepsy treated. Both groups were predominantly composed of children with focal epilepsies. However, the majority of the post-intervention group had an identifiable brain lesion, presumably contributing to their epilepsy. Gender differences between the two groups were similar. Conversely, the post-intervention group was older than the pre-intervention group by nearly 5-years. After the start of the KDC, most patients initiated on the diet had Medicaid, in contrast to those started on the KD prior to the KDC. Only 2% of the post-intervention group was African-American, while the pre-intervention group was comprised fully of Caucasians. More striking dissimilarities between the two groups were noted with the number of AEDs and seizure frequency. The post-intervention group had harder to control epilepsies as noted by three diet initiations for status epilepticus, although this was not significant, statistically. Furthermore, the post-intervention group was on more AEDs at the time of diet initiation compared to the pre-intervention group, although it is important to note, means were not statistically compared due to the small sample size. The post-intervention group was noted to have more identified MRI lesions and an older average age than the pre-intervention group, possibly affecting seizure severity and etiology. Although statistical significance was not established with study group comparisons of demographics, nearly twice as many KD initiations took place after the start of the interdisciplinary KDC as they did prior to its development. This could be due to more knowledge about the KD among neurology providers as well as a more concerted effort to consider the diet for all pediatric refractory epilepsy patients.

Epilepsy Related Outcomes

The ketogenic diet is an efficacious treatment for refractory epilepsy. Efficacy in epilepsy treatment is often noted by reporting seizure frequency, number of AEDs, and QOL. This evaluation analyzed both seizure frequency and number of AEDs, which are inversely related to QOL. Both groups exhibited patients with a reduced seizure frequency at each encounter. Again, although statistical significance was not established, the post-intervention group produced five seizure free patients at the 4-6-month encounter and maintained at least two seizure free patients through the 15-month study, including the patient who had rare seizures at the time of KD initiation. The pre-intervention group produced seizure freedom in a maximum of three patients at the first follow-up interval, but this was not sustained and ultimately, no patients in the pre-intervention group remained seizure free at the last follow-up appointment. Due to the inverse relationship of seizure frequency and QOL, the KDC group may have experienced an increase in QOL compared to the pre-intervention group. In both groups, patients exhibiting daily seizures did not experience a dramatic reduction in seizure frequency with the pre-intervention group decreasing from four to two patients, and the post-intervention group decreasing from seven to five. However, the majority of parents in this group expressed satisfaction with the KD due to improvements in cognition and/or development, as noted in the EMR. The difference in percent of patients from each group who experienced a reduction in seizures was not statistically significant, although the pre-intervention group had a minimum of 50% of patients experience a seizure frequency reduction, compared to 22.22% minimum noted in the post-intervention group. Reduction in seizure frequency is congruent with established KD seizure reduction rates (Hallbook et al., 2015; Khoo et al., 2016; Lambrechts et al., 2017; Martin et al., 2016; Pasca et al., 2018). However, it is important to note the post-intervention group may have had more difficult to control seizures as evidenced by seizure frequency and noted number of AEDs at the time of KD initiation.

Moreover, both groups experienced reductions in number of AEDs at the first and second follow-up appointments. But, the post-intervention group concluded the study on a greater number of AEDs than at initiation. The number of patients, however, in the post-intervention group who were able to reduce their AEDs was greater than those in the pre-intervention group, although this was not statistically significant. Again, QOL is inversely related to number of AEDs, although this was not explicitly analyzed. While 50% of the patients participating in the KDC experienced a reduction in numbers of AEDs, the remaining patients may have had additional AEDs added to their treatment regimen.

Finally, patients participating in the KDC were less likely to be admitted to the hospital, although this was not statistically significant. Patients in the pre-intervention group had nearly three times as many admissions per patient as the patients in the post-intervention group. Although patients participating in the KDC tended to be on more AEDS, they had fewer epilepsy related hospital admissions.

