MANAGEMENT INFORMATION & DECISION SUPPORT EPILEPSY TOOL (MINDSET): DEVELOPMENT OF A SELF-MANAGEMENT TOOL FOR THE HISPANIC COMMUNITY

by

Refugio Sepulveda

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O Merciful Jesus! O Merciful Jesus! ¡Oh Dios de misericordia!

¡Jesús en ti confió!
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ABSTRACT

Background: Hispanic people with epilepsy, especially those who are primarily Spanish speaking, may be at an increased risk of disparities in managing their epilepsy. This may be due to limited communication between patients and healthcare providers (HCPs) and/or the scarcity of epilepsy self-management tools available to them. Self-management has been shown to help people with epilepsy increase their self-confidence and better cope with their disease. Despite advances in the field, educational interventions for epilepsy self-management are still limited. To help mitigate these challenges, this study renovated and translated into Spanish an existing epilepsy self-management support tool known as Management Information and Decision Support Epilepsy Tool (MINDSET). MINDSET is a tablet-based clinical aid designed for use by both patients and their HCPs to promote shared informed treatment and behavioral change decision-making. MINDSET uses information that the patient enters into a tablet-based application to create a patient profile and an action plan tailored to the patient’s self-management “at-risk” behaviors for review by the patient and their HCP during consultation.

Purpose: The overarching goal of this study was to develop a theoretically-enhanced and empirically tested Spanish version of the MINDSET program tailored to the Hispanic community, taking into consideration a series of social, cultural, and economic factors unique to the community. This tool has been culturally tailored to help improve care to underserved Hispanics and address disparities in epilepsy care. A Spanish version of MINDSET will provide Hispanic patients with epilepsy with a tool that can help them acquire a better awareness of their health condition and to learn new skills to help them improve their epilepsy self-management, ultimately resulting in improved treatment compliance, fewer seizures, and reduced health care related costs.

Methods: The usability study of this project consisted of two parts. Part 1 consists of the software development of the new Spanish version of MINDSET (both content and technical features). Part 2 consists of the usability testing of MINDET (i.e. the degree to which the program can be used by patients to achieve quantified objectives with effectiveness, efficiency, and satisfaction in its use). Part 1: The MINDSET assessment questionnaire (My Epilepsy) was revised by integrating systematic reviews from eight members of a research team composed of experts in communication technology, behavioral science, public health, and in the clinical management of epilepsy. MINDSET includes questions related to patient seizure history, seizure and medication management, and lifestyle management. A new module in the program (My Goals and Strategies) was created to list all of a patients’ at-risk items in each self-management domain and to identify items (i.e. Goals) for improvement. The patient is then asked to select from a list of behavioral strategies to meet their selected goals, estimate confidence to perform these behaviors; list any barriers for achievement, and brainstorm strategies to overcome any barriers. A new Action Plan is then created as a
social contract between the patient and their doctor, where the patient commits to improving any self-management items that may need improvement. The Action Plan also serves as a communication tool to facilitate discussion between the patient and their doctor. Lastly, the new version of MINDSET was programmed for use. This step was completed by software programmers under contract with the research team. Once programmed into the computer tablets, the program was “alpha-tested” within the research team (i.e. a form of in-house acceptance testing) to identify any technical problems with the program before testing it with patients. Part 2: A usability study of the new version of MINDSET (4.1) was conducted with a sample of Hispanic patients (n=8) in four neurology clinics in Arizona and Texas. A usability rating scale and exit interview were used to collect quantitative and qualitative usability data after patients completed MINDSET. Prior to translating MINDSET into Spanish, the program was revised to address any comments and/or feedback provided by the patients during the first usability test of the program. MINDSET was then translated into Spanish, programmed into the tablets, and tested by a different group of Spanish-speaking patients (n=8) in four clinics in Arizona and Texas.

**Conclusion:** The English and Spanish usability testing of MINDSET proved to be very effective. Patients participating in the usability study identified gaps and concerns with MINDSET and they provided their feedback and recommendations for improving the program (i.e. both content and interface). Overall, most of the patients perceived MINDSET as having a positive impact on managing their epilepsy (62.5-100%), found the program to be credible (87.5-100%) and found that the program was easy to use (87.5%). The new version of MINDSET (4.1) mark significant improvements over previous versions of the program in terms of its focus on prioritization and goal setting for self-management practice. The new Spanish version of the program (Span-MINDSET) will help address disparities in the care of epilepsy amongst Hispanic Spanish-speaking patients by making available a tool that will help them improve their knowledge, capacity, and better management of their epilepsy. Positive usability findings suggest that tablet-based Spanish language decision support is acceptable for Spanish speaking Mexican-American patients with epilepsy. These results also indicate a relationship between positive self-management behaviors and better health outcomes.
CHAPTER 1: INTRODUCTION

1.1 Dissertation Format (Professional/Practical)

This is a multi-site collaborative study involving researchers and clinicians from the University of Arizona’s Department of Neurology and the Mel and Enid Zuckerman College of Public Health; the University of Texas, School of Public Health in Houston, and the Epilepsy Foundation of Central-South Texas. This study was funded as a health promotion and disease prevention Special Interest Project (SIP) by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC).

The goal of this project proposed as a Managing Epilepsy Well (MEW) Collaborating Center was to develop a completely new version of MINDSET culturally tailored for the use of Hispanic Spanish-speaking patients with epilepsy. Support for the development, implementation and evaluation of MINDSET is provided by the Managing Epilepsy Well Network (MEW).

The work described in this dissertation pertains exclusively to the development and the usability testing of the new Spanish version of MINDSET. Please note that the larger MINDSET study (i.e. efficacy trial), is funded for a total of five years and extends beyond the work described in this dissertation. All of the work described in this dissertation report pertains to the work that I personally completed as part of the usability study of the MINDSET program.

For this project, I took on the role of a Research Specialist, Senior and I was responsible for leading the research team in the overall management, development and usability testing of the new Spanish version of the MINDSET program. The study was conducted with Hispanic patients in treatment for epilepsy attending four clinic sites along the U.S. and Mexico border in Tucson Arizona (Banner University Medical Center, Alvernon and South Campus clinics) and Texas (Epilepsy Foundation, Harlingen and San Antonio clinics).
1.2 Sponsoring Organization and Research Team

The Sponsoring Organization (i.e. The University of Arizona, Department of Neurology) is aware and acknowledges that I will use my work on this study for my professional dissertation project towards the completion of the Doctoral of Public Health (DrPH) degree program with the University of Arizona, Mel and Enid College of Public Health. My work on the MINDSET study that will be used for my dissertation project includes years 1 and 2 of the larger MINDSET study related specifically to the Development and Usability Testing of MINDSET. Years 3-5 of the study will involve more in-depth testing of MINDSET (i.e. feasibility and efficacy testing of the program) and are NOT included as part of this dissertation project. Attached you will find a letter of support from the sponsoring organization acknowledging that they are aware that I will be using my work on the MINDSET project as a dissertation project towards the degree requirements for the DrPH program at the Mel and Enid Zuckerman College of Public Health (see appendix A).

The core research team for the MINDSET study was composed by a diverse team of physicians and health and behavioral scientists. The research team at the University of Arizona included David Labiner, MD (Neurologist, Professor, and Department Head), Jenny Chong, PhD (Health Services Researcher and Behavioral Scientist) with the Department of Neurology and Refugio Sepulveda, MPH (Research Specialist, Senior) with the Mel and Enid Zuckerman College of Public Health. The research team at the University of Texas was comprised by Charles Begley, PhD (Health Services Researcher) and Ross Shegog, PhD (Behavioral Scientist), with the University of Texas, School of Public Health. In addition, two monolingual neurologists from the Banner University Medical Center and two bilingual neurologists from the UT, Medical School participated in the Patient-Provider advisory groups (PPAG).
1.3 Background and Significance

Epilepsy is one of the most common neurological conditions in the world. Epilepsy is considered a long-term chronic health condition. Epilepsy affects individuals of all races, ages, and race/ethnic groups\(^1\). About three million people in the United States have a diagnosis of epilepsy. It is estimated that an additional ten percent of the U.S. population will probably experience at least one seizure during their lifetime\(^1\). Individuals diagnosed with epilepsy is defined by experiencing more than one unprovoked seizure\(^1\). Approximately one-half of people living in the United States are currently burdened by long-term health conditions\(^2\), making epilepsy one of the nation’s top neurological conditions.

All patients, with any chronic health disorder, need both educational and psychosocial support to better understand and manage their condition. Specifically, patients need the appropriate knowledge and psychosocial support that promotes self-management. Epilepsy “self-management” has been defined as “a class of adaptive behaviors used by persons to control their seizures”\(^3\). Over twenty-percent of patients with epilepsy continue to have breakthrough seizures even when taking anti-seizure medications (AEDs). This suggests that patients must increase their knowledge, improve their self-management skills, and modify their lifestyle and healthcare behaviors in an effort to reduce seizure frequency and improve quality of life.

Individuals living with epilepsy must understand their health condition, and they have to develop and sustain the skills to manage it\(^4\). Patients with epilepsy who don’t understand their condition and effective ways of managing it are more prone to experience adverse health outcomes than patients who understand and manage their disease well\(^5,6\). Research suggests that improving patients’ knowledge about their epilepsy will positively influence their self-efficacy and ability to self-manage their disease, thus improving their symptoms and prognoses\(^7,8,4\).
1.4 Epilepsy Self-Management

The prevalence of epilepsy among Hispanics varies depending on the geographic location. Along the United States-Mexico border, Hispanic adults with epilepsy primarily seek epilepsy care from outpatient clinics rather than from emergency departments. Hispanics are significantly less likely to receive preventative epilepsy care compared to non-Hispanic Whites.

Available research suggests that disparities in epilepsy care exist for all minorities, this may be a consequence of language barriers, or a lack of understanding and knowledge in the community about epilepsy, which may engender low self-efficacy and self-management among people with epilepsy. Self-efficacy is the belief in one’s ability to carry out tasks in new and novel circumstances. Notwithstanding cultural differences, barriers to self-management for patients with epilepsy appear to be similar for Hispanics and non-Hispanics although solutions to address the barriers may be different.

Information about epilepsy self-management among Hispanics with epilepsy in the United States is scarce. Epilepsy self-management comprises three broad areas including treatment management (e.g. adherence to prescribed medication, and clinical visit regimens), seizure management (e.g. preparation for, and response to, seizure episodes), and lifestyle management (e.g. avoiding behaviors that may trigger seizures and/or the adverse consequences of seizures). Predisposing determinants for epilepsy self-management behavior include the patient's degree of self-efficacy or confidence to perform self-management behaviors, behavioral capability, ability to set goals, valuing independent management, acceptance of the diagnosis of epilepsy, and perceived stigma related to epilepsy. Epilepsy is often associated with anxiety, depression, behavior problems, and/or cognitive dysfunction, and epileptic seizures have been known to be precipitated by psychological triggers such as stress, anxiety, anger, and emotions.
1.5 Theoretical Framework: Quality of Care and Clinical Guidelines

Most research reports shape the problem statement of their respective studies within the context of a conceptual or theoretical framework. A description of these frameworks enhances a report in two ways. First, by identifying research variables and second by clarifying relationships between the variables. A theoretical framework describes a theory or set of theories that a researcher identifies to guide his/her research. A theoretical framework provides the context and rationale for examining a problem and serves as a frame of reference for research designs through the application of a theory, or a set of concepts drawn to offer an explanation on the problem.

This section will describe the theoretical framework that helped guide the research variables of this study exclusively pertaining to the quality of care and clinical guidelines related to the care of epilepsy (i.e. time-tested theories and medical investigations). The theoretical underpinnings of this study are based on existing quality of care criteria and clinical guidelines for epilepsy, Social Cognitive Theory and Self-Regulation Theory, motivational enhancement strategies, the 5A Model (i.e. Ask, Assess, Advise, Assist, Arrange) and the use of evidence-based motivational interviewing strategies. MINDSET uses validated scales to assess self-management behavior, self-efficacy, depression, and epilepsy medication side-effects.

Enabling determinants for epilepsy self-management include skills that are required for competent self-management by the individual and family, access to medical care, information and training. Reinforcing determinants of epilepsy self-management behaviors include an active partnership between the healthcare provider (HCP), the patient, and the patient’s family or significant others to aid in the adherence to the treatment plan and stimulate improvements in management. Discrepancies between the patient and HCP regarding the patient's attitudes
regarding epilepsy and self-management abilities, and/or poor communication between the two, can undermine the adoption of self-management behavior.

Management Information and Decision Support Epilepsy Tool (MINDSET) was originally developed as an electronic computer-based tool to help improve the self-management of epilepsy. MINDSET was originally designed as a tablet-based clinical aid for both patients and their HCPs to promote shared informed treatment and behavioral change decision-making. MINDSET is consistent with validated measures of epilepsy self-management where a patient and their HCP can assess personal efficacy of the patient’s treatment and make informed treatment decisions.

MINDSET is mounted on a portable tablet PC and asks patients a series of questions aimed at obtaining a patient’s self-management profile and prompt goal-directed communication. MINDSET asks a patient a series of questions on a number of epilepsy related topics including, seizure history, medication management, and lifestyle behaviors. MINDSET then uses the information that the patient entered into the tablet-based application to create an action plan tailored to the patient’s self-management problem behaviors for review by the patient and their HCP during consultation. MINDSET aids patient-HCP discussion, highlights issues that can aid patient-HCP interactions and increases patient awareness of epilepsy related issues11-13.

Two of the top concerns among practicing physicians working with epilepsy patients are adherence to treatment protocols and the need for patient communication workshops to improve the self-management skills of their patients23. Previous studies related to the self-management of epilepsy has shown that seizure management, treatment and its side effects are not always discussed by patients during clinical visits. In addition, patients have also been shown to disagree with their physicians regarding specific topics such as lifestyle behaviors that may trigger seizures and medication side effects25. Such disagreements are eased if patients are “primed” to discuss
topics such as side effects before meeting the physician. Since MINDSET gathers relevant information at each clinic visit and recommends discussion topics, patients may improve self-management skills through goal setting and better understanding of their condition.

Research into chronic disease management among Hispanics supports the importance of self-efficacy. Believing in one’s ability to exercise control over one’s health condition strongly influences health behavior and the initial improvement in self-efficacy also predicts future health outcome. Self-efficacy among Hispanic patients with epilepsy in a clinic setting has been found to be positively associated with improved social support and negatively associated with depression. Improvements in self-efficacy among Hispanic patients with epilepsy has also shown to improve self-management. By adapting MINDSET in a culturally appropriate way for Hispanic patients, this study demonstrates that patient-HCP communication may be improved, knowledge of epilepsy needs increased, and self-efficacy and self-management norms improved.

Figure 1: Theoretical Framework: Clinical Outcome Measures Embedded in MINDSET
1.6 Conceptual Framework: Healthcare Innovation

Connected to the problem statement, the conceptual framework “sets the stage” for the presentation of the particular research question(s) that drives the investigation being examined. A conceptual framework can be defined as “the result of bringing together a number of related concepts to explain or predict a given event, or give a broader understanding of the phenomenon of interest or research problem”, in this case, epilepsy self-management. The combination basically represents an ‘integrated’ way of looking at the problem\textsuperscript{35}. Thus, a conceptual framework is derived from a set of concepts, in-so-far as a theoretical framework is derived from a theory\textsuperscript{35}.

The theoretical framework discussed in the previous section provided for a general representation of the theoretical groundworks related to existing quality of care criteria and clinical guidelines for epilepsy. The conceptual framework, on the other hand, embodies the specific direction by which the research will have to be undertaken. This section depicts the translation of the clinical guidelines (i.e. theoretical framework) of the study into clinical practice (i.e. conceptual framework). This section will describe the conceptual framework of this study, that is, our idea of how the issue of epilepsy self-management needs to be addressed, Healthcare Innovation.

The public health and the healthcare industries have experienced an increase in innovations aimed at improving preventative care, life expectancy, quality of life, diagnostic and treatment options, as well as the efficiency and cost effectiveness of the healthcare system. Information technology has played an important role in the innovation of healthcare systems. Despite the rise in technology, research on the art and science of healthcare innovation has been limited\textsuperscript{36}.

Innovation can be defined as “the intentional introduction and application within a role, group, or organization, of ideas, processes, products or procedures, new to the relevant unit of adoption, designed to significantly benefit the individual, the group, or wider society”\textsuperscript{36}. This
definition captures the three most important qualities of innovation: 1) novelty, 2) an application component and 3) an intended benefit\textsuperscript{37,38}. Consistent with this definition, Healthcare Innovation can be defined as “the introduction of a new idea, concept, service, technologies, or products aimed at improving research, education, prevention, diagnosis, and treatment, all of these with the long-term goals of improving the quality, cost, and effectiveness of patient care\textsuperscript{39}.” From the patient’s point of view, the intended benefits are either improved health or reduced suffering due to illness\textsuperscript{40}.

One of the driving forces in research is a conceptual framework that provides researchers with the foundation upon which studies are built. Based on the proposed definition and dimensions of healthcare innovation, this dissertation explores a new model to improve the self-management of epilepsy. We have developed a new framework to specify key aspects of epilepsy self-management, wherein providing direction for future research and further development and testing of a theory of epilepsy self-management.

MINDSET has been developed as a healthcare innovation tool to enhance patients’ knowledge of epilepsy, self-management therapy and lifestyle issues to prevent seizures and maximize quality of life. The original version of MINDSET is the only epilepsy self-management tool that provides a clinic-based decision support system for the patient and, at the same time, flags important topics that should be discussed during consultation with the HCP. MINDSET translates clinical guidelines for improving the quality of care for chronically ill patients into clinical practice using behavioral assessment and strategies to enhance patient self-management. MINDSET has the potential of assisting both patients and clinicians to approximate guideline implementation and enhance review of, and intervention on, patient self-management practices. The new version of MINDSET described in the study will be the first of its kind self-management tool that can be used in clinical settings for Spanish speaking patients with epilepsy.
Additionally, the tablet-based program is flexible, adaptable to newer needs, inexpensive, highly reliable, scalable, and easily disseminated. Further, significant strengths are the inter-institutional and interdisciplinary collaboration of a team with extensive experience in design, development, and implementation of technology-based decision-support interventions for promoting self-management of epilepsy and extensive experience in recruiting and maintaining patients with epilepsy in clinic-based studies, including Hispanic patients. This study will make a significant contribution to the public health challenge of epilepsy management among Hispanic patients. Based on the preliminary studies of MINDSET, I am hopeful that this project will help address disparities in epilepsy care among Hispanic Spanish-speaking patients by making available to them a tool that will help them better manage their epilepsy.

**Figure 2: Conceptual Framework of Healthcare Innovation**\(^{39}\)
1.7 Research Questions and Hypotheses

This study examines the development and usability testing of the new and enhanced version of MINDSET tailored for the unique needs of the Hispanic community.

The following questions guided the long-term goals of the larger (5-year) MINDSET study:

- Can MINDSET be successfully used in a clinical setting (i.e. be understood, accepted, credible, and motivational) for Hispanic patients with epilepsy?
- Can MINDSET improve patients’ awareness, knowledge, and social and behavioral ability to better self-manage their epilepsy?
- Can MINDSET help improve validated measures of self-management and self-efficacy among Hispanic patients with epilepsy compared to the conventional standard of care?
- Can MINDSET be used by physicians and clinical staff to track and monitor patient self-management progress on clinical and psychosocial parameters?

The hypotheses tested for the usability phase of the larger MINDSET study, as they pertain to the work described in this dissertation, are as follows:

- Usability: Patient ratings of the Sp-MINDSET will indicate acceptable usability for the parameters of ease of use, credibility, understandability, acceptability, and motivational appeal (Usability scale).
- Duration: Provider and patient ratings of the Sp-MINDSET will indicate acceptable perceived time-on-task (Usability and Feature Rating Scales), and minimal disruption to usual care activities (Exit Interview).
- Communication, shared decision making: Patients who use the Sp-MINDSET in their clinic visits will report acceptable physician communication (Communication Scale) and shared control of management (Shared Decision Making Scale).
- Improved Self-Management: Patients with epilepsy who use MINDSET in the context of their usual clinic visits will significantly improve their ability to manage their epilepsy and their self-management behaviors compared to patients who do not use MINDSET.
1.8 Purpose of Project

E-technology and m-Health (health support through mobile devices) as a field has grown rapidly and has been effectively used in the healthcare field to improve provider support and patient self-management of chronic conditions, including epilepsy. Self-management helps people with epilepsy increase their self-confidence and better cope with their disease. Despite advances in the field, educational interventions for epilepsy self-management are still limited.

This study represents an innovative and significant contribution to the field of self-management education for Hispanic patients with epilepsy and their HCPs. This study addresses the need for a clinic-based Decision-Support System tool (DSS) to assist physicians in profiling the epilepsy self-management needs of their Hispanic Spanish-speaking patients by providing a salient, tailored intervention. MINDSET looks to improve existing disparities in the care of epilepsy by making available a quality tool that will assist Hispanic patients improve their ability to self-manage their epilepsy. The redesigned MINDSET (new version) is for clinic-based use to facilitate the HCPs role in assisting patients in periodically assessing, maintaining, and ultimately improving their epilepsy self-management.

This project looks to address disparities in the care of epilepsy among Hispanic patients by making available a new tool that will help them to improve their knowledge, self-confidence, and ability to self-manage their epilepsy. The new version of MINDSET will give a significant majority of Hispanic patients with epilepsy the opportunity to use a tool that can help them acquire awareness of their medical condition and to learn skills that can help them improve the self-management of their epilepsy, ultimately resulting in improved treatment compliance and fewer seizures. This work will help contribute uniquely to the literature on the potential of educational technology and decision support as an adjunct to successful clinical management of epilepsy.
1.9 Goals and Objectives

The global goals for the larger MINDSET study include:

1) Development of first of its kind clinic-based decision support system for Hispanic Spanish-speaking patients with epilepsy (i.e. Spanish-MINDSET).

2) Increase patient awareness about their self-management behaviors.

3) Provide immediate feedback on self-management behaviors compared to benchmarks.

4) Provide a list of at-risk self-management behaviors for patient prioritization.

5) Provide the potential for improved patient to healthcare provider communication and the discussion and reinforcement of self-management goals and strategies.

6) Improve patients’ ability to self-manage their epilepsy (i.e. seizures, medication(s), and lifestyle management behaviors).

The specific objectives for the usability trial of the larger MINDSET study include:

1) Redesigning the existing version of MINDSET, including the medical content, user design and interface, translation, encoding, programming, and other technological features.

2) Recruit the patient-provider advisory group (PPAG) comprising clinicians and Spanish speaking epilepsy patients from four clinics (n=16 patients and n=4 physicians).

3) Develop design documents (informed by literature review and PPAG input) to tailor MINDSET for the Spanish speaking community.

4) Translate the newly redesigned version of MINDSET into Spanish. Program Spanish MINDSET (Sp-MINDSET) (working title) as a tablet-based tool.

5) Test the usability of Sp-MINDSET with a Patient-Provider Advisory Group (PPAG).

6) Revise Sp-MINDSET as needed (based on PPAG input).
CHAPTER 2: REVIEW OF THE LITERATURE

2.1 Epilepsy: A Life-Changing Chronic Health Condition

Epilepsy is a common neurological disorder; not well understood and often not well addressed, despite being widely recognized\textsuperscript{41}. Epilepsy consists of “involuntary, recurrent seizures that arise from excessive discharges of neurons in the brain. Seizures vary in type, severity and intensity, and can manifest by changes in consciousness, movement, sensation, or behavior\textsuperscript{42}.”

Epilepsy involves the incidence of more than one unprovoked seizure and affects both male and females; although gender-specific patterns have been observed. Women appear to develop epilepsy at greater rates during their first five years of life, but the incidence in males predominates after that, with the biggest differences noted in older age groups\textsuperscript{43}. Though seizures may begin at any age, children and the elderly are the most vulnerable. Epilepsy related symptoms in children include some of the most devastating forms, many of which have lifelong impacts. While epilepsy is a physical disorder of brain function, it has a substantial social burden that manifests in high unemployment rates, depression, and personal isolation among those affected\textsuperscript{44}.

Epilepsy can be a self-limiting condition or one that is easily treatable if diagnosed accurately; yet for many people, epilepsy is a lifetime disorder resulting in significant morbidity and increased mortality\textsuperscript{42}. Co-morbidities related to cognitive problems and depression add to its burden. Available treatment options include antiepileptic drugs, surgery, vagus nerve stimulation, and the ketogenic diet, yet large gaps in access to care make it difficult to diagnose and treat epilepsy. It is common for several years to pass before a patient receives a precise diagnosis and treatment plan. It is estimated that over 40% of patients with epilepsy continue to have seizures regardless of their current treatment plan, while many others pay a hefty price in side effects from treatment\textsuperscript{45}. 
2.2 Epilepsy in the United States: Fast Facts

- A seizure is a transient disruption of brain function due to abnormal and excessive electrical discharges in brain cells. Epilepsy is a disorder of the brain that causes seizures.