Clinic Outcomes

"No Shows" were a significant problem among all outpatient appointments in the CNC. Typical "no show" rates in the general clinic were approximately 20% during the study period (A. Jennings, personal communication, February 26, 2020). There were no "no shows" documented in the pre-intervention group. Conversely, there were two in the KDC group, accounting for 15.4% of the sample, although not statistically significant. The "no show" rate in the KDC is, therefore, lower than the current general neurology clinic.

In addition to "no show" rates, it is important to note if standards of care were appropriately delivered in both groups. The full, recommended follow-up schedule was followed more consistently in the pre-intervention group compared to the post-intervention group, although this was not statistically significant. Possible causes of the discrepancy may be related to available KDC appointments. When the KDC was initiated, the clinic was held for one, half-day, each month for a total of four KDC appointments, per month. In 2016, the KDC days increased to two, half-days, each month for a total of eight KDC appointments, per month. All appointments were full during KDC days with exception of late cancelations or “no shows”. Therefore, it is possible that patients were unable to be seen for a recommended follow-up appointment at the recommended interval due to lack of availability.

Monitoring therapeutic levels of BOH and AEDs is another vital component in the management and monitoring of patients on the KD. Standard of care recommends levels to be monitored before each scheduled appointment. Not only must BOH and AED levels be ordered appropriately by the provider, but they also require patient and family compliance to ensure they are obtained as ordered. Furthermore, therapeutic BOH and AED levels indicate optimal management of both the KD and AEDs. BOH levels were drawn more often and in proportionately more patients in the post-intervention group, compared to the pre-intervention group, although this was not statistically significant. However, it was clinically significant, allowing optimization of KD management when this occurred. Conversely, therapeutic BOH levels were noted more often in the pre-intervention group. It is important to note the pre-intervention group included only five, BOH levels in four patients, whereas the post-intervention group included 33 levels in 10 patients. Similarly, to BOH levels, AED levels were drawn more often and in proportionately more patients in the post-intervention group compared to the pre-intervention group. Again, this association was not statistically significant. Contrary to the BOH levels, AED levels were more often therapeutic in the post-intervention group compared to the pre-intervention group. BOH and AED levels were obtained more appropriately in the post-intervention group, compared to the pre-intervention group with therapeutic AED levels noted more often in the post-intervention group, but therapeutic BOH levels noted more often in the pre-intervention group.

Finally, discontinuation rates were analyzed to determine if there were any differences between the two groups. Discontinuation rates of the KD within the 15-months of data collection were similar between the two groups. However, discontinuation due to lack of efficacy was noted only in the pre-intervention group, with one patient. Discontinuation of the KD due to side effects was noted in both groups. Therefore, participation in the interdisciplinary KDC did not appear to affect discontinuation rates when compared to the pre-intervention group.

Limitations

The retrospective design of the evaluation created significant limitations. First, only patients established on the diet in the past were utilized, limiting the sample size. Parametric analysis was not possible due to this small sample size. Furthermore, the small sample size limited statistical significance with non-parametric analysis, as well. The sample size was reduced further as patients had missing data for some follow-up appointments. Furthermore, in prior studies patient and family satisfaction improved in MDCs and IDCs (Moe et al., 2016; Williams et al., 1995). The retrospective design did not allow for the collection of information regarding patient, family, or team member satisfaction, although, it is important to note all original members of the CNC KDC anecdotally expressed high satisfaction with the KDC. Data were collected from chart-reviews within two EMR systems and documented by different providers. Furthermore, different providers were responsible for establishing refractory epilepsy as the patient's diagnosis creating possible inaccuracies. Lastly, cost-effectiveness or actual costs of the KDC were not analyzed. However, with the decrease in inpatient admissions and large number of patients reducing their number of AEDs in the KDC group, the financial burden of epilepsy may be reduced on the patient, family, and healthcare system, overall when utilizing an IDC approach. Likewise, QOL scores were not assessed. However, with the established inverse relationship of seizure frequency and number of AEDs with QOL, the positive effect of the KDC on QOL can be inferred.