- Epilepsy can be caused by different conditions that affect a person’s brain. Many times the cause is unknown. Some causes include: stroke, brain tumor, traumatic head injury, central nervous system infection, vascular diseases, and other neurological disorders.

- A person with epilepsy is not contagious and cannot give epilepsy to another person.

- Epilepsy can decrease a person’s life expectancy, and severely diminish their total well-being and participation in daily activities. People with epilepsy also often experience other health and social disparities, such as inferior health related quality of life and low socioeconomic status.

- Patients with epilepsy are likely to suffer from other chronic health conditions that require management, such as heart disease, diabetes, depression, and asthma.

Incidence, Prevalence, and Economic Costs

- Approximately 3 million people in the U.S. have epilepsy.

- Reportedly, 150,000 new cases of epilepsy in the U.S. each year (i.e. 48 out of 100,000 people).

- “1 in 26 people in the U.S. will develop epilepsy at some point in their lifetime.”

- More than one-third of patients with epilepsy will continue to have uncontrollable seizures because no available treatment works for them.

- Of people with epilepsy, 60-70% do not know the cause of their seizure disorder.

- Epilepsy accounts for about $15.5 billion in direct costs (medical) and indirect costs (lost or reduced earnings and productivity) each year.
2.3 Public Health and Epilepsy

The health of our nation is becoming increasingly burdened by the rise in chronic illnesses. Epilepsy is one of these chronic conditions that affects about three million Americans every year and a lot more family, friends, and caregivers regardless of age, sex, race and ethnicity\textsuperscript{42}. With the changing demographics of our country, the faces of epilepsy are changing. While seizures can begin at any age, they are most common in children and the elderly, “with new-onset seizures in older Americans fast outpacing any other segment of our society\textsuperscript{42}.”

Epilepsy is a common neurological disorder that, unfortunately, is largely un-diagnosed and not treated as important by many sectors of our society. Largely misunderstood, epilepsy is a collection of neurological disorders that have different causes, consequences, and outcomes. For many patients, epilepsy can be a “self-limiting” or an easily controlled health problem, but for others, epilepsy can be a lifetime disorder requiring constant treatment and huge resources to manage and prevent, if possible, other disabling physical, social, and cognitive problems\textsuperscript{42}.

Sadly, major shortcomings in our national approach to managing epilepsy exist, including the lack of an agreed upon protocol among HCPs for aggressive control. Many patients accept lack of seizure control as inevitable or unavoidable, and physicians too often endorse a similar philosophy. Unfortunately, those affected may never receive a referral to see a neurologist or, when they do, it is only after many years of uncontrolled seizures. Efforts to stop, prevent and adjust the development of epilepsy must include faster, more aggressive, and systematic care. Our public health system needs a model of specialized care that works better for people with epilepsy. One that ensures that patients in rural areas have the same expectations and quality of care as those in urban America. Because epilepsy affects so many aspects of everyday life, we must also make sure that people obtain the necessary “non-medical” services needed to tackle these problems\textsuperscript{42}. 
For many years, epilepsy, while clearly a chronic illness with both medical and social elements, was not a public health priority. In part, this was due because public health has been traditionally concentrated on tracking sources of infectious disease and related health hazards with a goal of managing and preventing their effects and promoting a healthier society. Nevertheless, as medical care lengthens the lives of the chronically ill, their problems are influencing the social fabric and the character of public health. “The need to track the incidence, prevalence, mortality, health status, quality of life, and social outcomes of chronic disease is now more pressing, requiring the public health community to pay greater attention to these issues, using many of the same strategies with which they formerly monitored infection and its management.”

Despite considerable efforts, the public health community has recognized an ongoing lack of awareness regarding the seriousness of epilepsy and available treatment options among patients with epilepsy, health care providers, and the overall public resulting in delays, disagreements, gaps, and inconsistencies in epilepsy outcomes. Disparities in how patients with epilepsy are diagnosed, educated, and treated are further complicated by the social, economic, and cultural complexities of our society. The critical issues associated with epilepsy need to be re-examined, assessed properly, and managed more effectively by the public health community.

In 2012, the Institute of Medicine (IOM) released *Epilepsy Across the Spectrum: Promoting Health and Understanding*, a report that calls for more public health action on epilepsy. The report makes recommendations for improving and increasing access to care; surveillance and prevention efforts; partnerships; and professional, patient, and public education. For the last couple of years, the public health community, through the work of the Centers for Disease Control and Prevention (CDC), has been paying more attention to epilepsy including its epidemiology, diagnosis, treatment, prevention – as well as the need for greater public awareness.
The core functions of public health, assessment, policy development, and assurance, have been used to improve knowledge and awareness of epilepsy’s impact on both individuals and the greater community and to develop a chain of strategic, evidence-based solutions to the disease.

The *assessment* function of public health has been used to determine what data is needed to identify and address fundamental problems associated with epilepsy, using epidemiological and surveillance methods to observe the extent to which epilepsy affects Americans and the health outcomes experienced by patients\(^42\).

*Policy development* is a central public health function that uses assessment data to identify and adopt effective programs, services, and other health care resources needed for the proper care of patients with epilepsy, and to identify remedial policies and strategies that eliminate barriers to effective care\(^42\).

The *assurance* function of public health is just as critical to assure patients with epilepsy, and their respective caregivers (i.e. family and friends) are getting the programs and health care services they need to manage effectively the challenges of living with an unpredictable, sporadic neurological disorder like epilepsy. Regardless of its impact on the individual and the larger community, epilepsy remains a covert disorder, difficult to measure and, until recently, largely nonexistent in the nation’s public health agenda\(^42\).
2.4 Epilepsy Self-Management

Individuals with epilepsy may experience relatively mild or difficult courses. However, as with all chronic diseases, those affected are challenged to self-manage their treatment and lifestyle behaviors in a way that maintains the highest quality of life possible\textsuperscript{26}. The CDC’s MEW network defines epilepsy self-management as a summation of practices a person uses to optimize seizure control, to minimize the chances of having a seizure, and to maximize quality of life in partnership with their physician\textsuperscript{51,52}. This definition includes aspects of self-management that are specific to epilepsy and chronic care self-management that is applicable to most chronic conditions. Epilepsy self-management comprises three broad areas including treatment management (e.g. adherence to prescribed medication, and clinical visit regimens), seizure management (e.g. preparation for, and response to, seizure episodes), and lifestyle management (e.g. avoiding behaviors that may trigger seizures and/or the adverse consequences of seizures)\textsuperscript{11}.

We can think of self-management in epilepsy as both a process and set of behaviors\textsuperscript{46}. Most commonly, self-management is defined as the steps or behaviors people with epilepsy and/or caregivers use to manage their epilepsy, treatment plan, and the impact of seizures on their daily lives. Self-management is an essential part of patient-centered care that is the keystone of many physicians and epilepsy care centers. The IOM report on epilepsy emphasizes the importance of self-management care as part of epilepsy teams, and within community settings\textsuperscript{49}.

Key factors associated with epilepsy self-management behavior include the patient's understanding of epilepsy self-management and how to perform adequate self-management behavior, and self-efficacy or confidence to perform these behaviors\textsuperscript{53,54,55,56}. Another important aspect of patient self-management is a working partnership between physicians and patients. The IOM report on epilepsy called for the awareness and endorsement of patient-centered and
collaborative methods in the care of epilepsy and comorbid health disorders. With the increasing recognition of the importance of self-management, physicians are frequently asked to help their patients in meeting their self-management needs as part of the patient-centered model of care for people with epilepsy. Disagreement between the patient and physician regarding the patient's feelings and thoughts about epilepsy and self-management capabilities, and/or poor communication between the two can undermine the acceptance of self-management behavior.

Relatively few epilepsy-specific self-management programs have been developed and tested; none have been replicated. All of the programs have demonstrated some positive outcomes, and newer programs show much promise in improving options for the delivery of patient and family education. Studies comparing the effectiveness of generic chronic care versus epilepsy-specific education programs, individually, and in combination, are needed. People with epilepsy and their families should receive access to up-to-date, accurate information about epilepsy and treatment options to assist them in the self-management of their epilepsy. High-quality, validated epilepsy education programs can provide patients with the necessary knowledge and self-management skills to solve problems, make decisions, use resources, develop partnerships with health care providers, and participate actively in patient centered care.

2.5 Preliminary Studies

The motivation for this project began when a team of researchers from the University of Texas, School of Public Health found that patients with epilepsy face similar challenges to self-management, regardless of the patient’s background or characteristics. This led to the development of a clinic-based Decision Support System (DSS) prototype of MINDSET. To date, preliminary research related to the original version of MINDSET has been conducted with mostly non-Hispanic English speaking epilepsy patients. This included an initial usability testing with eight
patients, followed by a clinic-based feasibility trial with 29 patients, followed by a clinic-based efficacy trial at three different clinic sites with 38 patients. Preliminary results were positive, with the majority of patients rating MINDSET favorably on time to complete, helpfulness, likeability, motivational appeal, and perceived impact on thinking about and managing their epilepsy. Patients also rated the quality of interaction with their HCP to be high for items such as “attended to me nonverbally; praised me for things well done; and listened to me and made me feel understood.” Providers mentioned that they would recommend MINDSET to other providers and would continue to use MINDSET in their clinic given the opportunity.

In 2012-13 another field test was conducted on a revised version of MINDSET (Version 3.1) re-designed for longitudinal use over two visits. It included an initial usability test conducted with six patients and three providers from the Patient-Provider advisory group (PPAG) followed by a feasibility test with a small sample of patients (n=24) at three clinic sites over two visits. The longitudinal test of MINDSET demonstrated functionality for patients to enter epilepsy management data; to provide a printable action plan tailored to the patient’s self-management goals; and to track the change in the patient’s self-management behavior over time.

While not powered to assess impact, reported behavioral problems between clinic visits were found. Most favorable patient feasibility ratings were: 1) appropriate time duration for data entry; 2) minimal disruption to clinic visits; 3) useful and motivational. Least favorable ratings were for understandability. Patients needed more explanation and clarification for some questions with novel content. Findings of implementation indicated that MINDSET is feasible and useful for identifying and discussing self-management issues, for assessing changes in behaviors over time, and for developing a tailored action plan as part of a regular clinic visit.
CHAPTER 3: METHODOLOGY

The organization of Chapter 3 is as follows: a description of the research design used for this study, description of research locations, research team, study population, data collection measurement instruments, procedure, and analysis.

3.1 Research Design

*Intervention Mapping* (IM), a stepped protocol using theory, empirical evidence, community input, and participant involvement to systematically develop, implement, and evaluate health promotion programs was used to guide the research design of this study. Intervention mapping provides public health program managers with a systematic design procedure for effective decision making during each phase of the intervention development process\(^\text{57}\).

The methods and procedures used in intervention mapping provides a system that allows for the integration of theory, empirical evidence, and information collected from the target population (i.e. patients with epilepsy). This framework represents an innovation for the practice of public health. Intervention mapping consists of five steps: 1) creating a model of program objectives, 2) selecting theory-based intervention practices and practical strategies, 3) program design, 4) outlining implementation plans, and 5) creating program evaluation plans\(^\text{57}\).

Linking intervention mapping with participatory health research is beneficial for identifying and improving culturally appropriate and theoretically sound interventions. By engaging a team of health care providers, academic researchers, and patients in the development of MINDSET, this study was able to adapt the new Spanish version of MINDSET, by matching it to the particular needs of the Hispanic community in the delivery setting. It also ensured external validity and improved the likelihood of dissemination and use by practitioners and patients.
Employing a custom IM protocol, the following five steps guided the planning and development of MINDSET. First, an examination of the problem (i.e. the prevalence of epilepsy within the Hispanic community and the identification of self-management “risk” factors unique to the community). Second, review and selection of clinical based-guidelines and theory-based intervention methods, and practical strategies to improve epilepsy self-management. Third, the software development for MINDSET (i.e. programming and technological features). Fourth, adoption and implementation of MINDSET (i.e. diagnoses and shared-treatment plan between patients and physicians). Fifth, program evaluation and modification based on patient feedback.

Intervention Mapping is meant to make the steps in planning interventions clear enough to explain the process to enable collaborative planning by individuals of varying credentials. The philosophy of health education and promotion is built on the principle of self-determination of people and communities through empowerment and the capacity-building effects of participation in health decisions. For MINDSET we describe program development as requiring a connection between a resource system (physicians), an intermediate user system (research staff), and an end user system (patients)58-59. The relationship can lengthen the range from inclusion of prospective program participants and intermediary operators as planning team members, through a community empowerment model in which patients are the planners.

The steps of the intervention mapping framework for the MINDSET program are illustrated in Figure 4. Each step requires performance of several specific tasks leading to a product that provides the basis for the subsequent steps. The result is the intervention "map," consisting of matrices and plans that guided the design, implementation, and evaluation of MINDSET. Guided by this systematic intervention design approach, MINDSET has the potential to help patients with epilepsy in the self-management of their seizures.
MINDSET was designed following intervention mapping principles\textsuperscript{60} in collaboration with a Patient-Provider Advisory Group (PPAG) comprised of patients with epilepsy and their HCPs. MINDSET is theoretically and empirically based on social cognitive theory\textsuperscript{61}, self-regulation models\textsuperscript{62,63}, the 5-A's model of behavior change\textsuperscript{64}, motivational enhancement therapy\textsuperscript{65}, quality-of-care criteria and clinical guidelines for epilepsy\textsuperscript{66,67,68,42}, and formative studies\textsuperscript{69,70}. Its development was informed by a literature review that looked at the epilepsy prevalence among the Hispanic community; an analysis of epilepsy self-management “at-risk” behaviors; a review of existing decision support systems; and an analysis of two previous pilot studies\textsuperscript{71,72,73,74}.

“MINDSET has been developed as a healthcare innovation tool aimed at providing real-time self-management decision support to patients (N=18 years) diagnosed with epilepsy and their HCPs in the context of their clinic visit”\textsuperscript{72,73}. MINDSET is a tablet-based clinical questionnaire mounted on a portable computer tablet based on a Windows operating platform.

MINDSET is designed to promote shared decision-making where a patient and HCP can assess the need for improvements (both medical and psychosocial) and make subsequent informed treatment and behavioral change decisions. MINDSET assesses self-management in three domains including: 1) seizure management (seizure history and frequency) and seizure behaviors; 2) medication-management (current anti-seizure medications, side effects, medication adherence, adherence barriers, and other behaviors); 3) lifestyle-management (including mood, social life (physical activity, safety, record keeping, social support, and clinic visits)). MINDSET comprises three steps: 1) patient data entry 2) patient review of any flagged “at-risk” behaviors” and selection of goals and strategies to overcome these behaviors, 3) provider data review, and 4) patient and provider discussion of issues, goals, and strategies.

(See Chapter 4: Software Development for a detailed description of the flow of MINDSET).
Figure 4: Intervention Mapping Process of MINDSET

#1) Examination of the Problem
- Prevalence of Epilepsy Among Hispanics
- Social, Cultural, Economic Barriers to Care
- Identification of Self-Management "At-Risk" Behaviors
  (i.e. Seizure, Medication, and Lifestyle)

#2) Selection of theory-based intervention methods and practical strategies
- Theoretical Framework: Quality of Care and Clinical Guidelines
- Conceptual Framework: Healthcare Innovation

#3) Software Development
- Assessment and Modification of MINDSET
- New Module Addendum (My Goals and Strategies)
- Redesigned Action Plan
- Software Design, Interface, Encoding, Technological Features

#4) Adoption and Implementation of MINDSET
  *Clinical Application: Diagnose and Shared-Treatment Plan
- My Epilepsy
  *Screening Questionnaire
  *Identification of "at-risk" behaviors
- My Goals and Strategies
  *Physician recommended goals and strategies
- Action Plan
  *Social Contract (patient/provider)

#5) Program Evaluation
- PPAG (i.e. patient and HCP feedback)
3.2 Description of Research Locations *(Clinical Sites)*

This is a multi-site collaborative study involving researchers and clinicians at the University of Arizona (UA), UT School of Public Health Houston (UTSPH), and the Epilepsy Foundation of Central and South Texas (EFCST). This study was conducted with epilepsy patients in treatment at three clinics in Arizona (UA Banner Health, Alvernon, La Cholla, and South Campus Clinics) and two in Texas (EFCST, Harlingen and San Antonio Clinics).

The University of Arizona’s Banner Health Network has a number of clinics in Arizona, with the South Campus and Alvernon locations in Tucson serving the largest number of Hispanic patients. Across the two clinics, approximately 30% of Hispanic patients prefer to speak Spanish, with the majority of the Hispanic Spanish-patients seen at the South Campus site. Patients are diverse in terms of age and socioeconomic status.

The participating Texas clinics are in Harlingen and San Antonio, and managed by the Texas affiliate Epilepsy Foundation of Central and South Texas (EFCST). The clinics in Harlingen and San Antonio are outreach clinics for indigent persons with epilepsy in the EFCST service area (Central and South Texas) who do not otherwise have access to specialized medical care. The majority of the patients at both of these locations are Spanish speaking. The San Antonio clinic sees about 10 patients per day and the Harlingen clinic about 35 patients per day.
3.3 Study Population Eligibility Criteria, Patient Recruitment, and Informed Consent

A total of 16 patients were recruited to participate in the study. Of these 16 patients, eight were recruited from the Banner-UHC and eight from the UT-EFTX clinics. Inclusion criteria for potential participants included male or female Hispanic patients with a diagnosis of epilepsy. Inclusion criteria also included participants 18 years of age or older, who were willing and able to complete the screening tool. Participants with other medical disorders, motor impairments, learning difficulties, and/or psychiatric/behavioral problems were not eligible to participate as these conditions could have inhibited their ability to use the tablet, complete surveys, or practice self-management activities. For tests involving the Spanish MINDSET, participants had to be fluent Spanish speakers.

Physicians identified patients at each of the participating clinic sites. Physicians were asked to review patients scheduled for medical appointments, determine if they met the eligibility criteria of the study, and to send letters to the patients inviting them to participate in the study. In the letter, the patients were asked to call or return a signed “consent to contact” form if interested in being called by a member of the research staff with more information about the study. If the form or a phone call was returned by the patient(s), research staff then explained the study to them and sent consenting documents for the patient to review.

Upon arrival, patients were advised about informed consent procedures and the use of the MINDSET tablet. All patient questions were answered and all informed consent documents were signed before the beginning of the study. Patients were advised that refusal to be in the study would not in any way impact their regular treatment. They were informed that they had the right to refuse to participate, could withdraw at any time, and that withdrawal would not adversely impact their current right to medical care.
3.4 Data Collection Measurement Instruments and Analysis

This section will return to the original roots of the research questions and the hypothesis introduced in Chapter 1 and will explain the data sources and methods used to answer these questions and test the study hypotheses in relation to the usability of MINDSET.

This study merges quantitative and qualitative data to evaluate patient perceptions on the usability of MINDSET. Self-reported data describing patient epilepsy characteristics, self-management behavior, confidence, seizure frequency, current prescription(s) plan, medication side effects, and depression symptoms was collected from patients via data entry embedded in MINDSET and a written questionnaire and interview. After the clinic visit, usability data from the program was collected at the end of the study, using written surveys administered to the patients and providers. Informed consent forms were obtained for the analysis of tablet and interview data collected during the PPAG (i.e. clinic visit).

Quantitative data and descriptive analysis was performed to evaluate patient perceptions of the usefulness, practicality, credibility, likability, and understandability of the MINDSET program. This analysis provided basic summaries about the sample and the measures. Together with graphics analysis, they formed the basis of virtually every quantitative analysis of data. Quantitative data for this study was assessed using descriptive measures of central tendency.

Quantitative and qualitative research differ somewhat in their approach to data analysis. In quantitative research, data analysis most often occurs after all or much of the data in a research study has been collected. Please note that because this project only includes the usability-testing of the larger MINDSET study, analysis for the quantitative data will be limited as the feasibility and efficacy-testing phases of the larger MINDSET study are still in progress.
The qualitative data for this study was analyzed using an inductive thematic-content approach. “There are two fundamental approaches to analyzing qualitative data (although each can be handled in a variety of different ways): the deductive approach and the inductive approach. Deductive approaches involve using a structure or predetermined framework to analyze data.” In contrast, the inductive approach consists of analyzing data with minimum or no predetermined theory, structure or framework and uses the actual data itself to determine the structure of analysis. This approach is comprehensive and therefore time-consuming and is most suitable where little or nothing is known about the study phenomenon. This is the case for MINDSET as the first of its kind computer-based decision support system for patients with epilepsy.

This study will use an inductive approach for analyzing the evaluation data collected with the purpose of proving a simple and direct approach for determining findings in the context of the evaluation questions that patients were asked. While there are a variety of inductive approaches available for analyzing qualitative data, the method of analysis described in this paper is that of thematic content analysis, and is, perhaps, the most common method of data analysis used in qualitative work. Thematic content analysis is often very similar in all types of qualitative research, in that the process involves analyzing transcripts, identifying themes within the data and gathering together examples of those themes.

3.4.1 Patient Demographics

Patient demographic data was collected by survey questionnaire before the visit. Patient demographics was collected using a modified 20-item survey evaluating the patient's gender, age, race/ethnicity, epilepsy status (seizure frequency), education, marital status, income, health insurance coverage, employment, and computer experience.
3.4.2 Clinical Measures (Self-Management Behavior, Depression Adverse Events)

Epilepsy self-management questions were embedded into MINDSET using the 38-item Epilepsy Self-Management Dilorio Scale\(^53\). The Dilorio scale evaluates seizure management, medication management, and lifestyle management. Responses to the self-management questions are entered using a button selection on a 5-point Likert scale ranging from ‘never’ to ‘always.’\(^26\).

Patient negative affect and depression is assessed using the 6-item Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) Screening Tool embedded in MINDSET\(^76, 77, 78\). The response set is a 4-point Likert scale ranging from ‘never’ to ‘always’ or ‘often’. Patients are prompted to provide the answer that best describes them over the last 2 weeks for ‘everything is a struggle’, ‘nothing I do is right’, ‘I feel guilty’, ‘I’d be better off dead’, ‘I feel frustrated’, and ‘I had difficulty finding pleasure’. An NDDI-E score of more than 15 indicates that a patient may have depression. Patient adverse drug effects are assessed using an adapted 19-item Epilepsy scale.

An Adverse Events profile embedded in MINDSET measures reported problems during the previous four weeks from a list of 19 adverse effects (unsteadiness, tiredness, restlessness, aggression, nervousness, hair loss, skin changes or rash, blurred vision, upset stomach, concentration difficulty, mouth/gum problems, shaky hands, weight gain, dizziness, sleepiness, depression, memory problems, and disturbed sleep)\(^79\). The original instrument uses a 4-point Likert scale response set: 1=never a problem, 2=rarely a problem, 3=sometimes a problem, and 4=always a problem\(^80, 81\).

“The ability of the tool to measure clinical epilepsy characteristics and self-management behaviors over time included documenting and comparing the number of seizures, at-risk self-management behaviors, depressive symptoms score, number of missed doses of medications, and number of medication side effects during the two visits”\(^90\).
<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
<th>Source/ Citation</th>
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<tr>
<td>Epilepsy Self-management Scale</td>
<td>38 items with Likert scale response format assessing frequency of epilepsy self-management practice in 5 management domains (medication, information, seizure, safety, and lifestyle). Cronbach’s alpha: 0.81-0.84.</td>
<td>Diorio et al., 1992&lt;sup&gt;27&lt;/sup&gt;, 1994&lt;sup&gt;26&lt;/sup&gt;, 2003&lt;sup&gt;17&lt;/sup&gt;, 2004&lt;sup&gt;28&lt;/sup&gt; (See Appendix D)</td>
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<tr>
<td>Neurological Disorders Depression Inventory for Epilepsy (NDDI-E)</td>
<td>6 item scale with Likert response format assessing frequency of depressive symptoms within the last week (range: 1-4, “never”, “rarely”, “sometimes” and “always or often”) providing a total NDDIE score (range 6 – 24). A scores ≥ 15 indicates depression (specificity: 90%, sensitivity: 81%; and positive predictive value of 0.62). Cronbach’s alpha:0.85, test-retest reliability: 0.78.</td>
<td>Gilliam et al., 2006&lt;sup&gt;77&lt;/sup&gt;; Friedman 2009&lt;sup&gt;76&lt;/sup&gt;; NIDDI-E, 2010&lt;sup&gt;41&lt;/sup&gt;</td>
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<tr>
<td>Adverse drug effects</td>
<td>Adapted 19-item Epilepsy Adverse Events scale assessing reported problems during the previous four weeks from a list of 19 adverse effects (unsteadiness, tiredness, restlessness, aggression, nervousness, hair loss, skin changes or rash, blurred vision, upset stomach, concentration difficulty, mouth/gum problems, shaky hands, weight gain, dizziness, sleepiness, depression, memory problems, and disturbed sleep). The original instrument uses a 4-point Likert scale response set: 1 (never a problem) to 4 (always a problem). Score range: 19 to 76. Cronbach’s alpha: 0.90 (baseline) and 0.91 (3-month follow-up).</td>
<td>Panelli et al., 2007&lt;sup&gt;30&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
3.4.3 Patient Perceptions of Usefulness (Usability Questionnaire and Exit Interview).

Data on perceived usability was gathered from patients participating in the PPAG meetings using written surveys. A quantitative usability questionnaire and an open-ended qualitative exit interview were collected from participants who tested MINDSET. Both, the usability questionnaire and the exit interviews were collected from patients at the end of the PPAG meeting(s).

Usability (i.e. practicality) was assessed using a revised 19-item survey adjusted to correspond with the MINDSET functions. “Usability parameters including likability, credibility, understandability, usefulness, and motivational appeal were assessed using adapted Likert scale ratings (n=19)”82. Likability was measured for the MINDSET program including design elements of color, buttons and sliders, and the tablet platform using a 5-point Likert scale ranging from 1 (dislike a lot) to 5 (like a lot). Likability was also measured on whether or not the time it took to use MINDSET was too long, just right, or too short. Credibility was evaluated on whether the content could be trusted (can be trusted, cannot be trusted, and do not know) and whether it was helpful (helpful, not helpful, and do not know). Understandability was evaluated on whether the words used were understandable and if help was required from others to be able to use MINDSET.

Usefulness was measured on whether MINDSET was more, as, or less useful than other surveys or seizure programs used in the clinic26. “Perceived impact was assessed using 5 items with a 3-point Likert scale (yes, no, and do not know) assessing the impact of MINDSET to aid thought about epilepsy management (The information in this section helped me to think carefully about my epilepsy), aid in managing epilepsy in the present (I think the information provided in MINDSET will help me better manage my epilepsy) and in the future (I think the information provided in this section will help me manage my epilepsy better in the future), and aid in communicating with the HCP (I think the information provided in this section will help me talk to
my doctor or nurse about my epilepsy). Motivational appeal was assessed by determining if the patient would recommend MINDSET to another patient or patients or use MINDSET again themselves using a 3-point Likert scale (‘yes’, ‘no’, and don’t know)\textsuperscript{26,90}.

The Usability questionnaire consisted of summarizing patient perceptions on the ease of use and usefulness was based on the portion of patient agreement with positive statements and disagreement with negative statements on the ease of use, duration, credibility, understandability, attitudes about its effect, usefulness, motivational appeal, and likability\textsuperscript{90}. The communication scale score, shared decision-making scale score, and concurrence checklist were examined to assess the quality of the communication between the patient and their healthcare provider. Patient views of communication and shared decision-making using MINDSET were assessed by examining the mean scores on each item\textsuperscript{90}.

\textbf{3.4.4 Health Care Provider Feature Checklist and Exit Interview}

The perceived usability of MINDSET by physicians was obtained at the end of the study using a 4-item adapted usability scale that compares the experience of using MINDSET in the clinic to not using MINDSET for managing patients with epilepsy in general and in four management domains: identifying seizure, medication, and lifestyle problems among each of their patients; identifying patient goals, strategies, and barriers for achieving optimal self-management behaviors; developing an action plan for patients to assist them in improving their epilepsy self-management “at-risk” behaviors; and improving communication and shared-care decisions among patients\textsuperscript{83}. “For each domain, a 5-point (range: 1–5) semantic differential scale was used to measure the following: ease (easier/harder), time (less time/more time), thoroughness (more thorough/less thorough), accuracy (more accurate/less accurate), and communication (improves communication/interferes with communication)”\textsuperscript{26}.
<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Demographic Questionnaire</td>
<td><strong>Patient variables</strong>: Gender, race/ethnicity, age, epilepsy symptoms status. &lt;br&gt;<strong>Provider variables</strong>: gender, race/ethnicity, age, and professional experience. (See Appendix E-1: Demographic Questionnaire)</td>
</tr>
<tr>
<td>3. MINDSET</td>
<td>Epilepsy self-management questionnaire embedded in MINSET. (See Table 1. Outcome Measures Embedded in MINDSET) &lt;br&gt;(Appendix D-1: Epilepsy Self-Management Scale by Dilorio)</td>
</tr>
<tr>
<td>4. Usability Questionnaire</td>
<td>Patient Perceptions of Use and Usefulness (Appendix E-2: Usability Questionnaire)</td>
</tr>
<tr>
<td>5. Exit Interview</td>
<td>Open-ended interview for patients and providers on their experiences with MINDSET (including usability, impact, and recommendations for future use) based on 12 open-ended questions, adapted from correlates of technology acceptance. (Appendix E-3: Exit Interview)</td>
</tr>
<tr>
<td>6. Clinic Visit Interaction Checklist</td>
<td>Adaptation of a 12-item Likert scale assessing provider communication in the clinic visit context. (Appendix E-4)</td>
</tr>
<tr>
<td>7. Healthcare Provider Questionnaire</td>
<td>HCP questionnaire on their experience with MINDSET using a 4-item adapted usability scale that compares the experience of using MINDSET in the clinic to not using MINDSET. (APPENDIX F: Health Care Providers Questionnaires)</td>
</tr>
</tbody>
</table>
CHAPTER 4: SOFTWARE DEVELOPMENT

This chapter will discuss the steps taken to develop the new version of MINDSET, including the medical content, user design and interface, translation, encoding, programming, and other technological features. The Usability Testing (i.e. execution, usefulness, functionality, practicality, and credibility) of MINDSET will be discussed later in Chapter 5.

4.1 Step 1: Assessment and Modification (My Epilepsy)

In Step 1, the epilepsy self-management assessment questionnaire (My Epilepsy) was revised by integrating systematic reviews from eight members of the research team. These included experts in communication technology, behavioral science, public health, and neurologists specializing in the clinical management of epilepsy. Based on an initial assessment of the original version of MINDSET, we developed a culturally appropriate approach for the planning of the Spanish version of MINDSET. The revised script included a self-management questionnaire tailored specifically to Spanish speaking patients within the Hispanic community. The questions were designed to be clear, relevant, and understandable for the average adult with epilepsy.

The first section of MINDSET (My Epilepsy), is comprised of three validated assessment scales related to epilepsy self-management, including: 1.) seizure history, frequency, symptoms of depression, current prescription(s) and side effects; 2.) patients’ adherence to medication management; 3.) patients’ lifestyle management as it relates to their seizure disorder and any possible seizure triggers (see Table 1: Clinical Measures Embedded in MINDSET). MINDSET then compares the patient’s responses to benchmarks drawn from the literature and vetted expert consultants and provides a summary of “at-risk” items that require improvement for achieving ideal behaviors that may help patients reduce their seizure frequency.
4.2 Step 2: New Module Addendum (My Goals and Strategies)

In Step 2, a new module (My Goals) was created for prioritizing patients’ at-risk behaviors for improvement (Fig 9-A). A comprehensive list of suggested behavioral goals and strategies to assist patients in overcoming self-management barriers was created. Goals and strategies were developed for every at-risk behavior(s) identified by a patient in Step 1 of the program (i.e. My Epilepsy) as a recommendation for improving their self-management.

The new module lists all of the at-risk items in each of the three self-management domains and prompts the patient to identify one Goal in each of the domains for improvement before their next clinic visit (Fig 11-12). The patient is then asked to select from a list of behavioral strategies suggested by the HCPs to meet these goals. The patient is then asked to estimate his/her confidence to perform these behaviors; lists any barriers for achievement and brainstorms strategies to overcome the barriers. The behavioral goals were created around the primary aim of the study, that is, to help patients improve the self-management of their epilepsy.

Selection of these performance goals was informed by the literature review and by the input of the physicians participating in the study\textsuperscript{84}. Determinants of behavioral change (i.e. social cognitive theory\textsuperscript{85} and self-determination theory\textsuperscript{86}) guided the selection of the psychological constructs to support change in patients’ behavior to meet their selected goals. Social cognitive theory and self-determination theory were selected, as both have proven to be useful in the development of effective behavioral change interventions in\textsuperscript{87,88}. Social cognitive theory identifies several constructs that influence learning and the adoption of new health behaviors\textsuperscript{89}. Self-determination theory focuses directly on what motivates people to change behaviors. Specifically, the goals designed for this study were based on competence and behavioral capacity (skills), self-efficacy, expectations and expectancies (attitudes and beliefs), autonomy, and social support.
4.3 Redesigned Action Plan

Step 3 involved the design of an Action Plan which includes a summary of the patient responses to the self-management questionnaire; “at-risk” behaviors in each of the three epilepsy self-management domains; and the goals and strategies selected by the patient.

For each of the three self-management domains, the revised action plan provides a report of the patient's “at-risk” behaviors, presents the goal and the strategies selected by the patient to overcome the “at-risk” behavior(s), provides a blank space for the patient to list any barriers that he/she may have for achieving their selected goals, and lastly provides a blank space for the patient to record any other questions or comments that he/she may have for their physician.

The action plan can be reviewed on the tablet but two copies of the report are printed (i.e. one for the patient and another for the physician) to review in the clinic room. The patient and the physician can then use the Action Plan to engage in discussion and shared decision-making regarding confirmation of optimal behavior, the need for behavioral change, and goal setting.

The revised action plan also includes a longitudinal tracking and comparative reporting function to monitor self-management behaviors over time. The patient's responses on self-management behaviors at each clinic visit are compared to their responses during the previous visit. The action plan then indicates whether self-management behaviors improved, did not change, or worsened. The Action Plan was ultimately designed to be used as a social contract between patients and their physicians, where a patient commits to improve any “at-risk” item(s) that may need improvement (Fig. 15).
4.4 Software Design, Interface, Encoding, and Technological Features

In Step 4 (Software Design, Interface, and Technological Features), the newly revised English version of MINDSET was programmed into the computer software to be used by any Windows operating system. During this phase of the project I worked closely with a team of computer software developers to redesign the interface and technological features of the original version of MINDSET (informed by literature review and input from the research team). During this part of the project, I also worked with the software development team to rewrite and streamline the existing version of the Action Plan as described in the previous section (4.3).

4.5 Programing and Alpha Testing of the new version of MINDSET

When the final script of the revised English version of MINDSET was completed, I oversaw the programming activities in liaison with Radiant LLC (a Texas based IT development and consulting firm), conducting formative evaluations of the program prototype during development. Once the software developers completed the re-programming of the MINDSET application, I conducted an extensive alpha-test (i.e. a form of in-house acceptance testing) of the program to identify any issues with both the content and the technological features of the program before testing it with the patients.

The research team (i.e. physicians and neurology staff) from Arizona and Texas were asked to participate in the alpha-testing of the program to help identify and address any issues and problems with the program. Upon completion of the Alpha test, I advised Radiant of any technical related problems that need correction. Radiant then made the requested changes to the program prior to the usability testing of the program with patients.
4.6 Spanish Translation, Programming, and Alpha Testing

The final step before developing the Spanish version of MINDSET was to carefully test the revised English version of the program within the research team. Once the new English version of MINDSET was tested and finalized, the content of MINDSET was downloaded as an XML document for translation into Spanish. I was responsible for the original translation of the program and a back-translation will be conducted by the UT research team. Once correspondence is achieved between the versions, the Spanish documents will be tested for understandability and readability. All of the study instruments will also be back-translated and tested with the PPAG before field trials. Once the Spanish-script was translated, I oversaw the programming activities in liaison with Radiant, conducting formative evaluations of the program prototype during development. After Radiant completed the programming of the Spanish version of MINDSET, I conducted the same extensive alpha-test of the program to identify any issues with both the content and the technological features of the program.

MINDSET 4.1 (English and Spanish) consists of both improved and new features to increase patient self-management and communication: The revised script resulted in a Flesch-Kincaid Grade Level of 5.7 for My Epilepsy (Table 3). The Flesch–Kincaid readability tests are tests designed to indicate how difficult a passage in English is to understand. The Flesch-Kincaid Grade Level means the number of years of education required to understand this text.

<table>
<thead>
<tr>
<th>Table 3: MINDSET Readiness Flesh-Kincaid Grade Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flesch Reading Ease</td>
</tr>
<tr>
<td>Flesch Kincaid Grade Level</td>
</tr>
</tbody>
</table>
4.7 Visual Narrative: Clinical Flow, Questions, and Technical Functions

Figure 5: MINDSET Screen Shot (Introduction and Log-in)

- Home screen
- Welcome Screen and instructions
- Patient is prompted to select the language of their choice (i.e. English or Spanish)
- For security and patient confidentiality, each patient was assigned a unique user identification number.
Part 1, “My Epilepsy”, asks patients a series of questions related to their seizure history and the self-management of their epilepsy.

Seizure History questionnaire asks patients a series of questions related to their seizure types, activity, symptoms.

Attached is an example of a Seizure History question (e.g. seizure frequency and symptoms).
**Figure 7: MINDSET Screen Shot (Seizure Management)**

Seizure Management section, asks patients a series of questions related to the self-management of their epilepsy including any behaviors that may help improve or worsen seizure frequency.

Attached are two examples of some of the questions in the Seizure Management (e.g. seizure triggers).
Figure 8: Medication Management

Attached are two examples of some the questions in the Medication Management section, asking patients a series of questions related to the self-management of their seizure medication(s).
Figure 9: Lifestyle Management

*Lifestyle Management* section asks patients a series of questions related to lifestyle behaviors that may trigger seizures or avoid their occurrence.

Attached are two examples of *Lifestyle Management* questions (e.g. sufficient sleep, exercise, regular healthy diets).
Patient depression is assessed using the Neurological Disorders Depression Inventory for Epilepsy (NDDI-E) Screening Tool.

Attached is an example of the Depression questionnaire.
Note: These questions are included in the Lifestyle Management section.

Patients are prompted when they complete the 1st part of the program, “My Epilepsy”.

Figure 10: Neurological Disorders Depression Inventory for Epilepsy (NDDI-E)
Part 2, “My Goals”, compares the patient's responses to medical benchmarks and provides a summary of “at-risk” items that require improvement for achieving ideal behaviors that may help patients reduce their seizure frequency.

If patient has no “at-risk” behaviors the system will congratulate the patient for managing their seizures well.

Space is provided to give patients the opportunity to ask any other questions or concerns that they would like to discuss with their doctor.
My Goals Selection w/ “At-Risk” items

My Goals lists all of the “at-risk” behaviors in each of the three self-management domains and prompts the patient to select one of the behaviors as a goal for improvement before their next clinic visit.

Patient is asked to select from behavioral strategies to meet their selected goal in each of the three domains.

Patient is then asked to estimate his/her confidence to perform these behaviors and achieve their selected goal.
Part 3, “My Plan”, provides the patient with a summary of their responses to the questions in the first part of the program (i.e. My Epilepsy) and the goals and strategies that they selected in part 2 (i.e. My Goals).

Patients are given the option of printing a copy of the report in the language of their choice. A copy of the report is printed in English and attached to the patient medical file.

The first page of the report (i.e. My Epilepsy) includes a summary of the patients’ seizure history, their current medications, and their responses to the epilepsy self-management questionnaire.
Figure 14: Summary of Self-Management Goals (in each of the 3 domains)

The last three pages of the Action Plan report will include a brief summary of the patients’ responses to the self-management questions in each of the three domains (i.e. seizure, medication, and lifestyle) and the goals and strategies that were selected for improvement.
Figure 15: My Action Plan Printout

The first page of the Action Plan includes a summary of the patient's seizure history, current prescription plan, and their responses to the self-management questions.

Pages 2-4 includes a summary of the self-management behavioral Goals that the patient selected for improvement before their next clinic visit. These pages also include a summary of the list of strategies that the patient selected to achieve their goals and the level of confidence in achieving their goals. Lastly, each page includes an open space for the patient to write-in any additional questions or comments for their physician that might not have been covered in the program.
CHAPTER 5: USABILITY TESTING AND ANALYSIS

5.1 Usability Testing of MINDSET

This chapter will discuss the usability testing (i.e. user friendliness, usefulness, practicality, functionality, applicability, and credibility) of MINDSET and will provide an analysis of its perceived health benefits among Hispanic Spanish-speaking patients. The usability study of MINDSET was designed following intervention mapping principles in collaboration with a Patient-Provider Advisory Group (PPAG) comprised of patients with epilepsy and their physicians. Please note, the terms “usability testing” and “PPAG” will be used interchangeably.

Four different PPAG group meetings were coordinated during the two years of the project to evaluate the technical and medical related content of MINDSET, including: software layout, self-management questionnaire, and the user-friendliness of the program. Each of the four PPAG groups was composed of four different Hispanic-patients and one physician. The meetings were conducted with patients and physicians from both Arizona and Texas clinic locations. Patients who participated in the first two usability trials were asked to test and evaluate the newly revised English version of MINDSET (4.1) and to provide feedback on needed revisions before translating the content to Spanish. Patients participating in the last two usability trials were asked to test and provide feedback to the newly translated Spanish version of MINDSET.

A total of 16 patients were recruited to participate in the study from four different neurology clinics near the U.S.-Mexico border in Arizona and Texas (n = 16). Eligible patients were identified by the physicians at each of the participating clinic sites. Physicians were asked to review patients scheduled for medical appointments, determine if they met the eligibility criteria of the study, and to send letters to the patients inviting them to participate in the study. In the letter, the patients were asked to call or return a signed “consent to contact” form if interested in being
called by a member of the research staff with more information about the study. If the form or a phone call was returned by the patient(s), research staff then explained the study to them and sent consenting documents for the patient to review. Patient PPAG members were offered a $30 incentive for participating in the study.

The patient-provider advisory groups were conducted in “laboratory” conditions and were not associated with the patients’ regular clinic visit. Patients were asked to complete an informed consent form prior to the beginning of the study. Informed consent forms included permission to obtain and analyze data collected during the study. Prior to beginning with the usability testing of the program, patients were provided with a brief literature review of epilepsy self-management and informed of the primary purpose and the goals of MINDSET. Each meeting lasted 2-3 hours.

Patients participating in the first two usability trials were asked to test the newly revised English version of MINDSET (4.1). The first usability test was held in Arizona with four patients (n=4) and the second usability test was held in Texas with four different patients (n=4). After an initial orientation of the MINDSET, patients were asked to access all of the elements of the program including the patient profile, medical and seizure history, self-management data, goals, strategies, and the action plan. Patients were encouraged to describe, verbally, their opinions and attitudes about the program during the test. I made notes of any problems or issues with the program during the test but restrained from helping patients, unless patients asked for assistance.

Based on the PPAG reviews from the first two usability trials, several adjustments were made to improve the understandability of the program and lower data entry burden based on patient feedback. The revised content was then translated into Spanish prior to conducting the usability testing of the Spanish version of the program. Two additional usability studies were then organized using a different cohort of Spanish-speaking patients to test the new Spanish version of MINDSET.
Patients participating in the last two PPAG groups (n=8) were asked to test the new Spanish version of MINDSET. The third usability test was held in Texas with four new patients (n=4) and the fourth usability test was held in Arizona with another four different patients (n=4). Patients participating in the Spanish usability trials were required to speak Spanish. As with the previous PPAG trials, patients were asked to access all elements of the Spanish MINDSET program and to provide feedback on the usability of the program.

After completing the program, patients completed a usability survey and exit interview rating program satisfaction, Spanish language terminology, ease of use, acceptability, credibility, and the applicability of the program to their medical needs. At the end, there was an open discussion with patients about potential enhancements to help improve the functionally and user experience with the system. Note that statistical significance is not required to determine major usability problems.

**Figure 16: PPAG Study Patients**
5.3 Study Demographics

In the usability study, patients were mostly female (62.5%), 19 to 70 years of age ($\bar{x}=45.4$ years), Hispanic (100%), with mean age at diagnosis of 13.3 years, and reported seizures in the last 12 months at 87.5%. Most (62.5%) reported more than one seizure per month and 12.5% had been seizure free in the last 12 months. Most had insurance (6.25%) or were on Medicaid (68.75%).

Table 4: Demographics and Insurance Coverage

<table>
<thead>
<tr>
<th>Category</th>
<th>PPAG (English)</th>
<th>PPAG (Spanish)</th>
<th>Total Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>N (%)</td>
<td>(n=16)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-40</td>
<td>6 (75.0)</td>
<td>6 (75.0)</td>
<td>12 (75.0)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>2 (25.0)</td>
<td>2 (25.0)</td>
<td>4 (25.0)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2 (25.0)</td>
<td>4 (50.0)</td>
<td>6 (37.5)</td>
</tr>
<tr>
<td>Female</td>
<td>6 (75.0)</td>
<td>4 (50.0)</td>
<td>10 (62.5)</td>
</tr>
<tr>
<td><strong>Race/ Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>8 (100.0)</td>
<td>8 (100.0)</td>
<td>16 (100.0)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Insurance Coverage</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individually purchased insurance</td>
<td>2 (25.0)</td>
<td>0</td>
<td>2 (12.5)</td>
</tr>
<tr>
<td>Medicaid Medicare</td>
<td>6 (75.0)</td>
<td>5 (62.5)</td>
<td>11 (68.75)</td>
</tr>
<tr>
<td>Employer provided insurance</td>
<td>0</td>
<td>1 (12.5)</td>
<td>1 (6.25)</td>
</tr>
<tr>
<td>No coverage</td>
<td>0</td>
<td>2 (25.0)</td>
<td>2 (12.5)</td>
</tr>
</tbody>
</table>

* PPAG Visit 1 (n=8); PPAG Visit 2 (n=8)
5.4 Results: Patient Perceptions of MINDSET

After an orientation to MINDSET, completing the data entry section, and reviewing the profile and action items, the patients were asked to rate usability on parameters of likeability, usefulness, thoughts about impact, understandability, durability, and credibility. Patients were then asked to offer recommendations for improvement. Usability ratings were largely favorable (range of agreement with positive statements: 75%–100%). A number of adjustments were made to MINDSET to improve understandability based on the PPAG review.

Patients rated the time taken to use MINDSET as appropriate (75-100%) and mostly agreed that MINDSET was helpful (87.5%), enjoyable (62.5-100%), and understandable (75-100%). Patients perceived MINDSET as having a positive impact on how they think about, control, and manage their epilepsy (75-100%). All of the patients understood and found positive use of the action plan (100%). MINDSET was perceived as minimally disruptive by patients though the range of agreement for Spanish-MINDSET’s motivational appeal varied widely (25-75%). Participants expressed comfort with using MINDSET, felt it was thorough, and indicated that they would recommend it to other patients with epilepsy.

MINDSET was positively rated by patients on usability factors including: likability, usefulness, thoughts about impact, understandability, durability, and credibility. Patients rated MINDSET favorably on all usability features (Table 5). Most patients rated MINDSET as likable (75–100%), credible (87.5–100%), useful (75–87.5%), and appealing (62.5–100%). Patients perceived MINDSET as encouraging better thought about self-management behavior, and improved communication. MINDSET was seen as impactful in thinking, managing, and talking about epilepsy self-management (62.5–100.0%). The words used in MINDSET were rated as understandable (75–100.0%). The acceptance of the time it took to use MINDSET was 75-100%.
Table 5: Patient Assessment of Usability (% agreement) *

<table>
<thead>
<tr>
<th>Domains</th>
<th>PPAG Visit 1 (English)</th>
<th>PPAG Visit 2 (Spanish)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Likeability (like a lot)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The entire program.</td>
<td>6 (75%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>The colors used in the program.</td>
<td>7 (87.5%)</td>
<td>7 (87.5%)</td>
</tr>
<tr>
<td>The buttons and slider bars used in the program.</td>
<td>5 (62.5%)</td>
<td>6 (75%)</td>
</tr>
<tr>
<td>The hand-held device (i.e. computer tablet) used for the program.</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>The size of the letters were easy to read.</td>
<td>5 (62.5%)</td>
<td>6 (75%)</td>
</tr>
<tr>
<td>The action plan printout.</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
</tr>
</tbody>
</table>

* PPAG Visit 1 (n=8); PPAG Visit 2 (n=8)
Table 5: Patient Assessment of Usability (% agreement)

<table>
<thead>
<tr>
<th>Domains</th>
<th>PPAG Visit 1 (English)</th>
<th>PPAG Visit2 (Spanish)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usefulness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MINDSET was useful compared to other clinical surveys.</td>
<td>6 (75%)</td>
<td>7 (87.5%)</td>
</tr>
<tr>
<td><strong>Thoughts about impact.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information in MINDSET was helpful.</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>MINDSET will help me better manage my epilepsy.</td>
<td>7 (87.5%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Questions in MINDSET helped me to think carefully about how I manage my epilepsy.</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>MINDSET will help improve my communication with my doctor or nurse about my epilepsy.</td>
<td>5 (62.5%)</td>
<td>7 (87.5%)</td>
</tr>
<tr>
<td>I would tell other patients to use MINDSET.</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>I would use MINDSET in a regular clinic visit.</td>
<td>8 (100%)</td>
<td>7 (87.5%)</td>
</tr>
</tbody>
</table>

* PPAG Visit 1 (n=8); PPAG Visit 2 (n=8)
Table 5: Patient Assessment of Usability (% agreement)

<table>
<thead>
<tr>
<th>Domains</th>
<th>PPAG Visit 1 (English)</th>
<th>PPAG Visit2 (Spanish)</th>
</tr>
</thead>
</table>

**Understandability**

- I knew and understood most of the words used in MINDSET. 8 (100%) 6 (75%)
- I did NOT need help answering the questions in MINDSET. 6 (75%) 7 (87.5%)
- MINDSET was easy to use. 7 (87.5%) 7 (87.5%)

**Duration**

- Time to use MINDSET was just right. 8 (75%) 8 (100%)

**Credibility**

- Information in MINDSET can be trusted. 7 (87.5%) 8 (100%)

* PPAG Visit 1 (n=8); PPAG Visit 2 (n=8)
5.4.2 Usability Test Results: Exit Interviews

Exit interviews were conducted with all of the participating patients in Arizona and Texas (N=16) upon completing MINDSET. The exit interviews assessed a number of elements of MINDSET including what that patients liked the best and the least about the program; any questions or items in the program that may have upset, embarrassed, or made them uncomfortable; and any other question(s), information, or features patients felt would have been useful to incorporate in the program.