Conclusion

Childhood refractory epilepsy may affect up to 30% of all children diagnosed with epilepsy. The diagnosis can be devastating for the child and family. Traditional medical management is widely known to be grossly ineffective at treating epilepsy once a patient has failed two appropriately trialed and chosen AEDs. Furthermore, the patient will experience side-effects, sometimes debilitating, with each medication added to the regimen. Therefore, it is vital to be able to offer efficient and effective, coordinated care capable of offering an alternative treatment to these patients. The KD is a safe and effective treatment for refractory epilepsy.

Several treatment outcomes of pediatric refractory epilepsy patients on the KD can be optimized with an interdisciplinary team that includes both the patient and family. The interdisciplinary KDC at a local CNC utilized a coordinated care approach where the patient and family interacted with the primary neurologist, a dietician trained in the ketogenic diet and other dietary approaches, a social worker capable of identifying needs and resources of the patient and family, and a pediatric neurology nurse practitioner capable of managing diet modifications, AED changes, and family education. The interdisciplinary approach aided in the facilitation of the patient through the KD program, offering the patient and family vital information and education about the KD. Although not statistically significant, epilepsy management through the interdisciplinary KDC yielded more patients becoming and remaining seizure free, improved adherence to KD standards of care, reduced the number of epilepsy related inpatient admissions, and allowed more patients to reduce their number of AEDs when compared to the traditional approach.

In the future, prospective studies should be conducted with a larger, multicenter sample to better determine statistical significance of an IDC approach to management of children on the KD. Patients include in future studies should be determined to have refractory epilepsy based on continued seizures despite failure of appropriate AEDS, reducing potential for bias and inaccurate diagnoses. Furthermore, consistent approaches to KD patient management noted within a KDC may better yield the ability for prospective, randomized controlled trials to be performed and assist with future ketogenic diet and epilepsy developments, compared to the traditional approach. Patient, family, and team member satisfaction should be analyzed in addition to changes in QOL through valid and reliable satisfaction and QOL tools. Additionally, costs associated with an interdisciplinary KDC should be performed. Data from this interdisciplinary clinic and future studies may ultimately be adapted for use to support the creation of IDCs in other areas in the future, such as an interdisciplinary pediatric refractory epilepsy clinic.

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Tables

Table 1

Interdisciplinary Ketogenic Diet Clinic Evaluation Outcomes

Epilepsy Related Outcomes	**Definition**
Seizure Frequency	Status epilepticus Daily Weekly Monthly < Monthly No seizures
Number of AEDs	
Number of Epilepsy Related Admissions	Number of admissions during timeframe

Clinic Related Outcomes	**Definition**
Patient Compliance:	
“No Show” rate	More than one “no show”
Therapeutic Serum Beta-Hydroxybutyrate Levels	serum beta-hydroxybutyrate (BOH) levels ≥ 2mmol/L
Therapeutic AED Levels	Therapeutic as determined by lab
Discontinuation Rates	Number of patients discontinuing the diet in timeframe
Adherence	Entire recommended follow-up schedule followed (yes or no)

Note. Antiepileptic Drugs (AEDs)

Table 2

Patient Demographics

	Pre-Intervention (*n* = 7)	Post-Intervention (*n* = 13)
Mean age at initiation years (*SD*)	1.72 (1.52)	6.56 (5.8)
Gender		
% Female (*n*)	57.1% (4)	38.5% (5)
% Male (*n*)	42.9% (3)	61.5% (8)
Race		
% White (*n*)	100% (7)	84.6% (11)
% African-American (*n*)	0% (0)	15.4% (2)
Insurance		
% Medicaid (*n*)	42.9% (3)	84.6% (11)
% Private (*n*)	57.1% (4)	15.4% (2)

Note. N = 20

Table 3

Patient Epilepsy Characteristics

	Pre-Intervention (*n* = 7)	Post-Intervention (*n* = 13)
Type of Epilepsy		
% Generalized (*n*)	28.6% (2)	30.8% (4)
% Focal (*n*)	42.9% (3)	38.5% (5)
% Multifocal (*n*)	28.6% (2)	30.8% (4)
Lesion identified on MRI		
% Yes (*n*)	28.6% (2)	69.2% (9)
% No (*n*)	71.4% (5)	30.8% (4)
Mean Number of AEDs (*SD*)	2.71 (1.38)	3.38 (1.5)
Seizure Frequency		
% None	0% (0)	7.7% (1)
% < Monthly	0% (0)	7.7% (1)
% Monthly	14.3% (1)	0% (0)
% Weekly	14.3% (1)	7.7% (1)
% Daily	71.4% (5)	53.8% (7)
% Status	0% (0)	23.1% (3)