Mostly, patients had positive remarks about the program and provided the research team with valuable feedback, which was later used to improve the most recent version of program before beginning the latter phases of the larger MINDSET study. Many patients commented that the program was easy to understand. Others volunteered that it was helpful and user-friendly.

- “The questions were easy to understand and the layout of the program made it very easy for me to go over and choose my answers without help.”
- “The program was fast and easy to use. Overall I feel good about my self-management now that I’ve gone through the questions.
- “I learned a lot. Since it was my first time using a tablet, I feel confident using it again. I liked the fact that it was on a tablet.”
- “I really enjoyed the program. At first I was a little intimidated because I have very limited computer or any kind of technology skills but the staff was very helpful and patient walking me through the program. At the end I felt so comfortable that I was able to finish the program without any help”. I really loved the program, as it was so user friendly even for people like me with limited computer skills.”
Several patients also indicated they would recommend the program to other patients living with epilepsy, as they believed the program would be beneficial in educating and informing those patients with any type of treatment and lifestyle behavioral problems or challenges and, thus, not adequately managing their epilepsy.

- "It was very clear and easy to use. The questions provided food for thought about epilepsy management, and I assume that the information would be, mostly, extraordinarily helpful for someone who isn't managing their condition, especially if they don't have a good doctor who is lay in asking questions."
- “Would tell other patients to use the program to learn more about their seizures”.

Many patients also found the program useful and valuable as it allowed them to learn more about their epilepsy and ultimately reflect on their personal self-management, what they could do to improve their overall health, and the frequency and severity of their seizures. Lastly, other patients thought the program would be a useful tool that would help improve communication and shared-decision treatment options with their doctors.

- I also liked the space that the program provided for me to think about and note questions or any concerns before meeting with my doctor so that I can bring them up and they are covered during my discussion with my doctor.”
- “It's an excellent program. The program really allows you to learn more about your own epilepsy and make you feel more comfortable and at ease with your illness”.
- “Best part of the program was that it helped me organize my thoughts about my treatment and management and goals. Which can be overwhelming before meeting.”
- "It helped me to explain what I am going through and what I can do to better manage my epilepsy”. Program will also help me improve my communication with my doctor.”
While most of the patients felt overall comfortable with most of the features and questions in the program, other patients expressed some discomfort and concerns. Most of these concerns were predominantly associated with the questions related to mood and depression.

- "The depression survey made me feel uncomfortable. I know I have depression; I hate being asked that stuff over and over."
- “Not sure if she likes or feels comfortable with the depression related questions.”
- “The depression questions area was a little uncomfortable but the rest was great.”

A very small number of patients found the program to be too long. These patients believed there were too many questions, with some of them being irrelevant and/or confusing.

- “The program was a little long and had too many questions.”
- “Would have liked the program to be more specific on some of the questions that it was asking. For example, what do you mean by "finding pleasure?"
- “Finds that some of the red flagged items are not relevant.”

Other patients indicated that need for more opportunities and space in the program to write-in their own questions and concerns for their physician.

- “Would have liked to have more places to write in concerns that I identify as most important and pressing. Places to write in questions and treatment, like surgery.”
- “Would like more write-in space, for example I want to get pregnant. Would like it on the tablet b/c she may be too shy to ask doctor.”

Another small number of patients had difficulty with technical related features of the program.

- “Did not like that the screen doesn’t scroll up unless you use the small scroll bar”.
- “Not sure how to punch the "Go on" button or the scroll screen.”
- “Wasn’t clear to me how to write in comments, questions open-ended questions.”
5.4 Strengths

Strengths of this study include the systematic patient-centered development and usability testing of the intervention, randomized control design, standardized tablet-based data collection for all patients, an experienced research team with recruitment and retention of epilepsy patients, and an innovative approach to clinic-based self-management intervention.

The study addresses an important chronic disease that can adversely affect a broad population but may be mediated by good patient management. This project addresses a significant need for self-management assessment in clinical settings and guidance in selecting interventions for Hispanic patients with epilepsy. To date, there is a lack of attendance to self-management needs in clinical settings in general and for Hispanics in particular. By providing tools and procedures for identifying and assisting patients with self-management needs, this study will make a significant contribution to the CDC-Managing Epilepsy Well (MEW) goal of promoting self-management and self-determination principles in the care of people with epilepsy.

This study provides an innovative technological application to translate knowledge from social and behavioral research on epilepsy to the clinic setting. With the inclusion of Hispanic Spanish-speaking patients in this current study, the subject population reflects a broad range of socio-economic groups, particularly with regard to income, education, and insurance coverage.

This new version of MINDSET translated to Spanish will provide Hispanic patients with a tool that can help them acquire better awareness of their health condition and to learn new skills to help them improve their epilepsy self-management, ultimately resulting in improved treatment compliance, fewer seizures, and reduced health care related costs.
5.5 Limitations

Limitations of this study include a modest sample size, potential contamination, inclusion criteria, and a lack of detailed training of clinicians in mental and behavioral health. All of these items limit the generalizability of the findings to other settings and patient populations.

**Sample Size.** Limitations of this usability study include a “modest sample (both patients and providers), a single group design that limits causality to communication effects, data limited to self-report regarding what subdomains were discussed, lack of information on what behaviors within subdomains were discussed, and the quality of the discussion”\(^{26}\). The modest sample (both patients and providers) is appropriate for a usability study but may limit the generalizability of findings and the power to detect pre- and post-test difference.

**Potential Contamination.** With the same providers managing treatment and comparison condition subjects, there is a likelihood of a between-group contamination, with physicians perhaps asking the PPAG patients questions probed by MINDSET normally not asked in a traditional clinic visit. In addition, patients may become more aware of their condition having their interaction with the research and clinical staff about self-management prior to using the program.

**Inclusion Criteria.** Electronic decision support systems hold promise to improve clinical care over their paper-and-pencil predecessors because of their ability for data storage, retrieval, sharing, analysis, and reporting, as well as the use of logic for real-time behavioral cuing and treatment alerts. However, the inclusion and exclusion criteria of this study may have unintentionally narrowed the patient sample to a “subset of people living with epilepsy who are amenable to using the tablet-based system, i.e., excluding those with learning difficulties and psychiatric problems”\(^{90}\). Thus, caution is advised when generalizing the results of this study.
**Mental health training.** The redesign of MINDSET embodied a concession between “minimizing disruption in clinic flow and optimizing awareness-raising and physician self-management remediation. Elimination of information on behavioral determinants items that assess self-efficacy regarding self-management behaviors, while providing a more streamlined user experience, may undermine the potential of the program to more thoroughly define a patient's self-management needs and provide a salient tailored intervention. It remains to be seen if such approach can be effective in the absence of information on behavioral determinants that have been documented as important in impacting behavioral change. Lack of detailed training of clinicians in behavioral change techniques may reduce the effectiveness of provider behavioral intervention. However, this is not inconsistent with the aims of this project.

**Patient-Provider Communication:** Further, the current study did not explore the impact of MINDSET within the traditional clinical encounter to provide understanding of who initiated discussions, if patients were more proactive in raising issues for discussion that represent at-risk behaviors, and if providers were more responsive to these issues.

Despite all of these limitations, this usability study provides indication of the potential usefulness and feasibility of this tool in facilitating the assessment of a comprehensive set of self-management issues in patients during clinic visits and developing patient-centered goals for sustainability and improvement. Furthermore, please note that statistical significance is not required to determine major usability problems, with the best cost-benefit ratio achieved with 3-5 users in total.
CHAPTER 6: DISCUSSION, RECOMMENDATIONS, AND CONCLUSION

6.1 Discussion

We are hopeful that this project will help contribute uniquely to the literature on the potential of educational technology and decision support systems as an adjunct to successful clinical management of epilepsy and will broadly inform the field of clinic-based decision support.

“The potential contribution of MINDSET is the provision of a tool for quickly documenting the variety of self-management behaviors in individuals living with epilepsy during a clinic visit, identifying and discussing behavioral issues, and developing a plan for continual self-management improvement and/or sustainability”\(^{90}\). Providing a decision aid to record self-management behaviors and develop an action plan for epilepsy is consistent with tools used in other chronic diseases such as asthma\(^{91}\). For epilepsy self-management, such tools have been limited to severe seizure management and not inclusive of a broader set of self-management domains such as medication and lifestyle behaviors\(^{92}\).

The good usability ratings for MINDSET show that burden and time commitment were acceptable. “The positive ratings on the impact of the data entry and action plan components are encouraging in a group of patients experienced in living with epilepsy. Preliminary analysis of the feasibility data of the larger MINDSET study also indicating a decline in at-risk lifestyle self-management behaviors over the two visits, while medication and seizure management behaviors remained constant, is an encouraging finding. The focus on lifestyle might be expected given that lifestyle behaviors may tend to be more neglected than medication and seizure management in clinical discussions without the use of a decision aid”\(^{90}\).
Evaluations of the quality of communication and perceptions of shared decision-making between the patient and HCPs were highly positive across a range of parameters\textsuperscript{90}. More research is needed to determine who initiates the discussion of self-management and the quality of communication with respect to scope of content (e.g., biomedical vs. socioemotional)\textsuperscript{93}, depth of discussion (discussed superficially vs. at length) as well as the quality of interaction (e.g., use of nonverbal communication, reinforcement, and reflective listing)\textsuperscript{94}.

Similarity, the “at-risk behaviors” discussed by the patient and provider, and those flagged by MINDSET appeared to be consistent for some domains according to the patient exit interviews (e.g. medication-management, depression, and social support); but not for others. According to some patients, there was also limited discussion of some behavioral domains that were nor flagged. “It is not clear what the rationale is for providers not discussing any of the flagged “at-risk” behaviors, whether they are overriding the cue to a decision that is not, in fact, a problem (a false positive); whether it is of lower priority than other behavioral domains, or whether there were constraints such as time that limited the scope of the discussion”\textsuperscript{90}.

The use of a computer tablet also appeared to be well received by the patients. This method is a rational development given the versatility, convenience, and validity of this process of patient data collection when compared to traditional paper data collection\textsuperscript{95}. “Using a printed version of the action plan as a common focus of discussion in the clinic encounter appears to have benefits of flexibility and mobility”\textsuperscript{90}. 
6.2 Recommendations

This study tested the capacity of the newly revised version of MINDSET (4.1) to track and monitor patients’ self-management progress on clinical and psychosocial parameters for both English and Spanish speaking patients. The results from the current study suggest that the use of an electronic computer-based decision-support tool like MINDSET can enhance the patient and provider experience during the neurology clinic visit. “Potential contributions of MINDSET include an operationalization of clinic-based patient-oriented self-management assessment, enhanced understanding of self-management issues, and goal-oriented communication between patients and physicians without compromising clinic flow”\textsuperscript{26}.

This study shows that a decision-support program like MINDSET can provide patients with an opportunity to list and discuss their epilepsy traits and self-management behaviors, leading to patient and physician awareness and goal setting without disrupting clinic flow\textsuperscript{90}. “Initial analysis of this new version of MINDSET indicates that it is feasible and useful for identifying and discussing self-management issues, for developing a tailored action plan as part of a regular clinic visit, for facilitating high-quality communication and shared decision-making between patients and physicians, and for potentially assessing changes in epilepsy characteristics and self-management at-risk behaviors over time”\textsuperscript{90}.

The work of this study will help both English and Spanish speaking patients and HCPs make shared informed decisions, guide self-management, and improve treatment outcomes. Such a standardized tool may help the consultation highlight issues otherwise not addressed, and help mitigate avoidable disparities by making the patient-provider interaction more consistent across patients. We hope that the research findings from this usability study will provide an initial platform on which to study the feasibility and effectiveness of the program.
6.3 Advocacy and Public Health Policy Considerations

Public policy and advocacy for people with epilepsy embrace a wide range of national, state, and local situations. Advocacy efforts and campaigns have previously been used to target policy makers and influential individuals in an attempt to improve their knowledge and their awareness about epilepsy and to request their support for those individuals living with epilepsy, their family, and those organizations that conduct research, offer treatment, and provide services.

There are a number of organizations dedicated to the research, treatment, and support for people with epilepsy including, the Epilepsy Foundation of America, the American Epilepsy Society, and the CDC Managing Epilepsy Well Network (MEW), among others. These and other organizations have historically advocated and led public health policy campaigns in support for new programs and laws that assist and protect individuals with epilepsy, such as civil rights, disability and social security benefits, family and community support, driving laws, access to medical and pharmaceutical services, and public awareness.

The MEW network addresses the public health challenge of epilepsy through multiple strategies and players including HCPs, academic researchers, and other professionals. The MEW network is dedicated to the development of programs that create a more supportive environment for people with epilepsy by elevating epilepsy as a public health issue to motivate public policy and funding new programs, services, and activities. This study directly addresses a substantial portion of the MEW network’s objectives as outlined in their mission statement, including, developing and testing self-management tools appropriate for the full spectrum of epilepsy and community stakeholder engagement. Although the study focuses on Hispanic patients, it will make an overall significant contribution to the promotion of self-management and self-efficacy principles in the care of people with epilepsy, particularly those in underserved communities.
Throughout this study we worked in collaboration with members of the MEW network. I had the opportunity to work closely with staff from the MEW network and provide them with updates of all phases of the project during its monthly meetings. MINDSET addresses the MEW mission by studying new methods to enhance epilepsy self-management and by investigating health communication technology channels to disseminate self-management interventions. The results of our study will be disseminated to our partners within the MEW network so that other researchers, HCPs, and people with epilepsy can benefit from our program. We hope that MINDSET will serve as a model for our colleagues within the MEW network for establishing and expanding existing surveillance and data collection efforts to describe the burden of epilepsy, identify risk and protective factors, evaluate prevention efforts, and prioritize program development. By providing tools and procedures for identifying and assisting Hispanic patients with self-management needs, this study will make a significant contribution to the MEW Network’s goal of promoting self-management and self-determination principles in the care of subgroups of people with epilepsy, particularly underserved Hispanics.

This study provides an evaluation of an innovative technological application to facilitate the dissemination of social and behavioral research knowledge on epilepsy self-management into clinical practice, targeting traditionally underserved populations. This study directly addresses the Healthy People 2020, Health Communication Health Information Technology objectives #1.1 (HCP provision of easy-to-understand instructions), #9 (easy access to health information), and #11 (increase in meaningful users of health information technology). This study also addresses Healthy People 2020, Disability and Health objective #6 (increasing the proportion of people with epilepsy and uncontrolled seizures who receive appropriate medical care).
6.4 Conclusion

The quality of life for individuals with epilepsy can be obstructed in varying ways; “it may result in limits on the person’s ability to drive and on his or her employment, and can have effects on social interactions and family dynamics. These challenges result in significant indirect costs for individuals, their families, and society that include lost productivity connected to unemployment, underemployment, and premature mortality. Throughout the centuries, misperceptions about epilepsy have developed and been perpetuated in popular culture, resulting in stigma and social isolation, which can affect health and further diminish quality of life. This history of discrimination and stigma has been difficult to reverse”49.

In spite of these challenges, there are many continuing efforts to improve the lives of individuals with epilepsy and their families. Efforts must continue and reinforced so that, eventually, all people with epilepsy can have access to the complete range of necessary health and community services. Education endeavors for patients with epilepsy and their loved ones need to be detailed and sensitive to health literacy and cultural considerations49.

There is a lot that is being done but more is needed to educate people with epilepsy and about the disorder, the range of treatment options, and the array of community services that might be helpful to achieve optimal self-management49. Self-management should be thought of as a path toward behavioral change that supports health. Information about themes such as epilepsy diagnosis, prognosis, treatment, healthy, and self-management skills can increase an individual’s sense of empowerment, promote adaptation to the disorder, and enhance overall quality of life96. Obtaining the essential education, and skills related to epilepsy and its management can also increase awareness, well-being and improved quality of life for individuals with epilepsy and their families, help prevent misconceptions about the condition, and reduce concerns about stigma49.
The recent IOM report, *Epilepsy Across the Spectrum*, brought attention to the importance of self-management to improve the quality of life of people living with epilepsy\(^49\). The IOM report describes its vision for achieving a better understanding of the public health dimensions of epilepsy and for promoting patient health and understanding. The committee’s vision for the future includes access to relevant and usable tools for all people living with epilepsy that meets their individual needs and allows them to participate effectively in patient-centered care, to achieve optimal self-management of their epilepsy, and to attain the highest possible physical and emotional well-being.

Self-management researchers have identified the range of knowledge and problem-solving skills that patients need to be partners in their own care\(^{51,97}\). Physicians and other HCPs caring for people with epilepsy must facilitate the development and research of self-management programs\(^{42}\). To successfully care for patients with epilepsy, it is imperative that HCPs increase their understanding of patients’ motivations to engage in specific self-management behaviors\(^{98}\).

The evidence from this study supports the effectiveness of the use of MINDSET. MINDSET has been developed as a decision tool to facilitate documentation of self-management issues and goal setting during clinic visits. I am hopeful that this program will help improve the educational needs of patients with epilepsy and their self-management. MINDSET needs to be acknowledged because at any stage in life, health-promoting behaviors integrated into the lifestyles of epilepsy patients leads to improved overall health and generation of a better quality of life.

**6.5 Abstracts and Poster Presentations - American Epilepsy Society**

The results of the usability testing of MINDSET have been published in two abstracts with the *American Epilepsy Society* (AES). These results have also been shared in poster presentations at the annual AES conference in 2015 (Philadelphia, PA) and 2016 (Houston, TX) (see Appendix \(H\)). The results were presented by Refugio Sepulveda (UA) and Sarai Rueda (UT).
CHAPTER 7: PROTECTION OF HUMAN SUBJECTS OVERVIEW

7.1 Human Subjects Involvement and IRB Approval

Approval from the respective institutional review boards (IRB) from the Human Subjects Protection Program at the University of Arizona (UA), the Site Review Authority at the University of Arizona Health Network (UAHN), and the Review Board Committees for the Protection of Human Subjects at the University of Texas Health Science Center- Houston and the Epilepsy Foundation of Southern Texas was sought prior to conducting any research with human subjects (see Appendix B). The target population comprised patients with a diagnosis of epilepsy who receive their primary epilepsy clinical care at one of four epilepsy clinic sites. Two of these clinics are part of the University of Arizona Health Network (UAHN) in Tucson (Alvernon Clinic and South Campus Outpatient Clinic). The other two clinics are in Texas (Harlingen and San Antonio, TX) and they are managed by the Epilepsy Foundation of Southern Texas (EFSTX).

7.2 Authorization for access to Protected Health Information (PHI)

In accordance with the Healthcare Information Portability and Accountability Act of 1996, the Subject Consent Form will include PHI. The content of this information will comply with the regulations governing the authorization. All prospective study subjects were given a detailed explanation of PHI and our request to access their PHI and how it was to be used. They were given adequate time to read the Subject Consent Form and they were given the opportunity to ask questions. Once all questions had been answered and the principal investigator is assured that the individual understands the implications of the PHI requests made within the Subject Consent Form, the subject was asked to sign the form. The authorization form remains in effect until revoked by the subject. The principal investigator provided a copy of the signed Subject Consent Form to each subject. Subjects who did not sign the PHI Form were not be permitted to participate.
7.3 Cost to Subjects, Compensation, and Withdrawal

There were no costs to participate other than the patient’s time, although subjects were responsible for transportation to clinic for the PPAG meeting. Patients received a $30 compensation for participating in the study. Subjects could withdraw at any time without penalty.

7.4 Potential Risk and Procedures for Minimizing Risks

Risks to participating in the study were minimal and related primarily to issues of confidentiality. Use of the MINDSET tablet-based decision support system did not limit any transference of sensitive data. No names were entered in the computer for data collection or for intervention activities – only unique study identification numbers were used. The master list linking participant names and study identification numbers was stored electronically, under password protected software, and was kept separate from any data files.

7.5 Potential Benefits of the Proposed Research to the Subjects and Others

Patients had the potential to benefit from receiving the intervention which was designed to enhance self-management skills related to medication adherence and epilepsy self-management and also encourage conversation between the patient and his/her medical care provider regarding self-management. Importance of the Knowledge to be Gained. Patients with epilepsy face many serious challenges related to managing their condition. Few theory- and technology-based behavioral interventions have been developed and evaluated for the clinic setting. By developing and pilot testing a tablet-based decision support system for clinic use, MINDSET had the potential to expand knowledge regarding effective ways to educate patients with epilepsy. This research could further inform the understanding of technology-based adherence and self-management training and could have broader implications on clinic-based interventions across health domains.
7.6 Provisions to protect the privacy of subjects and the confidentiality of data

*Protection of subject privacy and data confidentiality.* Efforts were made to keep all study related information confidential. During the consenting process, every attempt was made to approach the subject in the privacy of an examination room. The study visits were conducted in the privacy of a consulting room. Patients will be identified by a research ID in the databases to be shared with collaborators. Confidential information (provided by the patient using the contact information document) contained only patient’s contact information and research ID. This information was destroyed at the end of the study. Information about the study subjects and Signed Subject Consent Forms was stored and kept in a secured room, available only to authorized research personnel and computers will be protected with a password.

Records of subject participation were held confidential except as disclosure is required by law or as described in the Subject Consent Form (under the Confidentiality section). The principal investigator, the sponsor or persons working on behalf of the sponsor and under certain circumstances, the United States Food and Drug Administration (FDA) and the University of Arizona’s Human Subjects Protection Program (HSPP) are able to inspect and copy confidential study related records which may identify a subject by name. Only de-identified patient data was shared between the researchers from the two universities.
7.7 Data and Information management

Subjects were notified of any information discovered during the course of the study that might cause them to change their mind about study participation. Subjects had the option to contact the research staff and/or the physician assigned to the study at any time during their study participation. There are no plans to apprise subjects of long term study results.

Data sharing occurred through the cloud – the UA has agreements with Google (for Google file share) and with Box Inc. (for businesses) so that projects such as ours can share (de-identified) files in a secure manner. The two sites uploaded site specific MINDSET tablet-based and paper survey data after each patient visit into the shared folders. The research staff at the UA and UT teams conducted monthly regular updates of the files. Communication was regular and meeting minutes were taken. The UA site trained the UT site on how to download and store the data available from MINDSET, following which both groups was responsible for reporting data – one group to report on survey data, and one group to report on MINDSET data. In this way, both groups were familiar with the data and allow data collection and input accuracy to be monitored through regular updates. Each group was responsible for the accuracy of their site’s data collection and management.
APPENDIXES
APPENDIX A: Sponsoring Organization

Appendix A-1: Letter of Acknowledgement

January 5, 2015

The University of Arizona
Mel and Enid Zuckerman College of Public Health
1295 N. Martin
Drachman Hall
PO Box: 245210
Tucson, AZ 85724

Re: Sponsoring Organization for Refugio Sepulveda

To who it may concern (Dissertation Committee):

It is with great pleasure that I accept to become the “sponsoring organization” for Mr. Refugio Sepulveda’s professional dissertation research project.

Mr. Sepulveda will work at our office at the University of Arizona’s Department of Neurology in a research project entitled “Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community”. We are aware and acknowledge that Mr. Sepulveda will be using the work from the MINDSET research project towards completion of his dissertation requirements for the DrPH program at the Mel and Enid Zuckerman College of Public Health.

I am confident that Mr. Sepulveda will be a great resource to our research project and I commit to provide him with an insightful and real-time learning experience that will advance his research and analytical skills.