Note. *N* = 20; Antiepileptic Drugs (AEDs)

Table 4

The Number of Patients Experiencing Different Seizure Frequencies in Each Group at Recommended Follow-up Intervals

Interval and Group	**Initial**		**0-3 months**		**4-6 months**		**7-9 months**		**10-15 months**	
	Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention	Pre-Intervention	Post-Intervention
None	0	1	3	3	1	5	1	2	0	2
< Monthly	0	1	0	0	0	0	1	0	2	0
monthly	1	0	0	0	1	0	0	0	0	1
Weekly	1	1	0	0	1	3	0	2	0	0
Daily	5	7	2	8	2	3	1	5	2	5
Status	0	3	0	0	0	0	0	0	0	0

Table 5

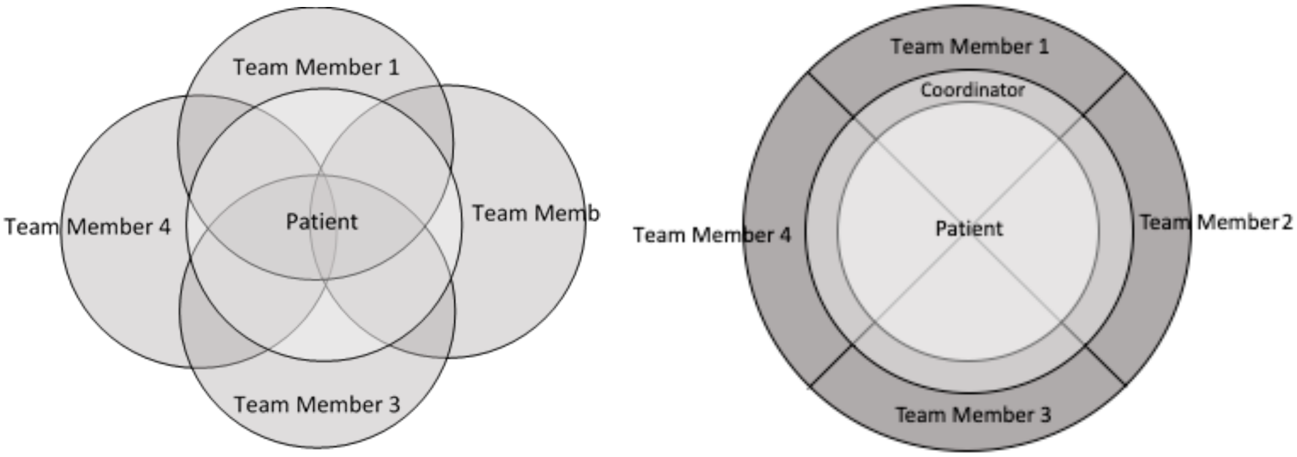
Average (M) Number of Antiepileptic Drugs (AEDs) per Patient

	Pre-Intervention		**Post-Intervention**	
Visit	***Mean (SD)***	**n**	***Mean (SD)***	**n**
Initial	2.714 (1.38)	7	3.385 (1.5)	13
0-3 months	2.167 (1.17)	5	3.09 (1.45)	11
4-6months	1.8 (1.3)	5	2.91 (1.58)	11
7-9 months	2.67 (2.08)	3	3.55 (1.51)	9
10-15months	2.67 (2.06)	4	3.75 (1.98)	8

Figures

Figure 1

Graphic representation of an *Interdisciplinary Clinic (IDC) versus a Multidisciplinary Clinic (MDC)*

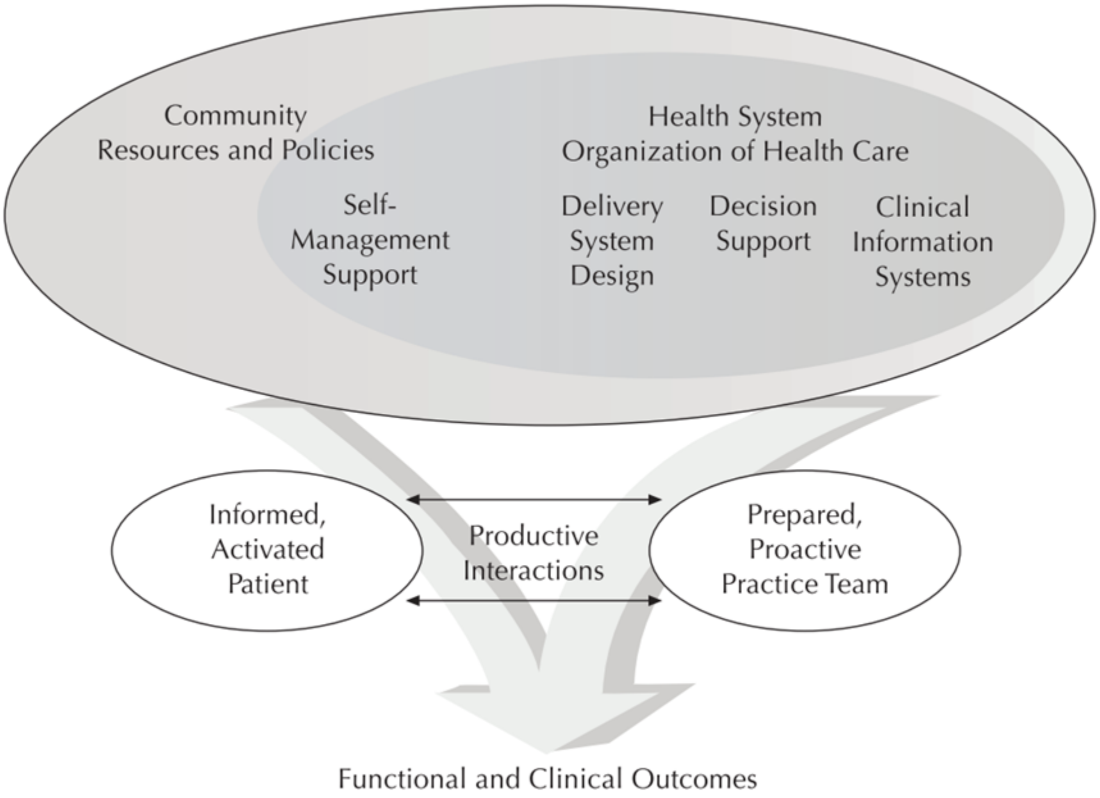


Interdisciplinary Clinic

Multidisciplinary Clinic

Figure 2

The Model for Effective Chronic Illness Care



Note. Adapted from 2002 Wagner, E. H., Davis, C., Schaefer, J., Von Korff, M., & Austin, B. (2002). A survey of leading chronic disease management programs: Are they consistent with the literature? *Journal of Nursing Care Quality, 16*(2), 67–80.