Sincerely,

David M. Labiner, MD
Professor and Department Head
Department of Neurology
University of Arizona
labinerd@neurology.arizona.edu
APPENDIX B: Human Subjects Protection- Approval Documents

Appendix B-1: IRB Study Approval Letter

Date: November 17, 2014
Principal Investigator: David M. Labnier
Protocol Number: 1410546690
Protocol Title: SIP: 14-007: Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community
Level of Review: Expedited
Determination: Approved
Expiration Date: November 13, 2015

Documents Reviewed Concurrently:
- Data Collection Tools: 01 MINDSET DecisionRules_09_01_13.docx
- Data Collection Tools: 1a Demographic questionnaire_English.Begley.110411.docx
- Data Collection Tools: 1b SIP12_Provider_Demographic.Begley.110411.docx
- Data Collection Tools: 2 SelfEfficacy Scale ESES.docx
- Data Collection Tools: 3a SelfMgmt Scale.docx
- Data Collection Tools: 3b PatientMoodScale NDDIE.docx
- Data Collection Tools: 3c Seizure and Meds Demographic.docx
- Data Collection Tools: 4 CommChecklist.docx
- Data Collection Tools: 5 PatientCommunicationScale.docx
- Data Collection Tools: 6 PatientControlScale.docx
- Data Collection Tools: 7 SIP12_Feature Checklist.docx
- Data Collection Tools: 8a PatientExitInterview.docx
- Data Collection Tools: 8b SIP12 ExitInterview_11_09_11.docx
- Data Collection Tools: MINDSET Contact Information.docx
- Grant/Contracts: Award Notice DP5002-01 REVISED 14-002,14-007 UNIVER OF ARIZONA.pdf
- Grant/Contracts: opprRFA-DP-14-011_CG_4-24.pdf
- HSPP Forms/Correspondence: F200 v2014-02 doc 9 25 2014 signed page.pdf
- HSPP Forms/Correspondence: MINDSET F107 v2014 EDIT.doc
- HSPP Forms/Correspondence: MINDSET F200 v2014-02 rev Nov 12 EDIT.doc
- Informed Consent/PHI Forms: PPAG T502a - ICF Consent Form v2014-01 11072914 (1).pdf
- Other Approvals and Authorizations: Labinder, MINDSET, SRA Final Authorization.pdf
- Participant Material: MINDSET CONSENT TO CONTACT 2014 11132014v1.docx
- Recruitment Material: Letter to Epilepsy Patients 11132014.docx

This submission meets the criteria for approval under 45 CFR 46.110, 45 CFR 46.111 and/or 21 CFR 50 and 21 CFR 56.
• The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).
• All research procedures should be conducted in full accordance with all applicable sections of the Investigator Manual.
• The current consent with the IRB approval stamp must be used to consent subjects.
• The Principal Investigator should notify the IRB immediately of any proposed changes that affect the protocol and report any unanticipated problems involving risks to participants or others.
• For projects that wish to continue after the expiration date listed above please submit an F212, Continuing Review Progress Report, forty-five (45) days before the expiration date to ensure timely review of the project.
• All documents referenced in this submission have been reviewed and approved. Documents are filed with the HSPP Office. If subjects will be consented the approved consent(s) are attached to the approval notification from the HSPP Office.

This project has been reviewed and approved by an IRB Chair or designee. No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.
Appendix B-2: Modification to Key Personnel and IRB Approval

### The University of Arizona

**Date:** January 23, 2015  
**Principal Investigator:** David M. Labmer  
**Protocol Number:** 1410546690A002  
**Protocol Title:** SEP. 14-007: Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community  
**Level of Review:** Expedited  
**Determination:** Approved  
**Expiration Date:** November 13, 2015

| Documents Reviewed Concurrently | HSPP Forms/Correspondence: F109-2014-01_07OTP Refugio 02292015.pdf |

This submission meets the criteria for approval under 45 CFR 46.110, 45 CFR 46.111 and/or 21 CFR 50 and 21 CFR 56.

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).
- All research procedures should be conducted in full accordance with all applicable sections of the Investigator Manual.
- The current consent with the IRB approval stamp must be used to consent subjects.
- The Principal Investigator should notify the IRB immediately of any proposed changes that affect the protocol and report any unanticipated problems involving risks to participants or others.
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This project has been reviewed and approved by an IRB Chair or designee. No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.
# FORM: Modification of Key Personnel (VOTF)

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<td>David Labiner, MD</td>
</tr>
<tr>
<td>Investigator UA netID:</td>
<td><a href="mailto:labinerdl@email.arizona.edu">labinerdl@email.arizona.edu</a></td>
</tr>
<tr>
<td>Official University Email:</td>
<td><a href="mailto:labinerdl@email.arizona.edu">labinerdl@email.arizona.edu</a></td>
</tr>
<tr>
<td>Phone: (520) 626-2006</td>
<td></td>
</tr>
<tr>
<td>Alternate Contact:</td>
<td>Jenny Chong, PhD</td>
</tr>
<tr>
<td>Official University Email and UA NetID:</td>
<td><a href="mailto:jchong@u.arizona.edu">jchong@u.arizona.edu</a></td>
</tr>
<tr>
<td>Phone: (520) 626-1986</td>
<td></td>
</tr>
</tbody>
</table>

### Approvals Required Prior to Modifying Research

Does this modification involve?  
- [x] No  
- [ ] Yes  

If Yes, Attach updated approval from:  
- Institutional Review Committee

### Personnel Added:
- Refugio Sepulveda, MPH

### Personnel Removed:
- Research Specialist

### Revised Privileges:

### Department Head or Designee Approval

I have reviewed these changes and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research in terms of time, facilities, staff, access to a subject population, and resources for care than subjects may need.

Departmental Chair or Supervisor Signature  

Date: 1/20/2015

### Investigator Acknowledgement

I agree to conduct this Human Research in accordance with applicable regulations and the University of Arizona's HSPP Investigator Manual.

Investigator signature  

Date: 1/20/2015
**FORM: Verification of Human Subjects Training Form (VOTF)**

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>FORM DATE</th>
<th>PAGE</th>
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<tr>
<td>F107</td>
<td>01/2014</td>
<td>2 of 3</td>
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### Use to list all current Key Personnel

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<th>Date</th>
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**Project Title:** SIP: 14-007: Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community

**Investigator:** David Labiner, MD

**Investigator's Official University Email:** labinerd@email.arizona.edu

**Investigator's Phone:** (520) 626-2006

**Alternate Contact:** Jenny Chong, PhD

**Alternate Contact's Official University Email and UA NetID:** jchong@u.arizona.edu

**Alternate Contact's Phone:** (520) 626-1986

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<table>
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<tr>
<th>Name</th>
<th>UA Net ID</th>
<th>Research Role</th>
<th>Department &amp; Institution</th>
<th>Consenter</th>
<th>CITI Training Date</th>
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<tr>
<td>David Labiner, MD</td>
<td>labinerd</td>
<td>PI</td>
<td>Neurology, UA</td>
<td>Yes</td>
<td>10/10/2014</td>
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<tr>
<td>Jenny Chong, PhD</td>
<td>jchong</td>
<td>Co-PI</td>
<td>Neurology, UA</td>
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<tr>
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<td>refugio</td>
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<td>No</td>
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Appendix B-3: Collaborative Institutional Training Initiative (CITI) Certification

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

**COURSEWORK REQUIREMENTS REPORT**

*NOTE: Courses on this Requirements Report reflect only the courses that the completion criteria have met. See below for details.*

- **Name:** Refajo Sepulveda (C0: 243886)
- **Email:** rsepjg@eallarbohooe.edu
- **Institution Affiliation:** University of Miami (C0: 766)
- **Institution Unit:** Public Health

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social & Behavioral Research Investigators
- **Stage:** Stage 2 - Referee Course

- **Report ID:** 16332671
- **Completion Date:** 04/19/2016
- **Expiration Date:** 04/19/2022
- **Minimum Passing:** 80
- **Reported Score:** 90

**REQUIRED AND ELECTIVE MODULES ONLY**

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<th>Module Description</th>
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<tr>
<td>SIE Referee 1 - Defining Research with Human Subjects (C0: 19239)</td>
<td>04/19/16</td>
<td>2/2 (100%)</td>
</tr>
<tr>
<td>SIE Referee 1 - Privacy and Confidentiality (C0: 18035)</td>
<td>04/19/16</td>
<td>2/2 (100%)</td>
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<td>SIE Referee 1 - Assessing Risk (C0: 18034)</td>
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<td>SIE Referee 1 - European States Research Ethics (C0: 307)</td>
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<td>SIE Referee 1 - Hybrid Course (C0: 830)</td>
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</tbody>
</table>

For this report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution. Identifiers for all learners are required to be independent learners.

CITI Program
Phone: 800-306-3100
Web: http://www.citiprogram.org
COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COURSEWORK TRANSCRIPT REPORT

**NOTE:** Scores on this Transcript Report reflect the most recent completions, including courses as optional supplemental elements of the course. See School to School. See separate Requirements Report for reported courses at the time all requirements for the course were met.

- **Name:** Rengo Seppeleza (ID: 2482060)
- **Email:** rengose@uah.edu
- **Institution Affiliation:** University of Arizona (ID: 765)
- **Institution Unit:** Pharmacy

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social & Behavioral Research Investigator
- **Stage:** Stage 2 - Rehearsal Course

- **Report ID:** 1630667
- **Report Date:** 04/19/2016
- **Current Score:** 90

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<th>Module Description</th>
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<tr>
<td>SII Refresher 1 -知情同意 (ID: 938)</td>
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<tr>
<td>SII Refresher 1 - Research in Educational Settings (ID: 940)</td>
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<td>SII Refresher 1 - Conducting Research with Human Subjects (ID: 15029)</td>
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<td>SII Refresher 1 - Assessing Risk (ID: 16034)</td>
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<td>2/2 (100%)</td>
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</table>

For this report to be valid, the learner identified above must now have a valid affiliation with the CITI Program subscribing institution identified above or now be a paid independent learner.

CITI Program
Email: citiprep@uah.edu
Phone: 305-243-7910
Web: [http://www.citiprogram.org](http://www.citiprogram.org)
Appendix B-4: UAHN Site Authorizations

---

**Jenny Chong**  
**From:** Site Review Authority <SRA@uahealth.com>  
**Sent:** Wednesday, October 22, 2014 4:34 PM  
**To:** David Labiner  
**Cc:** Jenny Chong; Rishel, Cindy J.; MacEwen, Jeffrey B.; Site Review Authority; Delfina Gaxiola  
**Subject:** Labiner, MINDSET, SRA Final Authorization

Dr. Labiner,

This email is to serve as the UAMC Site Review Authority (SRA) Final Site Authorization for your study titled, “Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community.” The SRA approval period will be as authorized by the University of Arizona Human Subjects Protection Program, including study renewals, through the study closure. You do not need to submit the final IRB approval documents, as the IRB will send them to the SRA upon study approval.

Please notify the SRA if significant modifications will be made to the study, including (but not limited to) the addition or removal of research staff, addition of procedures that require UAHN resources or additional UAHN recruitment sites.

Thank you.

Jeffrey MacEwen, BSHS, CISSP  
Information Assurance Officer &  
Practice  
Interim Privacy Officer  
Co – Chair, UAMC Site Review Authority

Cindy Rishel, PhD, RN, OCN  
Administrator, Nursing Research and  
Co-Chair, UAMC Site Review Authority
APPENDIX C: Patient Recruitment and Informed Consent Forms

Appendix C-1: Recruitment Letter

[Patient Address]

DATE

Re:

Dear [Name],

I am writing to invite you to take part in a project on behalf of myself and epilepsy researchers at the Department of Neurology at the University of Arizona. The project focuses on the use of an epilepsy self-management computer-based program called MINDSET that may help epilepsy patients improve their management of epilepsy, as well as to improve the communication between patients and their physicians.

If you choose to participate in this project, you will help the researchers make MINDSET be practical and useful. Your participation will be over two clinic visits. You will be paid $15 for each visit. During the visit, you will be asked to respond to questions related to how you manage your epilepsy. The program will use your responses to provide suggestions to help you manage your epilepsy better, if needed, as well as to give you a print out for you to discuss with your neurologist. You will be asked to come one hour earlier on the day of your next two clinic appointments to take part in the study. You will be paid for your participation.

You are being invited to take part because you are eligible for the study and your opinion and participation will help us develop strategies that may be helpful for most patients with epilepsy. If you accept the invitation, please either call the following number (520 626 1986) or return the form (Consent to Contact) in the stamped envelope so that the one of the research staff can call you to explain the study further.

Thank you for your attention.

Sincerely,

Refugio Sepulveda

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.
Appendix C-2: Consent to Contact Form

CONSENT TO CONTACT

The University of Arizona is working in collaboration with the University of Texas to develop a Spanish version of an electronic tool to help improve patient’s self-management of their epilepsy. If you are willing to take part in the project, please sign below to show that you allow your contact information to be released to the research staff. Signing below does not mean that you have agreed to take part in the study.

**Patient statement**

I, ____________________________, would like to find out more about the study involving the use of an electronic tablet to help patients manage their epilepsy. By signing, I allow the project staff to contact me about the study. I understand that I do not have to participate in the project if I am not interested.

<table>
<thead>
<tr>
<th>PATIENT’S NAME (PRINT)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT’S ADDRESS</td>
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<tr>
<td>COUNTY, ZIP CODE</td>
<td></td>
</tr>
<tr>
<td>HOME TELEPHONE</td>
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<td>MOBILE TELEPHONE</td>
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<td>OTHER TELEPHONE</td>
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<tr>
<td>EMAIL ADDRESS</td>
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</tbody>
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Appendix C-3: Patient IRB Informed Consent Form

T502a – Consent Form

The University of Arizona Consent to Participate in Research

Study Title: Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community
Principal Investigator: David Labiner, MD and Jenny Chong, PhD
Sponsor: Centers for Disease Control and Prevention

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

The purpose of this research is to develop a tool to help providers care for Hispanic people with epilepsy. You are being asked to take part as a Hispanic person living with epilepsy. This is a multisite study and we are collaborating with the University of Texas in Houston. This study is sponsored by the Centers for Disease Control and Prevention.

2. How many people will take part in this study?

A total of 20 people in Arizona and 20 also in Texas will be asked to take part in this feasibility testing.

3. What will happen if I take part in this study?

If you agree to take part in this study, you will use a new computer-based survey that is designed to help health care providers help epilepsy patients manage their epilepsy. This project will be conducted at the University of Arizona neurology clinic waiting rooms (Alvernon and South Campus).

Before you see your provider you will be asked to complete two forms/ questionnaires including a basic contact form and a demographic questionnaire. You then will be given a brief 15 minute orientation on how to use MINDSET, (a tablet-based epilepsy self-management tool) this will include a brief tutorial on how to use a tablet (a hand held computer) designed for use in the clinic.

You will then use this tablet to answer survey questions on the MINDSET program. The questions will be about your epilepsy (e.g. how often you have episodes), how you manage your epilepsy (e.g. what you do to prevent or treat episodes), your medication

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management (e.g. missed doses) and your lifestyle (e.g. sleep, diet, exercise, record
keeping, attitudes about epilepsy, mood, etc.)
Once you have finished answering these questions you will receive a printout of an
Action Plan that will be generated. You will show the printout to your doctor and/or
nurse practitioner for them to review during the clinic visit. They will use this to help you
plan your epilepsy management.

After you have seen your doctor or nurse practitioner you will fill in some questionnaires
about using the tablet, about your interaction with your provider, and your overall
thoughts about the use of the MINDSET program.

4. How long will I be in the study?

The study activities (using the electronic tablet and completing additional paper work)
will add 1 hour to your clinic visit. You will be asked to use the tablet for the next
planned visit (total of 2 visits).

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you
decide to take part in the study, you may leave the study at any time. No matter what
decision you make, there will be no penalty to you and you will not lose any of your usual
benefits. Your decision will not affect your future relationship with The University of
Arizona and your healthcare provider. If you are a student or employee at the University
of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

Risks to using the electronic survey and providing information about its content and
function are minimal. Provision of any information is voluntary.

7. What benefits can I expect from being in the study?

As a person living with epilepsy, you may receive no direct benefit from being in this
study; however, your taking part may help patients get better care in the future.

8. What other choices do I have if I do not take part in the study?

You do not have to take part in the study. You will not lose any benefits that you are
otherwise entitled.

9. Will my study-related information be kept confidential?

Provision of any information is voluntary. Information will be accessible to your health
care provider in the context of the clinic visit and to research staff for analysis, but this
information will remain confidential. Information you provide will not be identified with
you but will be assigned a unique identification number for study purposes. Information
that identifies you as a participant will not be shared with the researchers from the
University of Texas. However, please understand that representatives of some groups may
review your research and/or medical records for the purposes of verifying research data,
and will see personal identifiers. These groups include:

- Office for Human Research Protections or other federal, state, or international
  regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible
  Research Practices
- The sponsor supporting the study, their agents or study monitors
- Banner—University Medical Center Tucson (B-UMCT)

Identifying information will not appear on records copied or kept by the sponsor. You will not
be personally identified in any reports or publications that may result from this study. There is
a separate authorization form that you will be asked to sign which details the use and
disclosure of your protected health information.

Please note that data from this study will be shared with the Managing Epilepsy Well
Network Database (MEW-DB) which is coordinated by Case Western Reserve University
(CWRU). The MEW Network is a research community with each Network site conducting
independent epilepsy self-management research projects that have been funded by CDC.
The MEW-DB is a collection of combined data from epilepsy self-management studies
conducted by sites in the MEW Network. MEW-DB collects data for the purpose of
conducting secondary analysis of data, summarizing existing research findings, and to
provide leadership in data collection standards being adopted by the community as well as
research funding agencies. Please note that any of the data shared with MEW-DB will
NOT include any personal identifiers. Your name and other identifying information will
not be linked to the study data at any time.

10. What are the costs of taking part in this study?

The study activities of using the computer and completing additional paper work will add
1 hour to your clinic visit. Taking part in the study will not have any financial costs.

11. Will I be paid for taking part in this study?

You will be paid $15 for each visit, for a total of $30. By law, payments to subjects may
be considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The
University of Arizona has no funds set aside for the payment of treatment expenses for
this study.
13. What are my rights if I take part in this study?

If you choose to participate in the study, you can stop at any time without penalty or loss of benefits to which you are otherwise entitled. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Refugio Sepulveda (520) 626-2258 or Dr. Jenny Chong (520-626-1986) or Dr. David Labiner (520-626-2006) and their research staff at any time.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Refugio Sepulveda at (520) 626-2258.
127 **Signing the consent form**

128 I have read (or someone has read to me) this form, and I am aware that I am being asked to
129 participate in a research study. I have had the opportunity to ask questions and have had them
130 answered to my satisfaction. I voluntarily agree to participate in this study.

131 I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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<th>Signature of subject</th>
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<th>Signature of person authorized to consent for subject (when applicable)</th>
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132 **Investigator/Research Staff**

133 I have explained the research to the participant or the participant’s representative before
134 requesting the signature(s) above. There are no blanks in this document. A copy of this form
135 has been given to the participant or to the participant’s representative.

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Appendix C-4: Protected Health Information (PHI) Form

T504a – PHI Authorization Form

AUTHORIZATION FORM FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Project Title: SIP: 14-007: Spanish MINDSET: Expanding and Validating a Self-Management Tool for the Hispanic Community

The United States government has issued a new privacy rule to protect the privacy rights of individuals enrolled in research. The Privacy Rule is designed to protect the confidentiality of an individual’s health information. This document hereafter known as an “Authorization for Use and Disclosure of Protected Health Information for Research” describes your rights and explains how your health information will be used and disclosed for this study.

PURPOSE
You are being invited to participate voluntarily in the above-titled research project. The purpose of collecting Protected Health Information (PHI) for this study is help researchers answer the questions that are being asked in this research study.

WHAT INFORMATION MAY BE USED AND GIVEN TO OTHERS?
Information that will be collected about you includes:
• Your private identifiable information such as your date of birth and social security number.
• Information directly related to your seizure or epilepsy that is either provided by you. The information includes your seizure characteristics, the medicines you were prescribed and that you use, and the health services that you use.
• Information about your social, mental and physical health. This includes your quality of life, and your perception of how other people view your seizures.

WHO MAY USE AND RECEIVE INFORMATION ABOUT ME?
Information about you may be given out by the Principal Investigator and study personnel to:
• Representatives of regulatory agencies (including the University of Arizona Human Subjects Protection Program) to ensure quality of data and study conduct.
• Banner—University Medical Center Tucson (B-UMCT)
• Your personal physician.

WHY WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?
This information can be used by you and your physician to help you improve your epilepsy management. The results of this research may be published in scientific journals or presented at professional meetings, but your identity will not be disclosed.

HOW LONG WILL THIS INFORMATION BE USED AND/OR GIVEN TO OTHERS?
Your PHI will be linked to your identifying information until one year after the project has ended (September 30, 2020) After this time, all links will be destroyed and your identity will not be able to be determined. This authorization will expire on the date the research study ends.

Version 1 09/04/2015 Page 1 of 3 Form date: 01/2014
According to the policy of The University of Arizona, study data will be maintained for 6 years following the conclusion of this study.

MAY I REVIEW OR COPY THE INFORMATION OBTAINED FROM ME OR CREATED ABOUT ME?
You have the right to access your PHI that may be created during this study as it relates to your treatment or payment. Your access to this information will become available only after the study analyses are complete.

MAY I WITHDRAW OR REVOKE (CANCEL) MY PERMISSION?
If you do withdraw your authorization, any information previously disclosed cannot be withdrawn and may continue to be used. You may withdraw this authorization at any time by notifying the Principal Investigator in writing. The address for the Principal Investigator is David M Labiner, MD, Department of Neurology, 1501 N. Campbell, Tucson, Arizona, 85724.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?
You may refuse to sign this authorization form. If you choose not to sign this form, you cannot participate in the research study. Refusing to sign will not affect your present or future medical care and will not cause any loss of benefits to which you are otherwise entitled.

IS MY HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO OTHERS?
Once information about you is disclosed in accordance with this authorization, the individual or organization that receives this may redisclose it and your information may no longer be protected by Federal Privacy Regulations.

CONTACTS
You can obtain further information from the Principal Investigator, David M. Labiner, MD at (520) 626 2006. If you have questions concerning your rights as a research subject, you may call the Human Subjects Protection Program office at (520) 626-6721. If you would like to contact the Human Subjects Protection Program via the web (this can be anonymous), please visit http://orc.r.arizona.edu/hspp
AUTHORIZATION

I hereby authorize the use or disclosure of my individually identifiable health information. I will be given a copy of this signed authorization form.

Subject’s Signature

Date

Printed Name of Subject

Signature of Subject’s Legal Representative (if necessary)

Date

Printed Name of Subject’s Legal Representative

Relationship to the Subject
APPENDIX D: Data Collection Questionnaires (Embedded in MINDSET)

Appendix D-1: Epilepsy Self-Management Scale by Dilorio (MINDSET SCRIPT)

Epilepsy Self-Management Scale

The Epilepsy Self-Management Scale (ESMS) is a 38 item scale that assesses frequency of use of epilepsy self-management practices. Each item is rated on a 5-point scale ranging from 1, never, to 5, always. Items for the scale were developed from a review of the literature on epilepsy self-management and discussions with people with epilepsy and health care professionals caring for people with epilepsy. The 26 original items were categorized into three areas: a) medication-related, b) safety-related, and c) general lifestyle management. Total scores are found by reverse coding the 12 negatively worded items and summing responses to all 38 individual items. Total possible scores range from 38-190 with higher scores indicating more frequent use of self-management strategies.

The 26-item instrument was evaluated by a panel of experts in epilepsy management familiar with instrument development. Content validity was assessed on the original 26-item version using the procedures described by Waltz, Strickland, and Lenz (1984) yielding a content validity index (CVI) of 93% indicating strong agreement among the reviewers that the items measure self-management practices. Internal consistency reliability reported for a 26-item scale has ranged from .81-.86 (Dilorio et al., 1992; Dilorio et al., 1994). Twelve additional items were written to address lifestyle issues and safety measures and these items. The 38-item scale was factor analyzed yielding 5 factors: Medication, Information, Safety, Seizure, and Lifestyle Management (Dilorio et al., 2004).

References


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<table>
<thead>
<tr>
<th>ID</th>
<th>Questions</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROFILE_ INTRODUCTION</td>
<td>MINDSET will help you and your doctor or nurse plan your management. You will be asked questions about your epilepsy seizures, your medicines and your lifestyle. Please answer these questions as truthfully as you can.</td>
<td></td>
</tr>
<tr>
<td>MY EPILEPSY</td>
<td>“My Epilepsy” provides a series of questions to learn about your epilepsy and its management. For each question select the answer that is most correct for you then select the “Go On” button to move on to the next question.</td>
<td></td>
</tr>
<tr>
<td>SEIZURE HISTORY</td>
<td>Here are some questions about your seizures. Choose the answer that is most correct for you.</td>
<td></td>
</tr>
</tbody>
</table>
| SEIZURE HISTORY OVERALL HEALTH | Compared to my last clinic visit, I feel ________. | • Better [better] ()  
• Worse [worse] ()  
• Same [same] () |
| SEIZURE HISTORY FREQUENCY | Since my last visit, I have had about ________ seizures a month. | • 0 [0] (0)  
• 1-4 [1 to 4] (1)  
• 5 or more [5 plus] (1)  
• Don't know [don know] (1) |
| SEIZURE HISTORY SYMPTOMS | I experience the following symptoms related to my seizures (Select all that apply): |                                                                              |
|                  | • Unconsciousness [unconsciousness] ()  
• Convulsions [convulsions] ()  
• Brief loss of consciousness (e.g. “blanking out” or staring into space) [brief_loss_of_consciousness] ()  
• Single, jerking movements [single jerking] ()  
• Repetitive, jerking movements [repetitive jerking] ()  
• Spasms or head-turning [spasms] ()  
• Muscle stiffness, rigidity [muscle stiffness] ()  
• A drop or fall [drop fall] ()  
• Muscle numbness, tingling or other sensations [muscle numbness] ()  
• Unusual sensations affecting either vision, hearing, smell, or taste [unusual sensations] ()  
• Memory or emotional changes (e.g. feelings of anxiety or fear) [memory_emotional_changes] ()  
• Lip smacking, chewing, fidgeting, pacing and other repetitive, movements [lip-smacking] ()  
• Nausea or upset stomach [nausea] ()  
• Changes in awareness/thinking or confusion (e.g. unaware of surroundings, forgetting how to do common tasks or comprehend spoken words) [changes_in-awareness] ()  
• Feeling of overheating and sudden perspiration [overheating] ()  
• Language abnormality, inability to speak or slurred speech [language abnormality] ()  
• Uncontrolled bladder or bowel [uncontrolled_bladder_bowel] ()  
• Drowsiness [drowsiness] ()  
• Tongue biting [tongue biting] ()  
• Other symptoms [other_text_box] ()  
• I don’t know [don know] ()  |
I currently take the following medicines for my seizures: (Select all that apply)

- None [none] ()
- acetazolamide (Diamox) [Acetazolamide] ()
- carbamazepine (Carbatrol, Epitol, Tegretol, Tegretol XR) [Carbamazepine] ()
- clobazam (Frisium, Onfi) [Clobazam] ()
- clonazepam (Epitri, Klonopin, Rivotril) [Clonazepam] ()
- clorazepate (Transene) [Clorazepate] ()
- diazepam (Diastat, Diazepam, Valium) [Diazepam] ()
- diazepam rectal gel (Diastat Aclual) [Diazepamrectagel] ()
- divalproex sodium (Depacon, Depakote, Depakote ER, Epival) [Divalproex] ()
- eslicarbazepine acetate (Aptiom) [Eslicarbazepine] ()
- ethosuximide (Zarontin) [Ethosuximide] ()
- ezeagin (Potiga) [Ezogabine] ()
- felbamate (Felbatol) [Felbamate] ()
- gabapentin (Neurontin) [Gabapentin] ()
- lacosamide (Vimpat) [Lacosamide] ()
- lamotrigine (Lamictal, Lamictal XR) [Lamotrigine] ()
- levetiracetam (Keppra, Keppra XR) [Levetiracetam] ()
- lorazepam (Ativan) [Lorazepam] ()
- methsuximide (Celontin) [Methsuximide] ()
- oxcarbazepine (Oxtellar, Oxtellar XR, Trileptal) [Oxcarbazepine] ()
- perampanel (Fycompa) [Perampanel] ()
- phenoobarbital (Phenobarbital) [Phenobarbital] ()
- phenytoin (Dilantin, Epanutin, Phenytek) [Phenytoin] ()
- pregabalin (Lyrica) [Pregabalin] ()
- primidone (Mysoline) [Primidone] ()
- rufinamide (Banzel, Inovelon) [Rufinamide] ()
- tiagabine hydrochloride (Gabitril) [Tiagabine] ()
- topiramate (Topamax) [Topiramate] ()
- topiramate XR (Quictocor XR, Trokend XR) [TopiramateXR] ()
- valproic acid (Depakene, Depakine, Valproal, Valprosid) [Valproic] ()
- vigabatrin (Subril) [Vigabatrin] ()
- zonisamide (Zonegran) [Zonisamide] ()
- Other [other_text_box] ()
- Don't know [don't know] ()

In the past two weeks I have missed doses of my medicine on _____ days.

- 0 [ ] 0
- 1 [ ] 0
- 2-7 [ ] 0
- More than 7 [ ] 0
- Don't know [don't know] ()
### MEDICINE SIDE EFFECTS

I experience the following side effects from my seizure medicine(s)? (Select all that apply)

- Unsteadiness [unsteadiness] (0)
- Tiredness [tired] (0)
- Restlessness [restlessness] (0)
- Aggression [aggression] (0)
- Nervousness [nervousness] (0)
- Hair loss [hair loss] (0)
- Skin changes or rash [skin changes] (0)
- Blurred vision [blurred vision] (0)
- Upset stomach [upset stomach] (0)
- Difficulty concentrating [concentration] (0)
- Mouth/gum problems [mouthgumproblems] (0)
- Shaky hands [shaky hands] (0)
- Weight gain [weight gain] (0)
- Weight loss [weight loss] (0)
- Dizziness [dizziness] (0)
- Sleepiness [sleepiness] (0)
- Depression [depression] (0)
- Memory problems [memory problems] (0)
- Disturbed sleep [disturbed sleep] (0)
- Other [other] (0)
- None [none] (0)

### SEIZURE MANAGEMENT

Here are some questions about how you manage seizures. Choose the answer that is most correct for you.

#### SEIZURE MANAGEMENT - BEHAVIOR AWAY FROM HOME

- If I’m going away on a trip, I take my seizure medicine with me.
  - Never [never] (1)
  - Rarely [rarely] (1)
  - Sometimes [sometimes] (1)
  - Usually [usually] (0)
  - Always [always] (0)

#### SEIZURE MANAGEMENT - BEHAVIOR MORE THAN USUAL

- I call my doctor/nurse if I am having more seizures than usual.
  - Never [never] (1)
  - Rarely [rarely] (1)
  - Sometimes [sometimes] (1)
  - Usually [usually] (0)
  - Always [always] (0)

#### SEIZURE MANAGEMENT - BEHAVIOR BLOODTESTS

- When the doctor orders blood tests, I have them done.
  - Never [never] (1)
  - Rarely [rarely] (1)
  - Sometimes [sometimes] (1)
  - Usually [usually] (0)
  - Always [always] (0)

#### SEIZURE MANAGEMENT - BEHAVIOR AVOID TRIGGERS

- I stay away from things that I know make me have seizures (triggers).
  - Never [never] (1)
  - Rarely [rarely] (1)
  - Sometimes [sometimes] (1)
  - Usually [usually] (0)
  - Always [always] (0)
<table>
<thead>
<tr>
<th>MEDICINE MANAGEMENT</th>
<th>Here are some questions about how you manage seizure medications. Choose the answer that is most correct for you.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDICINE MANAGEMENT BEHAVIOR DOCTOR ORDERS</td>
<td>I take my seizure medicine the way my doctor orders it.</td>
</tr>
</tbody>
</table>
| | - Never [never] (1)  
  - Rarely [rarely] (1)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (0)  
  - Always [always] (0) |
| MEDICINE MANAGEMENT BEHAVIOR SPREAD DOSES | When my seizure medicine is running out, I spread out the time between doses. |
| | - Never [never] (0)  
  - Rarely [rarely] (0)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (0)  
  - Always [always] (1) |
| MEDICINE MANAGEMENT BEHAVIOR PUT OFF REFILL | I have to put off having my seizure medicine refilled because it costs too much money. |
| | - Never [never] (0)  
  - Rarely [rarely] (0)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (1)  
  - Always [always] (1) |
| MEDICINE MANAGEMENT BEHAVIOR SIDE EFFECT SKIP | If I have side effects from the seizure medicines, I skip a dose without asking my doctor. |
| | - Never [never] (0)  
  - Rarely [rarely] (0)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (1)  
  - Always [always] (1) |
| MEDICINE MANAGEMENT BEHAVIOR PLAN AHEAD | I plan ahead so that I do not run out of my seizure medicine. |
| | - Never [never] (1)  
  - Rarely [rarely] (1)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (0)  
  - Always [always] (0) |
| MEDICINE MANAGEMENT BEHAVIOR FORGET | I forget to take my seizure medicine. |
| | - Never [never] (0)  
  - Rarely [rarely] (0)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (1)  
  - Always [always] (1) |
| MEDICINE MANAGEMENT BEHAVIOR SAME WAY | I take my seizure medicine at the same time each day. |
| | - Never [never] (1)  
  - Rarely [rarely] (1)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (0)  
  - Always [always] (0) |
| MEDICINE MANAGEMENT BEHAVIOR PILL | I use a pill container for my seizure medicines. |
| | - Yes [yes] ()  
  - Sometimes [sometimes] ()  
  - No [not] () |
| MEDICINE MANAGEMENT BEHAVIOR REMIND MYSELF | I have a way to remind myself to take my seizure medicine |
| | - Never [never] (1)  
  - Rarely [rarely] (1)  
  - Sometimes [sometimes] (1)  
  - Usually [usually] (0)  
  - Always [always] (0) |
<table>
<thead>
<tr>
<th>LIFESTYLE</th>
<th>The following are statements about your ACTIVITIES WITH EPILEPSY.</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIFESTYLE_ACTIVITY_SLEEP</td>
<td>I make sure I get enough sleep.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
<td></td>
</tr>
<tr>
<td>• Rarely [rarely] (1)</td>
<td></td>
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<tr>
<td>• Sometimes [sometimes] (1)</td>
<td></td>
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<tr>
<td>• Usually [usually] (0)</td>
<td></td>
</tr>
<tr>
<td>• Always [always] (0)</td>
<td></td>
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<tr>
<td>LIFESTYLE_ACTIVITY_STRESS</td>
<td>I do things that I enjoy to help manage stress.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
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<tr>
<td>• Rarely [rarely] (1)</td>
<td></td>
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<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (0)</td>
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<tr>
<td>• Always [always] (0)</td>
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<tr>
<td>LIFESTYLE_ACTIVITY_RELAXATION</td>
<td>I have ways to help me relax to reduce my chances of having a seizure.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
<td></td>
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<tr>
<td>• Rarely [rarely] (1)</td>
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<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (0)</td>
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<tr>
<td>• Always [always] (0)</td>
<td></td>
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<tr>
<td>LIFESTYLE_ACTIVITY_EXERCISE</td>
<td>I get enough exercise.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
<td></td>
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<tr>
<td>• Rarely [rarely] (1)</td>
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<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (0)</td>
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<tr>
<td>• Always [always] (0)</td>
<td></td>
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<tr>
<td>LIFESTYLE_ACTIVITY_DIET</td>
<td>I eat regular, healthy meals.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
<td></td>
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<tr>
<td>• Rarely [rarely] (1)</td>
<td></td>
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<tr>
<td>• Sometimes [sometimes] (1)</td>
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<tr>
<td>• Usually [usually] (0)</td>
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<tr>
<td>• Always [always] (0)</td>
<td></td>
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<tr>
<td>LIFESTYLE_ACTIVITY_STAYING_OUT</td>
<td>I stay out late at night.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
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<tr>
<td>• Rarely [rarely] (1)</td>
<td></td>
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<tr>
<td>• Sometimes [sometimes] (1)</td>
<td></td>
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<tr>
<td>• Usually [usually] (0)</td>
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<tr>
<td>• Always [always] (0)</td>
<td></td>
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<tr>
<td>LIFESTYLE_ACTIVITY_ALCOHOL</td>
<td>I drink a lot of alcoholic beverages such as beer, wine, and liquor.</td>
</tr>
<tr>
<td>• Never [never] (1)</td>
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<tr>
<td>• Rarely [rarely] (1)</td>
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<tr>
<td>• Sometimes [sometimes] (1)</td>
<td></td>
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<tr>
<td>• Usually [usually] (0)</td>
<td></td>
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<tr>
<td>• Always [always] (0)</td>
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<tr>
<td>LIFESTYLE_SAFETY</td>
<td>Here are some statements about your SAFETY MANAGEMENT WITH EPILEPSY.</td>
</tr>
<tr>
<td>------------------</td>
<td>--------------------------------------------------------------------</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_DRVING</td>
<td>I avoid driving until I have been seizure free for at least 6 months.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (0)</td>
</tr>
<tr>
<td></td>
<td>• Rarely [rarely] (0)</td>
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<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (1)</td>
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<td>• Always [always] (1)</td>
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<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_SWIMMING</td>
<td>I go swimming alone.</td>
</tr>
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<td></td>
<td>• Never [never] (0)</td>
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<tr>
<td></td>
<td>• Rarely [rarely] (0)</td>
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<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (1)</td>
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<td>• Always [always] (1)</td>
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<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_POWER_TOOLS</td>
<td>I use power tools such as electric saws, electric hedge trimmers, or electric knives without an automatic shut off.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (0)</td>
</tr>
<tr>
<td></td>
<td>• Rarely [rarely] (0)</td>
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<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (1)</td>
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<td>• Always [always] (1)</td>
</tr>
<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_BATHS</td>
<td>I take showers instead of baths.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (1)</td>
</tr>
<tr>
<td></td>
<td>• Rarely [rarely] (1)</td>
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<tr>
<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<td></td>
<td>• Usually [usually] (0)</td>
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<td></td>
<td>• Always [always] (0)</td>
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<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_WATER_TEMP</td>
<td>I keep the water temperature in my home low enough so that it would not burn me if I had a seizure in the shower.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (1)</td>
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<td></td>
<td>• Rarely [rarely] (1)</td>
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<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<tr>
<td></td>
<td>• Usually [usually] (0)</td>
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<td></td>
<td>• Always [always] (0)</td>
</tr>
<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_CLIMBING</td>
<td>I climb on high stools, chairs, or ladders.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (0)</td>
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<tr>
<td></td>
<td>• Rarely [rarely] (0)</td>
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<td>• Sometimes [sometimes] (1)</td>
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<td>• Usually [usually] (1)</td>
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<td></td>
<td>• Always [always] (1)</td>
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<tr>
<td></td>
<td>• Not applicable (0)</td>
</tr>
<tr>
<td>LIFESTYLE_SAFETY_WEAR_INFORMATION</td>
<td>I wear a bracelet/necklace or carry information stating that I have seizures/epilepsy.</td>
</tr>
<tr>
<td></td>
<td>• Never [never] (1)</td>
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<td></td>
<td>• Rarely [rarely] (1)</td>
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<td></td>
<td>• Sometimes [sometimes] (1)</td>
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<td></td>
<td>• Usually [usually] (0)</td>
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<tr>
<td></td>
<td>• Always [always] (0)</td>
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</tbody>
</table>
| LIFESTYLE_SAFETY_CELLPHONE | I carry a cell phone with me to call someone if I need help. | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0)  
• Not applicable (0) |
| LIFESTYLE_SAFETY_COOKING   | When I am in the kitchen, I use safety precautions.       | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0)  
• Not applicable (0) |
| LIFESTYLE_RECORDS          | The following are statements about your RECORD KEEPING.     | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_RECORDS_OCCURRENCE | I keep a record of the seizures I have.                  | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_RECORDS_SIDEFFECTS | I keep track of the side effects of my seizure medicine.   | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_SUPPORT          | The following are statements about SUPPORT for your epilepsy management. | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_SUPPORT_HCP_SIDEFFECTS | I tell my doctor or nurse when I think I am having unexpected side-effects from my seizure medicine. | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_SUPPORT_HCP_MEDICINES   | I check with my doctor before taking other medicines.      | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_SUPPORT_TALK_TO_OTHERS | I talk to / chat online with other people who have epilepsy. | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE_SUPPORT_TEACH_FAMILY | I teach my friends and family what to do during a seizure.  | • Never [never] (1)  
• Rarely [rarely] (1)  
• Sometimes [sometimes] (1)  
• Usually [usually] (0)  
• Always [always] (0) |
| LIFESTYLE SUPPORT DISCLOSURE | I tell other people that I have epilepsy if they need to know. | Never [never] (1)  
Rarely [rarely] (1)  
Sometimes [sometimes] (1)  
Usually [usually] (0)  
Always [always] (0) |
|-----------------------------|--------------------------------------------------|---------------------------|
| LIFESTYLE SUPPORT CLINIC VISITS | I miss doctor or clinic appointments. | Never [never] (0)  
Rarely [rarely] (0)  
Sometimes [sometimes] (1)  
Usually [usually] (1)  
Always [always] (1) |

**MOOD_NDDIE**

| MOOD_NDDIE_1 Everything is a struggle | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |
|----------------------------------------|--------------------------------------------------|
| MOOD_NDDIE_2 Nothing I do is right. | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |
| MOOD_NDDIE_3 I feel guilty. | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |
| MOOD_NDDIE_4 I'd be better off dead. | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |
| MOOD_NDDIE_5 I feel frustrated. | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |
| MOOD_NDDIE_6 Difficulty finding pleasure. | Always or often [always_or_often] (4)  
Sometimes [sometimes] (3)  
Rarely [rarely] (2)  
Never [never] (1) |

**FEEDBACK**

Thank you for answering questions about your epilepsy management.
### MY GOALS (Goals and Strategies Embedded in MINDSET)