Figure 3

Seizure Frequency Exhibited by Patients in each Group

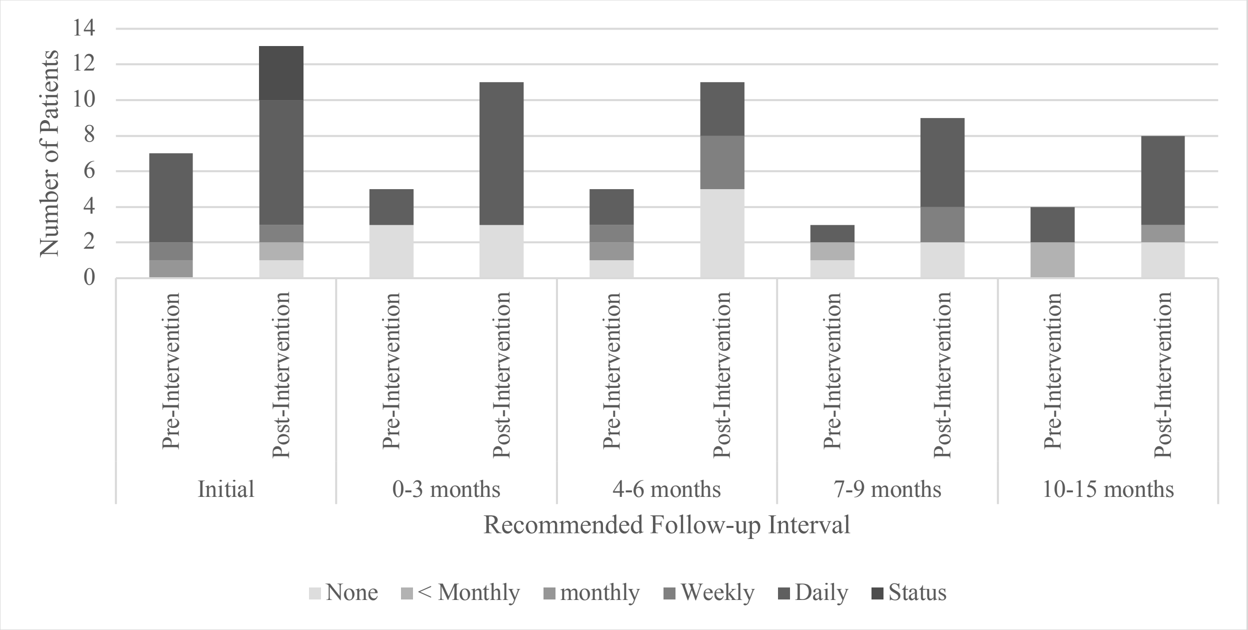
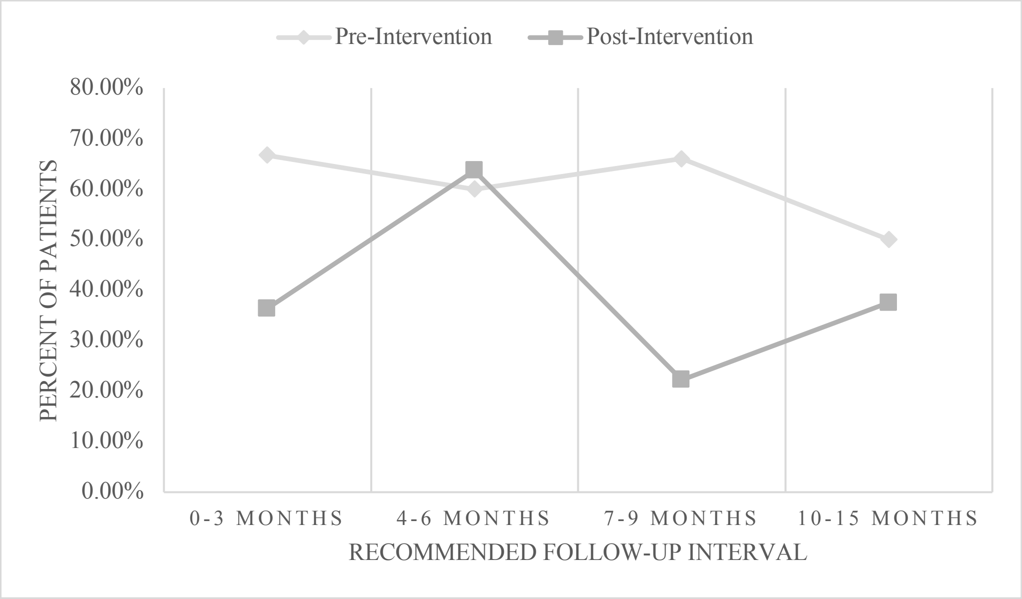


Figure 4

Percent of Patients Experiencing Reduction in Seizure Frequency



Note. p > .05

Figure 5

Mean Number of Antiepileptic Drugs (AEDs) by Recommended Follow-up Interval

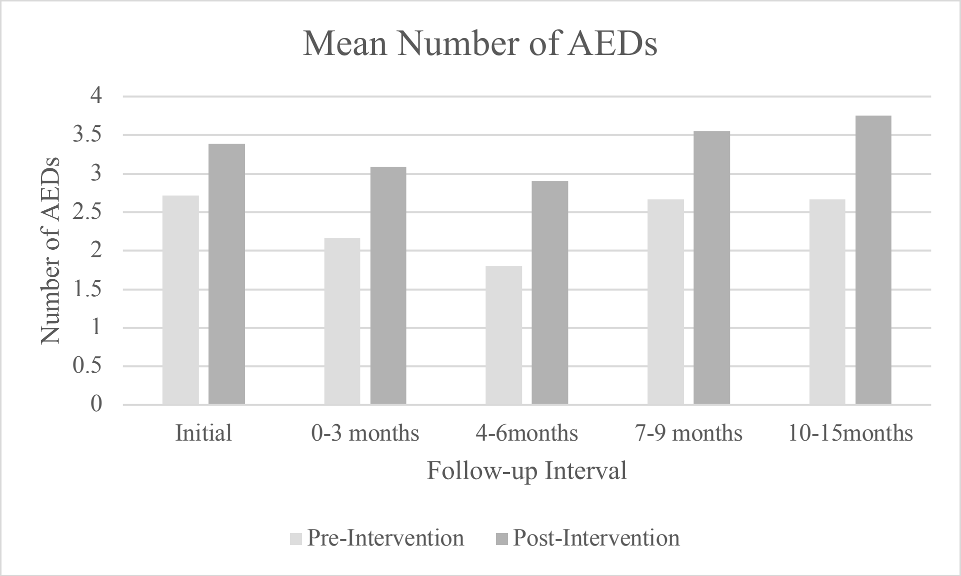
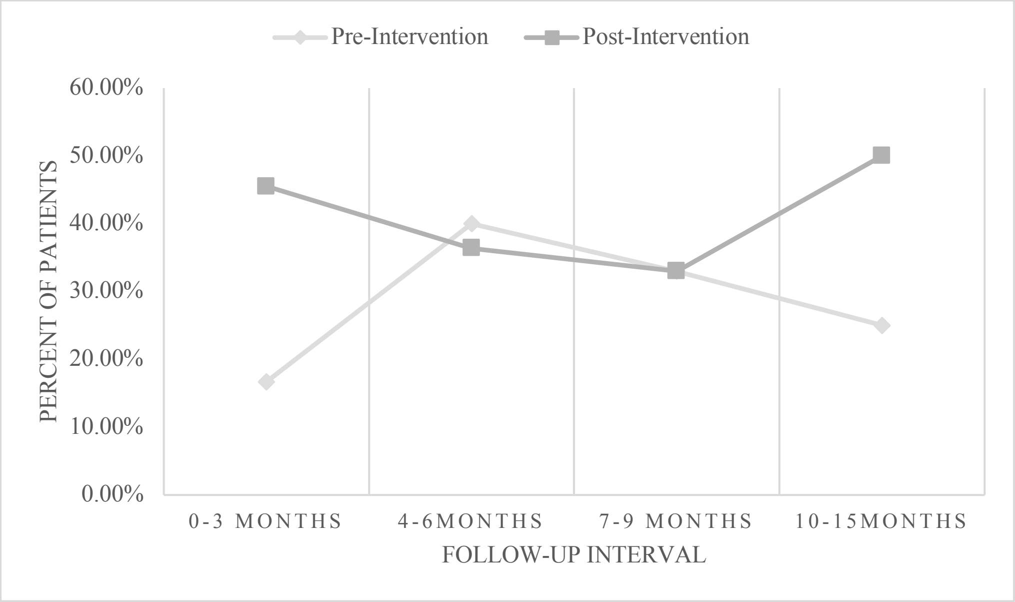


Figure 6

Percent of Patients Experiencing a Reduction in AEDs at each Recommended Follow-up Interval



Note. p > .05