<table>
<thead>
<tr>
<th>Question</th>
<th>Goal</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Seizure Management</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If I am going away from home, I take my seizure medicine with me.</td>
<td>Always pack the amount of medicine needed while away from home.</td>
<td>Plan ahead by making a list of the amount of medicine you will need. Consider taking more than the amount that you would need to avoid running out. Pack your medicine bag the day before you leave. Place your medicine in a pill container/box for easy access.</td>
</tr>
<tr>
<td>I call my doctor/nurse if I am having more seizures than usual.</td>
<td>Always contact your doctor or nurse when you are experiencing increased seizures.</td>
<td>Ask for the phone number for emergency/after-hours calls. Keep a log of your seizures so that you know if there is an increase.</td>
</tr>
<tr>
<td>I have a way to remind myself to take my seizure medicine.</td>
<td>Create a plan or a routine to remind yourself to take your medicine daily.</td>
<td>Take your medicine before or after one of your daily activities (e.g. breakfast, dinner, during a particular TV show, before going to bed) Use a pill container/box Use a paper calendar or a set a daily reminder on your phone’s calendar Use a seizure diary Have electronic reminders, via text or email, sent to you when it’s time to take your medicine (e.g. two good options are available with My Epilepsy Diary or Texting 4 Control).</td>
</tr>
<tr>
<td>When the doctor orders blood tests, I have them done.</td>
<td>Get all of your blood work done in a timely manner.</td>
<td>Try to get your blood work done as soon as you get an order from your doctor. Ask your doctor’s office about a lab that may be open earlier in the morning during weekdays or on the weekends if you have to fast. Ask your doctor’s office if they can perform your blood work there. Schedule your blood work at a date and time when you will have reliable transportation.</td>
</tr>
<tr>
<td>Identify triggers.</td>
<td>Use a seizure diary and write down the time your seizure happened, your symptoms, what you were doing when you had the seizure and the medicines you took before the seizure began. Make a note of any other life events that took place around this time (e.g. not sleeping well, sick with fever or illness, stress or missing medicines).</td>
<td>Get an average of 6-8 hours of sleep. Limit your alcohol consumption. Participate in activities that help you reduce your stress (e.g. exercise, meditation). Avoid noise, loud sounds, or other environmental stimulants. Use natural lighting when indoors. Focus on distant objects when riding in a car to avoid flickering lights or patterns. Avoid strobe lights or flashing bulbs on holiday decorations. Avoid clubs, discos or loud concerts. Use a computer monitor with minimal contrast glare or use a screen filter. Use earplugs or earphones, especially in noisy or crowded places. When you are in a high risk situation try to listen to relaxing music or sounds, or try distracting yourself by singing or focusing on a different activity.</td>
</tr>
<tr>
<td>I stay away from things that I know make me have seizures.</td>
<td>Avoid triggers.</td>
<td></td>
</tr>
<tr>
<td>Medicine Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the past two weeks I have missed doses of my medicine on ______ days.</td>
<td>Take your medicine as prescribed every day.</td>
<td>Use reminders to take your medicine daily (calendar, email, phone etc.) Prioritize taking your medicine even when your routine is interrupted or your schedule is hectic. Incorporate your medicine into your daily routine by always taking it at the same time or during a particular activity (e.g. breakfast) every day. Use a pill container/box. Refill your prescriptions in a timely manner.</td>
</tr>
<tr>
<td>Question</td>
<td>Goal</td>
<td>Strategies</td>
</tr>
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</tr>
<tr>
<td>I experience the following side effects from my seizure medicine(s)?</td>
<td>Reduce the number of side effects caused by your medicine.</td>
<td>Make a list of all your side effects and discuss during your next doctor’s visit. Ask your doctor about modifying your prescription to a lower dose, prescribing additional medicine for the side effects, or trying an alternative medicine.</td>
</tr>
<tr>
<td>(Check all that apply)</td>
<td></td>
<td>Prioritize taking your medicine even when your routine is interrupted or your schedule is hectic.  Incorporate your medicine into your daily routine by always taking it at the same time or during a particular activity (e.g., breakfast) every day.</td>
</tr>
<tr>
<td>I take my seizure medicine the way my doctor orders it.</td>
<td>Always take your seizure medicine the way your doctor prescribes it.</td>
<td>Use a pill container/box. Refill your prescriptions in a timely manner.</td>
</tr>
<tr>
<td>When my seizure medicine is running out, I spread out the time between</td>
<td>Always keep enough medicine.</td>
<td>Ask for a refill of your medicines at least two weeks before you run out. Enroll in an automatic refill plan. Many major pharmacies offer patients the option to enroll in a 60 or 90 day refill plan which not only saves you time but also money.</td>
</tr>
<tr>
<td>doses.</td>
<td></td>
<td>If you will be away from home for a prolonged period of time, talk to your doctor or pharmacist about a plan to ensure that you will not run out of medicine.</td>
</tr>
<tr>
<td>I have to put off having my seizure medicine refilled because it costs</td>
<td>Always have medicine in stock.</td>
<td>If you can’t afford a full month refill before your next paycheck, then work with your pharmacy for a partial refill. If you are due for a refill, most pharmacies will let you buy a partial supply (e.g., 2-3 days, one week) of your medicine if you tell them that you need more time to buy the rest.</td>
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<tr>
<td>too much money.</td>
<td></td>
<td>Many major pharmacies offer patients the option to enroll in a 60 or 90 day refill plan which not only saves you time but also money. Ask your doctor’s office or pharmacy about community or pharmacy based discount cards. Many local organizations (public and nonprofit) offer the uninsured with pharmacy discount cards which can reduce your prescription costs by up to 75%. Some major pharmacies also offer certain discount plans/cards for a small annual fee which could save you hundreds.</td>
</tr>
<tr>
<td>If I have side effects from the seizure medicines, I skip a dose</td>
<td>Talk to your doctor about all of your side effects before skipping</td>
<td>Make a list of all your side effects and bring it with you to discuss during your next doctor’s visit. Ask your doctor about the possibility of modifying your prescription to a lower dose, prescribing additional medicine for the side effects, or trying an alternative medicine if the side effects are too serious.</td>
</tr>
<tr>
<td>without asking my doctor.</td>
<td>your medicine.</td>
<td>Ask for a refill of your medicines at least two weeks before you run out. Enroll in an automatic refill plan. Many major pharmacies offer patients the option to enroll in a 60 or 90 day refill plan which not only saves you time but also money. If you will be away from home for a prolonged period of time, talk to your doctor or pharmacist about a plan to ensure that you will not run out of medicine.</td>
</tr>
<tr>
<td>I plan ahead so that I do not run out of my seizure medicine.</td>
<td>Plan ahead so that you always have enough medicine in stock.</td>
<td>Enroll in an automatic refill plan. Many major pharmacies offer patients the option to enroll in a 60 or 90 day refill plan which not only saves you time but also money. If you will be away from home for a prolonged period of time, talk to your doctor or pharmacist about a plan to ensure that you will not run out of medicine.</td>
</tr>
<tr>
<td>I forget to take my seizure medicine.</td>
<td>Find ways to remind yourself to take your medicine everyday.</td>
<td>Take your medicine before or after one of your daily activities (e.g., breakfast, dinner, after or during a particular TV show, before going to bed). Use a pill container/box. Use a paper calendar or a set a daily reminder on your phone’s calendar. Use a seizure diary to keep track of when you take your medicine.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have electronic reminders, via text or email, sent to you when it’s time for a dose of medicine (e.g., two good options are available with My Epilepsy Diary or Texting 4 Control).</td>
</tr>
<tr>
<td>Question</td>
<td>Goal</td>
<td>Strategies</td>
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<tr>
<td>I take my seizure medicine at the same time each day.</td>
<td>Take your medicine at the same time each day in order to establish a routine.</td>
<td>Take your medicine before or after one of your daily activities (e.g. breakfast, dinner, after or during a particular TV show, before going to bed).  Use a pill container/box.  Use a paper calendar or a set a daily reminder on your phone’s calendar.  Use a seizure diary to keep track of when you take your medicine.  Have electronic reminders, via text or email, sent to you when it's time for a dose of medicine (e.g. two good options are available with My Epilepsy Diary or Texting 4 Control).</td>
</tr>
<tr>
<td><strong>Lifestyle Management</strong></td>
<td></td>
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</tr>
<tr>
<td>Everything is a struggle.</td>
<td></td>
<td>Try counseling to help cope with seizures or other negative thoughts or feelings.</td>
</tr>
<tr>
<td>Nothing I do is right.</td>
<td></td>
<td>Consider attending a support group for epilepsy or stress management, or participating in group therapy.</td>
</tr>
<tr>
<td>I feel guilty.</td>
<td>Combat depression and/or negative thoughts.</td>
<td>Keep a daily journal of your thoughts and feelings. Journaling can be a great outlet for your feelings and it can help you see the issues more clearly.</td>
</tr>
<tr>
<td>I'd be better off dead.</td>
<td></td>
<td>Use &quot;time-out&quot; periods. Giving yourself a time-out allows you to take a step back from the stressor or the situation and think about how best to address it.</td>
</tr>
<tr>
<td>I feel frustrated</td>
<td></td>
<td>Try talking to a family member or a close friend about your thoughts and emotions.</td>
</tr>
<tr>
<td>I have difficulty finding pleasure.</td>
<td></td>
<td>Tell your doctor and nurse how you feel. The effects of stress can be harmful to your seizures, and your life. When mood changes last longer than expected, you may need help from a mental health professional too. If you feel emotionally unsafe, call your doctor or go to an emergency room to be evaluated.</td>
</tr>
<tr>
<td>I make sure I get enough sleep.</td>
<td>Get an average of 6-8 hours of sleep every night.</td>
<td>Try to regulate sleeping habits so you have a consistent schedule and get enough sleep.  Keep a log or diary of your sleep patterns.  Discuss your medicine schedule with your doctor or nurse. Changing times or doses at night may help sleep.  Limit caffeine and try to avoid it after noon time or mid-afternoon at the latest.  Avoid alcohol and nicotine prior to sleep.  Limit working or studying late at night. Stop work at least one hour before bedtime to allow time to relax.  Exercise in the early evening if possible.  Take warm showers or have someone give you a back rub before bedtime to decrease muscle tension.  Try relaxation exercises before bedtime.  Limit naps throughout the day and avoid naps in the early evening.  If anxious or worried, talk to someone or write down your feelings before going to sleep. Put this away and deal with these worries or concerns in the morning!  If you can’t fall asleep within 15 minutes get up and do something else for 15 minutes. Then go back to bed and try again. Don’t toss and turn in bed all night.</td>
</tr>
<tr>
<td>I do things that I enjoy to help manage stress.</td>
<td>Reduce your stress and practice relaxation techniques.</td>
<td>Exercise regularly. Lots of research has shown the exercise helps lower stress.  Learn relaxation exercises, deep breathing, yoga, or other strategies that help with stress and general well-being.  Set priorities for what is important in your life and let the rest go.  Exercise regularly. Lots of research has shown the exercise helps lower stress.</td>
</tr>
<tr>
<td>Question</td>
<td>Goal</td>
<td>Strategies</td>
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</tr>
<tr>
<td>I have ways to help me relax to reduce my chances of having a seizure.</td>
<td>Reduce your stress and practice relaxation techniques.</td>
<td>Learn relaxation exercises, deep breathing, yoga, or other strategies that help with stress and general well-being. Set priorities for what is important in your life and let the rest go.</td>
</tr>
<tr>
<td>I get enough exercise.</td>
<td>Incorporate exercise into your daily routine.</td>
<td>Exercise for at least 30 minutes a day (e.g. walk around your neighborhood, visit a park, go to the gym). Avoid exercising in the middle of the day during hot weather. Carry your seizure resuscitation medicine and identification information if your seizures are not controlled. Exercise in a safe place, for example ride a bike on bike paths, not on the street, play ball on grass not hard surfaces. Ask your healthcare team about any specific exercises to avoid.</td>
</tr>
<tr>
<td>I eat regular, healthy meals.</td>
<td>Take control of your diet.</td>
<td>Avoid foods that you know you may be allergic to and may cause a seizure. Talk to your primary care doctor to make sure there’s not a medical problem contributing to food sensitivities and seizures. Regulate meal times and patterns around sleep, activity, and medicine schedules. Have a well-balanced diet and eat at consistent times to avoid long periods without food. If your appetite is poor, try small frequent meals instead of skipping meals. If you are following a diet specifically for your epilepsy, be sure to follow the advice of your doctor and nutritionist about specific foods and amounts.</td>
</tr>
<tr>
<td>I stay out late at night.</td>
<td>Avoid staying up late/go to bed as early as possible.</td>
<td>Keep a regular sleep schedule Avoid staying up late. Don’t drink alcohol. Consult your doctor about how much alcohol is safe for you. Limit your drinking to one drink (12 oz. of beer, 4 oz. of wine or 1 oz. of hard alcohol) per 24 hours.</td>
</tr>
<tr>
<td>I drink a lot of alcoholic beverages such as beer, wine, and whiskey.</td>
<td>Avoid excessive drinking</td>
<td>Consult your doctor before you begin driving after you have had a seizure. If applicable (photosensitive seizures). Limit your driving to day light hours as flashing or glaring lights during the night may trigger a seizure. Schedule reliable transportation ahead of an appointment or an event. Swim in public pools with a life guard onsite and/or other people. Swim with a friend or family member. Wear a life jacket or vest if you swim alone.</td>
</tr>
<tr>
<td>I avoid driving until I have been seizure free for minimum amount of time in required my state.</td>
<td>Don’t drive until you have been seizure free for the minimum amount of time required in your state.</td>
<td>Consult your doctor before you begin driving after you have had a seizure. If applicable (photosensitive seizures). Limit your driving to day light hours as flashing or glaring lights during the night may trigger a seizure. Schedule reliable transportation ahead of an appointment or an event.</td>
</tr>
<tr>
<td>I go swimming alone.</td>
<td>Don’t go swimming alone</td>
<td>Swim in public pools with a life guard onsite and/or other people Swim with a friend or family member Wear a life jacket or vest if you swim alone.</td>
</tr>
<tr>
<td>I use power tools such as electric saws, electric hedge trimmers, or electric knives without an automatic shutoff.</td>
<td>Don’t use power tools while you are alone or without an automatic shutoff</td>
<td>Use power tools with an automatic or emergency shut-off switch/button Make sure you are not alone when you use power tools Ask someone else to complete tasks.</td>
</tr>
<tr>
<td>I take showers instead of baths.</td>
<td>Take showers instead of baths</td>
<td>Take showers instead of baths Install a shower in your home. Only bath if someone else is in the house.</td>
</tr>
<tr>
<td>I keep the water temperature in my home low enough so that it would not burn me if I had a seizure in the shower.</td>
<td>Keep your shower temperature low enough to avoid getting burned</td>
<td>Keep your water temperature low Only shower with slightly warm water.</td>
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<tr>
<td>Question</td>
<td>Goal</td>
<td>Strategies</td>
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<tr>
<td>I climb on high stools, chairs, or ladders.</td>
<td>Don’t climb on high stools, chairs or ladders</td>
<td>Have someone with you if you have to climb on high objects</td>
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<td>Keep regularly used items in places that you can reach without any assistance</td>
</tr>
<tr>
<td>I wear a bracelet/necklace or carry information stating that I have seizures/epilepsy.</td>
<td>Always carry an ID stating your epilepsy</td>
<td>Get a medical alert device.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wear a bracelet or necklace with health information, instructions on what to do in case of a seizure and/or emergency contact information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Always carry an ID with your correct address.</td>
</tr>
<tr>
<td>I carry a cell phone with me to call someone if I need help.</td>
<td>Carry a cell phone to call someone in case of an emergency</td>
<td>Carry a cell phone at all times.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Get a cell phone.</td>
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<tr>
<td>When I am in the kitchen, I use safety precautions.</td>
<td>Try to use safety precautions when cooking</td>
<td>Store knives when you are not using them.</td>
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<td>Use potholders or oven mitts.</td>
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<td>Wipe up spills immediately.</td>
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<td>Get a fire extinguisher for your kitchen</td>
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<td>Don’t leave boiling water/foods unattended</td>
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<td></td>
<td>Always close kitchen cabinet doors.</td>
</tr>
<tr>
<td>I keep a record of the seizures I have.</td>
<td>Keep a record of your seizures</td>
<td>Use a seizure diary and note data, time of day, symptoms, when seizures occur, and medications taken.</td>
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<tr>
<td></td>
<td></td>
<td>Record your seizures on a calendar</td>
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<td></td>
<td>Use a computer based program to record your seizures (e.g. <a href="https://my-epilepsy.com/diary/login-page.php">https://my-epilepsy.com/diary/login-page.php</a>)</td>
</tr>
<tr>
<td>I keep track of the side effects of my seizure medicine.</td>
<td>Keep a record of all the medication that you take and any of their side effects</td>
<td>Use a seizure diary and note all of the side effects of your medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Use a computer based program to record your seizures (e.g. <a href="https://my-epilepsy.com/diary/login-page.php">https://my-epilepsy.com/diary/login-page.php</a>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Call your doctor’s office and leave a message for your physician with his/her nurse</td>
</tr>
<tr>
<td>I tell my health care provider when I think I am having unexpected side-effects from my seizure medicine.</td>
<td>Tell your doctor about any unexpected side effects from your medications</td>
<td>Call your doctor’s office and describe any side effects from your medication.</td>
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<td></td>
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<td>Keep an updated list of all your medications with your pharmacy</td>
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<td>Ask a pharmacist about any potential hazardous interactions that other medicines may have on your AEDs</td>
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<td></td>
<td>Inform your primary doctor or any other physician that may prescribe you another medication that you are taking a seizure medication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Before you begin on any other medication, call your doctor’s office and let his/her nurse know that you are planning on starting another prescribed medication</td>
</tr>
<tr>
<td>I check with my doctor before taking other medicines.</td>
<td>Tell your doctor before taking any other prescribed medications as they may stop your AEDs for working.</td>
<td></td>
</tr>
<tr>
<td>I talk to / chat online with other people who have epilepsy.</td>
<td>Talk to other people who have epilepsy</td>
<td>Join an epilepsy support group (e.g. local/community groups or online)</td>
</tr>
<tr>
<td>Question</td>
<td>Goal</td>
<td>Strategies</td>
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</table>
| I teach my friends and family what to do during a seizure. | Teach your friends and family what to do for you during a seizure | Have friends/family describe your seizure(s) (e.g. symptoms, duration)  
Teach your family/friends to do the following in case of a seizure:  
1. Loosen clothing around your neck.  
2. Avoid holding you down or restraining you.  
3. Avoid inserting objects in your mouth.  
4. Reassure concerned bystanders who may be upset and ask them to give you room.  
5. Remove sharp objects (glasses, furniture, etc.) to prevent injury.  
After the seizure, ask them to lay you on your side to maintain an open airway and to prevent you from inhaling any secretions.  
After a seizure, you may be confused and should not be left alone.  
Call 911 if the seizure lasts longer than 5 minutes, or if another seizure begins soon after the first, or if the person cannot be awakened after the movements have stopped. |
| I tell other people that I have epilepsy if they need to know. | Tell those who you think may need to know about your condition | Tell a close friend  
Tell your family  
Tell your employer  
Tell anyone who may need to know about your condition or that may be of help during a seizure. |
| I miss doctor or clinic appointments | Attend all of your doctor’s appointments | Prioritize your schedule to give preference to your doctor’s appointment  
Write your appointment on your calendar  
Set appointment reminder on phone or text message service  
Notify the clinic if you cannot make the appointment and reschedule. |
APPENDIX E: Patient Questionnaires

Appendix E-1: Demographic Questionnaire

PATIENT DEMOGRAPHIC QUESTIONNAIRE

Date (MM/DD/YYYY): __ __ / __ __ / __ __ __ __

1. What is your gender? (Choose only one answer)
   □ Male
   □ Female

2. How old are you? ___________ (years)

3. What is your ethnic origin? (Choose only one answer)
   □ Hispanic or Latino
   □ Non-Hispanic or Non-Latino
   
   If Hispanic: Do you consider yourself to be:
   □ Mexican, Mexican American, Chicano
   □ Puerto Rican
   □ Cuban
   □ Central American
   □ South American
   □ Other Specify (________________________)

4. What is your race? (Please select one to which you feel you belong)
   □ White
   □ Black/African-American
   □ American Indian or Alaska Native
   □ Asian Indian
   □ Chinese
   □ Filipino
   □ Japanese
   □ Korean
   □ Vietnamese
   □ Native Hawaiian or Other Pacific Islander
   □ Other (Specify: ________________)

5. How long have you lived in the U.S? _____________ (years)

Collected by: __ __
MINDSET Feasibility Study 1
6. What is the highest level of education you completed? (Choose only one answer)
- Never attended school or only attended kindergarten
- Grades 1 - 8 (Elementary or Middle School)
- Grades 9 - 11 (Some high school)
- GED (High school graduate)
- College 1-3 years (Some college or technical school)
- College 4 years or more (College graduate)

7. Which best describes your marital status? (Choose only one answer)
- Married
- Separated/divorced
- Living together/common law married
- Widowed
- Single

8. Including all sources of income, what category is your annual household income? (Choose only one answer)
- Less than $10,000
- $10,000-$24,999
- $25,000-$49,999
- $50,000 or greater

9. What is your employment status? (Choose one)
- Employed for wages
- A Homemaker
- Unable to work
- Out of work for 1 year or more
- Self-employed
- Student
- Student and Employed
- Out of work for less than 1 year
- Retired
10. How do you pay for your health care? (Please check all that apply)
   □ Medicaid/AHCCCS
   □ Medicare
   □ Public insurance other than Medicaid/AHCCCS (Tricare, VA, CHAMPVA, IHS, other)
   □ Employer provided health insurance (Own plan)
   □ Employer provided health insurance (Dependent)
   □ Individually purchased health insurance
   □ No coverage
   □ Other

11. How old were you when you had your first seizure? _________ (years)

12. How old were you when you received a diagnosis of epilepsy? _________ (years)

13. Have you had a seizure in the last 12 months?
   □ Yes
   □ No

14. Have you had a seizure in the last 30 days?
   □ Yes
   □ No

15. If yes, how many? # _______ of seizures in last 30 days?

16. Would you say that in general your health is…?
   □ Excellent
   □ Very good
   □ Good
   □ Fair
   □ Poor
   □ Don’t know / not sure

17. Thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days, was your physical health not good?

   __ Number of days
   □ None
   □ Don’t know / Not sure

Collected by: __ __ MINDSET Feasibility Study 3
18. Thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?

__ Number of days

☐ None
☐ Don’t know / Not sure

19. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

__ Number of days

☐ None
☐ Don’t know / Not sure

20. Thinking about you and your health care provider interaction, please choose one of the following statements that best describes how you would like your treatment decision to be made:

☐ I prefer to make the final treatment decision.
☐ I prefer to make the final treatment decision after seriously considering my doctor’s opinion.
☐ I prefer that my doctor and I share responsibility for deciding which treatment is best.
☐ I prefer that my doctor makes the final treatment decision, but seriously considers my opinion.
☐ I prefer to leave all treatment decisions to my doctor.

21. Do you have access to a computer? (Choose only one answer)

☐ Yes
☐ No

22. Do you have access to a smartphone? (Choose only one answer)

☐ Yes
☐ No

23. In general what language do you read and speak?

☐ Only Spanish
☐ More Spanish than English
☐ Both equally
☐ More English than Spanish
☐ Only English
24. What language do you usually speak at home?
   - Only Spanish
   - More Spanish than English
   - Both equally
   - More English than Spanish
   - Only English

25. What language do you usually speak with your friends?
   - Only Spanish
   - More Spanish than English
   - Both equally
   - More English than Spanish
   - Only English

26. In what language do you usually think?
   - Only Spanish
   - More Spanish than English
   - Both equally
   - More English than Spanish
   - Only English
Appendix E-2: Usability Questionnaire

Instructions

Tell us what you think about "MINDSET."

This survey is designed to find out what patients think about this computer-based program. We want to know what they like and what they think could be better.

You do not have to answer any questions that make you feel uncomfortable. Your participation is voluntary. It is YOUR CHOICE to answer the questions on this survey.

It is very important that you answer every question as truthfully as you can.

MINDSET Usability Study

Collected by: ___ ___ 1
MINDSET Summary Feedback Form

The following questions ask about the MINDSET program as a whole. This includes the My EPILEPSY, My GOALS and the My ACTION PLAN section.

Please circle the answer that best describes how you feel about your experience with MINDSET:

<table>
<thead>
<tr>
<th></th>
<th>I think that the time it took to use MINDSET was:</th>
<th>Too quick</th>
<th>Just right</th>
<th>Too Long</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td>I think the information I got from MINDSET was:</td>
<td>Helpful</td>
<td>Not helpful</td>
<td>Don’t know</td>
</tr>
<tr>
<td>2)</td>
<td>I think the information I got from MINDSET:</td>
<td>Can be trusted</td>
<td>Can’t be trusted</td>
<td>Don’t know</td>
</tr>
<tr>
<td>3)</td>
<td>I think the information provided in MINDSET will help me manage my epilepsy better.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>4)</td>
<td>The information in MINDSET helped me to think carefully about my epilepsy.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>5)</td>
<td>The questions in MINDSET helped me to think carefully about how I manage my epilepsy.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>6)</td>
<td>I think the information provided in MINDSET will help me talk to my doctor or nurse about my epilepsy.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>7)</td>
<td>I knew and understood most of the words used in MINDSET.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>8)</td>
<td>I needed help to answer questions in MINDSET.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>9)</td>
<td>I would tell other patients to use MINDSET.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>10)</td>
<td>How does MINDSET compare to other seizure programs you’ve used in the clinic?</td>
<td>Less useful</td>
<td>As useful</td>
<td>More useful</td>
</tr>
<tr>
<td>11)</td>
<td>I would use MINDSET in a clinic visit.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>12)</td>
<td>The size of the letters made it easy to read.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
<tr>
<td>13)</td>
<td>MINDSET was easy to use.</td>
<td>Yes</td>
<td>No</td>
<td>Don’t know</td>
</tr>
</tbody>
</table>

MINDSET Usability Study

Collected by: ___

2
Please circle the answer that best describes how you feel about:

<table>
<thead>
<tr>
<th>15) The <strong>entire</strong> program.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16) The <strong>colors</strong> used in this program.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17) The <strong>buttons</strong> used in this program.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>18) The <strong>hand-held device</strong> used for this program.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>19) The size of the <strong>letters</strong>.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>20) The <strong>layout</strong> of the screens.</th>
<th>Like a lot</th>
<th>Like</th>
<th>Dislike</th>
<th>Dislike a lot</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you selected “Dislike” or “Dislike a Lot” please explain why:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MINDSET Usability Study

Collected by: ____ 3
Please tell us how easy it was to perform each of the following activities:

<table>
<thead>
<tr>
<th></th>
<th>Not easy</th>
<th>Somewhat easy</th>
<th>Very easy</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Enter your responses into MINDSET:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Understand instructions for “My Goals”:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>Choose a topic to work on:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Choose your strategies:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Understand the Action Plan:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MINDSET Usability Study

Collected by: ___

4
Appendix E-3: Exit Interview

UA, UTH

EXIT INTERVIEW

1) What did you like best about MINDSET?

2) What did you like least about MINDSET?

3) Was there anything that you would have liked to see in MINDSET but did not see? If so, what?

4) Was there anything in MINDSET that made you feel upset, embarrassed, or uncomfortable? If so, what?

5) What would you tell other patients about MINDSET?

Collected by: __ __ MINDSET Usability Study
Appendix E-4: Clinic Visit Interaction Checklist

MINDSET Topics Discussed

Please check (√) if you discussed the following items in your Action Plan with your physician today:

<table>
<thead>
<tr>
<th>Topic</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizure and Medication History</td>
<td></td>
</tr>
<tr>
<td>Recent seizures history</td>
<td></td>
</tr>
<tr>
<td>Seizure side effects</td>
<td></td>
</tr>
<tr>
<td>Medication side effects</td>
<td></td>
</tr>
<tr>
<td>Medication prescriptions</td>
<td></td>
</tr>
<tr>
<td>Seizure management</td>
<td>✓</td>
</tr>
<tr>
<td>Your seizure management issue(s)</td>
<td></td>
</tr>
<tr>
<td>Your seizure management goals</td>
<td></td>
</tr>
<tr>
<td>Your strategies for your goal</td>
<td></td>
</tr>
<tr>
<td>Your confidence related to the strategies</td>
<td></td>
</tr>
<tr>
<td>Your plan to overcome barriers</td>
<td></td>
</tr>
<tr>
<td>Medication management</td>
<td>✓</td>
</tr>
<tr>
<td>Your medication management issue(s)</td>
<td></td>
</tr>
<tr>
<td>Your medicine management goals</td>
<td></td>
</tr>
<tr>
<td>Your strategies for your goal</td>
<td></td>
</tr>
<tr>
<td>Your confidence related to the strategies</td>
<td></td>
</tr>
<tr>
<td>Your plan to overcome barriers</td>
<td></td>
</tr>
<tr>
<td>Lifestyle management</td>
<td>✓</td>
</tr>
<tr>
<td>Your lifestyle management issue(s)</td>
<td></td>
</tr>
<tr>
<td>Your lifestyle management goals</td>
<td></td>
</tr>
<tr>
<td>Your strategies for your goal</td>
<td></td>
</tr>
<tr>
<td>Your confidence related to the strategies</td>
<td></td>
</tr>
<tr>
<td>Your plan to overcome barriers</td>
<td></td>
</tr>
</tbody>
</table>

Collected by: __ __

SP-MINDSET Usability Study
APPENDIX F: Health Care Providers Questionnaires

Appendix F-1: Health Care Provider Profile

<table>
<thead>
<tr>
<th>Healthcare Provider Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Degrees and certifications</td>
</tr>
<tr>
<td>☐ Epileptologist</td>
</tr>
<tr>
<td>☐ General Neurology</td>
</tr>
<tr>
<td>☐ RN/LVN/LPN</td>
</tr>
<tr>
<td>☐ Nurse Practitioner</td>
</tr>
<tr>
<td>☐ Other: ____________________</td>
</tr>
<tr>
<td>2. Years in clinical practice.</td>
</tr>
<tr>
<td>3. Years at current practice.</td>
</tr>
</tbody>
</table>
Appendix F-2: Health Care Provider Exit Interview

HEALTH CARE PROVIDER EXIT INTERVIEW

1.) What can you tell us about your experience using MINDSET in your clinic?

- What were the good things about using MINDSET?

- What problems did YOUR STAFF experience in using MINDSET?

- How did you solve these problems?

- Do you have any recommendations for solving any of the problems that you encountered?

2. How did MINDSET influence the way that you manage Patients with epilepsy in your clinic (including those patients for whom you didn’t use MINDSET)?

- Can you give any specific examples?

- Anything else?

3.) How did MINDSET assist you in …?

- Identifying seizure, medication, or lifestyle management problems?

- Identifying patient self-management goals and strategies?

- Assisting in overcoming patient barriers to self-management?

- Providing a written action plan?

Collected by: _____
MINDSET Usability Study
Version 4/20/165
4.) What feedback did you get from Patients about their use of MINDSET?

5.) What would you tell other Health Care Providers about MINDSET?
   - Would you recommend that they use MINDSET?

6.) Would you continue to use MINDSET in your clinic if given the opportunity to do so? Why/why not?
Appendix F-3: Health Care Provider Feature Check List

MINDSET Health Care Provider Feature Checklist

1. Compared to practicing medicine without MINDSET, identifying seizure, medication, and lifestyle problems...

A. Was easier to do □ □ □ □ □ □ Was harder to do
B. Helped me make a more thorough assessment. □ □ □ □ □ □ Helped me make a less thorough assessment.
C. Helped me make a more accurate assessment. □ □ □ □ □ □ Helped me make a less accurate assessment.

D. How could this feature be improved? Write comments here...

2. Compared to practicing medicine without MINDSET, identifying patient goals, strategies and barriers....

A. Was easier to do □ □ □ □ □ □ Was harder to do
B. Helped me make a more thorough assessment. □ □ □ □ □ □ Helped me make a less thorough assessment.
C. Helped me make a more accurate assessment. □ □ □ □ □ □ Helped me make a less accurate assessment.

D. How could this feature be improved? Write comments here...

3. Compared to practicing medicine without MINDSET, developing an action plan for your patient...

A. Was easier to do □ □ □ □ □ □ Was harder to do
B. Helped me outline a more thorough treatment plan. □ □ □ □ □ Helped me outline a less thorough treatment plan.

C. Helped me make a more accurate treatment plan. □ □ □ □ □ Helped me make a less accurate treatment plan.

D. How could this feature be improved?
Write comments here...

4. Compared to practicing medicine without MINDSET, using MINDSET with my patient...

A. Took me more time □ □ □ □ □ Took me less time

B. Helped me improve my communication □ □ □ □ □ Interfered with my communication

C. How could MINDSET be improved?
Write comments here...
APPENDIX G: Usability Study (PPAG) Protocol and Agenda

Appendix G-1: MINDSET Usability Study Protocol

UA, UT

MINDSET

Protocol for Usability Study of MINDSET

Purpose: To collect quantitative and qualitative feedback from epilepsy patients on MINDSET’s functional redesign.

Who: Protocols for the study investigators and research staff.

When: Year one and two of the five-year study.

Where: The procedures will be used in meetings conducted at four clinics, two in Texas and two in Arizona.

Materials needed: Informed consent form, usability questionnaire, usability exit interview, pad, pen.

Procedures:

1. Patients will be invited to participate in a patient-provider advisory group (PPAG) to complete a usability survey which rates satisfaction, ease of use, acceptability, credibility, and applicability to their needs. They will then be interviewed on potential enhancements (content, function, and interface design). In addition to patient representatives the PPAG will also include healthcare providers at each clinic who will also use MINDSET and complete the survey. The PPAG will meet to participate in the usability study. Research staff members will lead the meetings that will be approximately 3 hours in duration.

2. PPAG recruitment. Participants for the advisory group will be selected by clinic healthcare providers on the basis of their being representative of the patient population, engaged in epilepsy management issues, interested in contributing to the field, over 18 years of age, speak English and have a preference for the English version of MINDSET. Two patients will be invited to participate from each of the four collaborating clinics in Arizona and Texas. A letter will be sent to potentially eligible patients inviting them to participate in the PPAG about epilepsy and its management. The letter will include a telephone number where participants can call and decline. One week after the letter has been mailed, a research staff member will contact the patient by telephone to confirm eligibility and invite him/her to participate. Patients will be informed that they have a right to refuse to participate, can withdraw at any time, and that withdrawal will not adversely impact continued medical care.

3. Participants will complete informed consent prior to the first meeting.

4. The PPAG meeting will focus on the functional redesign of the English version of MINDSET. PPAG participants will receive brief training and practice on “thinking aloud” by the research staff. The participants will be asked to “think aloud” by describing what they are doing and why, as they navigate through MINDSET on an electronic tablet. The research assistant will note problems but will not attempt to help, unless progress is prevented. The participant will be asked to access all elements of MINDSET (the screening tool, patient profile, recommendations, and action plan) and to verbally describe and interpret what they are seeing and doing, to complete the usability survey rating satisfaction, ease of use, acceptability, credibility, and applicability to their needs and to be interviewed on potential enhancements (content, function, and interface design).

5. Patients will be asked to give their opinions about MINDSET. This will include the layout and look (interface) of the decision support system, and information on how the system works, its content, and its functions. This will include appropriateness for use in the clinic by patients and information or functions that should be considered to enhance the patient experience with the system.

6. Patient members of the PPAG will receive an incentive payment of $30 after the meeting.

7. Patients will be assigned a unique identification number and no personal identifiers will be linked with the information collected.

8. The usability survey and exit interview will be stored in locked filing cabinets at the University of Texas and the University of Arizona and on secure servers.
MINDSET
Management Information & Decision Support Epilepsy Tool

Patient Provider Advisory Group (PPAG) Usability Study
MINDSET Overview
Epilepsy Self-management Decision-Support Tool

Hispanic people with epilepsy especially those who speak mainly Spanish may be at an increased risk of disparities in managing their epilepsy. This may be due to the limited communication between the patient and their doctor and the self-management tools available to them. To help mitigate these challenges we are renovating and translating an existing epilepsy self-management decision-support tool (MINDSET) to be used by Spanish speaking Hispanic patients during their clinical visits. MINDSET highlights the patient’s epilepsy self-management at-risk behaviors for discussion with their doctor and provides the patient with strategies to help them improve the management of their epilepsy.

The first part of MINDSET (My Epilepsy), includes a series of questions covering seizure frequency and symptoms, medications and medication side effects, and self-management domains related to seizure management, medication management, and lifestyle management. These questions are designed to be clear, relevant, and understandable for the average adult with epilepsy. The second part of the program (My Goals) lists all of the at-risk items in each self-management domain and prompts the patient to identify one to three items for improvement before their next visit. The third and final phase of the program (My Action Plan) is designed as a social contract between the patient and their doctor where the patient is asked to select a behavioral goal from flagged behaviors in each self-management domain. The patient is then asked to select from a list of suggested behavioral strategies to meet these goals, estimate their confidence to perform these behaviors, and list any barriers for achievement and brainstorms strategies to overcome these barriers.
# Patient-Provider Advisory Group (PPAG) Agenda

**University of Arizona, Department of Neurology**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00-10:15 AM</td>
<td>Welcome</td>
<td>Overview of MINDSET</td>
</tr>
<tr>
<td>10:15-10:30 AM</td>
<td>Usability Study Procedures</td>
<td>Program Instructions</td>
</tr>
<tr>
<td>10:30-10:40 AM</td>
<td>Consent &amp; Demographic Questionnaire</td>
<td>Authorization to participate in the study and demographic information</td>
</tr>
<tr>
<td>10:40-11:10 AM</td>
<td>Usability Test</td>
<td>Complete Program Trial (MINDSET)</td>
</tr>
<tr>
<td>11:10-11:20 AM</td>
<td></td>
<td>Break</td>
</tr>
<tr>
<td>11:20-11:35 AM</td>
<td>Usability Questionnaire</td>
<td>Program Survey Summary Feedback Form</td>
</tr>
<tr>
<td>11:35-11:55 PM</td>
<td>Exit Interview</td>
<td>Overall thoughts of program</td>
</tr>
<tr>
<td>11:55-12:20 PM</td>
<td>Debrief</td>
<td>Questions and Answers &amp; Patient Incentives</td>
</tr>
<tr>
<td>12:20-1:00 PM</td>
<td></td>
<td>Lunch</td>
</tr>
</tbody>
</table>
AES - 2015 Annual Meeting: Poster Session Acceptance

Sent on:
Aug 31, 2015 4:46 PM EDT

From: jamsden@aesnet.org
To: refugio@email.arizona.edu
Subject: AES 2015: Poster Notice

Dear Refugio Sepulveda,

We are pleased to inform you that your abstract, control ID # 2326008, has been accepted for a poster presentation at the 2015 Annual Meeting of the American Epilepsy Society. The meeting will be held December 4-8 in Philadelphia, PA at the Pennsylvania Convention Center. Poster Sessions are scheduled on Saturday, Sunday and Monday, December 5-7 at the Convention Center in Hall A, Level 200.

Below is your poster presentation assignment. The first number of your assigned poster number indicates the session you are scheduled. 1 = Saturday, Poster Session 1; 2 = Sunday, Poster Session 2; 3 = Monday, Poster Session 3. The next 3 numbers indicates what board you place your poster on. Please also inform your co-authors of this acceptance. You should plan on being at your poster during the assigned author present time. If you are not able to do so, please make arrangements with a co-author to attend the session.
Title: Development of an Epilepsy Self-management Decision-Support Tool: Spanish-MINDSET 4.1

Date: Poster Session 1, December 5, 2015

Poster Session #: 1.376

Tables beneath the poster board will not be available. We suggest you bring a plastic sleeve in which to place any handouts you may have. You may then tack this sleeve to the board so the handouts are readily available.

QR codes that link to pharmaceutical company websites are prohibited on the posters in the poster hall.

Poster tours will be held again this year. Please note that your poster may be included on a tour. These are small groups led by selected tour leaders.

You may upload your poster as a PDF file to be viewed on the AES website. Accept the poster invite and you will see where you can upload a PDF of your poster. This ePoster upload is optional and is not required. Please click on the "view invitation link" below to upload your ePoster.

View invitation

For further details about poster set up and presentation times, click here to access the Poster Session Instructions. To access the Program Preview, visit the Annual Meeting page on the AES website www.aesnet.org.

All presenters are required to register for the Annual Meeting and no one will be admitted to the poster sessions without a badge. Registration details are also available on the Annual Meeting page on the AES website www.aesnet.org.

If for any reason you need to withdraw your poster, please notify JoLynn Amsden at the AES Office immediately via email at jamsden@aesnet.org. Please note that empty poster boards are unwelcome in the poster hall. Failure to comply may make your abstract ineligible for a poster in the future. We look forward to your participation in what promises to be a very successful meeting!

Sincerely,

2015 AES Scientific Program Committee
Character count: with spaces 3,110 (Maximum = 3,200)

Development of an Epilepsy Self-management Decision-Support Tool: Spanish-MINDSET 4.1

BACKGROUND: Hispanic people with epilepsy, especially those who speak mainly Spanish, may be at an increased risk of disparities in managing their epilepsy. This may be due to limited communication between the patient and their healthcare provider (HCP) and self-management tools available to them. To help mitigate these challenges we are redesigning an existing epilepsy self-management decision-support tool (MINDSET 3.1) for use by Spanish speaking Hispanic patients within the clinic encounter (Spanish-MINDSET 4.1). MINDSET highlights the patient's epilepsy self-management 'at-risk' behaviors for discussion with the HCP and for improvement.

PURPOSE: To revise and develop a theoretically-enhanced and empirically tested version of MINDSET for translation into Spanish.

METHODS:

The research team met over a series of meetings to revise MINDSET. In Step 1, the MINDSET assessment questions (My Epilepsy) were revised by integrating systematic reviews from eight members of the research team. They include experts in communication technology, behavioral science, public health, and clinical management of epilepsy. In Step 2, a new module (My Goals) for prioritizing at-risk behaviors for improvement was created. This step was informed by results from a previously completed MINDSET efficacy trial and feasibility study. Step 3 involved streamlining the Action Plan to help the patient to select goals and strategies to overcome self-management barriers. In Step 4, the revised version of MINDSET was programmed for tablets. This step was completed by software programmers under contract with the research team. The final step before developing Spanish MINDSET was to test the revised English MINDSET usability with a sample of patients and their HCPs.

RESULTS:

The revised script for My Epilepsy includes questions covering seizure frequency and symptoms, medications and medication side effects, and self-management domains related to seizure management, medication management, and lifestyle management. The questions are designed to be clear, relevant, and understandable for the average adult with epilepsy. The new module (My Goals) lists all at-risk items in each self-management domain and prompts the patient to identify one to three items for improvement before their next visit. The revised Action Plan is designed as a social contract between the patient and their provider where the patient selects a behavioral goal from flagged behaviors in each self-management domain, selects behavioral strategies to meet these goals, estimates confidence to perform these behaviors; lists any barriers for achievement, and brainstorms strategies to overcome the barriers. The results of the usability test of the revised version of MINDSET will be reported at the meeting.

CONCLUSION:

MINDSET 4.1 enhancements are a marked improvement over previous versions in terms of its focus on prioritization and goal setting for self-management practice. Next steps will be the development and feasibility testing of Spanish-MINDSET.
Appendix H-3: American Epilepsy Society Poster Presentation 2015

Development of an Epilepsy Self-management Decision-Support Tool: Spanish-MINDSET 4.1

R. Sepulveda1, S. Rueda1, J. Chung2, C. Begley3, B. Snapp1

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2University of Texas School of Public Health, Behavioral Sciences, Houston, TX, United States

Background

- In Hispanic people with epilepsy may be at an increased risk of disparities in managing their epilepsy.
- An existing epilepsy self-management decision-support tool (MINDSET 4.1) is being translated for use by Spanish-speaking Hispanic patients.

MINDSET was originally developed as a mobile-based tablet application to highlight patient’s epilepsy self-management and task behaviors for discussion with their health care provider (HCP) and for improvement.

Purpose

- To review and develop a translated/demonstrated and ameliorated version of MINDSET for translation into Spanish.

Methods

- Findings from previous empirical studies informed the development of MINDSET 4.1.
- Results from previous study indicated that MINDSET enhanced patient self-efficacy for the management of their epilepsy behaviors.
- MINDSET 4.1 was developed by expert review, formal-evaluation and usability testing and testability assessment by patient/provider advisory groups (PPADs) (Fig. 2). (Table 1:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The patient enters their epilepsy episode/behaviors to integrate relevant information and prompts the patient to identify the key information.</td>
</tr>
<tr>
<td>2.</td>
<td>The patient enters their epilepsy episode/behaviors to integrate relevant information and prompts the patient to identify the key information.</td>
</tr>
<tr>
<td>3.</td>
<td>The patient enters their epilepsy episode/behaviors to integrate relevant information and prompts the patient to identify the key information.</td>
</tr>
<tr>
<td>4.</td>
<td>The patient enters their epilepsy episode/behaviors to integrate relevant information and prompts the patient to identify the key information.</td>
</tr>
</tbody>
</table>

Results

- MINDSET 4.1 consists of both improved and new features to increase patient self-management and communication.
- The revised Action Plan includes questions related to patient seizure history, outcome, and medication management, and literature management. The revised Action Plan resulted in a Fleisch-Kincaid Grade Level of 5.7 (by Epileptic (Table 1).

Table 2: Readability Statistics

<table>
<thead>
<tr>
<th>Measure</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fleisch Reading Ease</td>
<td>72.4</td>
</tr>
<tr>
<td>Fleisch-Kincaid Grade</td>
<td>5.7</td>
</tr>
</tbody>
</table>

- A new module in the program (My Goals) lists all the self-management items and highlights the actions to improve them.

- A new module in the program (My Actions) lists all the self-management items and prompts the patient to identify the needed improvement.

- A new module in the program (My Actions) lists all the self-management items and prompts the patient to identify the needed improvement.

- A new module in the program (My Actions) lists all the self-management items and prompts the patient to identify the needed improvement.

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Conclusion

- MINDSET 4.1 enhancements are a marked improvement over previous versions in terms of its focus on prioritization and goal setting for self-management actions.
- MINDSET 4.1 enhances ability to prioritize and testability testing of Spanish-MINDSET.

Acknowledgements

This manuscript is being reviewed by the Social and Behavioral Sciences Project Center for the Evaluation of Health Information Technologies (EHI) to ensure the manuscript is of high quality and in line with acceptable standards of scientific writing. The manuscript was revised by Spanish-speaking experts and following standing rubrics. The manuscript was edited by Spanish-speaking experts and following standing rubrics. The manuscript was revised by Spanish-speaking experts and following standing rubrics. The manuscript was edited by Spanish-speaking experts and following standing rubrics.

Fig. 1. Flowchart of MINDSET 4.1 focused on translating features to Spanish.

Fig. 2. Usability testing of MINDSET 4.1 focused on translating features to Spanish.

Fig. 3. Usability testing of MINDSET 4.1 focused on translating features to Spanish.

6/19/2017

University of Arizona Mail - AES - 2016 Annual Meeting: Poster Session Acceptance

Refugio Sepulveda <refugio@email.arizona.edu>

AES - 2016 Annual Meeting: Poster Session Acceptance

2 messages

jamsden@aesnet.org <jamsden@aesnet.org>
To: refugio@email.arizona.edu
Cc: mailing@conferenceabstracts.com

Fri, Sep 16, 2016 at 11:43 AM

Dear Refugio Sepulveda,

We are pleased to inform you that your abstract, entitled "Spanish-MINDSET: Usability and feasibility of epilepsy self-management decision support for Spanish speaking patients", has been accepted for a poster presentation at the 2016 Annual Meeting of the American Epilepsy Society. The meeting will be held Friday, December 2 - Tuesday, December 6 in Houston, Texas. Poster Sessions are scheduled on Saturday, Sunday and Monday, December 4 - 6 at the George R. Brown Convention Center, on Level 3, in Hall A3.

Below is your poster presentation assignment. Your poster session number reflects the poster session you are scheduled for (i.e., 1,001 - 1,030 is Poster Session 1, Saturday, December 3; 1,001 - 2,000 is Poster Session 2, Sunday, December 4; and 3,001 - 3,990 is Poster Session 3, Monday, December 5). Please also inform your co-authors of this acceptance. Authors must be present during designated "authors present" time. If you are not able to do so, please make arrangements with a co-author to attend the session.

Title: "Spanish-MINDSET: Usability and feasibility of epilepsy self-management decision support for Spanish speaking patients", (original submission number: 1993675)

Date: Poster Session 3, Monday, December 5

Poster Session #: 3,345 (this is the AES #)

AES does not utilize tables beneath the poster board. We suggest you bring a plastic sleeve in which to place any handouts you may have. You may then tack this sleeve to the board so the handouts are readily available.

QR codes will be allowed on posters as long as they do not link to a pharmaceutical/device website. Once on the site from the QR code, there cannot be any link to a commercial site. AES will monitor the use of QR codes on posters and will revise this policy if needed for future meetings.

Poster tours will be held again this year. Please note that your poster may be included on a tour. These are small groups led by selected tour leaders.

Please see the attached document for further details about poster set up and presentation times. To access the Program, visit the Annual Meeting page on the AES website www.aesnet.org.

Award Announcements and Platform Selections: Award announcements will be sent in a separate email by the end of this week. Announcements will only be sent to those who have been selected. If you are selected for a Platform, your poster will be viewed in the hall on your specific day and you will be asked to put together a brief presentation for the Platform sessions on Monday afternoon.

Registration: All poster presenters are required to register in advance at the appropriate registration rate. No one will be admitted in the poster area without a badge. The Program Preview and online registration and housing form are available on the AES website.

Registration must be completed by Monday, October 31 to qualify for registration discounts.

If for any reason you need to withdraw your poster, please notify the AES Office immediately via email at abstracts@aesnet.org. In the subject line, please add "Withdrawn Abstract." Please note that empty poster boards are unwelcome in the poster hall. Failure to comply may make your abstract ineligible for a poster in the future. We look forward to your participation in what promises to be a very successful meeting!

Sincerely,

2016 AES Scientific Program Committee

https://mail.google.com/u/0?i=1=2x5c655c5321618e64ee8f195a807d4U=en%26u%3D&v%3Demail%3Be%3A8%3A2%3Aesq%3Aq%3Dg%3Ay%3A15734208562d%3A%3A
Appendix H-5: AES Abstract 2016

Title: Usability and Feasibility of MINDSET by Hispanics to Improve Self-Management

Sepulveda R1, Labiner D2, Chong J1, Torres M3, Halavac N2, Begley C3, Shegog R2, Addy R2, Martin K2, Szabo4

1University of Arizona, Department of Neurology, Tucson, AZ, United States
2University of Texas School of Public Health, Behavioral Science, Houston, TX, United States
3Epilepsy Foundation of Central and South Texas
4University of Texas School of Medicine, San Antonio, Texas

Rationale: Despite evidence that self-management helps people with epilepsy increase both coping skills and health, there is limited availability of interventions to assess and improve epilepsy self-management. Hispanics in particular may be at an increased risk due to limited communication between patients and healthcare providers (HCP) and/or the scarcity of epilepsy self-management tools available to them. The Management Information and Decision Support Epilepsy Tool (MINDSET) is a computer program (available in English and Spanish) developed to assist patients and providers to quickly assess, monitor, and develop a plan for improving epilepsy self-management during regular clinic visits. MINDSET consists of a series of self-management questions in three domains (seizures, medication, and lifestyle). MINDSET then compares the patient responses to the ideal benchmarks and non-ideal behaviors are flagged. MINDSET prompts the patient to select at least one non-ideal behavior in each domain as a goal for improvement and specific strategies for achievement. An Action Plan is then created and printed for the patient to retain and review with their healthcare provider. The purpose of this study was to test the feasibility of using MINDSET during regular visits at neurology clinics.

Methods: The feasibility study of Sp-MINDSET was tested with a sample of patients (n=40) over two clinical visits at two neurology clinics in Texas and two in Arizona.

Patients had the choice of using the MINDSET program in English or Spanish. The patients completed MINDSET at each visit and discussed their action plan with their healthcare provider. A feasibility rating scale and exit interview were used to collect feasibility data after each visit. At the end of the study, the participating physicians were also interviewed regarding their opinion about the usability and feasibility of using MINDSET and the Action Plan.

Results: All 43 patients recruited for MINDSET completed the first visit and 38 had a second follow up visit. Patients were mostly female (62.5%), 19 to 70 years (mean = 45.4 years), with mean age of diagnosis at 13.3 years. Most reported seizures in the last 12 months (87.5%) with more than one seizure per month (62.5%). The majority had private insurance (62.5%) while 12.5% were on Medicaid. Most of the patients selected the English version (72% at first visit, 63% at second visit) of MINDSET and the rest Spanish.

The percentage of patients rating the time taken to use MINDSET as “just right” was 88%/78% (first visit/second visit). Most agreed that MINDSET was helpful (90%/92%), understandable (93%/95%) could be trusted (95%/92%), helped me manage my epilepsy (86%/86%), think carefully (98%/92%), talk to my doctor/nurse (88%/92%). Most patients thought MINDSET was very easy to use (95%/89%), choose a topic to work on (98%/92%), select strategies (93%/86%), and understand the Action Plan (98%/95%). Most indicated they would use MINDSET again (86%/89%) and recommend its use to other patients (93%/86%).

Four physicians participated in the study. The rating of three of the physicians on a 1-5 scale from easier to harder with or without MINDSET ranged from: 1-2 for identifying seizure, medication, and lifestyle problems, 1 identifying patient goals strategies and barriers, 1 developing an action plan for your patient. Using the same 1-5 scale from took more, less or same time the physician scores on developing an action plan were 2 and they would recommend to other healthcare providers if able to adjust patient flow and accommodate additional time needed.

Conclusion: Positive usability findings suggest that tablet-based Spanish language decision support is acceptable for Spanish speaking Mexican-American patients with epilepsy. The study indicates very positive ratings by Hispanic patients and their physicians of the usability and feasibility of using the tablet-based MINDSET during clinic visits. The physicians noted the additional time needed for patients to complete the program and discuss the Action Plan.

Spanish-MINDSET: Usability and Feasibility of Epilepsy Self-Management Decision Support For Spanish Speaking Patients
American Epilepsy Society Annual Meeting, Houston, TX, 2016
R. Sepulveda, N. Konar, C. Chong, C. Begley, K. Martin, D. Labine
University of Arizona, Department of Neurology, Tucson, AZ, United States.

Introduction

- Avoiding patients with self-management can be challenging in clinical practice.
- Patients with epilepsy may be at an increased risk of impaired self-management due to their condition.
- MINDSET is a web-based application for the tablet platform that highlights the patient's self-management profile, treatment plan, social, and psychological information to allow patients to set goals, select strategies, and monitor improvement (Figure 1).
- MINDSET can be completed in English or Spanish and provides information gathering, screening, and maintenance care to enhance self-management during clinical visits.
- MINDSET incorporates social cohesion, self-regulation, and motivational enhancement theory.

Purpose

The purpose of the study is to test the usability and feasibility of the Spanish version of MINDSET with Spanish-speaking patients at University of Arizona.

Methods

USABILITY was tested with a sample of patients (n=10) in four neurology clinics in Arizona and Texas. Patients enrolled in the study were asked to complete the self-management plan and strategies for improvement. Upon completion, patients were surveyed about their perceptions of the usability of MINDSET.

FEASIBILITY was tested with a sample of patients (n=41) at four neurology clinics during the regular clinic visits. The patients completed MINDSET in each visit and discussed their plan with their healthcare provider. At the end of each visit, patient perceptions of feasibility were collected.

Results

- The majority of patients agreed that MINDSET was helpful (87.9%), enjoyable (82.7%), credible (82.7%), and important for patients managing their epilepsy (90.1%).
- Patients expressed comfort using MINDSET, but it was through, that the time taken to use it was appropriate (83%), and that it was minimally disruptive (81%).
- The mean usability score was 5.0 (SD 0.5) through real-time interaction, they would recommend it to others.

Discussion

The program was well perceived by patients and was useful for improving self-management in epilepsy patients.

Conclusion

- Patient ratings of usability and feasibility were most favorable for:
  - Duration of data entry and goal setting about right
  - Credibility, helpfulness, and trustworthiness of information
  - Understanding of the questions
  - Usefulness of the information
  - Format appeal

- Patients rated the program favorably for:
  - Need for awareness to use MINDSET
  - Usefulness compared to other programs

MINDSET offers improved patient awareness and control of self-management behavior, goal setting, and decision making in epilepsy patients. The intervention with a health care provider in these patients increases understanding, motivation, and overall monitoring of improvement during regular clinic visits.

Acknowledgements

The authors are thankful to the patients who participated in the study. The American Epilepsy Society is thanked for their support in the development of the MINDSET application. The University of Arizona and University of Texas are thanked for their support in the implementation of this study.
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